

Postprandial glucose and insulin response to a cookie with or without added RS4 wheat starch after 3 days of pre-feeding: A double blind, randomized, controlled clinical trial

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ABSTRACT

Background: Research on the effect of resistant starch on postprandial glucose levels has mainly focused on the attenuation achieved by substituting it for the available carbohydrate (avCarb), few studies have looked at the effect on glucose levels when the resistant starch is added.

Objective: The objective of this study was to investigate the acute effect on postprandial glycemia and insulinemia of a cross-linked phosphorylated RS4 wheat starch (Fibersym® RW) in a test cookie compared to a control cookie matched for available carbohydrate after a 3-day habituation period.

Methods: This study used a double blind, randomized, cross-over design. Nineteen healthy subjects were screened of whom 16 were eligible and randomized into the study. A total of 15 subjects completed the study (5M:10F; 32±11y; 24.9±2.5kg/m²; BP 112/70mmHg). After 3-day pre-feeding of Control (dietary fiber 1.6 g/d) or Fibersym sugar snap cookies (dietary fiber 29 g/d), the subjects, after an overnight fast, consumed either the respective Control or Fibersym cookie, both meals contained 40g avCarb. Blood samples were collected over 2 h. Gastrointestinal (GI) symptoms were recorded during the pre-feeding period and during the postprandial visit. Subjective appetite scores were also measured over the 2 hours.

Results: The 90-min blood glucose incremental area under the curve (IAUC) was statistically significantly lower after ingesting the Fibersym cookie (71.9±8.5mmolxmin/L) compared to the Control cookie (86.7±9.3mmolxmin/L) (p<0.02). In addition, the Glucose concentrations at 30 and 45 min after consumption of the Fibersym cookie were significantly lower than the Control cookie (p<0.05). Insulin 90 min IAUC (p<0.016) and the 2-h (p<0.02) insulin IAUC's were significantly lower after consumption of the Fibersym cookie compared to the Control cookie. There were no significant differences in GI symptoms over the 3-day pre-feeding period and during the 2h postprandial visit between the two cookies and neither did the appetite scores differ significantly.

Conclusion: The cross-linked phosphorylated RS4 wheat starch, Fibersym® RW, when formulated into a cookie, is well tolerated and attenuates blood glucose and insulin levels in healthy subjects compared to a Control cookie containing the same amount of available carbohydrate.

INTRODUCTION

Consumption of whole grains has been recommended by most health agencies in order to increase dietary fiber intake with the ultimate goal to help maintain a healthy body weight and improve insulin sensitivity (WHO,2018). Despite these recommendations, most adults do not meet the recommended intake of 25–35 g per day of dietary fiber (Quagliani and Felt-Gunderson, 2017). Therefore, innovative ideas to increase dietary fibre intake are needed. One approach is to incorporate dietary fiber either by substituting it for other carbohydrate in a food or by adding isolated fibers to a food product. MGP Ingredients Inc has developed resistant starches (RS), including Fibersym® RW, a RS4-type resistant wheat starch, which are easily incorporated into foods and thereby increase their dietary fiber contents. Fibersym® is a RS4-type resistant modified wheat starch in which over 85% of the total starch is resistant starch as measured by AOAC method 991.43. It is meant to be consumed on a regular basis and doses up to 33g/day can be tolerated (Martinez et al 2010). The effect of a Fibersym-containing meal on postprandial glucose and insulin levels when compared to a control meal, where both meals contain the same amount of available carbohydrate, is not well known. This study therefore investigates the acute effect of a Fibersym cookie and a control cookie matched for available carbohydrate after a 3-day habituation period

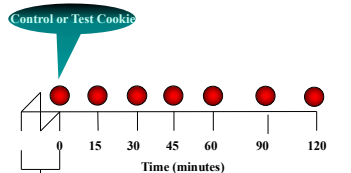
METHODS

Participant Characteristics

Participant Characteristics	Randomized (n=16)	Per Protocol (n=15)
Age	31 ± 11y	32 ± 11y
Gender	5M,11F	5M,10F
BMI	25.0 ± 2.4 kg/m ²	24.9 ± 2.5 kg/m ²
Systolic Blood Pressure	112 ± 9 mmHg	112 ± 9 mmHg
Diastolic Blood Pressure	70 ± 8 mmHg	70 ± 8 mmHg

Design

This study used a double blind, randomized, cross-over design. Subjects consumed either Control (dietary fiber 1.6 g/d) or RS4 Wheat Starch sugar snap cookies (dietary fiber 29 g/d) throughout the day (approx. 4 cookies) for 3 days prior to the test meal. In the morning, after an overnight fast, they were given the same cookies (approx. 3) they had been consuming during the preceding 3 days. Both the Control and RS4 Wheat cookie meal contained 40g avCarb and were consumed with 250ml of water. Blood samples were collected over 2 h. Gastrointestinal (GI) symptoms were recorded during the pre-feeding period and during the postprandial visit. Subjective appetite scores were measured at the same time points when blood



Composition of Test Meals

Test Meal	# Cookies	Weight (g)	Energy (kcal)	Protein (g)	Fat (g)	Total CHO (g)	Fibre (g)	Av CHO (g)
Control Cookie	3	78.1	400	3.8	25.0	41.2	1.2	40
RS4 Wheat Starch Cookie	3	97.8	374	3.0	22.4	62.3	22.3*	40

*Dietary fiber attributed to RS4 Wheat Starch; approximately 21g.

RESULTS

Postprandial Glucose Response

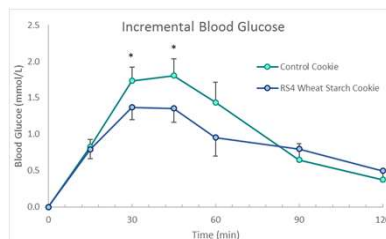


Figure 1: Incremental blood glucose levels after consumption of either Control Cookie or RS4 Wheat Starch Cookie, both test meals contained 40g available carbohydrate. Data are expressed as Mean±SEM. *p<0.05

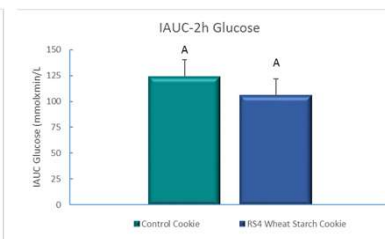


Figure 2: Blood glucose IAUC over 120 minutes (IAUC-120min) after consumption of either Control Cookie or RS4 Wheat Starch Cookie, both test meals contained 40g available carbohydrate. Data are expressed as Mean±SEM. Bars with different letters are significantly different (p<0.05).

Postprandial Serum Insulin Response

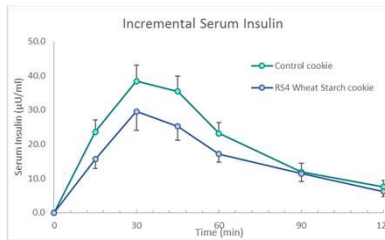


Figure 3: Incremental serum insulin levels after consumption of either Control Cookie or RS4 Wheat Starch Cookie, both test meals contained 40g available carbohydrate. Data are expressed as Mean±SEM.

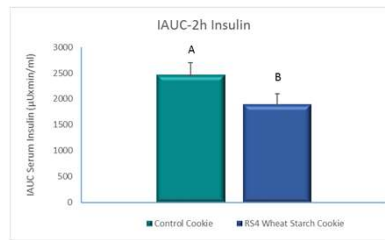


Figure 4: Serum insulin IAUC over 2 hours (IAUC-2h) after consumption of either Control Cookie or RS4 Wheat Starch Cookie, both test meals contained 40g available carbohydrate. Data are expressed as Mean±SEM. Bars with different letters are significantly different (p=0.02).

GI Symptoms and Appetite Score

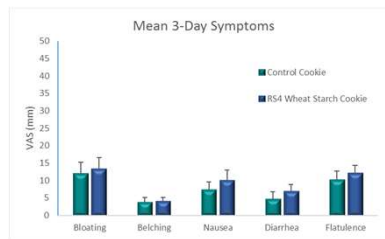


Figure 5: Mean 3 day gastrointestinal symptoms: bloating, belching, nausea, diarrhea and flatulence after consumption of either the Control Cookie or the RS4 Wheat Starch Cookie. Data are expressed Mean±SEM. Note: symptoms were recorded on a visual analogue scale (VAS) ranging from 0 to 100mm.

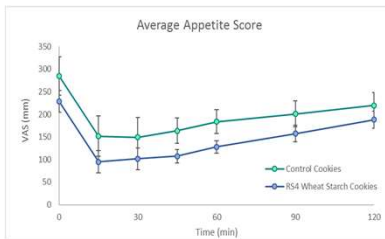


Figure 6: Average Appetite Score over 2 hours after consumption of either the Control Cookie or the RS4 Wheat Starch Cookie. Data are expressed Mean±SEM

CONCLUSIONS

- The 2h glucose IAUC was not statistically significantly different between the Control and RS4 cookie (p=0.08), however the 90-min glucose IAUC was significantly lower after ingesting the RS4 Wheat Starch cookie compared to the Control cookie (p<0.02).
- Glucose concentrations at 30 and 45 min after consumption of the RS4 Wheat Starch cookie were significantly lower than the Control cookie (p<0.05).
- Insulin 90 min IAUC (p<0.016) and the 2-h (p<0.02) insulin IAUC's were significantly lower after consumption of the RS4 Wheat Starch cookie compared to the Control cookie.
- There were no significant differences in GI symptoms over the 3-day pre-feeding period and during the 2h postprandial visit between the two cookies and neither did the appetite scores differ significantly at the different times point

In Summary: The cross-linked phosphorylated RS4 wheat starch, Fibersym® RW, when formulated into a cookie, is well tolerated and attenuates blood glucose and insulin levels in healthy subjects compared to a Control cookie containing the same amount of available carbohydrate.

REFERENCES

Martinez, I., Kim, J., Duffy, P.R., Schlegel, V.L., and Walter, J. 2010. Resistant starches types 2 and 4 have differential effects on the composition of the fecal microbiota in human subjects. PLOS ONE 5(11):e15406.
 Quagliani D., Felt-Gunderson P. Closing America's Fiber Intake Gap: Communication Strategies From a Food and Fiber Summit. J Lifestyle Med. 2017 Jan-Feb; 11(1): 80–85. Published online 2016 Jul 7.
 World Health Organization. Thirteenth general programme of work, 2019–2023. Geneva 2018.

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Clinical Trial Carried out by:



Formerly

