Author's response to reviews

Title: The Role of Meal Viscosity and oat beta-glucan Characteristics in Human Appetite Control: A Randomized Crossover Trial

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Author's response to reviews: see over
May 7, 2014

Nehme Gabriel, M.D.
Editor-in-Chief, Nutrition Journal
Central Florida Health Alliance
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Dear Dr. Gabriel:

The authors thank both reviewers for their helpful comments on this manuscript. We greatly appreciate the input, and we’ve enclosed a revised version that will hopefully address the concerns in the reviews, to which we detail our responses below.

**Reviewer 1**

**Major comments:**

*Only subjective measures of food intake were completed. Food intake was not measured although I do think that there is still some merit to the results using just VAS data I think the limitations of this should be commented on in the discussion.*

We agree that the desired directional changes in subjective measures of satiety are not the same as reductions in energy intake; nevertheless, appetite scores measured through VAS can be reproduced and are therefore feasible tools to measure appetite and satiety sensations. This point has been addressed among the limitations in the discussion.

**Minor revisions**

*"To determine the presence of colds or allergies that might affect taste, participants were required to complete a questionnaire and were asked to return on another day if such a condition was present."

Good control but what as this questionnaire? Did you simply ask them or was this a pretest questionnaire.

This is a questionnaire that was administered prior to consuming the cereal. A copy of the questionnaire is at the end of this document. If a participant answered ‘Yes’ to any of the questions they were rescheduled to another day.

*Table 2 - Energy and nutrient content of breakfast meals where does this come from - manufacturers info?*

The energy and nutrient content was obtained from the nutrition facts label. It has been added to the manuscript.

*Table 1 – There should be an astericks beside SD*

The abbreviation and footnote have been deleted.
Units of mm need to be given in Figure 1
Units have been added to Figure 1

Discretionary revisions
In the introduction you say “Fiber is a natural product and would likely appeal to consumers due to its association with wholesome foods. ”. A lot of the population knows about the benefits of fibre at this stage, it is not something new. Perhaps rephrase this to emphasis that what they do not know is that processing effects it.

A revision has been made.

Not much is made of the glycaemic load being different or the difference in molecular weight though this can have a big impact on GE which will influence satiety. You might want to look at Thondre PS1, Shafat A, Clegg ME. Br J Nutr. 2013 Dec;110(12):2173-9. doi: Molecular weight of barley #-glucan influences energy expenditure, gastric emptying and glycaemic response in human subjects.

The difference in the carbohydrate content of the cereals was marginal and we did not determine the glycemic indices, and thereby the glycemic load of the cereals. However, instant oatmeal is known to have a high glycemic index as does the RTEC and this aspect has been addressed in the discussion.

The effects on gastric emptying are mediated by viscosity as reiterated in the manuscript by Thondre et al. Viscosity is a function of the molecular weight. In the present study, the higher molecular weight of β-glucan in oatmeal may have contributed to the increased viscosity compared to the RTEC. We measured viscosity and its effects on cephalic phase effect, gastric emptying, and the glycemic response have been discussed. As stated in the manuscript, the differences in satiety were mostly at the 60 minute time point. Thus, the volume of food may have been too small to show differences at all of the other time points as the gastric emptying of this low volume may not have been delayed sufficiently. Further, delayed gastric emptying may influence the delivery of glucose to the duodenum; but, our in vitro study showed that there were no differences in the kinetics of starch digestion and glucose release.

Reviewer 2

Major Compulsory Revisions

- The trial is registered at ClinicalTrials.gov under the number NCT1666574. However, the registration describes another trial comparing the effect of two different oat-based cereals (250 kcal) on subjective appetite and ad libitum energy lunch. The correct clinical trials registration number should be stated and clinical trials registration should be updated.
The clinical trials number has been revised; however, the registration will be updated only after the study is published since most journals place an embargo on prior publication of the results elsewhere.

- Introduction
In the manuscript a previous study (in review) is cited in which the same breakfast cereals are compared, merely in a slightly larger portion size (+100kcal). The authors may refer to the rationale of testing the same products in two slightly different portion sizes and publish this separately. This should be addressed more clearly in the objectives of the introduction.

Instant oatmeal is processed differently from old fashioned oatmeal. In the previous study, instant oatmeal was not tested. Since processing affects the functionality of β-glucan, the objective of this study was to determine if processing affects the satiety response, as well as to determine the effects of a single serving (smaller portion size). The introduction has been revised for clarity.

The rationale for using the selected products is not completely made clear. Is RTEC thought as a control product? Why was a smaller amount of beta-glucan administered than in the other two products? This renders the results a consequence of a combination of beta-glucan characteristics and content, rather than comparing only beta-glucan characteristics. It might have been sensible to compare products containing equal amounts of beta-glucan and achieving iso-caloric meals by adding another food ingredient to the SO and IO meals. In the introduction the rationale for using RTEC should be stated, rather than merely noting that it was also used in another study.

A revision has been made to the introduction to clarify the rationale for the study.

- Methods: Subjects

Prior to study start participants were screened for a number of criteria. What was the reason for this comprehensive screening as most of these data are not presented in the manuscript?

Body mass index was not a criterion for exclusion; but, participants were required to be otherwise healthy. The laboratory tests and questionnaire were used to assess health. They were not study outcomes. The anthropometric measurements were for descriptive purposes.

No detailed description of inclusion criteria of participants is given. Please state the precise inclusion criteria (e.g. BMI, age (was there an upper limit), etc.), similarly as done with the exclusion criteria.

The inclusion criteria have been added to the manuscript.

Please describe the recruitment procedure of participants.
The recruitment procedure has been described in the manuscript.

- Methods: Study Design

Please add the location of study conduction.

It is already stated in the manuscript. ‘This study was approved by the Institutional Review Board of the Pennington Biomedical Research Center, Baton Rouge where the study was conducted.’

Please refer to instructions regarding liquid consumption before and during the examinations. Were there any restrictions? Please refer to whether alcohol consumption was restricted the day prior to examinations.

Participants were required to fast for 10 hours (except water), and refrain from alcohol for 24 hours prior to the breakfast meal. During the VAS testing they were restricted to the dining area and required to be nil per os. It has been added to the manuscript.

In the results section it is stated that no adverse events were observed. However, assessment of adverse events is not described in the methods section. Please include this in the methods description.

The assessment of adverse events has been added to the Methods section.

- Methods: Statistical analyses

Did authors attempt to adjust statistical analyses for gender, BMI (large SD) and age as well as possible symptoms of cold/allergies? If so, please state in the statistics paragraph. If not, please state the reasons for not including these co-variables and covariates.

The lack of the need for sub-analyses has been stated in the statistical analysis section and the appropriate reference has been provided.

No subject who had a cold or allergy completed any test. As stated in the manuscript, if the condition was present the subject was rescheduled for another day.

Study participants were a mixed population regarding BMI, including normal and overweight participants. Appetite sensation may differ between normal weight and overweight individuals. It may be sensible to conduct sub-analyses looking at the two groups separately.

We thank the reviewer for the suggestion. However, this study was designed to generalize the results among all population sub-groups. We hope to investigate the effects of oat based cereals on satiety in gender, age, and BMI sub-groups in a future larger study where random samples of these sub-groups are used to test the effects. It has been addressed among the limitations.
- Results: A description of the proportion of normal weight and overweight participants may be interesting.

Participants’ BMI categorization has been included in the Results.

- Results: Meal viscosities
It is referred to “initial” and “subsequent” viscosity. Please define this (which time points).

The explanations have been added to the manuscript.

- Figure 2 and 3 may benefit by being displayed as either bar plot or boxplot, rather than a combination of the two. Further, in figure 2 it should be made clear which scale (low and high viscosity values on y-axis) refers to which condition (initial and subsequent viscosity).

The figures have been separated.

- Discussion:
In the discussion a lot of focus is put on the content of sugars and protein contained in the treatment products. Although relevant, this should be shortened and more focus should be put on discussion of beta-glucan content and properties. Compare also in more detail to the existing literature on beta-glucan and appetite.

As breakfasts were different in beta-glucan content, it is difficult to conclude that differences in effects are due to physicochemical properties. Address more differences in beta-glucan content between the oatmeal treatments and RTEC.

The manuscript has been revised to reduce the focus on protein and compare the study with the existing literature on the satiety effects of β-glucan, particularly in relation to differences in β-glucan content.

Authors may refer to possible reasons for the greater initial viscosity found for IO compared to SO.

Ease of hydration may explain the increase in initial viscosity and this aspect has been addressed in the manuscript.

- Minor Essential Revisions
- Table 1: In the description of table 1 “race” is named, but not listed in the table. Please add this information to the table or delete it in the description. Further, in a footnote standard deviation is noted with an asterisk, without using this in the table. Please remove the footnote.

The table has been revised.
- Table 2: It may be sensible to present description of product composition (table 2) in the methods section rather than the results part.

Table 2 has been presented in the Results section because it includes the β-glucan content of the cereals which was measured in the study.

- Figure 1 should include units. Furthermore, “Time point” should be spelled in a consequent manner.

Figure 1 has been revised.

Cold and allergy questionnaire

Subject_________________________  M/F  Test: _________  Date: _______

1. Do you have a cold, allergy, nasal or sinus infection today?   Yes  or  No
   If yes,
   Is it interfering with your ability to taste your food?   Yes  or  No
   Is it interfering with your ability to smell your food?   Yes  or  No
   Is it interfering with your ability to enjoy your food?   Yes  or  No

2. Do you have a taste in your mouth today that is not normal?   Yes  or  No
   If yes, please describe it:______________________________________________

3. Did you take any prescription or nonprescription medications this morning?
   Yes  or  No
   If yes, list the name of the medication, dosage taken, and time at which it was taken.
   ____________________________________________________________________
4. Did you eat or drink anything other than water in the last 12 hours? 
   Yes  or  No 
   If yes, please describe: __________________________________________________

5. Did you consume any alcohol in the last 24 hours? 
   Yes  or  No 
   If yes, please describe the type of alcohol and the amount consumed. 
   ___________________________________________________________________

6. Did you engage in any exercise/physical activity this morning? 
   Yes  or  No 
   If yes, please describe the type of activity: ______________________________

Thank you again for your time and effort, and for helping to improve the manuscript. We hope 
that these changes have made it more appropriate for publication, and that it can now be 
approved. We look forward to your response.

Sincerely,

Frank Greenway 
Medical Director and Professor 
Pennington Biomedical Research Center