Glycemic Response to Ingested Dreamfields Pasta

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Introduction

It is well known in the food industry that raw, intact or partially milled whole grains and legumes contain high levels of RS1-type resistant starch, while cooking generally increases their starch digestibility to varying degrees. Further, it is also widely known that manufacturing processes render foods more or less digestible. By example, specialized manufacturing techniques are used to make starch from wheat and corn resistant to digestion, such as through heat moisture treatment and extraction of the naturally resistant high amylose portion (R2-type resistant starch (Kisida et al., 2001), hot and cold processing of the starch to retrograde or crystallize the starch (RS3-type resistant starch) (Vasanthan and Bhatty, 1998), or by chemically crosslinking the starch molecule (RS4-type resistant starch) (Yeon et al., 2008). These type of resistant starches are commonly added to process foods to increase their dietary fiber content, while also replacing digestible starch-containing flour.

Literature further shows that human glycemic response to food is related to food's macro- and microstructure (Teague, 1988; Dougherty et al., 1988; Edwards et al., 1995; Brennan et al., 1996; Tudorică et al., 2002; Autio et al., 2003; Brennan et al., 2004 and Brennan 2005). It is common to those skilled in the art of making pasta that traditional pasta made using standard manufacturing techniques and cooked using standard procedures results in pasta having a consistent protein-starch microstructure. This protein-starch microstructure is due to the indigenous structural protein present in durum wheat semolina that helps manage water absorption by the embedded starch granules. The protein-starch microstructure of traditional pasta provides a product that has a relatively low glycemic response, when compared to foods having a more porous or open microstructure (Autio et al., 2003). However, unlike traditional pasta, Dreamfields pasta uses a patent-pending composition of specific functional fibers and functional wheat proteins, and a specialized pasta production technology that creates a unique protein-fiber microstructure, rather than a protein-starch microstructure. The unique protein-fiber microstructure embeds the starch granules within reducing starch granule gelatinization during cooking by redirecting and binding water to minimize its migration to the starch granules. By minimizing water migration to the starch granules, much of the starch granules are maintained in their native, unswollen state. Starch granules in their unswollen and entrapped state are consistent with the definition of RS-1 type resistant starch as classified by Englyst and others (1992). Uncooked and

embedded starch granules are significantly more resistant to digestion by alimentary enzymes of the human small intestine as compared with cooked and exposed starch granules of traditional pasta, white rice, white bread, cooked potatoes and other cooked high starch foods. In addition to its influence on pasta and starch microstructure, the specific fiber blend added to Dreamfields pasta contains xanthan gum and pectin, which are viscous fermentable (soluble) fibers and inulin, a non-viscous fermentable (soluble) fiber. Many types of soluble fiber may benefit individuals with metabolic syndrome, through their effects on appetite, body weight, and blood lipid and glucose levels (Schulze et al., 2000). Their beneficial effects may also occur via effects on gastrointestinal (GI) motility. These fiber components are shown in literature to have influence on decreasing gastric empyting by thickening the chime, (pectin and xanthan gum) or improving relaxation of the proximal stomach and lumen, as well as delaying gastric emptying (GE) via short chain fatty acids (SCFAs) and /or GI peptides (inulin) (Jenkins et al., 1978; Trout et al., 1978; Holt et al., 1979; Osilesi et al., 1984; Osilesi et al., 1985; Sandu et al., 1987; DiLorenzo et al., 1988; Schwartz et al., 1988; Cuche, et al., 2000; Tungland and Meyer, 2002; Cherbut 2002; Cherbut 2003; Russo et al., 2010a,b). Metabolically, slower gastric emptying rates can positively affect both postprandial blood glucose levels and so help maintain better glucose homeostatis (Jenkins et al., 1978), as well as lipids (particularly triglycerides) levels (Brighenti, 2007; Russo et al., 2008).

When performing clinical testing using Dreamfields pasta, due to the potential for overcooking and adulterating its protective microstructure, clinical study protocols must strictly adhere to cooking instructions provided on each package. Further, as a subject's metabolism may vary significantly from day to day due to such things as their activity level and diet, clinical protocols must also utilize acceptable standards to ensure a subject has normal metabolism to minimize variability in test subject metabolic performance. Further, due to the potential for increased subject variability, diabetic subjects are not used as subjects for Dreamfields testing. For further technical information about the product refer to the professional section the Dreamfields website listed in the references.

Dreamfields has performed glycemic challenge tests with both traditional and Dreamfields pasta at an independent clinical research facility to show that the glycemic response for Dreamfields pasta is significantly lower than traditional pasta. In addition, as a measure of quality assurance and prior to releasing its products for commercial sale, Dreamfields also performs human glycemic tests on every production batch at an independent medical research facility. Data following show that only 5 grams of the 41 grams total CHO in a 56 gram dry weight serving is digestible to result in a blood glucose rise.

Dreamfields pasta compared with traditional pasta for its glycemic response

Method details: Dreamfields has performed a single blinded, randomized crossover study to compare the human glycemic response of ingested Dreamfields pasta with traditional pasta. The study used 8 randomized healthy subjects (4 males and 4 females) selected from the general population and rigorously prescreened for any metabolic disorders or hormonal issues using subject clinical history, blood chemistry analysis and oral glucose tolerance testing. Each of the test subjects was fed a dry weight serving of Dreamfields spaghetti or traditional high quality durum semolina spaghetti,

representative of 25 grams available CHO. The dose of 25 grams of available CHO was chosen for the glycemic testing, as this dose was determined from previous human dose/response studies to be in the linear range for glycemic response from pasta. Dose response studies showed that CHO doses significantly lower than 25 grams available CHO resulted in inadequate glycemic response curves, while higher pasta doses, (such as the 50 gram available carbohydrate dose in common use to determine the glycemic index of a wide range of foods) yielded curves that were irregular and broad; resulting in glycemic responses outside the linear range for accurate testing.

Available carbohydrate determination: The 25 gram available carbohydrate level used to test Dreamfields pasta was determined by measuring the product's total starch and simple sugar (fructose, glucose, sucrose, maltose, lactose) content using official Association of Official Analytical Chemists (AOAC) methods, 979.10 for total starch and 997.20 for the simple sugars. Results of the available carbohydrate in a 100 g portion using chemical analysis were also compared to those calculated using proximate analysis (total carbohydrate in a 100g portion minus its dietary fiber content). The difference between the calculated value based on proximate analysis and that measured using the official analytical methods was insignificant, only 0.07 g per 100g pasta.

Sample and subject treatment: As previously noted, strict adherence to using specific cooking times for Dreamfields is necessary to obtain consistent and accurate glycemic results. In this comparison study subjects arrived at the independent clinical research facility following an overnight fast. Subjects were either fed Dreamfields pasta, high quality durum semolina traditional spaghetti or a white bread obtained locally in Gainesville, FL. Each pasta type was cooked as specified on their respective packages. Subject baseline fasting blood glucose values were determined in duplicate. As a measure of consistency, if a subject's duplicate fasting blood glucose values varied by more than 8 mg/dL, the subject was not allowed to continue testing on that day. Each subject was fed triplicate servings of each of the food types containing 25 grams of available CHO over several days until all testing was completed. In this randomized crossover study, the glucose response was determined every 15 minutes for a 2h period after ingestion of each CHO "meal."

Sample testing interval: Dreamfields pasta glycemic testing uses a two-hour postprandial testing procedure as it is well known that healthy people typically have digested the majority of the carbohydrate in a meal within this time frame. Dreamfields confirmed that two-hour testing is acceptable by testing its products using extended feeding studies up to six hours at an independent testing facility. Data from 68 individual extended feeding tests in healthy subjects show that the majority of the healthy subjects (80%) had their blood glucose levels return to their fasting baseline level within 2 hours. Subjects whose blood glucose level did not return to its fasting level within 2 hours, had their levels return to baseline within 2.5-3 hrs. No additional blood glucose rise has been observed in subjects after 3 hours of extended glycemic testing. However, it was determined that none of the peak area associated with the increased testing time to reach the fasting baseline level in the slow responding subjects was significant to the overall area under the curve (AUC), and did not have any effect on the calculated GI values. Data indicate that a 2-hour postprandial testing period is sufficient to capture the most significant peak area associated with the glucose responses from subjects consuming Dreamfields pasta.

Comparison study results: Once each glycemic challenge test was complete, the area under the blood glucose response peak (AUC) was determined mathematically using peak area analysis software. The white bread "meals" were used as a standard glycemic reference for the pasta blood glucose response curve area, so as to calculate a glycemic index and glycemic load using the following calculations:

Eq. 1: Glycemic Index (GI): AUC_{Pasta} / $AUC_{Bread\ Standard}$ X 100, where AUC means Area Under the Curve.

Eq. 2: Glycemic Load (GL): [AUC_{Pasta} / $AUC_{Bread\ Standard}$] X 38.0*

*[NOTE: The value of 38 is used as a factor to adjust the study's dry serving to the 56 grams dry serving size established for nutrient labeling by the FDA.]

Because the eating properties of the two pasta types were indistinguishable and the study was single-blinded, subjects were unaware if they were consuming Dreamfields spaghetti or the traditional spaghetti.

The mean blood glucose results and variability of triplicate testing are shown in Figure 1, while the study's statistical summary data are shown in Table 1. Blood glucose results show that ingestion of Dreamfields pasta results in a 65% reduction in glycemic response as compared with traditional pasta.

It is important to note that for its 65% GI reduction label claim, Dreamfields pasta has relied on published glycemic index (GI) values. The GI value of 38 used for traditional pasta, shown on the front of its package in the lower left hand corner, was taken from The New Glucose Revolution, published by Brand-Miller and others in 2003. The pasta results published in this reference indicate pasta that was cooked for 5 minutes, a relatively short period of time, and thus, produced a relatively low GI value. The low GI value, while being from somewhat undercooked pasta, was deemed most appropriate for use in labeling as a conservative value, given the variability of glycemic index testing. More recent data published by Atkinson and others (2008) show traditional pasta having a glycemic index of 49 ± 2.

Dreamfields Production Glycemic Testing

In addition to a comparative study, Dreamfields also performs quality assurance glycemic testing prior to releasing production product for commercial sale. Every production batch of Dreamfields pasta undergoes glycemic testing with healthy humans in an independent clinical testing facility located in Gainesville, FL. As described previously, subjects are rigorously prescreened for possible metabolic issues prior to being accepted as test panelists; their test results are monitored continually for deviations and anomalies that could render inaccurate results. During Dreamfields quality assurance glycemic testing, each of three test subjects is fed 38 grams (dry weight serving) of Dreamfields pasta, representative of 25 grams available CHO. Pasta is cooked using times specified on the package for its shape. Each subject's blood glucose level is measured every 15 minutes for 2h after ingestion. The resulting blood glucose response curve's area is determined mathematically using a peak analysis software system and compared with the area derived from the same subject's response to a reference

locally-produced white bread to calculate a glycemic index and glycemic load, as previously described. The glycemic index and glycemic load are calculated using equations defined in the comparison study. Dreamfields has over 1200 challenge tests on file, done since the product was introduced in 2004. The mean blood glucose responses for the white bread standard and Dreamfields pasta is shown in Figure 2, while the summary results of these challenge tests, presented in Table 2, reinforce Dreamfields' claim of 5 grams of digestible carbohydrates per dry weight serving of its pasta. Low number of tests for some shapes listed in Table 2, such as angel hair, are the result of their recent commercial introduction.

Concluding Remark

Since 2004, controlled-subject glycemic challenge testing, using a 25 gram available carbohydrate dose and a standard 2hr postprandial method, has consistently provided glycemic response data from Dreamfields pasta that is significantly lower than that published for traditional pasta as shown in peer-reviewed literature. These results were further supported through single blind randomized crossover study comparing Dreamfields pasta glycemic response with traditional pasta.

Figure 1. Blood glucose response comparative data.

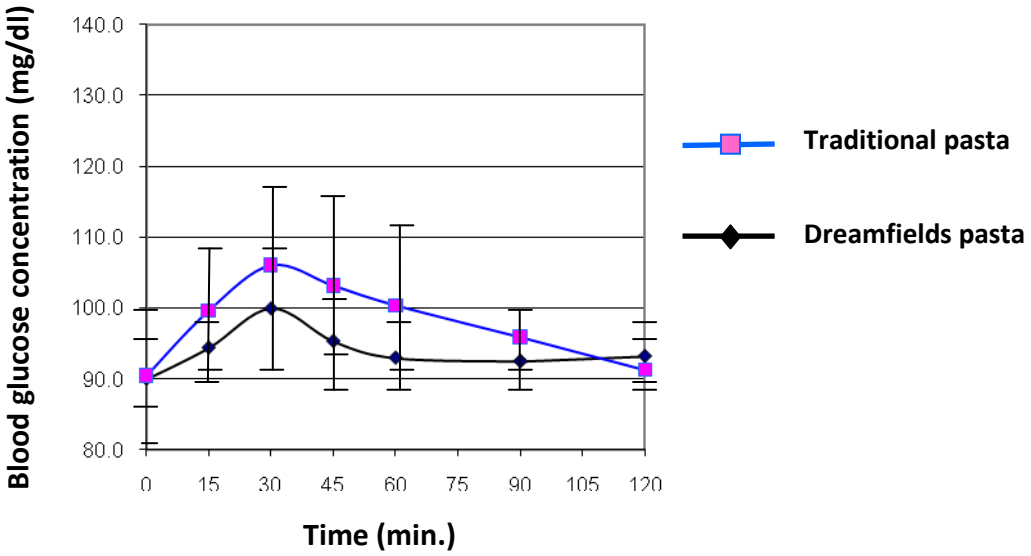

Table 1. Comparison of triplicate testing of Traditional and Dreamfields spaghetti.

Subject	Mean Bread AUC	Mean DF Pasta AUC	Mean DF pasta GI	Mean DF pasta GL	Mean Trad. Pasta AUC	Mean Trad. Pasta GI	Mean Trad. Pasta GL
1	2545	264	10.4	3.7	591	23.2	9.3
2	1882	389	20.7	7.4	875	46.5	18.5
3	2312	184	8	2.8	1398	59.0	23.5
4	2518	255	10.1	3.6	993	39.4	15.7
5	1928	341	17.7	6.3	447	23.2	9.2
6	1854	108	5.8	2.1	705	38.0	15.1
7	1593	219	13.7	4.9	475	29.8	11.9
8	3564	261	7.3	2.6	1217	34.1	13.6
Mean	2275	253	11.7	4.2	838	36.7	14.6
STDEV	622	87	5.3	1.9	348	12.1	4.8

Figure 2. Mean Blood glucose Responses to White Bread Standard and Dreamfields Pasta

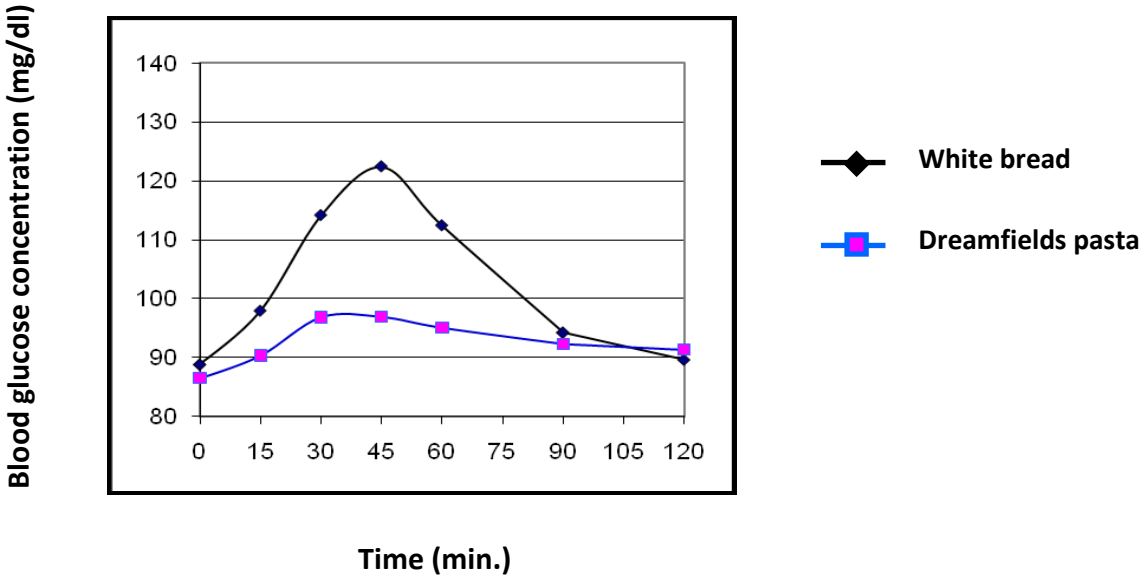

Table 2. Human production quality control *in vivo* Glycemic Index and Glycemic Load data.

Pasta Shape	Number of Production Tests	Glycemic Index	Glycemic Load
Elbows Mean	129	15.6	5.6
Elbows SDEV		8.6	3.1
Lasagna Mean	133	15.9	5.8
Lasagna SDEV		7.1	2.6
Linguine Mean	179	14.5	5.3
Linguine SDEV		8.8	3.2
Penne Mean	254	15.3	5.5
Penne SDEV		7.3	2.6
Rotini Mean	112	16.2	6.0
Rotini SDEV		8.5	3.1
Spaghetti Mean	380	12.3	4.4
Spaghetti SDEV		8.4	3.0
Angel Hair Mean	44	15.3	5.6
Angel Hair SDEV		8.6	3.2
POOLED MEAN	**1231**	**15.0**	**5.4**
POOLED SDEV	**1231**	**8.2**	**3.0**

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