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Hi-maize® Resistant Starch and Its Benefits in Maintaining Glycemic Health

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Introduction

Glycemic health – the maintenance of healthy blood glucose and insulin levels – is an issue at the forefront of the medical community and in health and public policy discussions. The effects of poor glycemic health have, in certain instances, reached 'epidemic proportions' according to the Centers for Disease Control. While the mechanisms are complex, a great deal of research has shown that increased insulin resistance and the often corresponding elevation of blood glucose levels lead to prediabetes – defined by the American Diabetes Association as a non-disease state where blood glucose (sugar) levels are higher than normal but not yet high enough to be diagnosed as diabetes.[1]

This paper focuses on studies that have been conducted on Hi-maize® resistant starch to help maintain glycemic health. In particular, the studies examine the use of Hi-maize as a replacement for rapidly digestible (high glycemic) carbohydrates and also as a stand-alone supplement to typical diets.

The Role of Carbohydrates

Foods containing carbohydrates are an important part of a healthy diet, but their impact on health has been intensely debated. The debate centers on the impact of carbohydrates on blood glucose — in other words, their glycemic impact. Most carbohydrates consumed from foods break down and are digested quickly in the small intestine, causing a rapid and high rise in blood glucose. Insulin produced in response to the blood glucose, acts like a key to unlock cells so glucose can be transported inside the cell. The glucose is either used as energy or stored.

In contrast to glycemic carbohydrates, dietary fiber and resistant starch are not digestible in the small intestine, do not break down into glucose, and do not cause the production of insulin. They pass through the small intestine undigested and reach the large intestine. These less processed whole foods and/or foods high in dietary fiber produce a lower glycemic response – with a lower rise in blood glucose and insulin levels.

While it has been well understood that glycemic health is important in managing type 2 diabetes, it is becoming increasingly apparent that preserving glycemic health is important for maintaining overall health and wellness in non-diabetic populations as well, and especially in the millions of people with metabolic syndrome and/or prediabetes and people at risk of developing these conditions.

The Health Issues Surrounding Insulin Resistance

Insulin resistance develops when the receptors on the muscle cells and tissues become ***less sensitive*** to the effects of insulin. Glucose transport into cells becomes less efficient and blood glucose levels rise, triggering the production of more insulin. Higher levels of circulating insulin are needed to keep blood glucose levels under control. Some people have an enhanced risk for developing insulin resistance because of a genetic predisposition (i.e. Hispanics, African Americans and Native Americans.)

Insulin resistance may also be accelerated in individuals who are overweight. The fatty tissues release cytokines into the blood stream which cause inflammation. Inflammation inhibits the action of insulin, which cause higher levels of insulin to be produced in order to keep blood glucose levels under control.

With ongoing inflammation and increasing insulin resistance, the body may not be able keep up with the demand for insulin to control blood glucose. When this happens, blood glucose levels rise above healthy levels and a person is considered to have impaired glycemic control.

High levels of insulin inhibit the use of fat as energy. It also increases the production of fatty acids. Thus, high levels of circulating insulin promote fat storage and prevent fat from being utilized as energy. This helps to explain the fact that approximately 80% of people with type 2 diabetes are also overweight. Lowering the levels of circulating insulin will help to increase fat burning and decrease fat storage. Thus, reducing insulin resistance may lead to improvements in weight control as well as blood glucose control.

Insulin Resistance and Prediabetes

The American Diabetes Association has defined the following criteria for "normal" blood glucose levels:

- Hemoglobin A1C reading (an indicator of long term glycemic control) of less than 5.7% or
- Fasting plasma glucose levels of less than 100 mg/dl.

In people with healthy glycemic responses, blood glucose levels are regulated and range between about 70 mg/dl and 130 mg/dl, regardless of how little or how much carbohydrates they eat.[2] This tight control is achieved through the release of insulin from the pancreas. Insulin triggers the transportation of glucose into the muscles and tissues, where it is either used for energy or stored as glycogen.

In "normal" blood glucose levels, it has traditionally been assumed that insulin levels are also normal. However, insulin levels are the first to change in when glycemic health is impaired. People with healthy blood glucose levels may already have the beginnings of insulin resistance without knowing it and may have elevated insulin levels.

As insulin resistance increases, glycemic control starts to suffer. When blood glucose levels meet one of the following criteria, an individual has become "prediabetic," according to the American Diabetes Association:

- Hemoglobin A1C levels between 5.7% and 6.4% or
- Fasting plasma glucose levels between 100 mg/dl and 126 mg/dl

The Centers for Disease Control have estimated that 35% of U.S. adults aged 20 years or older and 50% of those 65 years or older have prediabetes.[3] This means that they have slightly elevated levels of blood glucose (but not high enough to be diagnosed with diabetes) illustrating a degree of insulin resistance. One study stated that more than 50 percent of the U.S. population could have prediabetes or diabetes by the year 2020.[4] That same study projected a $3.4 trillion increase in healthcare and related costs in the next decade. Another study found that only 7.3% of people with prediabetes are aware that they have the condition.[5]

The current recommendations for increasing insulin sensitivity (reducing insulin resistance) focus on increasing exercise and losing weight. These lifestyle changes can effectively increase insulin sensitivity thereby lowering blood glucose levels.[6] Currently, lifestyle therapies are more effective than drugs in improving insulin sensitivity.[7,8]

Hi-maize Resistant Starch

Natural Hi-maize® Resistant Starch

Hi-maize resistant starch begins with high amylose corn hybrids produced through traditional plant breeding. A mild heat/moisture treatment helps to align the amylose chains within the natural starch granule. Because it retains its natural granule structure, it is a Type 2 Resistant Starch (RS2). Hi-maize contains a portion of slowly-digestible starch, which is digested within the small intestine and slowly absorbed as glucose. Hi-maize also contains a portion of resistant starch, which is not digested in the small intestine. The resistant starch component of Hi-maize reaches the large intestine where it is fermented by the beneficial bacteria and produces short-chain fatty acids. These short-chain fatty acids are believed to trigger additional beneficial metabolic changes, including the production and release of satiety hormones from the large intestine.

Hi-maize resistant starch helps support healthy blood glucose levels via two major mechanisms: (1) it reduces the glycemic response to foods, and (2) it helps to improve insulin sensitivity (i.e., reduces insulin resistance).

Hi-maize Resistant Starch Reduces the Glycemic Response to Foods

When Hi-maize 260 resistant starch is used as a substitute for flour or other rapidly-digested carbohydrates, it lowers the glycemic impact of that food. The addition of higher levels of Hi-maize and removal of more glycemic carbohydrates will drive the glycemic response even lower. More than twenty human clinical trials have been published examining the **glycemic and short-term insulin response** to foods containing Hi-maize resistant starch or resistant starch from high amylose corn.[9-30]

In April of 2011, the European Food Safety Authority confirmed this reduced glycemic response of Hi-maize resistant starch by approving the following labeling claim: **"Replacing digestible starch with resistant starch induces a lower blood glucose rise after a meal."**[31]

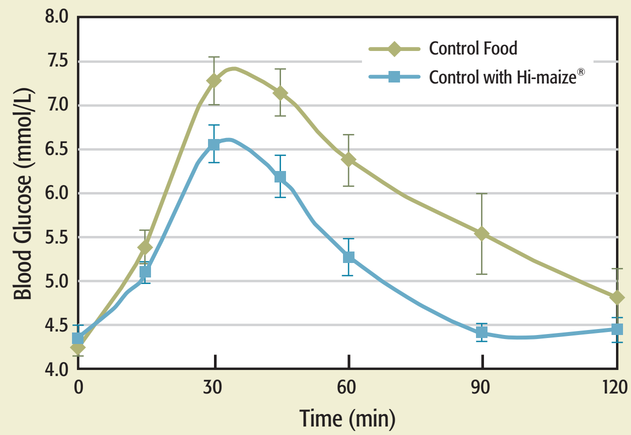
Hi-maize Resistant Starch Increases Insulin Sensitivity

Six randomized clinical studies have been completed showing that Hi-maize resistant starch significantly **increases insulin sensitivity** in adults. Five out of six of these studies included healthy individuals,[32-36] while one study included individuals with type 2 diabetes.[30] In contrast to the previous studies in which Hi-maize replaced glycemic carbohydrates, these studies added Hi-maize in addition to participants' normal diet and an equal amount of digestible starch was added to the control condition. **Thus, the benefit was found independent of a glycemic reduction of food or the diet.**

Two studies have been published in healthy adults.[32,33] **Improvements in insulin sensitivity of 33-69% were seen following consumption of 30-60 grams of dietary fiber from Hi-maize 260 resistant starch.** The effect first appeared 20 minutes following consumption, lasted at least a day after consumption and was maintained over four weeks. The researchers also found a reduction in the glycemic response and insulin response to the standard meal and enhanced glucose uptake into muscle tissues, even when corrected for lower insulin concentrations.

One study examined the effects of Hi-maize resistant starch on insulin sensitivity in adults with type 2 diabetes.[30] **Two-thirds of the study subjects were reported to be obese.** The study found significant improvements in the Insulin Sensitivity Index as well as reductions in fasting glucose, postprandial glucose levels, postprandial insulin levels and Body Mass Index.

Comparison of Glycemic Response



One study has been published in **African American adults at risk for developing type 2 diabetes**.[34] These participants were fed 3 slices of bread containing approximately 7 grams of dietary fiber from Hi-maize resistant starch per day. The study did not find an improvement in insulin sensitivity, but noted that one individual who had been diagnosed with prediabetes at the start of the study showed a significant improvement in insulin sensitivity. The authors hypothesized that the dose was too low to see the benefits in the rest of the participants.

Two studies have been completed in **insulin resistant adults.** One study has been published,[35] while data from another clinical trial have been presented at a scientific conference.[36] In the Johnson study, men and women with insulin resistance were fed 40 grams of dietary fiber from Hi-maize resistant starch and **19% improvement in insulin sensitivity was found, while the control group had 14% deterioration**. In the Maki study, men and women with **abdominal obesity** were fed two doses of dietary fiber from Hi-maize resistant starch. **The 15 gram dose resulted in a 56% improvement in insulin sensitivity in men. The 30 gram dose resulted in a 73% improvement in insulin sensitivity in men.** The study did not find an effect in women. The authors suggested that the women were less insulin resistant and were not controlled with respect to menstrual cycle in the study, both of which could have obscured the potential effects.

There appears to be a relationship between the magnitude of the benefit seen and the degree of insulin resistance in the test population. A lower quantity of Hi-maize resistant starch yields a beneficial effect in individuals with significant insulin resistance while individuals without insulin resistance require a higher quantity to demonstrate an improvement in insulin sensitivity. This is favorable because insulin sensitivity benefits are most needed in insulin resistant individuals as they have a higher risk for developing prediabetes.

Researchers have not identified the mechanisms responsible for these benefits. While early work suggested that short-chain fatty acids from the fermentation of the resistant starch portion of Hi-maize is likely responsible,[17] a more rapidly engaged mechanism is also likely because the improved insulin sensitivity benefit has been seen 30 minutes after food consumption[16] – well before fermentation would be expected to occur. Currently, both the slowly digestible portion of Hi-maize resistant starch and the resistant starch portion are believed to contribute to the insulin sensitivity benefits.

Conclusions

The dietary consumption of modest levels of Hi-maize resistant starch can offer support in the pursuit of better glycemic health – both as a replacement for high glycemic food ingredients and as a standalone supplement to the diet. In particular, it can support healthy individuals and individuals at risk for prediabetes in maintaining healthy blood glucose levels and improve their overall glycemic health.

Definitions

Glycemic management is an emerging opportunity. Because clear understandings do not exist within this area, we are including definitions for terminology utilized within this paper.

Glycemic Health describes the state of maintaining healthy blood glucose (sugar) and insulin levels.

Glycemic Management describes the process of managing glycemic health.

Glycemic Impact describes the impact on blood glucose (sugar) from dietary consumption of carbohydrates.

Metabolic Syndrome is the combination of at least three of the following characteristics: elevated waist circumference, elevated triglycerides, reduced HDL cholesterol levels, elevated blood pressure and elevated fasting glucose; that increases the risk of developing type 2 diabetes and cardiovascular disease.[37] One of the underlying risk factors for this condition is insulin resistance. The other is abdominal obesity. Thus, improving insulin sensitivity may have benefits in maintaining cardiovascular health as well as glycemic health.

Three major methods are being used to measure the glycemic impact of foods: Glycemic Index, Glycemic Load and Glycemic Response. Due to confusion regarding these methods and interpretation of the results generated by foods tested under these methods, their definitions are included here:

- **The Glycemic Index** ("GI") was first defined by David Jenkins and colleagues at the University of Toronto in 1981,[38] as the area under the curve for the increase in blood glucose after the ingestion of 50 g of "available" or "glycemic" carbohydrates in a food during the 2-hr post-prandial period, relative to the same amount of glycemic carbohydrates from a reference food (white bread or glucose) tested in the same individual under the same conditions and using the initial blood glucose concentration as a baseline. In this test, both the reference and test food are standardized on a specific quantity of glycemic carbohydrates (50 grams each). Thus, if a high-fiber food is being tested, the subjects will consume a larger quantity of that food than the reference food because it contains less glycemic carbohydrate.

  Multiple studies have been published examining the Glycemic Index of foods containing Hi-maize resistant starch. The results are contradictory, as some studies have found significant reductions in Glycemic Index while other studies have shown no effect. It is unclear whether the different quantity of foods required by the methodology or if other factors are responsible for the inconsistent results.

- The **Glycemic Load** has been defined as the weighted average of the GI of individual foods multiplied by the percentage of dietary energy as carbohydrates.[39] It is based upon the GI, but adjusts the Index to account for differences in serving sizes. For example, foods such as carrots, which have a high GI, provide a low amount of glycemic carbohydrates in one serving, and thus have a low Glycemic Load.

- **Glycemic Response** was recognized by the 2005 Dietary Guidelines Advisory Committee as the effects that carbohydrate-containing foods have on blood glucose concentration over the time course of digestion. While this definition is less standardized than the GI, it can be used to measure the impact on blood glucose of a consistent, consumer-friendly portion of food (such as that labeled as one serving on the Nutrition Facts panel). Unlike the GI, it does not require equal amounts of glycemic carbohydrates in the standard and test foods and therefore does not penalize high-fiber foods, as the impact on blood glucose from equal-sized portions of the test and standard food can be compared directly. For example, the GR of two slices of high-fiber bread can be compared to that of two slices of white bread. Unless otherwise noted, the glycemic impact of foods containing Hi-maize resistant starch utilizes a glycemic response method.

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