

BAYWOOD RESEARCH MODULE

RELIABLE INFORMATION FOR INFORMED DECISIONS

IN THIS MODULE:

**Uptake and
Absorption of
Carbohydrates**

**Sources of
Carbohydrates**

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Triple Action Formula**

**In Vivo Effectiveness
of a Starch Absorption
Blocker in a Double-
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RELATED MODULES:

**Fat Eliminator
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Carb eliminator™

Carbohydrates are among the most abundant organic molecules in nature. In the human body, carbohydrates are responsible for a range of functions including:

- ~ Providing a significant fraction of the energy in the diet
- ~ Acting as the storage form of energy in the body, and
- ~ Serving as cell membrane components that mediate many forms of intercellular communications

UPTAKE AND ABSORPTION

The principal sites of dietary carbohydrate digestion are in the mouth and intestinal lumen. This digestion is rapid and usually completed by the time the stomach contents reach the junction of the duodenum and jejunum. Monosaccharides (simple sugars) are present in low concentrations mainly in a diet of mixed animal and plant origin. Disaccharides present the majority of carbohydrates found in the human diet, being of either animal (such as glycogen) or plant origin (starch, composed of amylose).

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Digestion of carbohydrates begins in the mouth where, during mastication (chewing), salivatory glands produce the enzyme alpha-amylase that acts quickly on the bonds between the carbohydrate rings, resulting in formation of smaller, molecules of the sugar. Carbohydrates are the only dietary component for which degradation begins in the mouth. Upon entering the stomach, digestion of carbohydrates halts temporarily due to inactivity of enzymes in the acidic environment of the stomach. When acidic stomach content enters the small intestine, they are then neutralized by bicarbonate secreted by the pancreas and now pancreatic alpha-amylase continues the process of digestion. The final digestive process occurs in the inner layer of the small intestine (upper jejunum) with several enzymes being secreted by intestinal wall. The duodenum and upper jejunum absorb the majority of the dietary sugars. The mechanisms needed for such absorption differ for each sugar. Insulin is not needed for the uptake of glucose by the intestinal cells.

Since predominantly monosaccharides are absorbed through the intestinal wall, any defect in the enzyme structure of its activity causes the loss of undigested carbohydrates into the large intestine. Most common defects are lactose intolerance, isomaltase-sucrase intolerance, as well as a variety of intestinal diseases, malnutrition, drugs, injuries etc.

SOURCES OF CARBOHYDRATES

Although many monosaccharides have been identified in nature, only a few have metabolic significance in humans. Glucose is the most common, along with fructose and galactose, which occur in significant amount and contribute to energy metabolism of the body. About 15% to 20% of the calories, or around 100 grams per day, contained in the western diet are supplied by fructose alone, derived from sucrose (table sugar) that breaks into equal amount of fructose and glucose. Fructose is also found as a free monosaccharide in many fruits and vegetables and in honey. Unlike glucose, fructose metabolism is fully insulin independent. High-fructose diets can adversely affect liver metabolism.

A constant source of blood glucose is an absolute requirement for human life. Glucose is the preferred source of energy of the brain and many other tissues of the human body, especially in exercising muscle. Blood glucose can be obtained from three primary sources:

- ~ Diet (sucrose - table sugar)
- ~ Degradation of glycogen (sugar stored in cells, and
- ~ Gluconeogenesis (synthesis of glucose)

The major dietary source of galactose is lactose obtained from milk and milk products. Galactose can also be obtained by degradation of complex carbohydrates. Like fructose, galactose entry into cells and its metabolism is not insulin dependant.

Dietary intake of glucose and its precursors, such as starch, monosaccharides and disaccharides, is often insufficient and sporadic. Therefore, the human body has developed mechanisms for storing a supply of glucose in a rapidly mobilized form such as glycogen. In the absence of a dietary source of glucose, glucose can be quickly released from liver glycogen, and similarly, in working muscle. When glycogen stores (400 grams in muscles and around 100 grams in healthy liver) are depleted, specific tissues synthesize glucose from the body's proteins in the pathway called gluconeogenesis.

CARB ELIMINATOR™

Carb Eliminator™, with its unique Triple Action Formula, has been designed to serve as a carbohydrate blocker, appetite suppressant and stimulant-free energizer, acting on several paths of carbohydrate metabolism.

Carbohydrate blocking

Carbohydrate blocking has been achieved by a proprietary blend contained of Phaseolamin 2250™, Glucosol™, Gymnema Sylvestre Leaf, Fenugreek Seed and Zhi Shi.

Phaseolamin 2250™

Phaseolamin 2250™ is a standardized, clinically studied, all-natural ingredient, developed to delay starch digestion. By possibly causing a temporary malabsorption of dietary starches, it also enables undigested dietary starches to pass the digestive system without converting to glucose, or energy. Phaseolamin, discovered in 1975, is derived from kidney beans, Pheaseolus Vulgaris, and contain a proteinaceous inhibitor of α -amylase. By binding with the enzyme α -amylase, pheaseolamin destructs this enzyme temporally inhibiting its functions (described earlier).

Pharmachem Laboratories, Inc. performed in vitro quantitative tests that demonstrate that one (1) gram of this powerful standardized extract "neutralizes" over 560 grams of dietary starch, or over 2,250 starch calories. Other lab-based tests are equally compelling. The material survives in undiluted gastric and intestinal solutions in laboratory tests. Preliminary results of a European clinical study are very promising, demonstrating an average weight loss of eleven (11) pounds in healthy adults, without changes in diet and exercise, and reduction of the conversion of dietary starch to glucose by an average of 57%.

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Glucosol™

Glucose transport is one of the most important and required parts of any cell metabolism needed to acquire energy. Several different types of glucose transporters are known in cell membranes of mammalian tissues. Modifications of the activity of glucose transport would cause several physiological effects, including lowering blood glucose level. Only a few compounds have been known to affect glucose transport activity. Several human hormones, primary insulin and glucagons, are closely involved and present an essential part of carbohydrate metabolism. Glucagon is known as a mobilizing hormone, while the primary function of Insulin is storage of metabolic fuels.

Corosolic acid, a main active ingredient of Glucosol™, is derived from *Lagerstroemia speciosa L.* concentrate that is prepared by boiling powder of sliced dry leaves in distilled water. Corosolic acid shows significant glucose transport stimulating activity at very small concentration. A recent study indicates that oral administration of corosolic acid can result in hypoglycemic effects. Stimulation of glucose transport from blood into tissue cells is an essential part in the metabolic process needed to convert dietary components into useful body energy. This hypoglycemic effect of Glucosol™ was studied in hereditary Type II diabetic mice, in which plasma glucose levels increased in the control group. This increase was completely suppressed in the mice given Glucosol™. The results indicate large oral doses of *Lagerstroemia speciosa L.* produced blood sugar reduction similar to that produced by two units of insulin. The peak reduction occurred two hours after the administration and repetition of the dose. After two hours, *Lagerstroemia speciosa L.* caused the blood sugar level to remain low (or even lower than the first effect) for more than 4 - 5 hours.

Gymnema Sylvestre Leaf

Long known in Indian medicine, *Gymnema Sylvestre* has been used for centuries as an efficient therapeutic for the treatment of non-insulin dependent diabetes mellitus and obesity. Alcoholic extracts of *Gymnema Sylvestre* leaves have a direct effect on pancreatic islets of Langerhans and several beta-cell lines, which among other functions produce insulin. *Gymnema Sylvestre* has stimulatory effects on insulin release indicating increasing cell permeability without long-term changing of regular pathways.

Gymnemic acid, a mixture of glycosides extracted from the leaves of *Gymnema Sylvestre*, is also known to inhibit the intestinal absorption of glucose in humans by inhibiting the absorption of oleic acid in the intestine and in a dose dependent and reversible manner. The extent of inhibition and the recovery progress are similar to the response of the human body after glucose absorption.

Clinical studies from Japan evaluated the effects of *Gymnema Sylvestre* on plasma and liver lipids. Extract of *Gymnema Sylvestre* leaves induced apparent fat digestibility, though not the protein digestibility. Results showed that *Gymnema Sylvestre* extract also was efficient to reduce the levels of plasma triglycerides and cholesterol influencing over a wide range of lipid metabolism, as well as to suppress body weight gain, and accumulation of fat drops in kidney and other tissues. It is found that *Gymnema Sylvestre* has similar results to those of chitosan, even if they are given together.

Zhi Shi

Zhi Shi (in traditional Chinese medicine) is also known as green orange, sour orange and bitter orange in other parts of the world. Synephrine, that is the main active compound found in the fruit of a plant called *Citrus aurantium*, is chemically very similar to the ephedrine and pseudo-ephedrine found in many weight loss and energy supplements which contain Ma Huang, but with significantly fewer side effects.

Because synephrine is a stimulant, similar to caffeine and ephedrine, it is thought to have similar effects in terms of providing an energy boost, suppressing appetite and increasing metabolic rate and caloric expenditure. In traditional Chinese medicine, Zhi Shi is used to help stimulate the Qi (energy force). Although synephrine and several other compounds found in Zhi Shi are structurally similar to ephedrine and are known to act as stimulants by increasing adrenergic activity, Zhi Shi does not appear to have the same negative central nervous effects of Ma Huang. Through its stimulation of specific adrenergic receptors, Zhi Shi is theorized to stimulate fat metabolism without the negative cardiovascular side effects experienced by some people with stimulation of all adrenergic beta-receptors by Ma Huang.

The most likely explanation for weight loss effects attributed to citrus aurantium supplements is the amphetamine-like effects of the alkaloids. Although this effect is likely to be somewhat less dramatic than effects induced by Ma Huang, the human body can still expect variable effects including reduced appetite and heightened feelings of energy very similar to those of caffeine - both of which are likely to result in weight loss.

Fenugreek Seed

The last (but not least) ingredient of the Carb Eliminator™ proprietary carbohydrate blocking blend is Fenugreek Seed, *T. foenum graecum*. Another traditional Asian medicinal plant, Fenugreek seed has several effects in carbohydrate metabolism. It has also been traditionally used in treatment of diabetic subjects but its bitter taste prevented any wide spread use. Today's availability of extracted fenugreek seeds allows us to use them in powder form.

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Fenugreek has a direct effect on glutathione increasing its plasma levels, as well as on glutathione s-transferase enzyme in the liver, increasing its activity. Fenugreek treatment also showed a small but consistent increase in erythrocytes. An active amino acid found in fenugreek seeds is 4-hydroxysoleucine, which also shows interesting effects on increased insulin production and can also mimic insulin, restoring the normal levels of sugars in the blood.

Appetite suppression

Another important part in achieving desired effects of carbohydrate elimination is suppression of the appetite. Such has been achieved by a proprietary blend containing Yerba Mate Leaf, Korean and Siberian Ginseng root, and Green Tea Leaf Extract.

Yerba Mate Leaf

One of the foremost beverages of South America is *ilex paraguariensis*, or yerba mate. In current practice in industrialized, modern Argentina and Paraguay, maté tea is made from the leaves steeped in hot water. A large quantity of ground leaf is first soaked in cold water, then the hot water is added, over and over again, until all the parts have been extracted. In between each addition of hot water, the tea is ingested through a special wood or metal straw.

Among the native Peruvian tribe Guarani, the natural use of maté for healthful purposes has persisted. They use it to boost immunity, cleanse and detoxify the blood, tone the nervous system, restore youthful hair color, retard aging, combat fatigue, stimulate the mind, control the appetite, reduce the effects of debilitating disease, and so forth.

Several attempts to characterize part or all of the constituents of maté have been made during the last few decades. The one thing that unites the various assays is the consistent detection of numerous vitamins and minerals. There is the usual array of resins, fiber, volatile oil and tannins that characterize many plant substances. But then there is the growing list of vitamins and minerals, including carotene, vitamins A, C, E, B1, B2, B complex, riboflavin, nicotinic acid, pantothenic acid, biotin, vitamin C complex, magnesium, calcium, iron, sodium, potassium, manganese, silicon, phosphates, sulphur, chlorophyll, choline, and inositol to name a few.

Korean and Siberian Ginseng Root

The main component in this unique blend of two different kinds of very potent ginseng roots is a diverse group of steroidal saponins known as ginsenosides. There are over twenty-five known ginsenosides that have been separated and detected based on their sugar units. The ginsenosides demonstrate the ability to target a myriad of tissues, producing

a range of responses quite different from one another. A single ginsenoside can initiate multiple or opposing actions in the same tissue, making the effects of ginseng complex. Such effects include:

- Cognitive-learning function
- Antioxidant effects
- Antiviral activity, and
- Decrease of alcohol levels, heart effects, and hypoglycemic effect

Ginseng decreases blood sugar through glucose metabolism related to adrenergic receptors, improving psychophysical performance, and reducing fasting blood glucose and weight.

In traditional Chinese medicine, Ginseng has been used for centuries for loss of appetite, and control of gastric disturbances and vomiting. The blend in Carb Eliminator™ of Korean and Siberian ginseng is designed to give greater response in this field, while minimizing other effects ginseng has on the human body.

Green Tea Leaf

Natural green tea extract is made from the leaves of *Gamellia sinensis*, whose major active compounds are the tea polyphenols. The primary polyphenols found in green tea are the catechins: epicatechin, epigallocatechin, epicatechin-3-gallate, epigallocatechin-3-gallate. Of all the catechins found in green tea, epicatechin-3-gallate is known to be the most powerful. Recently, green tea has been the focus of much scientific and biomedical research. This research combined evidence from traditional and epidemiological sources that support its preventive health capabilities. The polyphenols from green tea have long been known to have multifunctional properties including their effects on carbohydrate metabolism.

Many important enzymes are involved in the metabolism of carbohydrates (as previously described). All of these enzymes contribute to the digestion of carbohydrates at different points in the digestive tract as well as after sugars enter the blood. Studies have shown the inhibitory activity of green teas polyphenols on alpha-amylase. Similar studies have shown that tea catechins could also inhibit the activities of sucrase and alpha-glucosidase. The administration of various amounts of tea polyphenols suppresses both plasma glucose and insulin levels after starch ingestion. It was also found that tea polyphenols could prevent carbohydrate digestion in the small intestine.

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In regulating human metabolism, green leaf tea extract also has several effects on lipid metabolism, decreasing plasma total cholesterol, and increasing total fecal excretion of lipids and cholesterol.

Proprietary Digestive Enzyme Blend

The third portion of the Triple Action Formula of Carb Eliminator™ is the proprietary digestive blend, which contains bromelain, papaine, and peptizyme, some of the numerous enzymes essential in the metabolism of carbohydrates in the human body. As described earlier, from ingestion each step is accompanied with several enzymes that are essential to catalyze the chemical reaction needed to complete that step of metabolism. Enzymes improve, and significantly increase speed of many reactions, making them a functional, vital part of living organism.

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Phaseolamin 2250™ is a trademark of Pharmachem Labs, Inc. Baywood is not an agent or employee of Pharmachem Labs, Inc.

Glucosol™ is a trademark of Soft Gel Technologies, Inc. Baywood is not an agent or employee of Soft Gel Technologies, Inc.

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IN VIVO EFFECTIVENESS OF A STARCH ABSORPTION BLOCKER IN A DOUBLE-BLIND PLACEBO-CONTROLLED STUDY WITH NORMAL SUBJECTS

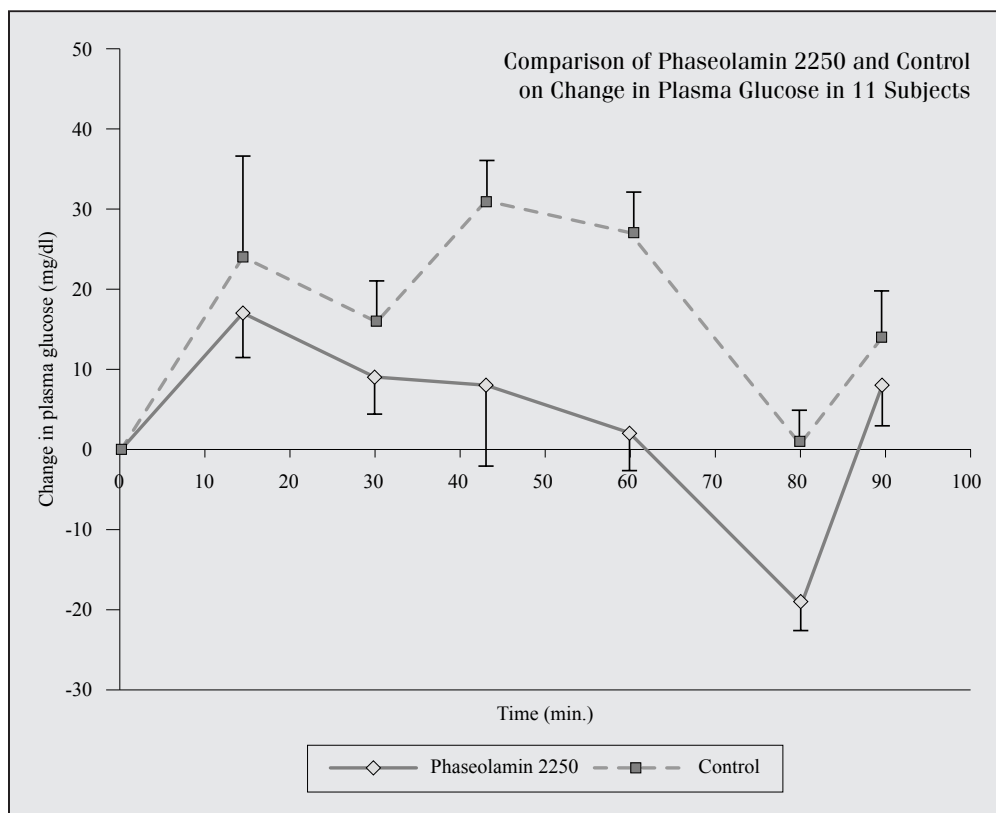
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Analysis data was obtained from the first study done reported on September 6, 2001 and the second study on November, 20, 2001. The total subjects from both studies numbered twenty (20). Nine (9) were excluded who did not furnish all blood samples or who had a negative area for the plasma glucose-time curve and were therefore poor absorbers.

Of the eleven (11) subjects, eight (8) were female and (3) were male, ranging in age from 21 to 57. The Phaseolamin 2250 group had significantly lower plasma glucose at 60 minutes and almost significantly lower glucose at 45 minutes. The average area under the plasma glucose-time curve was 234 ± 353 (SEM) for Phaseolamin 2250 and for the control 1091 ± 362 . The paired t-test value

was $p < 0.1$, almost significant. The area of the curve, which represents glucose absorption and metabolism, was 79% lower with Phaseolamin 2250.

This product shows effectiveness in both sedentary college-age subjects and physically active adults.



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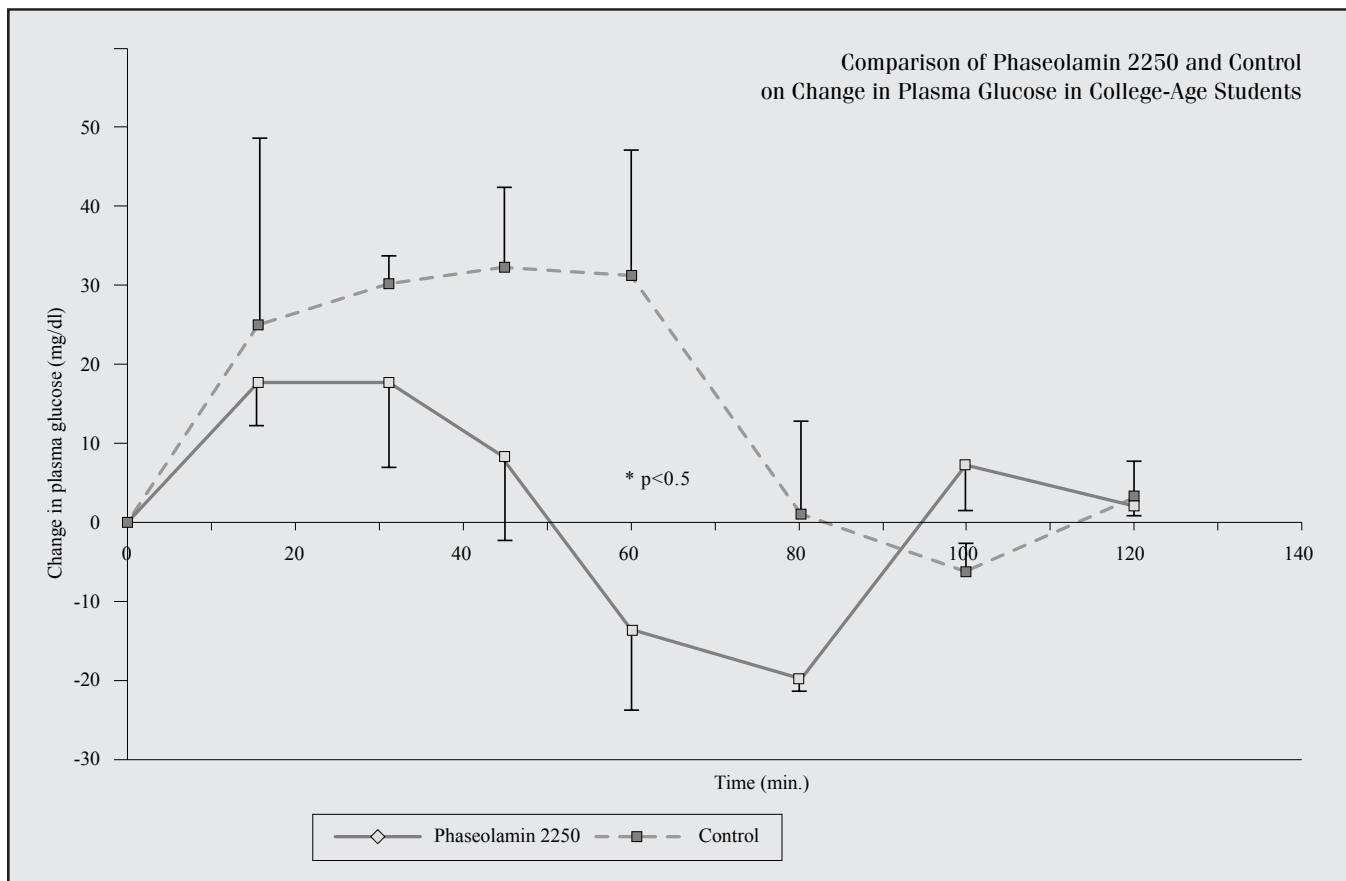
IN VIVO EFFECTIVENESS OF A STARCH ABSORPTION BLOCKER IN A DOUBLE-BLIND PLACEBO CONTROLLED STUDY WITH NORMAL COLLEGE-AGE SUBJECTS

Inhibition of carbohydrate metabolism or absorption is one mechanism to reduce hyperglycemia in normal and especially in diabetic subjects. Another possible benefit is the decrease in calorie intake after eating carbohydrates for obesity and weight loss. In the 1980's there were several reports of in vitro and in vivo effectiveness of a natural starch blocker that worked by inactivating the enzyme amylase. We investigated this hypothesis with an initial pilot study. After this initial study with subjects who were physically active during the study, we did a second study to confirm the results. In this second study, again there was a double-blind placebo-controlled crossover trial with ten subjects (five (5) males and five (5) females aged 21 to 27) who participated with informed consent. After an overnight fast the subjects appeared in the morning and were given in a random fashion either 1) placebo consisting of 4 slices of white bread (60 g of carbohydrate), 42 g of soybean oil margarine, and 4 g of Sweet N'Low; 2) experimental comprising the control plus 1.5 grams of Phaseolamin 2250 (Pharmachem Laboratories). The subjects rested between blood drawings. Plasma glucose was measured from blood sample drawn at baseline and every 15 minutes for 1 hour, then

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every 20 minutes for the second hour. Two (2) subjects did not complete the study and four (4) subjects were poor/non-absorbers as the area under the glucose-time curve was negative. Therefore the data of the remaining 4 subjects was used.

As expected, the control bread produced an increase in glucose in the normal subjects that reached a broad peak after 45 minutes. The peak glucose for the Phaseolamin group occurred at 30 minutes. This dose of Phaseolamin produced a smaller increase than the control from 15 to 80 minutes, with an almost significant difference ($p < 0.1$) at 45 and 60 minutes. The glucose cleared from the plasma about 30 minutes earlier with the Phaseolamin compared to the control. The area under the plasma glucose-time curve (a measure of glucose absorption and metabolism) was 85% lower with the Phaseolamin, $p < 0.05$. Thus only 15% of the glucose in the bread compared to the control found its way into the body in the presence of Phaseolamin. These results show the effectiveness of the product in decreasing the absorption of glucose from complex carbohydrates from this group of subjects.



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MISSION

At Baywood, we are ardent advocates for advancing the quality of life. Our goal of "Making Life Better"™ is based around understanding that everyone is unique as individuals so that we can develop nutraceuticals of the highest quality while providing the highest accessibility amongst all consumer channels.

OUR COMMITMENT TO CHANGE

At Baywood, we are actively involved in the trends that affect our consumers. As the nutraceutical industry continues to advance, we strive to refine our competitive edge by refining the products we offer to the marketplace. We achieve this objective by identifying new scientific advancements for the ingredients we use and quickly modifying product formulations to changing consumer needs and demands. We ask that you expect this change within our product formulations as you grow with us as a customer. From time-to-time, you might see improvements in products that you already purchase from us. This is our commitment to you as our customer. This is our commitment to change. This is our commitment to "Making LIFE Better".

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