CLINICAL RESEARCH BRIEFS

health practice advisors

Thomas A. Cutler Ph.D.
Chief Science Officer

Unicity International, Inc.
1201 North 800 East
Orem, UT 84097, USA

The Unicity Difference

The boom in the health supplement industry has resulted in a multiplicity of supplements competing for shelf space in the stores. The confused consumer is left to decide which product is safe and effective. With such consumers we wish to share the Unicity Difference.

OUR NUTRITIONAL PRODUCTS
Unicity manufactures and sells exceptional quality nutritional supplements to help augment poor nutrition, alleviate conditions that promote ill health, and supply the body with nutrients that boost immunity. Some of our products ameliorate minor illnesses and help prevent or retard degenerative conditions. These products are delivered as capsules, tablets, liquids, and bulk powders.

RESEARCH AND DEVELOPMENT
Conception and design of our top quality products are driven by health needs and nutritional gaps; new scientific discoveries; and newly researched or developed ingredients. Our scientists indefatigably review experimental and clinical studies that back existing and novel ingredients to ensure that safe and effective ingredients are combined in appropriate amounts for maximum potency.

PRODUCT QUALITY AND SAFETY
Quality and safety are the hallmarks of Unicity products, which are manufactured in U.S. FDA-approved facilities under stringent good manufacturing practices (GMP), as defined by government regulatory procedures. The team of scientists at Unicity works in partnership with the scientists and technicians at our manufacturing plants to ensure that the products' quality is unequivocal.

Theoretical formulation does not guarantee efficacy. Thus, we painstakingly select the best raw ingredients and quarantine them until tested and proven to meet our specifications, before release for use. Naturally occurring toxicants in botanicals, as well as potential environmental contaminants, are always screened in the ingredients and in the finished products. Where applicable, patented and standardized ingredients are used in the formulating and production processes. We do our best to use only natural ingredients and avoid artificial colorings and flavorings. All finished products are sampled and analyzed to certify compliance to label claims. We strive to exceed our clients' expectations. Proof of efficacy of an increasing number of our products is backed by clinical studies, which are published in peer reviewed medical journals as well as the Physicians Desk Reference. If primary research on a product is not yet available, the product is designed based on clinical research on individual ingredients.

OUR SERVICES
We do not leave our associates helpless when difficult and scientific product issues need to be addressed. Our fully staffed customer service center answers clients' questions. Technical questions that cannot be answered by the customer service department are referred to our scientists. We also maintain a science email address (science@unicity.net) for answering technical questions and offering support to our associates.

We track questions, complaints, and adverse reactions reported by our associates and review these for patterns, so we can take any steps needed to maintain quality and safety. We train associates through conferences, presentations, and events and support them by providing business development and educational tools.

Yours sincerely,

Thomas A. Cutler Ph.D.
Chief Science Officer
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Clinical Research

This Science Brief Booklet will discuss highlights of the groundbreaking Framingham Heart Study, as well as some research studies that have been completed on Bios Life™. This is meant only to give an overview of these studies, as there are numerous studies ongoing.

The studies we will cover here are:

- The Framingham Heart Study
- The Cleveland Clinic Study
- The Type-II Diabetes Trials
- The Philippines Trial
- The Utah Trial
- The Pacific Rim Trial
- University Of Sydney Australia Study

Though not specifically related to Bios Life, it is important to discuss The Framingham Heart Study first. Begun in 1948, it is the longest ongoing study on heart disease. This will provide a basic understanding of cardiovascular disease and the findings resulting from this research.

1. The Framingham Heart Study

The relationship between the risk for cardiovascular disease (CVD) and cholesterol levels has been extensively researched. The most accurate data gathered from this research is the epidemiology study. In this type of study, researchers simply observe the cholesterol levels of a specific large group of individuals and then count how many cardiovascular events occur in a given time. That is exactly what has been done in the Framingham Heart Study which began in 1948 under the direction of the National Heart, Lung, and Blood Institute (NHLBI).

The Framingham Heart Study, the most well known epidemiology study, has observed the population of the town of Framingham, Massachusetts, for a period of over 50 years. This ongoing study has included several generations of the town's population. Researchers have kept track of many parameters and lifestyle habits of the inhabitants and their health concerns. In this way, the researchers have been able to relate certain diets, lifestyles, and blood parameters to the onset of disease.

As one can imagine, there is great mathematical and statistical talent needed to make the calculations necessary to connect the many variables to a specific disease. The outcome is often complicated and it is difficult to make generalized statements from the data. This study, however, concluded that high LDL (low-density lipoprotein) levels cause cardiovascular disease, and that high HDL (high-density lipoprotein) levels protect against it.

Continued

A formula has been derived based on the study stating that:
For every 1% one is able to lower LDL, there is a 2% risk reduction for CVD in the next 10 years.
For every 1% increase in HDL, there is a 3% reduction in the risk for CVD.
It has therefore been concluded that in order to lower the risk for CVD it is best to lower LDL and raise HDL at the same time.

(It is also important to note that the Framingham Study has found that no one with total cholesterol below 150 has ever suffered a heart attack. –

More detailed findings can be found on the Framingham Heart Study website:
www.framinghamheartstudy.org

2. The Cleveland Clinic Study

Between the years 2000 and 2002, Bios Life™ was studied for its capacity to improve cholesterol levels by the Cleveland Clinic Foundation under the guidance of Dr. Dennis Sprecher. This institute has been recognized as America's #1 Heart Center for 12 years in a row. No heart program has more experience, knowledge and better access to technology, and is therefore an ideal facility to confirm the effectiveness of Bios Life.

The study involved 119 patients that had a fasting LDL-c concentration of at least 130 mg/dL, making them moderate hypercholesterolemics (high blood cholesterol). The average age for the study participants was 50 years. They could not be using any medication to lower their cholesterol. The subjects were divided between two groups:

- A placebo group taking a non-active product
- A group using the fiber and vitamin portion of Bios Life.

Before intervention began, both groups followed a low fat diet for eight weeks. This design was chosen to ensure similar dietary habits between the two groups. After the diet, both groups used their assigned products for a period of eight weeks. At the end of the study, 99 subjects completed the full protocol.

The Bios Life Group:

- Reduced their LDL values from 159 mg/dl to 145 mg/dl on average, or a percent reduction of 7.9%
- HDL value increased from 48 mg/dl to 51 mg/dl over the eight week period
- Total cholesterol was reduced from 237 to 227 mg/dl, and triglycerides from 146 to 119 mg/dl.

Continued

The Placebo Group:

- Showed an LDL increase of 2.4% in the same time period

In addition to lipid values, the study also monitored homocysteine (Hcy) and apolipoprotein B. Homocysteine, like high cholesterol, is recognized as a risk factor for cardiovascular disease. The mechanism is not entirely clear, but high homocysteine have been shown to increase injuries to the vascular system and contribute to early atherosclerosis. In this study, the HCy level was reduced from 9.8 mmol/l to 8.7 after eight weeks. Apolipoprotein B is a part of the LDL particle, and is therefore sometimes used as a surrogate marker for CVD risk. This parameter, also, was reduced from 139 to 110 mg/dl.

In conclusion, the Cleveland Clinic study showed that the fiber portion of Bios Life is effective in reducing the risk for cardiovascular disease. Since both groups started off with a low-fat diet, the overall effect of Bios Life may have been limited in this group. The subjects had already lowered their lipid parameters with diet alone. Consequently, the additional effect of Bios Life may have been more modest than by using subjects eating a more "normal" diet. The study was published in 2002 in the highly acclaimed journal, *Metabolism* (Metabolism, 2002, Vol 51: pp 1166 – 1170).

3. The Type-II Diabetes Trials

Bios Life™'s mechanisms are designed to lower cholesterol, but they also interfere with carbohydrate (sugar) absorption in the gastrointestinal (GI) tract. Therefore, two studies at present have been performed with Type-II diabetics. Type-II diabetics are patients with low to zero response to insulin either from their body's own production, or from injections.

The two studies were performed by Steven Freed and David Joffe, both registered pharmacists and editors of the worldwide known publication, *Diabetes in Control*. The first study, performed in the years 1999 to 2000, involved a small group of 15 patients that took the fiber portion of Bios Life for a period of 90 days. The protocol involved measuring HbA1c, glucose and cholesterol values, blood pressure, and weight at the beginning and end of the trial.

The pre-prandial glucose values (before the meal, at fasting) were reduced by 17% in the study period, indicating that the overall carbohydrate consumption during the day was lowered. The acute carbohydrate consumption was also reduced, as indicated by a 36% drop in the total glucose concentration two hours after the meal. Total cholesterol dropped 12%, triglycerides 42% and HDL increased 6%. In addition, the subjects lost an average of 6 pounds and were able to reduce their blood pressure from 145/82 mmHg to 131/77 mmHg, on average.

Continued

The drops in glucose absorption resulted in a HbA1c change from 9.2% to 7.8%. This value indicates the overall glucose level over the three month study, and is a powerful indicator of risk for complications due to diabetes later in life, such as blindness, kidney failure, and the like. These results clearly demonstrate the glucose balancing effects of Bios Life and make a good case for daily use of Bios Life by diabetics. Since diabetics have even lower target values for cholesterol, the cholesterol effects of Bios Life are a potentially life saving side-benefit for this group. The study was published in *Diabetes in Control*, Issue 15 (1), 12 – 18 (2000).

Encouraged by these results, investigators initiated a second study in a much larger group of 78 Type-II diabetics using a similar study protocol. In this group, the average reduction in glucose values over a 90 day period was from 278 mg/dl to 237 mg/dl, resulting in a drop of 10% in the HbA1c value. Interestingly, LDL dropped 28.7% and HDL increased 27.9% in the study.

The study was presented at two major conferences: the 6th Annual Conference on Arteriosclerosis, Thrombosis and Vascular Biology, held in April 2005 in Washington D.C., and the 65th Scientific Sessions of the American Diabetes Association, held in June 2005 in San Diego, California.

The American Heart Association selected this study to be released to the press at this scientific meeting. International news agencies carried the press release.

4. The Philippines Trial

Bios Life™ has also been studied internationally. The first of such studies was performed in the Philippines by Dr. Norberto Yumul, M.D., from the Angeles Foundation Medical Center, in Angeles City, Philippines.

In this study, Dr. Yumul selected patients with dyslipidemia (abnormal blood lipid levels). One hundred and three subjects completed the four week intervention protocol. This was a mixed population, with approximately 22% of the group being diabetic. Some people had even suffered a myocardial infarction earlier in life.

Dr. Yumul analyzed the response to Bios Life in different age groups and gender. The overall result was that total cholesterol was reduced 15.8%. The study analyzed the results of LDL reduction in terms of the risk categories as formulated by the National Cholesterol Education Program. The main conclusion was that for all age groups, subjects moved from the "undesirable" LDL group to the "borderline" group, and from the "borderline" group to the "desirable" LDL group.

Continued

Interestingly, the effect of Bios Life was more dramatic in the younger population (65 years or younger), providing additional evidence that Bios Life use should begin early in life so that the risk reduction effect is the greatest. The study was presented by Dr. Yumul at the 34th Annual Convention of the Philippine College of Physicians

5. The Utah Trial

Since the development of Bios Life Complete™ with its four cholesterol lowering mechanisms, Unicity International has performed a number of clinical trials with the new formulation. The first of these trials was performed in Orem, Utah.

For the study, a group of subjects was chosen randomly without regard to whether they had any cholesterol problems in particular (though many of them had, in line with the general population statistics). The average baseline LDL cholesterol value for the whole group was 131 mg/dl.

Twenty-five subjects completed the eight week protocol. They all took two packets of Bios Life per day. The average reduction in LDL cholesterol in eight weeks was 4.8%, reflecting the relatively young, healthy state of the participants. Interestingly, when looking at the responders in this group (responders denoting persons who demonstrated a positive result), the average reduction was 24.7%.

Seventy-two percent of the subjects were responders, indicating that the other 28% were likely not adequately compliant. The most important observation was that subjects with higher LDL levels at baseline had better results after 8 weeks. Subjects with LDL levels of least 160 mg/dl at baseline reduced their cholesterol with 30.6% after eight weeks.

This indicates the power of Bios Life as a first line treatment option for people with high cholesterol. HDL cholesterol was raised by 28.6% in the group of responding subjects with baseline levels lower than 40 mg/dl. These changes resulted in a 24% drop in the cardiovascular risk ratio for the subjects having ratios higher than 5 at baseline.

The results of this study are currently being considered for peer-review publication in a major scientific journal and are therefore not public yet.

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6. The Pacific Rim Trial

The next step in the journey of proving the efficacy of Bios Life™ is the study performed in the practice of Dr. Vincent Duenas. This study included both users and non-users of statin medication. The rationale for this design was to observe the effect of Bios Life as an adjunct to the cholesterol lowering effect of statin medication.

For the statin user trial, only subjects were selected that had reached the statin-floor, meaning that they did not have any change within 10% for their last two LDL measurements. This group of people was selected since it was prudent to exclude subjects still on the slope of LDL reduction due to statin intervention. Otherwise, the effects of using two products at the same time (statins and Bios Life) could make it impossible to determine which of the products was yielding the result.

The average LDL reduction of the 15 statin users in this trial with baseline levels of 130 mg/dl or higher was 21.1% in six weeks. For HDL, the increase was 23.3%. These results are considered impressive, because they mean that even if one is taking statin medication, adding Bios Life will improve the risk for cardiovascular disease in addition to the effect reached by statins: an extra drop in LDL and a meaningful increase in HDL.

In particular, this last effect is valuable to statin users, since statins are not known to have any effect on HDL levels. The study was presented at the 7th Annual Conference on Arteriosclerosis, Thrombosis, and Vascular Biology in Denver in April 2006.

Tips and terms to remember:
The important point to remember from this chapter is that Bios Life has been proven to be effective. It reduces LDL cholesterol, increases HDL cholesterol, and aids in regulating glucose levels in the body – and it does all this naturally, without negative side-effects!

7. The effects of a fiber-rich nutritional supplement, Bios Life® Slim, on the glycemic index of three starchy foods

Background: Glycemia is defined as the presence of glucose or sugar in the blood. Research has shown that glycemic control, or blood sugar management, is an accurate indicator for overall health and wellness. Further research has shown that long term consumption of high glycemic index diets lead continual surges in blood sugar and insulin levels which have been correlated to increased risks for diabetes, cardiovascular disease and most recently, obesity.

Objective: The objective of this study was to quantitatively measure the impact of a fiber-rich nutritional supplement on the glycemic index of three common foods, white bread, white rice and instant mashed potatoes.

Design: Lean, healthy subjects (n=10) consumed 50 grams of glucose in water and three starchy foods (white bread, white rice and instant mashed potatoes) along with 7.25 g of Bios Life Slim or 14.5 g of Bios Life Slim dissolved in 250 ml of water. Using standardized methods for determining glycemic indices, plasma samples were collected and analyzed for glucose and insulin levels. The data were plotted, curves were generated and areas under the curves (AUC) were calculated. Glycemic and insulinemic indices were calculated by dividing the two-hour plasma glucose or insulin AUC by the two-hour plasma glucose reference AUC and multiplying that value by 100 to obtain a percentage.

***Results**: One dose of Bios Life Slim reduces the glycemic index of white rice, instant mashed potatoes, white bread and by 16.0%, 16.9% and 20.5% respectively. Two doses of Bios Life Slim reduces the glycemic index instant mashed potatoes, white rice and white bread by 20.4%, 24.7%, and 27.7% respectively. One dose of Bios Life Slim reduces the insulinemic index of instant mashed potatoes, white rice and white bread by 10.4%, 16.9% and 21.3% respectively. Two doses of Bios Life Slim reduces the insulinemic index of instant mashed potatoes, white bread and white rice by 15.1%, 27.0% and 27.3% respectively.*

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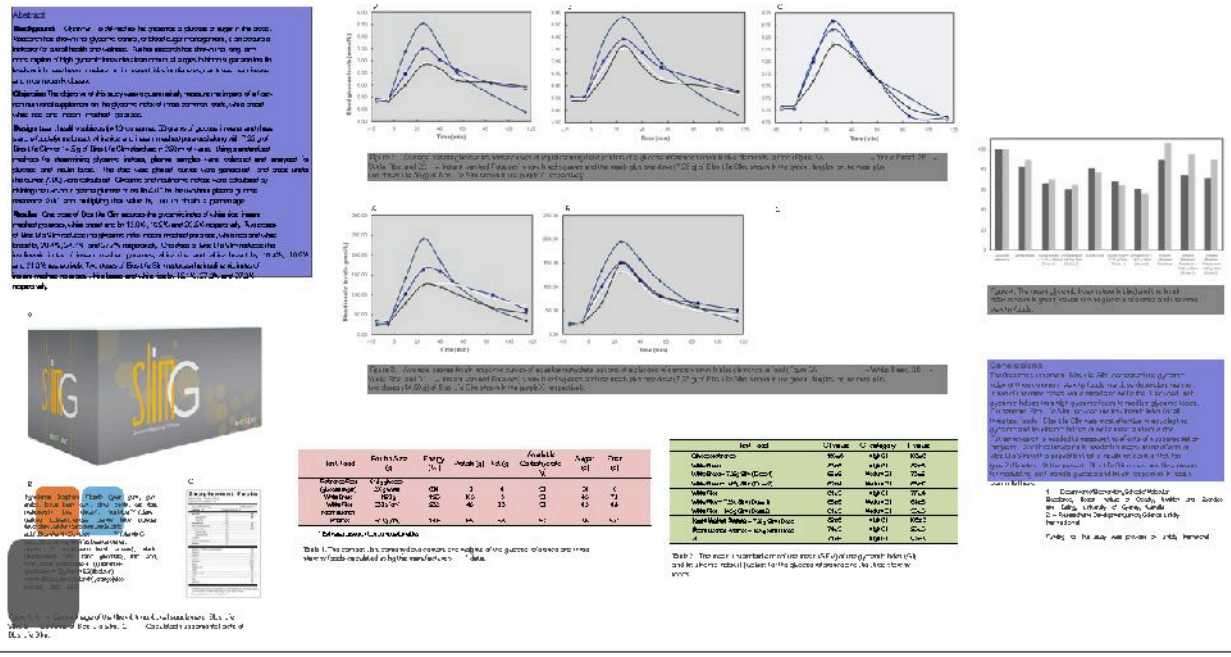
The effects of a fiber-rich nutritional supplement, Bios Life® Slim, on the glycemic index of three starchy foods.

Jennie Brand-Miller [1], Fiona Atkinson [1], and Thomas Cutler [2]



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Abstract

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Supplement Facts

Serving Size: 1 Packet (7.25 g)
Servings Per Container: 60

Amount Per Serving		% Daily Value**
Calories 10	Calories from Fat: 0	
Total Fat	0 g	0%
Saturated Fat	0 g	0%
Trans Fat	0 g	
Cholesterol	0 mg	0%
Total Carbohydrate	5 g	2%
Dietary Fiber	4 g	16%
Soluble Fiber	4 g	
Insoluble Fiber	0 g	
Sugars	0 g	
Other Carbohydrates	1 g	
Protein	0 g	
Vitamin A (100% as Beta-Carotene)		15%
Vitamin C		70%
Vitamin E		50%
Thiamin		100%
Riboflavin		100%
Niacin		100%
Vitamin B-6		90%
Folate		50%
Vitamin B-12		95%
Biotin		10%
Zinc		15%
Calcium		10%

** Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs.
† Percent Daily Value is not established.

Figure 1. A – Carton image of the fiber-rich nutritional supplement, Bios Life Slim. B – Contents of Bios Life Slim. C – Calculated supplemental facts of Bios Life

Ingredients: Biosphere Fiber® (guar gum, gum arabic, locust bean gum, citrus pectin, oat fiber, maltodextrin, beta glucan), Nutri-fiber™ (plant-derived polysaccharides, orange juice powder flavor blend, calcium carbonate, stevia, citric acid), Bios Vitamin Complex™ (vitamin C (ascorbic acid), vitamin A (as beta-carotene), vitamin E (d-alpha-tocopheryl acetate), niacin (niacinamide), zinc (zinc gluconate), folic acid, biotin, vitamin B1 (thiamine HCl), vitamin B6 (pyridoxine HCl), vitamin B2 (riboflavin), vitamin B12 (cyanocobalamin), orange juice powder, citric acid).

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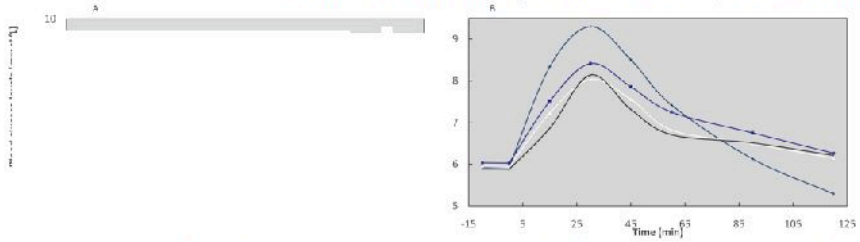

Figure 2. Average plasma glucose response curves of equal carbohydrate portions of a glucose reference shown in blue diamonds, a food (Figure 2A – White Bread, 2B – White Rice, and 2C – Instant Mashed Potatoes) show in red squares and the meals plus one dose (7.25 g) of Bios Life Slim, shown in the green triangles, or the meal plus two doses (14.50 g) of Bios Life Slim shown

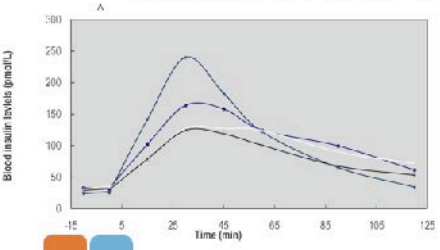

Figure 3. Average plasma insulin response curves of equal carbohydrate portions of a glucose reference shown in blue diamonds, a food (Figure 3A – White Bread, 3B – White Rice, and 3C – Instant Mashed Potatoes) show in red squares and the meals plus one dose (7.25 g) of Bios Life Slim, shown in the green triangles, or the meal plus two doses (14.50 g) of Bios Life Slim shown

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Test Food	Portion Size (g)	Energy (kJ)	Protein (g)	Fat (g)	Available Carbohydrate (g)	Sugar (g)	Fiber (g)
Reference Food (glucose drink)	51.4 g glucose 250 g water	800	0	0	50	50	0
White Bread	119.0 g	1195	10.5	3	50	4.5	7.1
White Rice Instant	63.0 g (dry)	932	4.6	0.3	50	0.3	0.4
Mashed Potatoes	67.3 g (dry)	1200	6.5	5.8	50	3.6	5.7*

* Estimated based on food composition tables

Table 1. The composition, carbohydrate content and weights of the glucose reference and three starchy foods calculated using the manufacturers' data.

Test Food	GI value	GI category	II value
Glucose reference	100 ± 0	High GI	100 ± 0
White Bread	83 ± 6	High GI	89 ± 5
White Bread + 7.25 g Slim (Dose 1)	66 ± 5	Medium GI	70 ± 5
White Bread + 14.5 g Slim (Dose 2)	60 ± 4	Medium GI	65 ± 7
White Rice	81 ± 5	High GI	77 ± 4
White Rice + 7.25 g Slim (Dose 1)	68 ± 6	Medium GI	64 ± 5
White Rice + 14.5 g Slim (Dose 2)	61 ± 5	Medium GI	56 ± 5
Instant Mashed Potatoes	89 ± 6	High GI	106 ± 3
Instant Mashed Potatoes + 7.25 g Slim (Dose 1)	74 ± 5	High GI	95 ± 6
Instant Mashed Potatoes + 14.5 g Slim (Dose 2)	71 ± 6	High GI	90 ± 3

Table 2. The mean ± standard error of the mean (SEM) of the glycemic index (GI) and insulinemic index (II) values for the glucose reference and the three starchy foods.

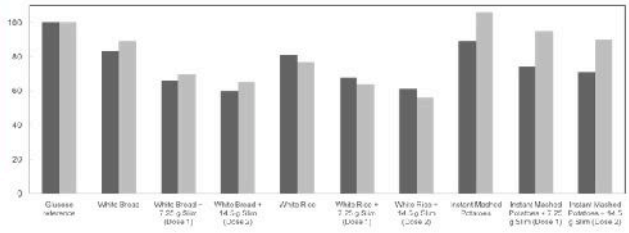

Figure 4. The mean glycemic index (show in blue) and the insulin index (shown in green) values for the glucose reference and the three starchy

Conclusions

The fiber-rich supplement, Bios Life Slim, decreased the glycemic index of three common, starchy foods in a dose dependent manner. In two of the three cases, white bread and white rice, it reduced their glycemic indices from high glycemic foods to medium glycemic foods. Furthermore, Bios Life Slim, reduced the insulinemic index for all three test foods. Bios Life Slim was most effective in reducing the glycemic and insulinemic indices of white bread and white rice. Further research is needed to measure the effects of supplementation long-term. Additional research is needed to measure the effects of Bios Life Slim with a population that is insulin resistant or that has type 2 diabetes. At the present, Bios Life Slim does provide a means for modulating post-prandial glucose and insulin

1 – Department of Biochemistry, School of Molecular Bioscience, Boden Institute of Obesity, Nutrition and Exercise and Eating, University of Sydney, Australia 2 – Research and Development, Unicity Science, Unicity International Funding for this study was provided by Unicity International