

# PGX<sup>®</sup>

( PolyGlycopleX<sup>®</sup> )

Regulates Glucose Levels · Lowers Cholesterol  
Controls Appetite · Increases Insulin Sensitivity  
Supports Weight Management

## History

PolyGlycopleX<sup>®</sup> ( $\alpha$ -D-glucurono- $\alpha$ -D-manno- $\beta$ -D-manno- $\beta$ -D-glucosyl- $\alpha$ -L-galacturono- $\beta$ -D-mannurono,  $\beta$ -D-glucosyl- $\beta$ -D-mannan), commonly known as PGX<sup>®</sup>, is a novel natural polysaccharide (fibre) complex invented by InovoBiologic Inc. of Calgary, Alberta. It comprises three materials that are combined in a proprietary way. In the early nineties researchers in the UK determined that two of these viscous polysaccharides had a synergistic effect.<sup>1</sup>

Researchers at InovoBiologic Inc. made the remarkable discovery that the addition of a specific third polysaccharide led to a product with an unexpected developing viscosity that was far higher than any of its individual components. Since the early 2000s, InovoBiologic has sponsored research around the globe in an effort to develop a body of scientific evidence in in vivo models on PGX<sup>®</sup>.

## Safety

PGX<sup>®</sup> has been evaluated by internationally recognized protocols and found to be exceedingly safe. Studies conducted in the USA, France, and Germany all proved that PGX<sup>®</sup> is safe to use and has no serious side effects. In an OECD 408 safety study (conducted in the USA<sup>2</sup>), PGX<sup>®</sup> was evaluated at a 5% level in food and found to be safe according to these standards. A double-blind, randomized, placebo-controlled human tolerance study (conducted in France<sup>3</sup>) concluded that PGX<sup>®</sup> was safe, and two genotoxicity studies (Ames and MMA, conducted

in Germany and the USA<sup>4</sup>) also concluded PGX<sup>®</sup> was safe. A paper based on the Factors Group of Nutritional Companies' post-market surveillance system showed that while 58 million single servings of PGX<sup>®</sup> have been sold between 2004 and 2008, the total number of adverse events reported during the same period is below 0.0003%, demonstrating that PGX<sup>®</sup> is well tolerated when used to supplement the diet.<sup>5</sup> Since then, several hundred million single servings have been sold, with similar adverse event recordings.

Work with the Burdock Group in the USA led to PGX<sup>®</sup> achieving Self-Affirmed GRAS (Generally Recognized As Safe) status as well as Self-Affirmed Medical Food GRAS status. The FDA subsequently granted PGX<sup>®</sup> No Objection GRAS and Medical Food GRAS status.

In Canada, PGX<sup>®</sup> is approved as a Novel Fibre complex by Health Canada. This means that fibre claims can be made on PGX<sup>®</sup> when it is incorporated into food and PGX<sup>®</sup> can now be claimed as a source of fibre on the nutrition facts panel.<sup>6</sup>

## Proprietary Composition

The method by which the water-soluble polysaccharides are transformed into PGX<sup>®</sup> is a proprietary process known as EnviroSimplex<sup>®</sup>. Each softgel, capsule, granule or powder product contains the precise ratio of components needed for maximum benefit, based on extensive research and development. All manufacturing, processing and packaging steps required for PGX<sup>®</sup> meet or exceed

government and industry standards and GMP (Good Manufacturing Practices) are adhered to. PGX<sup>®</sup> also has a USP Standard (1<sup>st</sup> of March 2013, 2<sup>nd</sup> Supplement to FCC8) and the composition of PGX<sup>®</sup> is patent protected (USA: 8062686, Canada: 2604253, Australia: 2006235625, Russia: 2473245, China: ZL20068002078, Japan: 5161762, New Zealand: 589922; 589923; 561819; 579777; 583396, South Africa: 2010/01368).

PGX<sup>®</sup> is a unique, novel complex of natural polysaccharides that complement each other and have been shown to act synergistically<sup>7,8</sup> to form strong interactions, resulting in a novel polysaccharide of extremely high viscosity (higher than any currently known individual polysaccharide or fibre blend).

### Delayed Viscosity

Complexation by processing (patent pending) results in the viscosity of PGX<sup>®</sup> developing more slowly than any of its individual starting components, as illustrated below (Figure 1). This delayed viscosity development makes for a palatable product, unlike konjac (glucomannan), which becomes viscous virtually immediately and therefore can potentially lead to a choking hazard. Figure 1 also shows that the viscosity of PGX<sup>®</sup> is greater than expected relative to its constituents. This very high viscosity level means that far less needs to be consumed and its delayed viscosity (developing over 15 to 30 minutes) renders its incorporation into foods and beverages easier and more palatable.

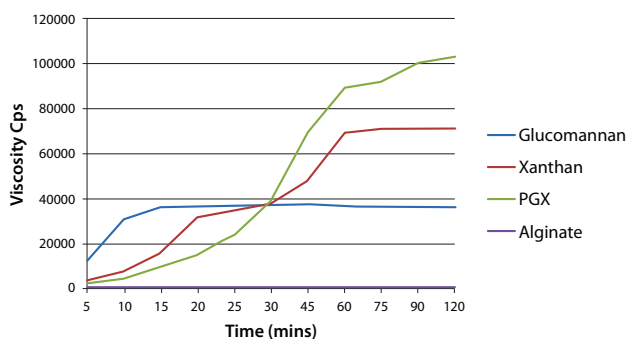


Figure 1: Viscosity of PGX<sup>®</sup> compared to its starting components after hydrating for 2 hours.

It is well known that the physiological effects and overall benefits to human health of a soluble fibre are directly proportionate to its viscosity, as shown by Jenkins et al.<sup>9</sup> The complexation of PGX<sup>®</sup> is one of the reasons why, gram for gram, far less PGX<sup>®</sup> is required to produce a physiological effect compared to other fibres. Unlike many other fibres, PGX<sup>®</sup> maintains its highly viscous

properties in spite of the influence of stomach acid and digestive enzymes. When PGX<sup>®</sup> is mixed with food or beverages it increases the volume of gastric content and slows gastric emptying and digestion, thereby extending the area for nutrient absorption further along the gastrointestinal tract. In the large intestine, viscous PGX<sup>®</sup> may influence gut microbial fermentation, enhancing the production of short-chain fatty acids which are the chief fuel source for the intestinal epithelial cells and as such may positively influence intestinal health and related metabolic functions.<sup>10</sup>

Therefore, PGX<sup>®</sup>'s highly viscous nature and delayed viscosity facilitate consumption of an efficacious dose, leading to ease of use, palatability, and cost effectiveness.

### Optimum Volume

Studies have shown that the volume of food creates a sense of fullness in the stomach and that extending the digestion and absorption of nutrients along the gastrointestinal tract triggers the release of various signalling hormones that alert the brain to stop eating. PGX<sup>®</sup> studies have shown that consuming PGX<sup>®</sup> affects these signalling hormones.<sup>11,12</sup> PGX<sup>®</sup> remains highly volumetric and viscous in the gastrointestinal tract, so when PGX<sup>®</sup> is taken before or with a meal or in a meal replacement, the sense of fullness and satiety that develops lasts for hours.<sup>13</sup>

### Clinical Evidence

Evidence-based information on improvements in blood lipid reduction, diabetes control, colonic function, and appetite and weight control, comes from clinical trials conducted at universities and contract research organizations in Australia, Canada, England, France, Germany, Japan, and the USA.

### 1 Glucose Control: Impact on the Glycemic Index

Research has shown that soluble fibre reduces the post-prandial glycemic response in direct proportion to the degree of viscosity the fibre imparts to the food. Since PGX<sup>®</sup> is a highly viscous fibre, a number of experiments have been undertaken to support its blood-glucose-lowering potential. All experiments followed the standard methodology for measuring the glycemic index (GI) of food.

The first study investigated the impact of PGX<sup>®</sup> on the GI when added to liquid (glucose) and solid (white bread plus margarine) high-carbohydrate food formulations. Three

different doses, 2.5, 5, and 7.5 g, were administered with each food or beverage and the glycemic index calculated for each dose. The results for the glucose drink showed that 2.5, 5, and 7.5 g of PGX<sup>®</sup> reduced the GI by 16.3, 22.3, and 27.5% respectively. The results for the white bread plus margarine showed that 2.5, 5, and 7.5 g of PGX<sup>®</sup> reduced the GI by 28.9, 44.2, and 49.2% respectively.<sup>14</sup>

In another set of experiments, the effect of PGX<sup>®</sup> on the GI was investigated when PGX<sup>®</sup> was added to commonly consumed foods with various GIs. The GI was determined for cornflakes with milk, rice, turkey dinner, and yogurt, with or without 5 g of PGX<sup>®</sup> sprinkled onto the foods. The addition of PGX<sup>®</sup> to cornflakes, rice, turkey dinner, and yogurt resulted in a 26, 45, 24, and 9% reduction in GI, respectively (Figure 2).<sup>15</sup> Thus some foods, such as rice, were converted from high to low GI products and others, like corn flakes, from high to medium GI products.

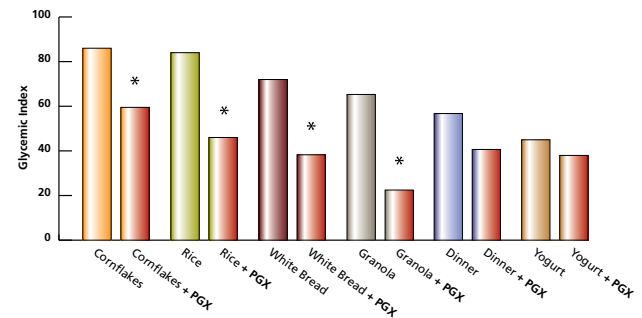
PGX<sup>®</sup> has also been incorporated into baked foods to see if its GI-lowering potential would be maintained. PGX<sup>®</sup> incorporated into a baked granola was found to reduce the GI of the granola. Compared to the control granola, the granolas containing 2.5 and 5 g of PGX<sup>®</sup> per serving reduced the GI by 45 and 64% respectively.<sup>15</sup>

Besides adding PGX<sup>®</sup> directly to foods, the glycemic effect of adding PGX<sup>®</sup> to water and consuming it alongside starchy foods (white bread, white rice, boiled potatoes, French fries, cornflakes and instant oatmeal/porridge) was also investigated.<sup>16</sup> On average, a dose of 2.5 g reduced the GI by 16–22% depending on the food and a dose of 5 g reduced the GI by 28–35% depending on the food.

The magnitude of the reduction in GI achieved with PGX<sup>®</sup> is far superior to many other commercially available functional fibre preparations. Inulin is commonly added to commercial foods as a prebiotic fibre<sup>17</sup> but a 5 g dose used as the control in the starchy food study above had no apparent effect on the GI.<sup>16</sup> Cornflakes, for example, with a dose of 5 g inulin generated a GI of 82, a value very close to the average of 81 found in the published literature.<sup>18</sup> Psyllium fibre consumed in solution or incorporated into foods such as breakfast cereal can reduce cholesterol absorption but a 5 g dose produces only a modest 14% reduction in postprandial glycemia.<sup>19</sup> A 5 g dose of  $\beta$ -glucan (derived from oats) consumed as a beverage reduced glycemia by 20% when consumed with bread.<sup>20</sup> In contrast, 5 g of PGX<sup>®</sup> produced an average reduction of 30% when consumed alongside starchy foods.<sup>16</sup>

Consuming PGX<sup>®</sup> within 15 minutes of the start or the end of the meal reduced glycemia just as effectively as when it

was taken with the meal.<sup>21</sup> The PGX<sup>®</sup> softgel capsules on the other hand demonstrated an important “second meal” effect, improving glucose tolerance at breakfast time when consumed with the previous evening’s meal.



**Figure 2:** Reductions of the glycemic index when PGX<sup>®</sup> is added to or incorporated into commonly consumed foods. \*Statistically different than food without PGX<sup>®</sup> ( $p < 0.001$ ).<sup>14,15</sup>

All the studies mentioned above demonstrate that adding PGX<sup>®</sup> to a variety of different foods or beverages is highly effective in lowering GI, irrespective of the type of meal it was added to. The extent of GI lowering may be greater when added to high GI foods and if PGX<sup>®</sup> is consumed on a regular basis, it could reduce the overall glycemic impact of the diet.

Reducing postprandial glycemia and dietary glycemic load is an identified objective in the management and prevention of obesity and type 2 diabetes. The recent Diogenes study (a large multi-centre trial in Europe) showed that reduction in dietary GI and glycemic load led to greater weight loss over 12 weeks and improved the ability to maintain the weight loss.<sup>22</sup>

PGX<sup>®</sup> is a practical and effective means of lowering postprandial glycemia, which may also be highly beneficial for individuals with insulin resistance, metabolic syndrome and/or type 2 diabetes. This reduction in postprandial glycemia offers great potential for the long-term use of PGX<sup>®</sup> in managing diabetes and controlling appetite and body weight.

## 2 Metabolic Syndrome, Prediabetes, and Diabetes

Viscous soluble fibres are beneficial for long-term glucose control. The American Dietetic Association’s position paper entitled “Health Implications of Dietary Fiber” states that viscous soluble fibres can help reduce postprandial glucose excursions and long-term glucose control in individuals with diabetes.<sup>23</sup> In addition, viscous fibres

have been recommended for persons with metabolic syndrome, to diminish the metabolic abnormalities that characterize it.

According to the American Heart Association, approximately 35% of adult Americans are suffering from metabolic syndrome and many of them will develop full blown diabetes in the years to come. In Canada it is believed that 19% or 1 in 5 Canadians have metabolic syndrome, according to results collected from the Canadian Health Measures Survey (2007–2009).<sup>24</sup> Metabolic syndrome often develops in physically inactive individuals with insulin resistance who exhibit the following traits: high waist circumference and the presence of excessive abdominal fat; modestly high blood sugar and blood pressure; lower HDL cholesterol and increased triglycerides.

PGX<sup>®</sup> is an effective natural health ingredient that can help diminish the risk factors that characterize this syndrome. Studies conducted on PGX<sup>®</sup> reduced the risk factors associated with metabolic syndrome by 1) reducing waist circumference and most likely reducing intraabdominal fat;<sup>25,26</sup> 2) lowering postprandial blood sugar levels;<sup>14,15,16</sup> 3) lowering cholesterol;<sup>3,25,27</sup> and 4) lowering insulin levels and improving insulin sensitivity.<sup>12,25</sup>

To assess the ability of PGX<sup>®</sup> to reduce developmental aspects of metabolic syndrome, the effects of PGX<sup>®</sup> on glycemic and insulenic control and lipid profiles (cholesterol and triglycerides) was studied in young Zucker diabetic rats (ZDFs). Histomorphometric assessments of liver, pancreas and kidney damage seen in developing diabetes were also done.<sup>28</sup> Young ZDFs were fed a diet containing 5% (weight/weight) cellulose, inulin, or PGX<sup>®</sup> for 8 weeks. Serum insulin in fasted and non-fasted states was significantly reduced by PGX<sup>®</sup> as was non-fasted blood glucose. More specifically, non-fasted animals in the cellulose and inulin groups were hyperglycemic, while glucose levels were reduced or maintained in the PGX<sup>®</sup> group to nearly non-diabetic levels. Insulin resistance, as measured by homeostasis model assessment (HOMA), was significantly reduced, and insulin sensitivity as measured by composite insulin sensitivity index (CISI) was significantly improved in the PGX group when compared to the cellulose and inulin groups, meaning that PGX<sup>®</sup> improved insulin sensitivity.<sup>28</sup> PGX<sup>®</sup> also significantly reduced serum total cholesterol and histological kidney and hepatic damage as well as reducing hepatic steatosis and cholestasis. A greater mass of pancreatic  $\beta$ -cells was found in the PGX<sup>®</sup> group. From these results it was concluded that PGX<sup>®</sup> may be a useful dietary additive in the control of the early development of metabolic syndrome.

PGX<sup>®</sup> has been studied in older ZDFs fed normal rodent chow supplemented with cellulose, inulin, or PGX<sup>®</sup> on a 5% weight/weight basis.<sup>12</sup> PGX<sup>®</sup> reduced non-fasted blood glucose but elevated insulin, suggesting an insulin secretagogic effect. At the end of the study, the oral glucose tolerance test showed no change in insulin sensitivity among groups, suggesting an insulinotropic effect for PGX<sup>®</sup>. PGX<sup>®</sup> also increases plasma levels of GLP-1, while HbA1c was significantly reduced. It was concluded that PGX<sup>®</sup> improved glycemic control and reduced protein glycation, most likely due to the insulin secretagogic effects of increased GLP-1.<sup>12</sup>

When PGX<sup>®</sup> is combined with a pharmacological treatment sitagliptin (S), a dipeptidyl peptidase 4 (DPP4) inhibitor, and fed to obese ZDF rats (PGX<sup>®</sup> [5% wt/wt] + S [10 mg/(kg-d)]), significant and clinically relevant reductions in both acute (weekly blood glucose measures in fed and fasted states, and OGTT) and long-term measures (HbA1c) of glucose response occurred in those rats, more so than those treated alone with PGX<sup>®</sup> or S.<sup>29</sup> Sitagliptin is an oral antidiabetic medication that works to competitively inhibit the enzyme dipeptidyl peptidase 4 (DPP-4). This enzyme breaks down the incretins GLP-1 and GIP, gastrointestinal hormones released in response to a meal. By preventing GLP-1 and GIP inactivation, they are able to increase the secretion of insulin and suppress the release of glucagon by the pancreas. This drives blood glucose levels towards normal. Independent administration of PGX<sup>®</sup> or S also effectively lowered food intake (both), increased lean mass (both), reduced LDL cholesterol and hepatic steatosis (PGX<sup>®</sup>), increased active GLP-1 (S) and GIP (PGX<sup>®</sup>) and increased insulin secretion and  $\beta$ -cell mass (PGX<sup>®</sup>). Therefore, independently PGX<sup>®</sup> and S can improve several metabolic outcomes in ZDF rats, but combined their ability to markedly reduce glycemia suggests they may be a promising dietary/pharmacological co-therapy for type 2 diabetes management.<sup>29</sup>

Despite the convincing evidence in animal models, studies examining the metabolic response to PGX<sup>®</sup> in the context of metabolic disease in humans was lacking. A study was then carried out to examine the effects of PGX<sup>®</sup> on various risk factors associated with metabolic syndrome in adults with abdominal obesity.<sup>30</sup> Daily ingestion of 15 g of PGX<sup>®</sup> over 14 weeks was associated with a significant reduction in total and LDL cholesterol, improvements in glucose tolerance, and a reduction in inflammatory cytokines (resistin and interleukin-6) compared to rice flour placebo. Moreover, waist circumference and visceral fat were reduced to a greater extent with PGX<sup>®</sup> than with placebo.<sup>30</sup> These improvements demonstrate

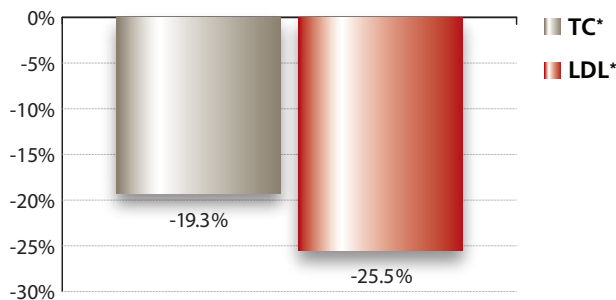


that PGX<sup>®</sup> supplementation is effective in reducing risk factors related to metabolic syndrome in adults with abdominal obesity.

Research in obese rodent models and humans shows that the physiological effects of PGX<sup>®</sup> can lead to improved metabolic health, thereby attenuating the risk factors associated with metabolic syndrome, which may then delay the development of type 2 diabetes, cardiovascular disease or stroke.

### 3 Cholesterol

In healthy subjects, 5 g of PGX<sup>®</sup> per day for 1 week followed by 10 g (2 x 5 g) over 14 days has been shown to reduce total cholesterol levels by 14% and LDL levels by 17%.<sup>4</sup> In overweight and moderately obese individuals (BMI ranging from 27 to 40 kg/m<sup>2</sup>), following a 14 week clinical weight loss program supplemented with 10–15 g of PGX<sup>®</sup> per day reduced total and LDL cholesterol levels by 19 and 25% respectively (Figure 3).<sup>25</sup> Although there was a trend in the results towards a reduction in triglycerides (TG) and an increase in HDL cholesterol values, the changes were not statistically significant.<sup>25</sup>



**Figure 3:** Percent change in plasma lipids from baseline after 14 weeks of PGX<sup>®</sup> (\* $p < 0.05$  from week 0).<sup>25</sup>

In non-dieting overweight and obese individuals, where no deliberate changes to lifestyle were made,<sup>31</sup> the diet was supplemented with 5–15 g of PGX<sup>®</sup> or inulin for 15 weeks. For those consuming PGX<sup>®</sup>, total and LDL cholesterol were reduced 9 and 13% respectively, in comparison to the inulin group where total cholesterol increased slightly and LDL levels remained close to baseline levels.<sup>31</sup>

Possible mechanism of action include changes in intestinal motility, increased generation of short chain fatty acids (SCFAs) inhibiting hepatic fatty acid synthesis, and/or increased excretion of bile acid through the stool

decreasing bile acids returned to the liver necessitating the use of cholesterol for the synthesis of new bile acids.

### 4 Weight

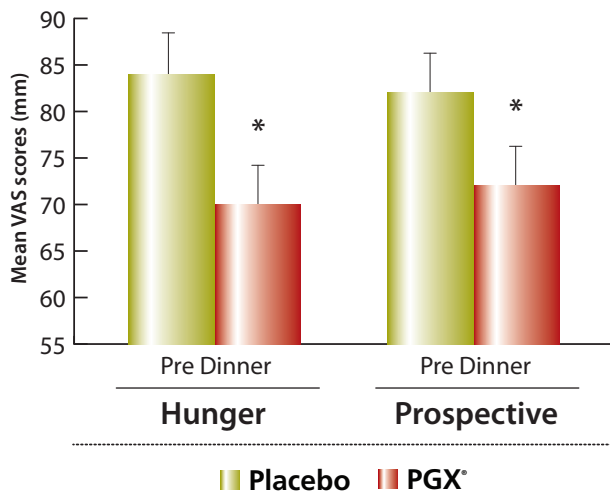
Obesity is a disease that arises through a multifaceted pathophysiology. Successful treatment of it requires a multi-strategic approach. It is hypothesized that consumption of PGX<sup>®</sup> leads to multiple effects for weight management and satiety in the human body, which include: mechanical actions (e.g., stomach distension and delayed gastric emptying); neuro-hormonal actions (e.g., gut-derived appetite regulating peptides PYY, ghrelin); prebiotic mechanisms (formation of short chain fatty acids, e.g., acetate); and metabolic effects (e.g., carbohydrate and lipid metabolism). Each pathway is critically important for appetite and body weight regulation. The ability of PGX<sup>®</sup> to target so many pathways makes it a very effective aid for weight management.

#### Appetite and Food Intake

When consumed, PGX<sup>®</sup> develops its full viscosity in the stomach and small intestine. This added volumetric and viscosity bulk in the stomach produces a feeling of fullness and decreases appetite. A number of factors may contribute to this increased satiety associated with high viscosity including increased gastric distension and delayed gastric emptying, a blunting of the postprandial glucose and insulin surge and the release of various satiety hormones, which alert the brain that the stomach is full. Therefore, its volume and viscosity may make it easier for overweight individuals to cut back on caloric intake.

Recently, the effect of using PGX<sup>®</sup> as a satiety aid when consuming a low calorie diet was studied. A diet of 1000 kcal/day was provided for 3 days with the intention that caloric restriction would accentuate feelings of hunger.<sup>13</sup> During the test period, subjects consumed breakfasts, lunches, and dinners immediately after the food was sprinkled with 5 g of PGX<sup>®</sup> or a placebo. Subjective appetite was assessed throughout the day, before, between, and after meals. The results showed that adding 5 g of PGX<sup>®</sup> to meals when consuming a low calorie diet helped manage appetite by increasing satiety and decreasing prospective consumption (the amount one thinks one could eat) (Figure 4).<sup>13</sup> This resulted in reductions above 10% compared to the placebo group, a magnitude considered to be of practical relevance.<sup>32</sup> With respect to time of day, PGX<sup>®</sup> was found to exert its strongest effects in the afternoon and evening, reducing total appetite, hunger, desire to eat, and prospective

consumption. These results are particularly helpful in managing obesity, given reports that food intake tends to be less in the morning and greater in the afternoon and evening in obese versus normal-weight individuals.<sup>33</sup> Therefore, adding PGX® to meals could be a useful weight management aid at the start of a low calorie diet to help lessen feelings of hunger and to moderate food portions.



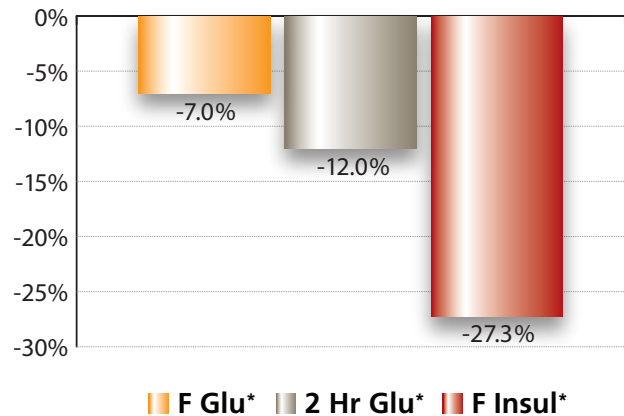
**Figure 4:** Comparison of pre dinner mean hunger and prospective consumption scores with either 5 grams of PGX or placebo at each main meal. Values are mean±SE (n=35). \* Significantly lower scores with PGX than the placebo supplement (p<0.05).<sup>13</sup>

### PGX® Weight Management Programs

The effect of PGX® as a weight management aid has also been assessed in various weight loss programs in a clinical setting (the Canadian Centre for Functional Medicine in Coquitlam, British Columbia). In these programs, participants received basic instructions in caloric reduction, recommended medium- to low-glycemic index foods, and exercise, and were instructed to consume 5 g of PGX® 2–3 times per day either in meal replacements, as granules, or in capsule form.

One program looked at the effect of PGX® granules on weight loss over a 14-week period in people who were sedentary and overweight or obese. There was a significant reduction (p< 0.05) from week 0 or baseline in group weight (-5.8±3.6 kg), waist circumference (-12.1±5.6 cm), percent body fat (-2.4±2.4%), and BMI (-2.26±1.2 kg/m<sup>2</sup>). Moreover, these latter changes were paralleled by a significant decrease in total cholesterol (-19.3%), LDL cholesterol (-25.5%), fasting glucose (-7.0%) and insulin (-27.3%) levels over a relatively short

time span of 14 weeks (Figure 5).<sup>25</sup> Body composition was measured (using the Bioelectrical Impedance Body Composition Analyzer; RJL Systems Inc.) and most subjects lost body fat and increased their lean muscle mass with little change in body water.



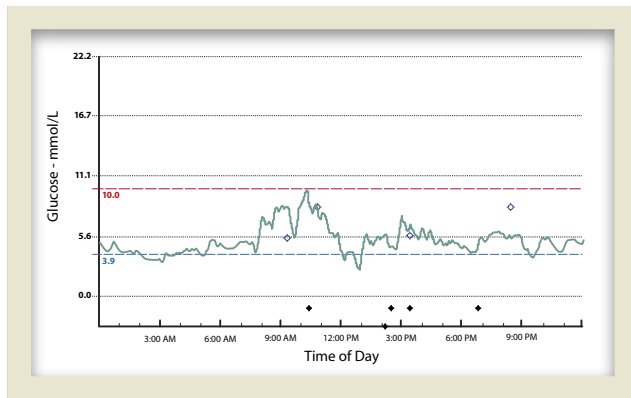
**Figure 5:** Percent change in fasting glucose, 2 hour postprandial glucose, and insulin from baseline after 14 weeks of PGX® (\* p < 0.05 from week 0).<sup>25</sup>

Another weight loss program involving people who were overweight or obese utilized a meal replacement containing PGX® and PGX® granules over a 12-week period. A registered dietitian recommended low-fat, medium- to low-GI foods for snacks and dinner meals, such that each volunteer was consuming a total of 1200 kcal/d. In the 52 subjects that participated, there was an average reduction in group weight of 4.7±3.7 kg, in waist circumference of 7.1±6.3 cm, and in hip circumference of 5.6±3.6 cm from baseline levels (p<0.0001).<sup>26</sup> Most subjects reported that the meal replacement drink created a sense of satiety and completely controlled their hunger for 2–4 hours.

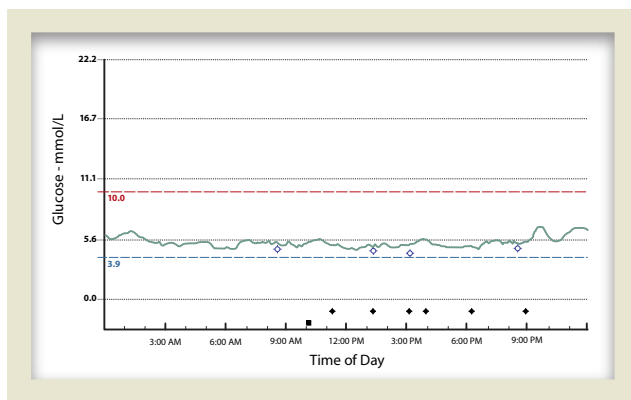
In addition, six subjects in the weight management group were connected to the continuous blood glucose monitoring system (CGMS) from Metronics, Inc. Results show that individuals with weight challenges have very volatile blood glucose levels with wide and frequent swings between hypoglycemia and hyperglycemia.<sup>25</sup>

Most overweight and obese subjects were found to have increased glycemic volatility at baseline and then exhibited markedly diminished glycemic volatility after administration of PGX® (Figures 6 and 7).

The weight loss consistently experienced on the PGX® Weight Management Programs translates into a healthy weight loss of about 0.25–0.8 kg (0.5–1.5 lbs) per week.



**Figure 6:** Uncontrolled and erratic blood sugar levels of an obese woman over 24 hours with a poor diet and no physical activity.



**Figure 7:** Controlled and balanced blood sugar levels of the same woman after consuming PGX for 6 weeks and experiencing a healthy weight loss of 2 pounds per week.

In a randomized, double-blind, controlled clinical trial in free-living, non-dieting overweight and obese men and women ( $n = 60$ ), granular PGX<sup>®</sup> was compared to inulin, a commonly used fibre supplement. The supplements were mixed into yoghurt and consumed 2–3 times per day. At the end of the 3-month treatment, body weight did not differ between groups but an interaction between sex and group was significant.<sup>31</sup> Accordingly, weight and hip circumference were found to be significantly lower in women in the PGX<sup>®</sup> group but not in men. Others have noted that women appear to be more sensitive than men to the effects of postprandial hyperglycemia and may have more to gain by adopting low GI diets. No difference was noted in the number or severity of the adverse effects reported in both groups. Adverse effects were mild and agreed with commonly reported reactions to increased dietary fibre intake. It was concluded that beneficial, although modest, effects appeared after several weeks of daily PGX<sup>®</sup> intake.<sup>31</sup>

In summary, by virtue of its multiple physiological effects, PGX<sup>®</sup> has been clinically shown to have beneficial effects in the following areas:

- Weight management
- Cholesterol lowering
- Blood glucose levels and glycemic index
- Appetite control and satiety hormones

Clinical studies represent InovoBiologic's commitment to research on PGX<sup>®</sup> to demonstrate its effectiveness. Research is most often performed as double-blind, randomized, placebo-controlled trials, and is published in peer reviewed journals.

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