Fenestra Research Labs

The World Leader In Wellness Studies

Human Clinical Trial

Evaluating the Safety and Efficacy of

A Randomized, Placebo Controlled,

Double-Blind Study

Product: ***Glucaloe™***

Manufacturer: **Lily of the Desert**

FINAL REPORT

SUBMITTED TO:

Lily of the Desert

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Research and Report by:
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STUDY OUTLINE AND DETAILS

PURPOSE: To provide scientific data to evaluate and establish the safety and effectiveness of ***Glucaloe™*** on stabilizing blood sugar levels for long term use measured as fasting blood sugar (FBS) and glycosylated hemoglobin (HbA1c), its effect on total body weight and body composition.

STUDY TYPE: Randomized Controlled Clinical Trial

STUDY DESIGN: Evaluation, Randomized, Double-Blind, Efficacy Study

OFFICIAL TITLE: A 90-Day, Double-Blind, Randomized, Multi-Center Study Evaluating ***Glucaloe™*** vs. a placebo, standard clinical testing protocol was followed.

FURTHER STUDY DETAILS: Following an initial screening at the Visit 1 (week-0), subjects enter a 1 week baseline period (subjects are to refrain from taking any unnecessary OTC's, prescription drugs or natural products for the remainder of the study). Subjects who meet all inclusion and none of the exclusion criteria at the check at Visit 2 (week-1) will be randomized thereafter into the randomized product period of the study during which they will receive either ***Glucaloe™*** or placebo product in double-blind fashion. Forty subjects were provided ***Glucaloe™*** and ten subjects were provided the placebo product following randomized protocol. Subjects digested either ***Glucaloe™*** or the placebo 30 minutes prior to three meals per day. The dosage of ***Glucaloe™*** was 500 mg per meal. Neither subjects nor testers were aware of the identity of the product provided to any subject. Re-testing was done at weeks 2, 4, and 8. Final evaluations of test subjects were done on visit 5 (week-13) of this study.

All subjects followed a diet and exercise protocol. Women and men were instructed to consume an average of 1900 calories per day and 2200 calories per day, respectively. Their intake was self-monitored. Both men and women walked 3 times per week for 30 minutes. The mean age of the participants was 38 ± 6 yrs. And the male to female ratio was 29:21.

EXCLUSION CRITERIA

- History of head trauma
- History of serious diseases or illness diagnosed at this time.
- Known moderate to severe renal insufficiency.
- Recent history (<6 months prior to Visit 1) of myocardial infarction.
- Subjects who regularly use oxygen therapy.

- Subjects with known active tuberculosis.
- Subjects with a history of cancer within the last 5 years.
- Subjects who have undergone thoracotomy with pulmonary resection within 1 year prior to the trial.
- Subjects who are currently in a pulmonary rehabilitation program or who have completed a pulmonary rehabilitation program in the 6 weeks prior to the screening visit (Visit 1).
- Subjects currently prescribed diuretic medications, cardiac stimulants, or any other prescribed or non-prescribed medication that may, in the opinion of the Fenestra Research staff, alter testing results.
- Use of opiate analgesics prescribed or otherwise obtained for any treatment reason including migraine treatment, or for recreation.
- History of drug or alcohol addiction.
- Females who are pregnant, lactating, or nursing or who may become pregnant during the course of the study.
- Patients diagnosed as HIV-positive, diagnosed with AIDS, or with any neuromuscular condition including CP, MS, ALS, or Huntington's Chorea
- Subjects who have used steroid therapy with-in the last 6-months.
- Patients with any condition not previously named that, in the opinion of the investigators or intake staff, would jeopardize the safety of the patient or affect the validity of the data collected in this study.

INCLUSION CRITERIA

- Subjects who signed a written informed consent consistent with required guidelines and meet prior to participation in the trial.
- Subjects 18 years of age or older, either sex.
- Subjects who have a fasting blood glucose level of at least 150 mg/dL and who are not taking diabetic medications or receiving insulin treatments
- Subjects who have had a fasting blood sugar level of at least 150 mg/dL for a minimum of 6-months consecutively.

- Subjects who are not on any medication or dietary supplement.
- Subjects who have normal kidney, liver, and thyroid functions, normal CBC prior to the start date of this study.
- Subjects who are able to follow the protocol as designed by Lily of the Desert and Fenestra Research Labs
- In generally good health.

STUDY OVERVIEW

Screening and Testing Procedures

Initial screening of subjects completed before the baseline data was taken for this test included; AST, ALT, to assess liver function, creatinine to help evaluate kidney function, TSH for thyroid assessment, a standard CBC panel was drawn. Each of these tests was run on arterial blood drawn following standardized protocol for the procedures and completed by healthcare professionals.

FBS measurements were taken at Baseline, 30-days, 60-days and 90-days. FBS measures blood glucose after you have not eaten for a minimum of 8 hours. Nothing except water can be consumed after this time. Normally, blood sugar levels increase slightly after food is consumed. This increase causes the pancreas to release insulin so that your blood sugar does not get too high. Blood glucose levels that remain high over time can damage your eyes, kidneys, nerves, and blood vessels.

HbA1c levels were measured at baseline and 90-days, total body weight was measured at baseline, 20-days, 40-days, 60-days and 90-days and body fat composition was measured at baseline and 90-days. HbA1c levels will determine **Glucaloe's** long-term effect on blood sugar levels and are representative of the subjects moving away from or towards better health. Body fat composition is measured to verify how much of the weight loss was from fat. This is of paramount importance as many people suffering from insulin resistance undergo weight loss, but not from fat. Instead, the loss is primarily from the detrimental sacrifice of muscle tissue to produce glucose for cellular energy.

Procedure for blood draws

Our healthcare professional:

- ✓ Wrap an elastic band around the upper arm to stop the flow of blood. This makes the veins below the band larger so it is easier to put a needle into the vein.
- ✓ Clean the needle site with alcohol.

- ✓ Insert the needle into the vein.
- ✓ Attach a tube to the needle to fill it with blood.
- ✓ Remove the band from the subjects arm when enough blood is collected into the vial.
- ✓ Apply a gauze pad or cotton ball over the needle site as the needle is removed.
- ✓ Apply pressure to the site and then a bandage.

Procedure for Blood Glucose Measurement

A) Standard blood glucose tests were done only after the subjects have consumed at least one meal that day.

B) All procedures in previously listed Procedures for blood draws were followed

C) A standardized blood glucose meter was then used to test the whole blood of each subject.

D) Each sample was tested three separate times within a span of 3 minutes. The charted blood glucose level is the average of those three samples.

Protocol for FBS Days

a) Each subject's last meal was consumed the previous night before 7PM. This meal consisted of only two Balance Bars and water.

b) Upon arrival each subject was assessed for general health and well being

c) A blood draw for FBS was taken from each subject at zero (0) minutes to establish a Baseline.

d) Thirty-minutes prior to consuming the glucose drink subjects received 500mg of ***Glucaloe***™.

e) A blood sample was drawn at 30 minutes.

f) A standardized blood glucose testing product of 75g was consumed completely by each test subject.

g) Blood samples were taken at each interval from each subject and recorded at: 0, 30, 45, 60, 75, 90, 120 and 150 minute time schedule.

Procedure for HbA1c Measurement

a) We use the Enzymatic HbA1c assay method

b) Enzymatic HbA1c assay utilizes a novel enzyme, fructosyl valine oxidase (FVO) that specifically cleaves glucose from hemoglobin's N-terminal valine residue's beta chains with concomitant production of hydrogen peroxide (H2O2).

c) Whole blood samples are drawn using the above standard method.

d) The blood sample is lysed by a lysis buffer to release hemoglobin molecules

e) Theses molecules are subjected to extensive proteolytic digestion to produce glycated valine or short peptides containing glycated valines that serve as substrates of fructosyl valine oxidase.

f) Two ready-to-use liquid stable reagents are then used, they do not contain latex particles, and thus do not contaminate cuvettes of analyzers

g) The data from each test is collected and noted in subjects charts

Procedure for Weight Measurement

The Body Pod is made by Life Measurement and is a licensed medical devices designed to provide the most accurate body composition and metabolic assessments in infants, children, and adults.

a) Subjects are weighed at the same time of day on each office visit

b) Each subjects enters the Pod wearing nothing except underwear and a subject paper gown as to maintain the most accurate measurement possible.

c) Each subject remains in the Pod for 5-6 minutes when the devise calculates weight and body fat index.

Procedure for OWT

Blood Samples

a) Blood samples were drawn using the above standard method.

b) A 5cc syringe is used the draw out 3cc's of blood from the collection tube.

c) Syringe is placed on the OWT analyzer and sample is tested.

Saliva Samples

a) No liquid or food will be consumed for at least 15 minutes before saliva sample is collected.

b) Saliva is collected into a clean cup

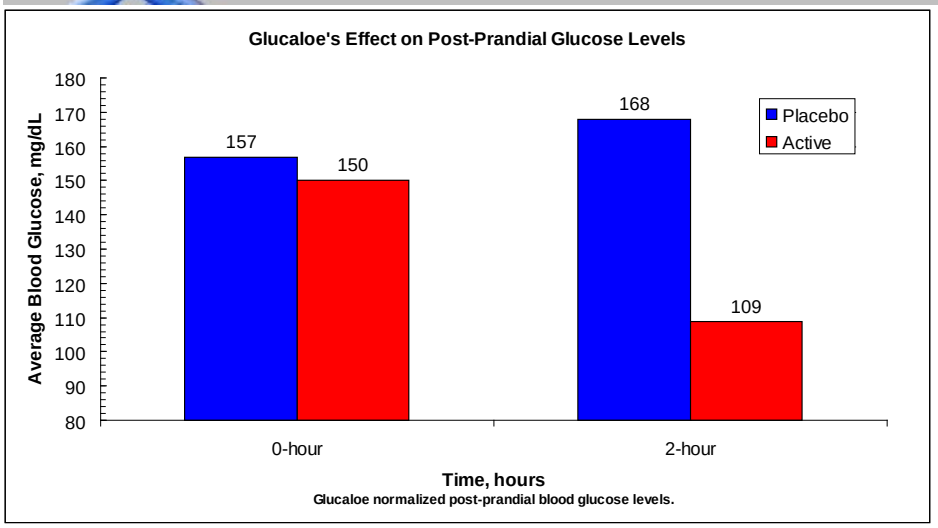
c) Salvia is drawn from the clean cup into a 5cc syringe.

d) No air bubbles, food particles, nor any other foreign objects are collected into the syringe.

e) Syringe is placed on the OWT analyzer and sample is tested.

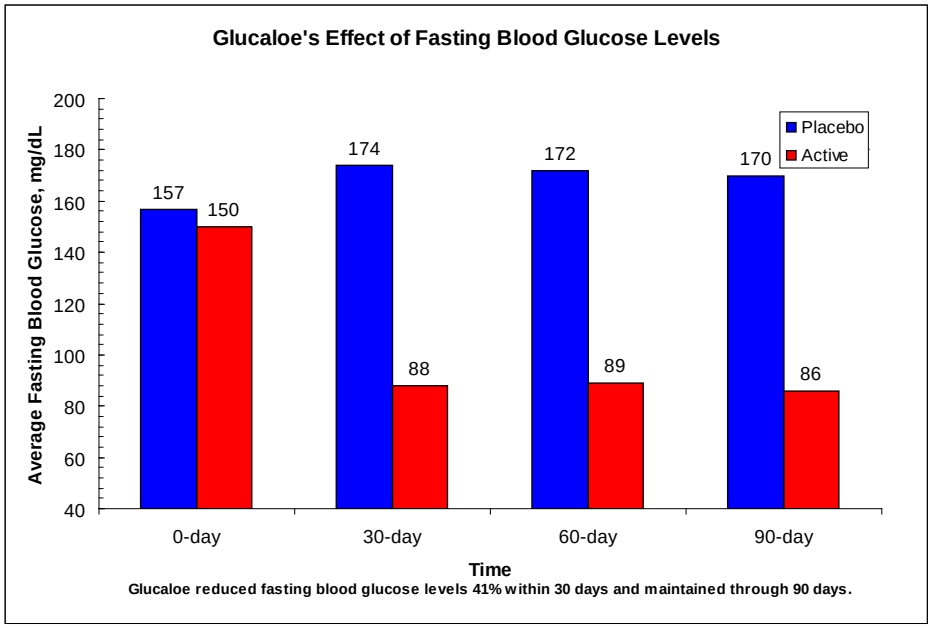
TEST RESULTS

On day one an FBS test was conducted to determine ***Glucaloe's*** effect on post-prandial blood glucose levels of the placebo and the active group. Graph 1 illustrates the average blood glucose levels in mg/dL for the placebo and the active group at time 0 hours (the subject's fasting blood glucose level) and at time 2 hours after ingesting a 75g dose of glucose.



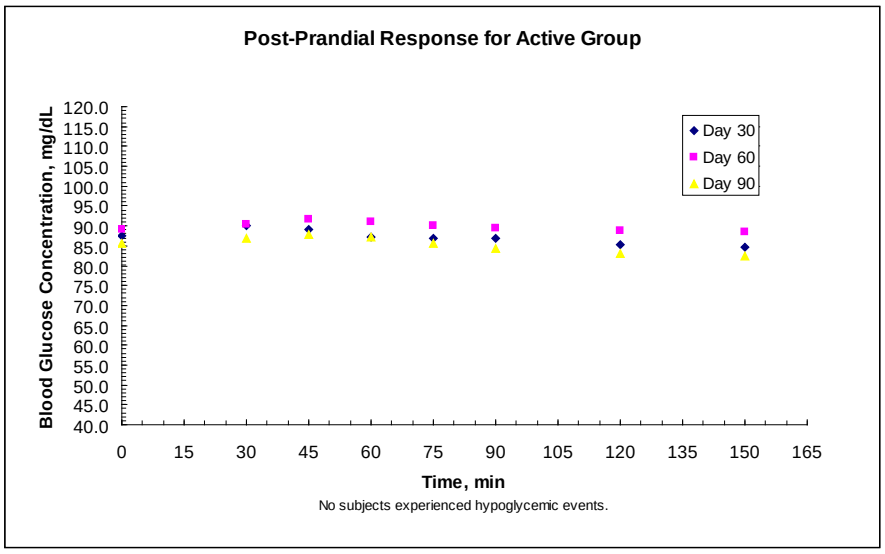
Graph 1. ***Glucaloe's*** effect on post-prandial glucose levels. (P-value: $p < 0.02$)

As illustrated, ***Glucaloe™*** normalized post-prandial glucose levels within 2 hours. The placebo had no effect on its subjects. Fasting blood glucose was measured at day 0, 30, 60 and 90. Graph 2 illustrates the average fasting blood glucose levels of the placebo and active group.



Graph 2. ***Glucaloe's*** effect on fasting blood glucose levels. (P-value: $p < 0.02$)

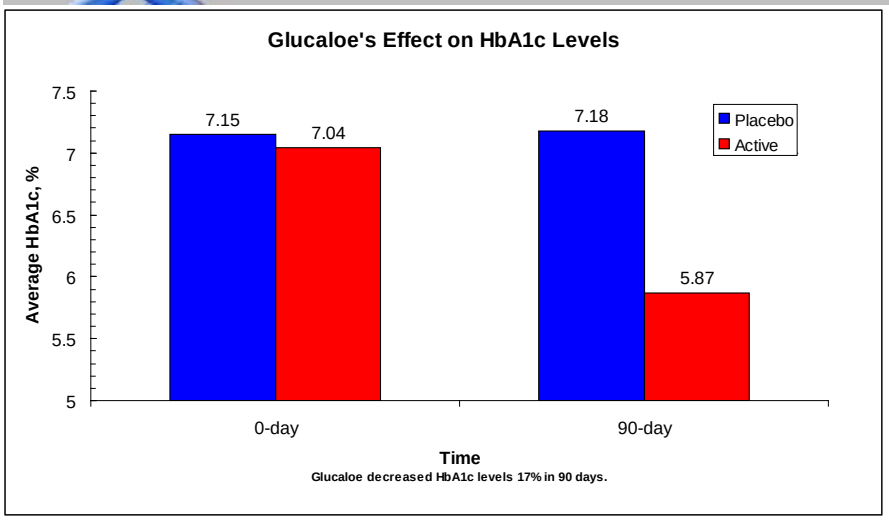
Glucaloe normalized fasting blood glucose levels within 30 days and maintained them through 90 days. The active group's fasting blood glucose levels were reduced 43%. The placebo had no effect on its subjects. Graph 3 illustrates the average fasting blood glucose level at time 0 and the post-prandial blood glucose levels at 15 minute intervals over a 2 hour period for the active group during the FBS Tests on Day 30, 60, and 90.



Graph 3. Post-prandial Response for Active Group on FBS tests days. (Pvalue: $p < 0.01$)

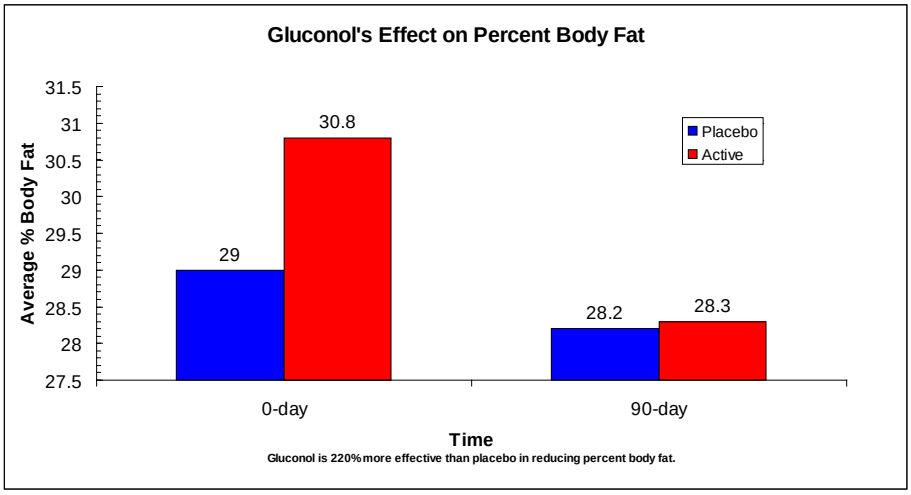
The average fasting blood sugar levels were normal on day 30, 60, and 90. Graph 3 illustrates that after ingesting ***Glucaloe™*** and a dose of 75 grams of glucose there is a minimal increase in blood sugar and that after 2 hours the blood glucose levels return to baseline without decreasing below normal blood glucose levels of 80-100 mg/dL. This is a strong indicator that ***Glucaloe™*** does not cause hypoglycemic events. In addition, no hypoglycemic events were reported by any subject during the entire study. Graph 3 also indicates a significant reduction in glycemic index. This response minimizes the conversion of blood sugar to stored body fat, thus Glucaloe's effect on weight management.

Glycosylated hemoglobin was measured on day 0 and 90. Graph 4 illustrates Glucaloe's effect on HbA1c levels.



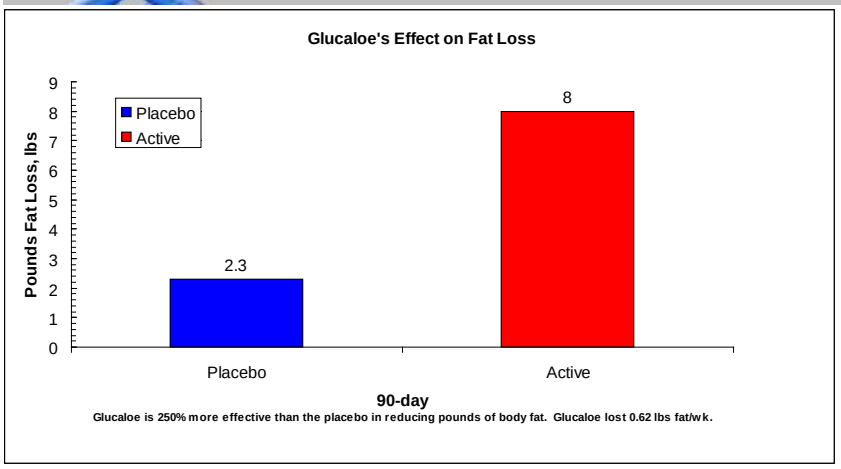
Graph 4. ***Glucaloe's*** effect on HbA1c levels. (P-value: p < 0.02)

Glucaloe™ decreased HbA1c levels by 17 percent. The placebo had no effect on its subjects. Percent body fat was measured on 0 and 90 days. Graph 5 illustrates the effect of ***Glucaloe™*** and the placebo on percent body fat.



Graph 4. ***Glucaloe's*** effect on percent body fat. (P-value: p < 0.02)

Glucaloe™ was 220% more effective than the placebo in reducing percent body fat. Total weight was measured at 0, 20, 40, 60 and 90 day. Multiplying the total weight by the percent body fat gives total fat. Graph 5 illustrates the total fat loss for the active and placebo group at the end of the 90-day trial.



Graph 5. Glucaloe's effect on fat loss. Pvalue ($p < 0.02$)

The active group was 250% more effective than the placebo group in reducing total body fat. The active group lost a total of 12% body fat in 90 days.

DISCUSSION OF TEST RESULTS

The average fasting blood glucose for the active subjects at the start of the study was 150 mg/dL compared to 86 mg/dL at the end of the study. This is decrease of 43 percent. With ***Glucaloe***™, ***100 percent*** of the subjects' blood glucose levels were reduced to normal levels of 80-100 mg/dL with no occurrence of hypoglycemic events.

Glycation is the binding of excess blood glucose to functional proteins in the body that impairs their function and leads to poor health. Glycation is measured as HbA1c. American Diabetes Association's goal for diabetics is less than 7.00%. With ***Glucaloe™***, subjects achieved an average of 5.87%, well below the ADA goal.

Active subjects lost an average of 0.63 lbs/week and a maximum of 1.38 lbs/week. More significantly, the total weight loss from fat was 97.7% of total weight loss. This shows that with ***Glucaloe™***, the weight loss was not from the detrimental sacrifice of muscle tissue to produce glucose for cellular energy.

Optimal Wellness Testing (OWT)

The OWT has become a standard in the Human clinical Studies industry. Because of its wide range of measuring and evaluating cellular parameters for Wellness it can provide us with a powerful look at a products effects on the body. Its 39 different measurements provide a complete look at how a product works, if it truly does work, and is it safe to be taking on a daily bases. Below is a list of the 39 different measurements that the OWT evaluates. All of the below

indicators help us provide the statement that this product is a safe and effective product for human use.

Optimal Wellness Test

Measured Values

Salts Balance Restivity	Surface Tension	Digestion	Acidosis
Conductivity	Refractometry	Carbohydrate Digestion	Cadmium Levels
Millie-watts	rH2	Toxicity	Silicon Levels
ORP (oxidation-reduction potential)	Volts	Mercury Levels	Iron Levels
Nitrates	Urea's	Aluminum Levels	hydration
Nitrites	Cellular Respiration	Lead Levels	
Ammonias	Renal Balance	Adrenal Balance	
Cations	Hepatic Balance	ATP Function	
Anions	Intra-cellular hydration	Anabolic Balance	

ORP (Oxidation-Reduction)

The oxidation-reduction potential is a true value. It is the actual measure of the fluids milli-volt (mV) potential, the measurement of the fluid's ability to donate or accept electrons.

The higher the ORP, the more reduced intermediates in the specimen, meaning the fluid is active, charged and has the ability to create energy. When the fluid is oxidized, the fluid has lost its capacity to create energy.

Redox (shorthand for **reduction-oxidation** reaction) describes all chemical reactions in which atoms have their oxidation number (oxidation state) changed. This can be either a simple redox process such as the oxidation of carbon to yield carbon dioxide or the reduction of carbon by hydrogen to yield methane (CH_4), or it can be a complex process

such as the oxidation of sugar in the human body through a series of very complex electron transfer processes.

The term *redox* comes from the two concepts of **red**uction and **ox**idation. It can be explained in simple terms:

- **Oxidation** describes the *loss* of electrons / hydrogen or *gain* of oxygen / *increase* in oxidation state by a molecule, atom or ion.
- **Reduction** describes the *gain* of electrons / hydrogen or a *loss* of oxygen / *decrease* in oxidation state by a molecule, atom or ion.

Why is ORP important to me?

The term that has become popular in the media today for ORP damage is free radical damage. Free radical damage is an important factor contributing to many different diseases.

The primary site of free radical damage is the DNA found in the mitochondria. Mitochondria are small membrane-enclosed regions of a cell which produce the chemicals a cell uses for energy. Mitochondria are the "energy factories" of the cell. Every cell contains an enormous set of molecules called DNA which provide chemical instructions for a cell to function. This DNA is found in the nucleus of the cell, which serves as the "command center" of the cell, as well as in the mitochondria. The cell automatically fixes much of the damage done to nuclear DNA. However, the DNA in the mitochondria cannot be readily fixed. Therefore, extensive DNA damage accumulates over time and shuts down mitochondria, causing the cells to die and the organism to age.

Hence, this free radical generation process can disrupt all levels of cell function. This is why free radical damage is thought to be such a basic mechanism of tissue injury. It damages us at the cellular level.

Conditions Free Radicals Cause

Just about any chronic, inflammatory, degenerative, immune-compromised disease can be related to oxidative stress from these unstable molecules.

Just to list a few:

* aging
* arthritis
* asthma
* atherosclerosis

* Alzheimer's	* cancer
* chronic fatigue	* cholitis/diverticulitis
* dementia	* diabetes
* diseases of the eyes	* fibromyalgia
* heart disease	* kidney disease
* liver disease	* and the list goes on.

Glucaloe™ produced a significant positive change in ORP in the human cellular body. This study showed how effective ***Glucaloe™*** is in helping the body to move from a negative ORP into a positive, more energy-producing ORP within a very short time. This positive change can help the body to reduce its free radical damage and therefore reduce the aging process. ***Adding Glucaloe™ to your daily intake can help your body reduce its free radical damage by an average of 50%.***

Nitrate & Ammonium Data

Both of these numbers influence the electromagnetic picture of the body fluids. Together they look at the amount of energy being lost from the system. Nitrate and ammonium are related to digestion, and they provide a look at the amount of usable energy being produced by digestion. The chemical reaction that takes place between food and digestive enzymes is vital to wellness. The correct balance of water, calcium, and oxygen in the body is necessary for usable energy to result.

The nitrate and ammonium particles are the result of poor digestion. The liver makes energy by inciting the urea cycle to occur and cannot use amino acids that have not been digested properly. Another cause of ammonium production is bacterial metabolism in the intestinal lumen. These released ammoniums are absorbed and transported to the liver. The liver treats the nitrates and ammoniums as toxins because the poor digestion has rendered the byproduct unusable. This unusable material is converted into urea and stored in the body. Urea can only be stored for 72 hours before it becomes toxic, at which time the urea is broken down to urea salts of Nitrate and Ammonium Nitrogen.

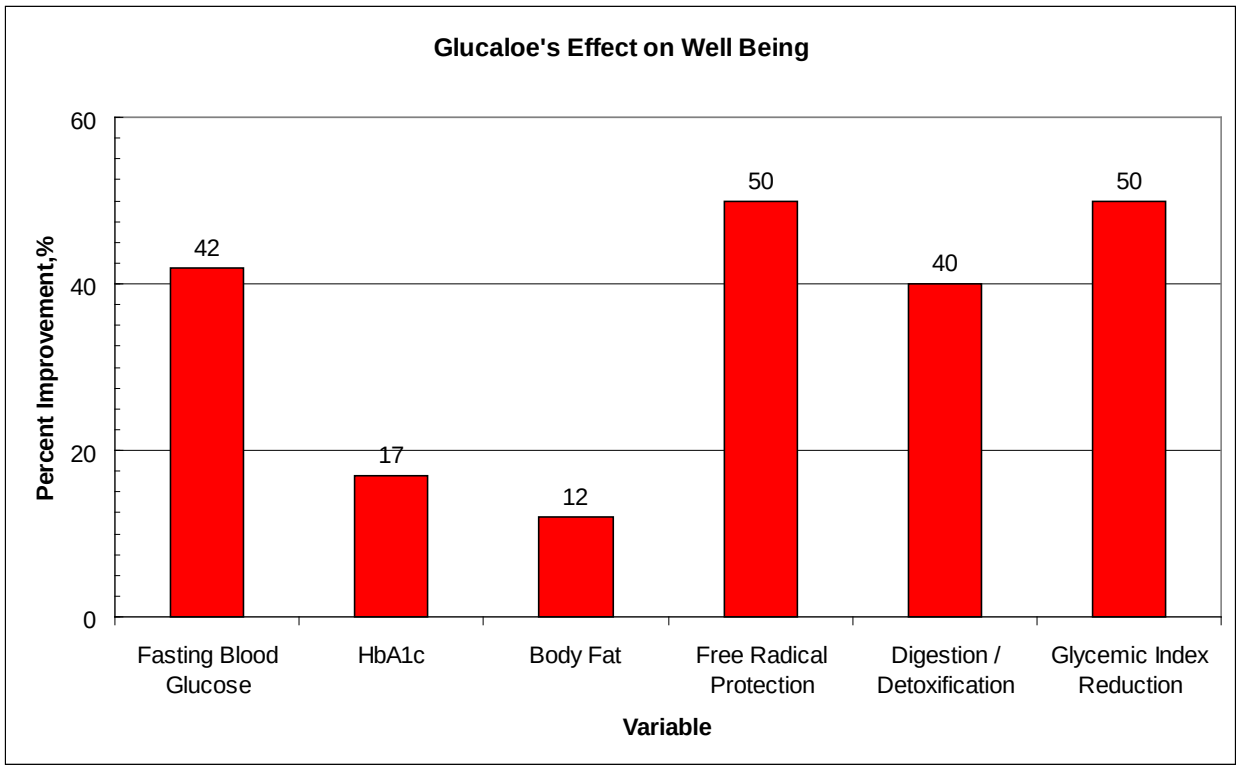
Glucaloe™ produced a significant positive change in the measurements of Nitrate and Ammonium Nitrogen produced in the body. This study showed how effective ***Glucaloe™*** is in helping the body to improve digestion within a very short time. This positive change can help the body to reduce its toxic load and enhance digestion of important nutrients. ***Glucaloe™ helped to improve digestion an average of 40%.***

Conclusions

This 90-day Human Clinical Study of ***Glucaloe™*** showed the most significant body fat loss, twelve percent, of any product that has been tested by Fenestra Research labs to this point. The body fat loss of approximately 97% of the total weight loss is a very significant indicator for people needing to lose body fat. ***Glucaloe™*** was 275% more effective than the placebo in reducing percent body fat. It was not at the expense of hard-earned muscle tissue. Minimal to no reduction in lean muscle mass maintains the body's metabolic rate and creates an environment to lose more body fat. ***Glucaloe™*** subjects lost on average 0.63 lbs/wk and a maximum of 1.38 lbs/wk.

As shown in the below graph several important areas of human health were also improved by ***Glucaloe™*** including; daily fasting blood glucose stabilization to normal levels without prescription intervention, normalization of HbA1c levels, a significant increase in free radical protection of 50%, and approximately 40% reduction in the cellular toxins of Nitrates and Ammonias for all subjects. A reduction in nitrates and ammonias indicates improved digestion and assimilation of nutrients.

It should be noted that no incidences of hypoglycemic reactions were recorded during the test. Therefore, ***Glucaloe™*** appeared to normalize blood glucose concentrations in the subjects in not only an efficient but also safe manner.



*The p-value measures consistency by calculating the probability of observing the results from your sample of data or a sample with results more extreme, assuming the null hypothesis is true.