



Multicenter study on an enhanced dietary fiber formulation originally created by Dr. Cade, combined with patent pending delivery technology, to improve efficacy and compliance for improving cholesterol and triglyceride levels

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Background: Plaque is created from cholesterol. There are two types of cholesterol: Bad or low density lipoprotein (LDL) and good or high density lipoprotein (HDL). Both types of cholesterol are comprised of a waxy, fatlike substance that is necessary for your overall health. It is an essential component of every cell and is required by the body to perform certain functions, such as helping the liver manufactures bile, helping the body digest fats, and acting as a building block for certain hormones. Cholesterol also coats and lubricates the body, helping the smooth flow of blood. It is usually produced in the liver, but if the body requires more than the liver can produce, it will create its own cholesterol from the foods we eat. However, if more cholesterol is produced than the body can process and use, it becomes deposited inside the walls of blood vessels.

Cholesterol is the precursor to all sex hormones, such as estrogen, testosterone, and progesterone. An increase in cholesterol is simply a part of the aging process.

As noted, there are two types of cholesterol, “bad” (LDL) cholesterol comes directly from the liver and is delivered to the cells of the body. If overproduced, it will live in the arterial walls.

The “good” (HDL) cholesterol acts in the reverse direction going the other way as blood transports this type from the arterial walls to the liver, where it is broken down and removed from the body.

An elevation of serum cholesterol, greater than 200mg/dl and serum triglycerides greater than 150mg/dl has been shown to be a causative factor in coronary artery atherosclerosis. A reduction of these lipids can lower the risk of coronary artery atherosclerosis and reverse atherogenesis.

Triglycerides are a type of fat your body obtains from the foods you eat. When your body digests food, fats in the food change to triglycerides. Your body can also make more triglycerides in the liver from fat, carbohydrates, and protein. Triglycerides also clog the arteries and contribute to all forms of heart disease.

Objective: Cholesterade® composed of organic Acacia fiber, sugar, maltodextrin, citric acid, natural flavors, enzymes, Stevia, Silica, and Soy Lecithin Phospholipids (Go-Somes™)

Cholesterade® is formulated with a proprietary and patent pending delivery technology under the trade name Go-Somes. This technology has the ability to deliver nutritional compounds in a more efficient

manner and is activated as soon as the Cholesterade® powder is mixed in water. The technology can envelope the ingredients in minute and discrete delivery spheres. Clinical research with the technology behind Go-Somes has demonstrated an ability to enhance nutrient bioavailability in a rapid fashion. In addition, other research has shown that Go-Some technology may create a sustained release of active compounds in human tissue models. The Go-Some spheres that deliver the Cholesterade® are multi-layered and therefore hold the acacia fiber at different individual layers within the sphere. The fiber is subsequently released into the GI tract so the body can better utilize the beneficial aspects of the Cholesterade® formula over an extended period of time. This not only improves efficacy, but tolerance as well. This helps the system to achieve the maximum benefits of Cholesterade®. The Go-Some Technology, as used in the dry form with the Cholesterade® powder, is believed to be the first and only delivery technology of its kind usable in powdered nutritional fiber formulas.

The soluble fiber in Cholesterade® causes a decreased amount of bile reabsorbed in the intestines. Acacia fiber interferes with the absorption of bile in the intestines. Bile is excreted in the feces. To make up for this loss of bile, the liver makes more bile salts. The body uses cholesterol to make more bile salts.

Methods: 100 patients with a history of hypercholesterolemia will be evaluated. There will be an eight week trial with instructions to patients to take 2 scoops per day of Cholesterade®. Blood work (Lipid profile) will be obtained prior to the start of taking Cholesterade® and repeated after the 8 weeks of taking Cholesterade®.

Blood results will be statistically analyzed as well as the patients will complete an exit survey.

Results: Dr. Cade's results in 8 week study showed:

Total cholesterol -17.9%

LDL -21.4%

HDL +12.9%

HDL/LDL ratio +44.0%

Triglycerides -50%

**To date patients taking Cholesterade have showed the following:**

**Compared to original Cade formula-**

**-We were able to achieve better efficacy with less fiber (virtually 50% less)**

**-With the improved formula, thus decreasing the dose from 4 servings per day to 2 servings per day, improvement went to 33% in lowering cholesterol, 25% improvement in LDL reduction, 13% improvement in HDL, and triglycerides saw a 53% reduction**

**-Dietary recommendation is 25 gram of fiber a day**

**-14 gram per day from in a Cholesterade, and the balance coming from dietary intake**