

Novel Composition

The present invention relates to a palatable baked nutritional composition which has a low glycaemic index and low glycaemic load and improved sensory characteristics such as crispiness and mouthfeel. Compositions of the present invention are suitable as a snack for people who are seeking options without added sucrose and for those with diabetes.

Diabetes is a metabolic disorder wherein the main problem is that the glucose in the blood does not get cleared at a normal rate leading to elevated blood glucose levels. This has been linked to the hormone insulin. There are two main types of diabetes. In type 1, the body is unable to produce insulin. Onset of type 1 diabetes usually starts in childhood or young adulthood. In type 2 diabetes, not enough insulin is produced or the insulin that is produced doesn't effect the appropriate response. Type 2 diabetes tends to affect people as they get older. In both types the result is an inability to control blood glucose levels, leading to hyperglycaemia. Hyperglycaemia is the cause of symptoms associated with diabetes, such as polydipsia, polyuria and polyphagia and may contribute to the development of macrovascular disease, which is associated with the development of coronary artery disease. Since the body is unable to control the level of blood glucose, a major aspect of life for a person with diabetes is to manage blood glucose levels as close to normal as possible. Control of diet, in particular distribution of carbohydrate and sugar, in meals throughout the day is therefore of importance.

WO 97/38593 describes a supplement bar for the prevention of night time hypoglycaemia which includes simple and complex carbohydrates, proteins and lipids. The compositions comprise uncooked corn starch.

US 6,248,375 describes a solid matrix composition designed for the person with diabetes comprising a carbohydrate system utilising a source of fructose in combination with a nonabsorbent carbohydrate to produce a glycaemic response comparable to more complex multi-component carbohydrate systems.

There remains a need to provide a palatable nutritional composition, for example a biscuit product, which will not result in the abnormal elevation of blood glucose levels and will provide a healthy nutritional and tasty snack for people who have diabetes.

Snack foods, such as biscuits normally contain sugar (sucrose) as the sweetener and also for providing the desired texture and physical properties. Clearly for the diabetic patient, it is appropriate that such snacks are replaced with those having no or low added sucrose. However, a problem observed with no or low added sucrose products is that they have poor mouthfeel and generally retain moisture resulting in lack of crispiness and other undesirable properties.

It is an object of this invention to provide a nutritional biscuit which has a low glycaemic index (GI) and glycaemic load (GL) whilst retaining crispiness and mouthfeel.

It has now been found that a palatable short dough nutritional crispy biscuit can be prepared by using fructose and fibre in combination with protein, fat, extruded crispy particles and enzymes.

Accordingly the present invention provides a short dough crispy texture nutritional biscuit composition comprising

- (a) fructose from 3.0 to 12.0 % w/w;
- (b) natural fibre from 1.0 to 8.0 % w/w;
- (c) protein isolate from 0.5 to 6.0 % w/w;
- (d) fat from 12 to 28.0 % w/w;
- (e) flour from 50.0 to 70.0 % w/w;
- (f) crispy particles from 0.5 to 10.0 % w/w;
- (g) emulsifier from 1.0 to 3.5 % w/w.

Compositions of the present invention comprise fructose from 3.0 to 12.0 % w/w, suitably from 4.0 to 10.0 % w/w and more suitably from 6.0 to 8.0 % w/w. Fructose provides sweetness whilst avoiding the negative effects of elevated blood glucose levels.

Compositions of the present invention further comprise natural fibre from 1 to 8% w/w, suitably from 1.5 to 6.0 % w/w, and more suitably from 2.0 to 3.5 % w/w. Fibre serves not only to provide a nutritional value but also helps to retain integrity and reduce breakage by binding the ingredients. Suitable sources of fibre include wheat fibre, oat fibre, fruit fibre, vegetable fibre and wheat bran and mixtures thereof.

Compositions of the present invention further comprise protein isolate from 0.5 to 6.0 % w/w, suitably from 1.0 to 4.0 % w/w and more suitably from 1.5 to 2.5 % w/w. Suitable sources of protein isolate include soy protein, whey protein, cereal protein and legume protein and mixtures thereof.

Compositions of the present invention further comprise fat from 12.0 to 28.0 % w/w, suitably from 14.0 to 25.0 % and more suitably from 15.0 to 20.0 % w/w. The level of fat used in the composition is important for the shortening characteristics and hence contributes to the crispiness. Suitable sources of fat include hydrogenated vegetable fat, unhydrogenated vegetable fat and interesterified fat. Suitable sources of hydrogenated fat include corn oil, soy oil, palm oil, coconut oil, peanut oil and sunflower oil and mixtures thereof.

Compositions of the present invention include crispy particles from 0.5 to 10.0 % w/w, suitably from 2.0 to 7.0 % w/w and more suitably from 4.0 to 6.0 % w/w. The inclusion of crispy particles contributes to the crispy texture. Crispy particles may be made from refined wheat flour, whole wheat flour, oat flour, rice flour and soy flour and mixtures thereof. Crispy particles for use in compositions of the present invention may be made by an extrusion process.

Compositions of the present invention comprise flour from 50.0 to 70.0 % w/w, suitably 53.0 to 63.0 % w/w and more suitably 55.0 to 60.0 % w/w. Suitable sources of flour may be selected from refined wheat flour, whole wheat flour, oat flour, rice flour and soy flour and mixtures thereof.

Compositions of the present invention will comprise emulsifier from 1.0 % w/w to 3.5 % w/w, suitably 2.5 % w/w to 3.5% w/w. Suitable emulsifiers include soy lecithin and glycerol monostearate and mixtures thereof.

Compositions of the present invention may also comprise milk powder from 0 to 10.0 % w/w, suitably 2.0 to 8.0 % w/w and more suitably 3.0 to 6.0 % w/w.

Other ingredients used in the preparation of compositions of the present invention include enzymes and leavening agents. Suitably enzymes are added during processing at from 0.06 to 0.14% w/w of the total ingredients. The purpose of the enzymes is to control the moisture, surface finish and texture and gluten level in the dough mixture. Suitable enzymes include protease and xylanase and mixtures thereof.

Suitably, leavening agents are added during processing at from 0.5 to 1.5 % w/w of the total ingredients. Suitable leavening agents include sodium bicarbonate, ammonium bicarbonate and monoacid calcium phosphate and mixtures thereof.

Other ingredients commonly used in nutritional products may be used in the preparation of compositions of the present invention such as artificial sweeteners, salt, flavours, preservatives, vitamins and minerals. Minerals are suitably in the form of salts of elements such as calcium, iron and zinc.

Preferred compositions of the present invention are made from the following ingredients and ratios:

1. Refined wheat flour : Whole wheat flour crispy particles from 6:1 to 20:1, suitably 9:1 to 15:1 and more suitably 12:1 to 14:1.

2. Refined wheat flour & Whole wheat flour crispy particles : vegetable oil from 3.1 to 3.5:1 .

3. Refined wheat flour : Enzymes from 14000:1 to 3000:1, suitably 9000:1 to 4000:1, more suitably 6000:1 to 4500:1.

Compositions of the present invention suitably contain the enzymes protease and xylanase in the ratio from 1:1 to 1:2, more suitably 1:1.2.

Compositions of the present invention suitably contain the leavening agents sodium bicarbonate, ammonium bicarbonate and monoacid calcium phosphate in the ratio 0.4:1:0.25.

Biscuit compositions of the present invention may be made by the following process:

- a) mixing the emulsifier with a sufficient amount of fat at 65°C to 75°C to form a paste;
- b) mixing the paste from step a) with the remaining fat at a temperature not exceeding
5 45°C;
- c) adding the crispy particles to the mixture from step b);
- d) adding the protein isolate and fibre to the mixture from step c);
- e) preparing a mixture of the fructose and other optional ingredients in water;
- f) adding enzyme and leavening agent in water to the mixture from step e);
- 10 g) adding the flour to the mixture from step f);
- h) forming a dough from the mixtures from steps d) and g);
- i) shaping the dough from step h) into biscuit shapes;
- k) baking the dough from step i) at a temperature in the range 180 to 350°C.

15 For the avoidance of doubt, glycaemic index (GI) is the increase in blood glucose (over the fasting level) that is observed in the two-hours following the ingestion of a set amount of carbohydrate in an individual food. Glycaemic load (GL) is the product of the glycaemic index of the food and the amount of carbohydrate in a serving (Sheard, N. F. et al., Dietary Carbohydrate (Amount and Type) in the Prevention and Management of Diabetes. A
20 Statement by the American Diabetes Association. Diabetes Care, Volume 29, No 9, September 2004, 2226-2271). As per international guidelines, a high GI value is 70 or more, a medium GI value is in the range 56-69 inclusive and low GI value is 55 or less. A high GL is 20 or more, a medium GL value is in the range of 11-19 inclusive and low GL value is in the range of 10 or less.

25 The invention is illustrated by way of the following examples:

1. Glycaemic Index – Short Dough Biscuit in Healthy Volunteers.

The glycaemic index for a short dough biscuit according to the invention was determined
30 by comparing the glycaemic response to the short dough biscuit with the response to 50g of glucose in 14 healthy volunteers after an overnight fast.

Methodology

Each study subject underwent three study phases for glucose and one for the short dough biscuit. At each phase the subject was given either a standard 50g glucose solution in 300ml of water or a serving of test biscuit to provide a 50g carbohydrate equivalent (11 biscuits). The study phases for each volunteer were randomised. This is in conformance to the globally accepted FAO/WHO protocol for Glycaemia Index testing. All necessary institutional procedures were followed and the study was carried out under the supervision of a diabetologist, at a unit in a hospital.

10 Blood Sampling

For each study phase eight venous blood samples were collected at t = -15, 0, 15, 30, 45, 60, 90 and 120 minutes. Blood glucose levels were measured.

Blood glucose levels were plotted against time to calculate the incremental area under the curve (IAUC) for each study phase. The GI was calculated for each volunteer as the incremental area under the curve for the biscuit divided by the mean incremental area under the curve for the 3 glucose tests. The mean GI of all the volunteers was a measure of the GI for the biscuit .

20 Results

The mean Glycaemic Index for the biscuits was 38 [$\pm$ 17]. The Glycaemic Load (GI x Carbohydrate per serve / 100) for a serve size of 21.4g (3 biscuits), was 5.

25 **1. Nutritional Composition of Biscuits per 100g (14 biscuits), 80g (11 biscuits) & 21.4g (3 biscuits).**

Nutrients	Unit	Biscuit		
		Delivery per		
		100g (14)	80 g (11)	21.4 g (3)
Energy	kcal	470	376	101
Carbohydrate	g	62.5	50	13.3
Fat	g	20	16	4.2
Protein	g	10	8	2.1
Fibre	g	3	2.4	0.64

2. Glycaemic Response – Short Dough Biscuit in Patients with mild to moderate Type 2 diabetes.

5 The glycaemic response to a short dough biscuit according to the invention was compared to that of an iso-caloric reference snack (white bread sandwich), in patients with mild to moderate type 2 diabetes. The patients were either on diet therapy or on oral hypoglycaemic drugs or a combination of both.

Study design

10 Prospective, single centre, randomised, comparative, cross over trial. All products were iso-caloric and the sequence of feeding was randomised.

Study Compositions

- 15 A. White bread sandwich, approximately 40g bread with mint chutney (94 kcal, 19.5g carbohydrate).
- B. 3 Short dough biscuits 21.4g (101 kcal, 13.39g carbohydrate)

Study Size

17 patients (9 male and 8 female) completed all the study periods.

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Methodology

Each subject had to undergo two study phases, one for the reference sandwich and one for the short dough biscuit. At each phase the subject was given either the reference sandwich or the biscuits (3 biscuits) with 200ml of water. The study phases for each volunteer were randomised. All necessary institutional procedures were followed and the study was carried out under the supervision of a diabetologist, at a diabetes unit in a hospital.

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Blood Sampling

Seven venous blood samples were taken at t = 0, 30, 60, 90, 120, 150 and 180 minutes,

30 Five capillary blood samples were taken at t = 0, 30, 60, 120 and 180 minutes.

The blood samples were analysed for glucose and for triglycerides to provide:

- a) Incremental glucose response over the course of 3 hours,
- b) 2h post prandial capillary glucose concentration,

c) Plasma triglyceride concentration 3h after consumption.

The incremental area under the blood glucose curve after the consumption of the test product was compared with that of the reference snack. For each individual, the glycaemic response was plotted on a graph. For the whole group the results were shown as mean $\pm$ standard error of mean.

The mean glycaemic (venous and capillary) and triglyceride response after the test product was compared with the response to the reference snack by Repeated Measures Regression Analysis using generalised estimating equation. Paired “t” test for the mean incremental blood glucose value at different time points and incremental area under the curve.

Results

The incremental blood glucose value for the test product was lower than for the reference snack, but the difference was not found to be statistically significant at any time point. The mean two hour post prandial capillary blood glucose value was below 180mg/dl in conformance with the American Diabetes Association guidelines.

Although the values for the test product were lower than the reference snack, results of the regression analysis for values over a period of 3 hours, showed no significant difference in the venous blood glucose values, capillary blood glucose values and triglyceride values for the biscuits compared to values for the standard sandwich.

The mean IAUC for venous blood glucose over a period of 3 hrs for the reference snack and biscuits was 3018.12 ± 1462.83 and 2544.87 ± 2127.93 respectively. There was no significant difference in IAUC of biscuits as compared to the reference snack.

Clinically, the data suggest that the glycaemic response for the test product (biscuits), was lower than for the reference snack (the bread sandwich). Statistically there was no difference and the response was comparable to that from a standard sandwich snack in patients with type 2 diabetes. Based on the acute glycaemic profile, in its recommended serve size, the short dough biscuit is suitable for consumption by people with type 2 diabetes.

CLAIMS

1. A short dough crispy texture nutritional biscuit composition comprising

- (a) fructose from 3.0 to 12.0 % w/w;
- (b) natural fibre from 1.0 to 8.0 % w/w;
- (c) protein isolate from 0.5 to 6.0 % w/w;
- (d) fat from 12 to 28.0 % w/w;
- (e) flour from 50.0 to 70.0 % w/w;
- (f) crispy particles from 0.5 to 10.0 % w/w;
- (g) emulsifier from 1.0 to 3.5 % w/w.

2. A composition according to claim 1 wherein fructose is present in an amount from 6.0 to 8.0% w/w.

3. A composition according to claim 1 or 2 wherein the natural fibre is present in an amount from 2.0 to 3.5% w/w.

4. A composition according any one of claims 1 to 3 wherein the protein isolate is present in amount from 1.5 to 2.5% w/w.

5. A composition according to any one of claims 1 to 4 wherein the fat is hydrogenated vegetable oil and is present in an amount from 14.0 to 25.0% w/w.

6. A composition according to any one of claims 1 to 5 wherein the flour is present in an amount from 53 to 63% w/w.

7. A composition according to any one of claims 1 to 6 wherein the crispy particles are present in an amount from 2.0 to 7.0% w/w.

8. A composition according to any one of claims 1 to 8 wherein the ratio of refined wheat flour to whole wheat flour crispy particles in from 6 : 1 to 20 : 1.

9. A composition according to any one of claims 1 to 9 wherein the ratio of refined wheat flour and whole wheat crispies to vegetable oil is from 3.1 to 3.5 : 1.

10. A composition according to any one of claims 1 to 9 wherein the ratio of refined wheat flour to enzyme is from 14000 : 1 to 3000 : 1.

- 5 11. A process for the preparation of a short dough crispy texture nutritional biscuit composition according to claim 1 comprising the steps of:
- a) mixing the emulsifier with a sufficient amount of fat at 65°C to 75°C to form a paste;
 - b) mixing the paste from step a) with the remaining fat at a temperature not exceeding 45°C;
 - 10 c) adding the crispy particles to the mixture from step b);
 - d) adding the protein isolate and fibre to the mixture from step c);
 - e) preparing a mixture of the fructose and other optional ingredients in water;
 - f) adding enzyme and leavening agent in water to the mixture from step e);
 - g) adding the flour to the mixture from step f);
 - 15 h) forming a dough from the mixtures from steps d) and g);
 - i) shaping the dough from step h) into biscuit shapes;
 - k) baking the dough from step i) at a temperature in the range 180 to 350°C.