Evaluation of clinical and biochemical parameters after short-term consumption of microparticulated protein fat substitute (Simplesse®) in a frozen dessert

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The tolerance of microparticulated protein product (MPP, Simplesse®), a protein-based fat substitute, was evaluated in a randomized, double-blind, three-way crossover study using 24 healthy adult subjects (12 males and 12 females). A regular cafeteria diet was given alone or together with two 196-ml servings (approximately 13 fluid ounces) per day of either superpremium ice cream (16% butterfat content) or frozen dessert made with MPP for 7 days. The ice cream and MPP desserts were administerd in a double-blind manner. Three-day dietary diaries were maintained for each 7-day period. Routine laboratory tests along with plasma lipid panels and amino acid profiles were done prior to study start and after each of the three regimens. Vital signs, body weight, and adverse experiences were monitored regularly. None of the three regimens had a clinically significant effect on routine laboratory tests, body weights, vital signs, or plasma amino acid profiles. Of interest, subjects on the ice cream regimen experienced statistically significant increases, although within the normal range, in plasma total cholesterol, LDL- and HDL-cholesterol, and in apolipoprotein A-1 and B concentrations compared to either of the other two regimens. Two mild gastrointestinal adverse experiences were reported during the ice cream regimen. No adverse experiences occurred during the MPP or regular diet regimens. Thus, MPP fat substitute is well tolerated and can safely be used in a low-fat diet regimen.

Introduction

The Surgeon General's Report on Nutrition and Health indicates that overconsumption of certain dietary components is a major concern for Americans. Among these dietary components, fat, especially saturated fat, and cholesterol have been linked to increased risk for obesity and some types of cancer (such as breast, colon, and prostate)[1]. There is also strong evidence for a relationship between dietary saturated fat intake, high blood cholesterol, and increased risk for atherosclerotic vascular disease and stroke[2]. Therefore, recommendations established by the National Cholesterol Education Program (NCEP) suggest lowering dietary fat intake from the present range of 35–40% of total energy to 30%; reducing saturated fat intake from 13–15% to 10% of energy; and lowering cholesterol intake from 350–450 mg/day to less than 300 mg/day[3].

The food industry has become an active partner in this process by developing new, reduced-fat and reduced-cholesterol products which will make it easier for individuals to adhere to a nutritious diet with decreased fat intake. Recently, a microparticulated protein product (MPP) fat substitute (Simplesse®, The NutraSweet Company, Deerfield, IL) was approved by the FDA for use in frozen desserts[4]. This food ingredient allows the manufacture of low-fat foods without the loss of palatability often associated with these products.

MPP is a protein-based fat substitute which is prepared from milk and/or egg white proteins in a patented process called microparticulation[5]. The proteins are heated under intense agitation, followed by rapid cooling to create small, round protein particles of uniform size (0.1–3 microns), which are perceived by the tongue as having the texture of fat. The microparticulation process does not alter the protein identity, quality, nutritional value[6], or the allergenicity/antigenicity of the proteins[7]. Because of the hydration of the proteins during the microparticulation process, MPP provides less energy than the original protein: about 1–2 kcal/g (4.2–8.4 kJ/g) compared to 4 kcal/g (16.7 kJ/g) for protein.

MPP can be used in many applications such as ice cream, salad dressing, yogurt, butter or margarine spreads, cheese (natural and processed), baked cheesecake, mayonnaise, and sour cream. In the conventional ice cream process, MPP replaces butterfat and undergoes the standard manufacturing procedures for making ice cream. Consequently, frozen dessert made with MPP has less than 1% fat content and about 50% of the

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energy of a superpremium ice cream (16% fat), and yet has a similar taste and mouthfeel[5].

The objective of this study was to evaluate the effect, if any, of MPP on various clinical and biochemical parameters, when it is consumed in a frozen dessert for seven consecutive days by healthy adult subjects.

Materials and methods

Subjects

The study was approved by the University of Kansas Medical Center Human Subjects Committee. Twenty-five healthy adult subjects (12 males and 13 females), who were recruited from the staff and student body of the medical center, gave their informed consent to participate in the study. The subjects were required to be within 20% of ideal body weight based on the 1983 Metropolitan Life Insurance Height/Weight Tables. They were also required to pass a physical examination and to have hematology, blood chemistry (including plasma lipids), and urinalysis laboratory values within the normal range. One female subject dropped out due to illness before consuming any test dessert. The 24 subjects who completed the study were a mean (+ SD) age of 26.0 ± 2.2 years (males) and 24.9 ± 5.0 years (females) and weighed 82.6 ± 7.9 kg (males) and 59.9 ± 6.1 kg (females) before the start of the study.

Study design

The study had a randomized, double-blind, three-period crossover design. Subjects were randomly assigned, in the order in which they were enrolled into the study, to receive one of six possible sequences of the three crossover regimens according to a random assignment schedule prepared prior to the study start. Each subject ate all of his/her meals in the hospital cafeteria for 21 consecutive days. They were allowed to choose whatever foods they wanted from the cafeteria menu. During one 7-day period, the diet was not supplemented. During another 7-day period, the diet was supplemented with two 196-ml servings (totaling about 13 fluid ounces) per day of chocolate-flavored 16% butterfat ice cream. During the other 7-day period, the diet was supplemented with an equivalent amount of chocolate-flavored frozen dessert made with MPP fat substitute. The ice cream and MPP desserts were labeled and administered in a double-blind manner. The unsupplemented diet period was not blinded.

The subjects reported to the hospital cafeteria three times per day for their meals. The amount of food they could consume was not restricted. One serving of the ice cream or frozen dessert made with MPP was ingested with the morning meal and one with the evening meal while the subjects were under observation by clinic personnel. The subjects were instructed in the maintenance of dietary diaries by a dietitian and recorded all food consumed during the last 3 days of each 7-day period.

The mean total daily intake of energy, carbohydrates, protein, fat, saturated fat, and cholesterol was calculated from these diaries by a modified Nutritionist III program (N-squared Computing, Salem, OR). From these data, the dietary RISCC rating (ratio of ingested saturated fat and cholesterol to calories) was determined[8]. The RISCC rating condenses the saturated fat, cholesterol, and energy intakes into one value which summarizes the serum lipoprotein-raising potential of a diet. For example, the RISCC rating of the typical American diet (fat intake of 35–40% of total energy) is between 24 and 28 while that of the NCEP Step I diet[3], which is characterized by a reduced fat intake, is 13 to 18. Stability in RISCC ratings over time provides evidence for stability of background dietary patterns.

The ice cream and frozen dessert made with MPP were manufactured by The NutraSweet Company (Mt Prospect, IL). They were packaged and labeled in individual serving containers holding 196 ml (about 6.6 fluid ounces). The nutritional content per container is given in Table 1. The ice cream and the MPP frozen dessert had undergone sensory evaluations and were found to exhibit similar sensory properties[5]. Subjects commented that they found both products acceptable and could not distinguish between them.

Table 1. Nutrient composition of test desserts*.

	Ice cream	Frozen dessert with MPP
Energy (kcal)	418	218
(kJ)	1749	912
Protein (g)	7.4	14.5
Carbohydrate (g)	37.6	37.1
Fat (g)	26.6	1.3
Saturated fat (g)	12.2	0.7
Cholesterol (mg)	121.5	9.9

*The nutritional analyses were done by Hazleton Laboratories America, Inc (Madison, WI) and were based on individual servings of 196 ml (approximately 6.6 fluid ounces).

MPP = microparticulated protein product (Simplesse®).

Within two weeks prior to study start and after each 7-day period, routine laboratory tests (hematology, clinical chemistry, and urinalysis) were done in the fasting state, and vital signs and body weight were monitored. At the same time, blood samples were collected by venipuncture into EDTA-containing tubes for fasting plasma lipid and amino acid profiles.

The subjects were questioned daily during the study regarding any adverse experiences or unusual symptoms they may have had. They were instructed to report any such incidents by telephone when they occurred away from the clinic. This information was recorded on the case report forms.

Assay methods

The analytical methods for plasma total cholesterol[9], total triglycerides[10], HDL-cholesterol[11], LDL- and VLDL-cholesterol[12,13], apolipoprotein A-1[14], and apolipoprotein B[15] have been described previously. The lipid analyses met current guidelines for accuracy and precision according to the lipid standardization program of the Centers for Disease Control. Plasma amino acids (excluding tryptophan) were measured by means of an amino acid analyzer (Beckman 6300; Beckman Instruments, Palo Alto, CA) with an on-line computing integrator (SP4200; Spectra-Physics, San Jose, CA). Plasma total tryptophan concentration was determined by the fluorometric technique of Denckla and Dewey[16] as modified by Bloxam and Warren[17].

Statistical analysis

The data were analyzed by an analysis of variance (ANOVA) appropriate for a three-period crossover study. Contrasts representing pairwise comparisons of the three 7-day periods (MPP vs regular diet, ice cream vs regular diet, and MPP vs ice cream) were tested from the above ANOVA. All analyses were conducted using SAS, Version 6.08 (SAS Institute, Cary, NC) at a significance level of $P<0.05$.

Results

Clinical characteristics

The clinical characteristics of the subjects, including body weights, body mass indices (BMI), vital signs, and the results of routine laboratory tests are contained in Table 2.

Neither the body weights nor the BMIs of the subjects changed significantly over the course of the study. Likewise, there were no clinically significant changes in vital signs (body temperature, heart rate, blood pressure, and respiration rate).

Routine laboratory tests

Although a few laboratory values showed statistically significant changes among the three dietary regimens, ie eosinophils, alkaline phosphatase, and glucose (see Table 2), these changes were small and not considered clinically significant. Serum total bilirubin concentration was significantly lower following the ice cream regimen compared to the other two regimens (Table 2). However, no clinical significance was ascribed to this difference

Table 2. Clinical characteristics* (n=24 subjects).

	Baseline	Regular diet	Frozen dessert with MPP	Ice cream
Age (y)	25.5 ± 3.8			
Height (cm)	170.9 ± 8.2			
Weight (kg)	71.2 ± 13.5	72.0 ± 13.3	72.0 ± 13.1	71.9 ±13.2
Body mass index (kg/m^2)	24.2 ± 2.8	24.5 ± 2.7	24.4 ± 2.7	24.4 ± 2.8
Temperature (°C)	35.5 ± 0.6	35.4 ± 0.6	35.6 ± 0.6	35.7 ± 0.7†
Heart rate (#/min)	66.9 ± 9.4	69.2 ± 7.3	70.3 ± 7.8	69.2 ± 11.5
Respiration rate (#/min)	13.7 ± 2.4	13.3 ±1.4	13.4 ± 1.4	12.8 ± 1.4
Sitting blood pressure (mmHg)				
Systolic	116.8 ± 14.8	115.3 ±11.8	117.8 ± 12.3	118.3 ± 12.1
Diastolic	71.0 ± 7.9	72.1 ± 8.7	72.5 ± 13.3	73.0 ± 6.6
Hematology				
Hemoglobin (g/l)	144 ± 12	141 ± 12	141 ± 12	142 ± 12
Hemacrit (%)	43.2 ± 3.4	42.6 ± 3.8	42.8 ± 3.7	42.5 ± 3.5
RBC (× 10^{12}/l)	4.7 ± 0.4	4.7 ± 0.4	4.7 ± 0.4	4.7 ± 0.4
WBC (× 10^9/l)	5.9 ± 1.3	6.5 ± 1.2	6.4 ± 1.3	6.5 ± 1.1
Polys/neurophils (%)	49.0 ± 9.8	49.5 ± 10.0	48.9 ± 9.3	48.2 ± 10.0
Lymphocytes (%)	38.0 ± 9.2	39.6 ± 10.8	39.5 ± 8.9	39.2 ± 9.0
Monocytes (%)	7.7 ± 3.1	6.1 ± 3.4	7.3 ± 3.4	7.6 ± 4.3
Eosinophils (%)	2.5 ± 1.7	3.0 ± 2.3	1.6 ± 1.8†	2.3 ± 1.9
Basophils (%)	0.5 ± 0.7	0.4 ± 0.6	0.5 ± 0.8	0.5 ± 0.7
Platelet count (× 10^9/l)	292 ± 59	307 ± 75	307 ± 79	308 ± 67
Clinical chemistry				
Creatinine (μmol/l)	90 ± 14	88 ± 17	88 ± 17	91 ± 16 †§
Uric acid (μmol/l)	298 ± 83	274 ± 65	274 ± 77	280 ± 73
Total protein (g/l)	75 ± 4	74 ± 4	74 ± 3	74 ± 4
Albumin (g/l)	43 ± 2	42 ± 2	42 ± 2	42 ± 2
BUN (mmol/l)	4.55 ± 1.16	4.50 ± 1.25	5.11 ± 1.24 †	4.25 ± 1.10 §
Total bilirubin (μmol/l)	14.2 ± 4.2	13.7 ± 3.8	12.0 ± 4.3	10.3 ± 2.6 †§
Alkaline phosphate (μkat/l)	1.18 ± 0.29	1.21 ± 0.26	1.17 ± 0.29	1.23 ± 0.30 §
LDH (μkat/l)	6.83 **	7.62 ± 1.39	7.58 ± 1.49	7.83 ± 1.37
ALT (SGPT) (μkat/l)	0.44 ± 0.14	0.50 ± 0.18	0.47 ± 0.16	0.50 ± 0.19
AST (SGOT) (μkat/l)	0.48 ± 0.11	0.47 ± 0.08	0.46 ± 0.13	0.48 ± 0.12
Calcium (mmol/l)	2.40 ± 0.07	2.37 ± 0.07	2.37 ± 0.06	2.37 ± 0.07
Inorganic phosphorus (mmol/l)	1.14 ± 0.10	1.26 ± 0.15	1.26 ± 0.13	1.29 ± 0.14
Sodium (mmol/l)	138.7 ± 2.2	140.5 ± 2.6	141.1 ± 2.1	140.6 ± 3.1
Potassium (mmol/l)	4.1 ± 0.3	4.0 ± 0.4	4.1 ± 0.4	4.1 ± 0.3
Chloride (mmol/l)	101.4 ± 2.1	103.8 ± 2.4	104.0 ± 2.3	103.8 ± 2.2
Carbon dioxide (mmol/l)	27.9 ± 2.2	28.0 ± 2.4	28.3 ± 2.5	27.8 ± 2.4
Glucose (mmol/l)	4.54 ± 0.49	4.47 ± 0.25	4.40 ± 0.24	4.57 ± 0.27 §

*Mean ± SD.
†Significantly different from regular diet, $P<0.05$.
§Significantly different from microparticulated protein product (MPP) regimen, $P<0.05$.
**n = 1 subject.

since all the subjects had serum total bilirubin levels within the normal range (3.4–17.1 μmol/l) following the ice cream regimen. Blood urea nitrogen (BUN) and plasma creatinine values also showed statistically significant changes. The mean BUN concentration was greater following the MPP regimen (5.1 mmol/l) relative to either the ice cream (4.2 mmol/l) or the regular diet (4.5 mmol/l) ($P<0.05$). However, all the subjects on the MPP regimen had BUN concentrations within the normal range (3.0–7.0 mmol/l). Mean serum creatinine concentrations were not clinically significantly different among the three regimens, although the difference between the ice cream regimen (91 μmol/l) and either the MPP regimen (88 μmol/l) or the regular diet (88 μmol/L) was statistically significant. All but two of the subjects had serum creatinine values within the normal range (44–106 μmol/l). The two subjects in question had slightly elevated creatinine values at baseline and throughout the study.

Macronutrient consumption

Subjects consumed a self-selected background diet which had a mean RISCC rating of 21 (Table 3). Therefore, the diet was lower in saturated fat and cholesterol than the typical American diet (RISCC of 24–28). The addition of the ice cream to the background diet produced a diet with a RISCC rating of 28 which is similar to that typically eaten in the United States. It contained (as a percentage of total energy) 40% as fat, 16% as saturated fat, and 573 mg of cholesterol. Compared to the baseline diet, the addition of the ice cream raised energy intake by 28%, fat by 60%, saturated fat by 76%, and cholesterol by 59%. When the frozen dessert made with MPP was added to the background diet, energy intake increased by about 9% (due to increased carbohydrate and protein), but fat and cholesterol intakes did not change. The resultant RISCC rating was reduced to 19 from the background rating of 21, and was slightly greater than that of the NCEP Step I diet (RISCC of 13–18).

Plasma lipid profiles

The mean values for the plasma lipids were within the normal range. However, there were statistically significant increases ($P<0.05$) in total cholesterol (9%), LDL- (9%) and HDL-cholesterol (12%), and apolipoproteins A-1 (6%) and B (5%) after the ice cream regimen compared to the MPP regimen (Table 4). None of these parameters were altered following the MPP regimen relative to the regular diet. There were no statistically significant differences in total triglyceride or VLDL-cholesterol concentrations among the three regimens (Table 4).

Plasma amino acid profiles

There were no clinically significant differences in plasma amino acid concentrations among the three dietary regimens and none of the analyses of variance revealed significant effects among treatments.

Adverse experiences

There were no adverse experiences reported during the MPP or regular diet regimens. During the ice cream regimen, two subjects reported mild gastrointestinal discomfort lasting for one day in one case and recurring over a few days in the other case.

Table 3. Mean daily macronutrient intake* (n=24 subjects).

Variable	Regular diet	Frozen dessert with MPP	Ice cream
Energy (kcal)	2305 ± 617	2520 ± 545†	2960 ± 597†§
(kJ)	9644 ± 2582	10544 ± 2280†	12385 ± 2498†§
Carbohydrates (g)	312 ± 97	345 ± 75†	352 ± 85†
(% of energy)	(54.1)	(54.8)	(47.6)
Protein (g)	92.1 ± 24.3	108.3 ± 23.6†	100.7 ± 21.4†§
(% of energy)	(16.0)	(17.2)	(13.6)
Total fat (g)	81.3 ± 33.0	80.4 ± 30.6	130.3 ± 31.5†§
(% of energy)	(31.7)	(28.7)	(39.6)
Saturated fat (g)	30.1 ± 13.4	29.9 ± 11.7	53.0 ± 12.0†§
(% of energy)	(11.7)	(10.7)	(16.1)
Cholesterol (mg)	360 ± 188	358 ± 206	573 ± 165†§
RISCC rating**	21 ± 7	19 ± 6†	28 ± 4†§

MPP = microparticulated protein product (Simplesse®).
*Mean ± SD.
†Significantly different from regular diet, $P<0.05$.
§Significantly different from MPP regimen, $P<0.05$.
**Ratio of ingested saturated fat and cholesterol to calories =
$[(1.01 \times \text{g saturated fat}) + (0.05 \times \text{mg cholesterol})] \div (\text{total kcal}/1000)$

See text and reference[8].

Table 4. Mean fasting plasma lipoprotein concentrations* at baseline and following each 7-day regimen (n=24 subjects).

	Baseline	Regular diet	Frozen dessert with MPP	Ice cream
Total cholesterol	4.31 ± 0.73	4.31 ± 0.60	4.25 ± 0.75	4.65 ± 0.66†§
Triglycerides	0.99 ± 0.43	1.04 ± 0.49	1.04 ± 0.43	1.07 ± 0.43
VLDL-C	0.38 ± 0.16	0.40 ± 0.19	0.40 ± 0.16	0.41 ± 0.17
LDL-C	2.60 ± 0.65	2.56 ± 0.55	2.55 ± 0.67	2.79 ± 0.59†§
HDL-C	1.34 ± 0.19	1.36 ± 0.22	1.30 ± 0.20	1.45 ± 0.27†§
Apolipoprotein A-1	106 ± 10	106 ± 9	105 ± 12	111 ± 12†§
Apolipoprotein B	73 ± 20	75 ± 14	75 ± 18	79 ± 17†§

MPP = microparticulated protein product (Simplesse®).
*mmol/l (except for apolipoproteins, which are mg/dl), mean ± SD.
†Significantly different from regular diet, $P<0.05$.
§Significantly different from MPP regimen, $P<0.05$.

Discussion

Subjects consuming two 196-ml servings of frozen dessert made with MPP (approximately 13 fluid ounces) per day for 7 days did not demonstrate any clinically significant changes in the clinical and biochemical parameters measured. There were no adverse experiences or untoward events associated with MPP consumption.

MRCA Information Services, Inc (Northbrook, IL), an organization which collects and analyzes food consumption data, has estimated the intake of MPP. Their survey was based on a nationally representative sample of 2000 households, containing 5042 individual household members. If MPP were contained in all frozen dessert products, its estimated consumption (14-day average, users only) would provide about 0.9 and 1.9 g protein/day at the mean and 90th percentile intake rates, respectively. Given that the average protein intake rate is approximately 72 g/day in adults (derived from reference[18]), MPP consumption would only modestly increase (1–3%) the daily protein consumption. The increase in protein consumption (1.9 g/day) provided by the estimated 90th percentile MPP intake is equivalent to less than 2 oz of whole milk.

The subjects in this study consumed about 11 g of additional protein/day from MPP. Thus, the subjects consumed almost six times the amount of protein as the 90th percentile, 14-day average, frozen dessert consumption rate (1.9 g/day). The absence of adverse experiences in this study demonstrates that MPP-containing products would be well tolerated by consumers.

The subjects' dietary protein intake increased during the MPP regimen (108 g/day) compared to the regular cafeteria diet (92 g/day) and the ice cream regimen (101 g/day). There was no concomitant increase in plasma amino acids. However, there was, as expected, an increase in mean BUN concentration during the MPP regimen, which was similar in magnitude to the increase in dietary protein intake. All the subjects on the MPP regimen had BUN concentrations within the normal range (3.0–7.0 mmol/l). The increase in BUN concentration was not associated with an increase in serum creatinine concentration.

The 16% butterfat ice cream used in this study had much the same appearance, taste, and texture as the frozen dessert made with MPP. However, unlike frozen dessert made with MPP, the addition of the ice cream to the regular diet produced a diet with a fat composition typical of the current American diet. This resulted in an expected plasma lipid increase which did not occur during the MPP regimen. The frozen dessert made with MPP contained about 50 g less total fat, 23 g less saturated fat, and 222 mg less cholesterol per total daily serving than the 16% butterfat ice cream. Subjects on the MPP regimen consumed similar amounts of total and saturated fat and cholesterol as the subjects on the regular cafeteria diet. Thus, the subjects did not adjust their fat intake in response to the low-fat content of the frozen dessert made with MPP. Subjects on the ice cream regimen consumed about the same amount of fat from other sources as the subjects on the regular diet regimen in addition to the fat contained in the ice cream. The plasma lipid profiles did not differ significantly between the regular diet and MPP regimens. However, the subjects on the ice cream regimen, who were consuming about 50 g more total fat per day than subjects on either of the other two regimens, showed statistically significant increases in plasma lipids and lipoproteins, although within the normal range, after 7 days. It is not surprising that a large quantity of 16% butterfat ice cream would result in an increase in fasting plasma lipids and lipoproteins, although, after only 7 days, the changes in lipid levels had probably not reached steady state. Nevertheless, a trend toward increased fasting lipid and lipoprotein levels was evident.

In conclusion, subjects ingesting about 400 ml (approximately 13 fluid ounces) of frozen dessert made with MPP per day for 7 days did not show any clinically significant changes in clinical and biochemical parameters or report any adverse experiences. Thus, MPP fat substitute is well tolerated and can safely be used in a low-fat diet regimen.

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摘 要

作者以24個健康成人（12男，12女）爲試驗對象，用隨機，雙盲，三種方式進行交叉研究，去評估他們對一種以蛋白質爲主的脂肪代用品－微粒蛋白產品（MPP, Simplesse）的耐受力。所有試驗對象在膳堂進食21天，7天只用基本膳食；7天除基本膳食外，另每日補充2次優質冰淇淋（含奶油16%），每次196毫升（約13 盎司）；7天除基本膳食外，另每日補充2次相同數量的用微粒蛋白產品製成的冰凍甜品。7天中進行3天食物登記。受試者在三種膳食前後均進行常規實驗室檢驗，血漿脂類及氨基酸測定。規律地監視活力指徵，體重和不良感受。結果顯示，三種膳食式樣對常規實驗室撿驗，體重，活力指徵，或血漿氨基酸水平均無臨床的明顯影響。有趣的是，補充冰淇淋膳食時，雖然受試者的血漿總膽固醇，低密度脂蛋白膽固醇，高密度脂蛋白膽固醇和戴脂蛋白A-1和B在正常範圍内，但均較基本膳食和補充微粒蛋白產品時明顯增高。補充冰淇淋膳食時，有2例發生中等度胃腸不適，而在用基本膳食或補充微粒蛋白產品膳食(MPP)時均無不良感受。因此，作者認爲健康成人對微粒蛋白脂肪代用品能很好地耐受，並應用在低脂膳食是安全的。