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# Postprandial metabolism of a reduced-fat meat product with added silicon from diatomaceous earth. A pilot randomized controlled four-way assay in humans

M. Pilar Vaquero, * María Dolores Álvarez, Belén Zapatera, Arancha Saiz and Susana Cofrades

The use of silicon (Si) in functional foods is innovative. Because meat products are versatile, nutritious and highly accepted by the population, in this study a reduced-fat meat product (pâté) with added Si from diatomaceous earth was assayed. The design was a four-way postprandial randomized crossover-controlled trial. Eighteen adults ($n$ = 18, mean age 58 ± 8 years, 68% women) consumed a standard meal with the following pâtés: control (C), with normal fat content; reduced-fat (RF), in which pork backfat was fully replaced by emulsions; the C with added diatomaceous earth powder as a source of Si (C-Si); and the RF pâté with the same Si source (RF-Si). Volunteers were characterized in terms of fasting lipemia, body weight, body composition, blood pressure, smoking habits, and medication. Blood samples were collected at 0, 1, 2, and 4 h after ingesting the standard meal containing each of the pâtés. Results show that, regardless of the type of patê, postprandial serum Si and triglycerides increased ($p$ = 0.015 and $p$ < 0.001), and insulin increased during the first hour and decreased thereafter ($p$ < 0.001) while glucose was unchanged. In conclusion, Si from diatomaceous earth is unabsorbed and has no effect on normal postprandial metabolism in adult men and women, suggesting that this inorganic source of Si should not be used as a bioactive ingredient in functional foods.

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## 1. Introduction

Silicon (Si) is a trace element with beneficial health effects. It is essential for bone matrix formation and bone mineralization.[1–3] It is involved in collagen metabolism and elastin biosynthesis, and is mainly found in bone, skin and tendons, but is also present in other elastic tissues such as arteries. Therefore, Si contributes to preserving the structural characteristics of bone and arteries. A decline in Si content in the normal aorta with age has been observed in both animals and humans. Furthermore, rabbits fed a hypercholesterolemic diet to induce atherosclerosis showed lower Si levels in their aortas compared to controls. In humans, aortas with moderate or severe atherosclerosis exhibited reduced Si content compared to those without atherosclerotic plaques, suggesting a potential protective role of Si against atherosclerosis.[4,5] In addition, postprandial assays in rats administered an organic form of Si (monomethylsilanetriol) together with oil and glucose *via* gavage (Si dose: 2 mg per kg body weight per day) demonstrated that Si reduced postprandial triglyceridemia and glycemia, indicating decreased fat and glucose absorption.[6] Another study in rats showed that chronic consumption of a high-cholesterol diet containing 22% restructured pork meat enriched with silicon dioxide improved the lipoprotein profile.[7] More recently, the same research group conducted a rat study using diatomaceous earth added to restructured pork meat at two Si doses (2 or 4 mg per kg body weight per day). They found that this form of Si was bioavailable and produced a dose-dependent reduction in postprandial triglyceridemia without affecting glycemia.[8] Similarly, a study using a diet-induced obesity mouse model reported that supplementation with 4% Si in the form of mesoporous silica reduced adiposity and body weight.[9] Si could also be beneficial in combating aluminum overload and protecting against the toxic effects of aluminum, a factor linked to the onset of Alzheimer's disease.[4,10]

In light of these findings, the use of Si in functional foods represents a promising area of research.[11] Diatomaceous earth powder, composed of millions of hard vegetal shells from single-celled algae known as diatoms, is a natural inorganic source of Si. During digestion, part of this material is converted into orthosilicic acid, the most bioavailable form of Si

*Institute of Food Science, Technology and Nutrition (ICTAN), CSIC, C/José Antonio Novais 10, 28040 Madrid, Spain. E-mail: mpvaquero@ictan.csic.es*

for humans.[12] Although there are still uncertainties regarding the bioavailability of this Si source in humans, unabsorbed Si may exert beneficial metabolic effects. In a previous study conducted by our research group, the incorporation of diatomaceous earth powder into various emulsions formulated with pork lard and stabilized with emulsifying proteins was shown to slow down *in vitro* gastrointestinal fatty acid digestion.[13] These results suggest that non-absorbed Si may interact within the gastrointestinal tract to reduce fat absorption.

In this regard, it is known that postprandial metabolism is crucial for the control of chronic diseases including diabetes, obesity, and cardiovascular disease. Humans spend a large part of the day in postprandial state, due to the intake of successive meals, and the most common situation is that a new meal is taken before the metabolism returns to fasting levels. Fat-rich meals result in an increase in postprandial triglyceride (TG) levels and abnormal transport and metabolism of TG-rich lipoproteins has been related to atherogenesis.[14] These lipoproteins entry the vascular wall and reside in the subendothelial space where they may further promote the formation of foam cells and endothelial damage and it is believed that TG-rich lipoproteins are more atherogenic that low-density lipoproteins (LDLs).[15]

In addition, postprandial lipid metabolism is crucial for diabetes control.[15] Insulin is an anabolic hormone that plays a key role in glucose and energy metabolism. Following a meal, insulin levels rise, promoting the uptake of glucose and fatty acids by peripheral tissues.[16] Consequently, in conditions of insufficient insulin secretion or insulin resistance, postprandial metabolism is impaired, leading to elevated and prolonged hypertriglyceridemia. In patients with type 2 diabetes, a link between insulin resistance and postprandial dyslipidemia has been reported, even when blood glucose control is adequate and fasting plasma TG levels are within the normal range.[17] Therefore, improving insulin sensitivity and reducing postprandial hypertriglyceridemia may contribute to lowering cardiometabolic risk and associated comorbidities.

Our research group has extensive experience in the design of fat analogues and new functional ingredients for the development of healthy meat products, that on one hand improve their fat content and on the other hand use them as a vehicle for the inclusion of bioactive compounds.[11,13,18,19] It is widely known that pâté, made primarily from pork liver and meat, is a rich source of high biological value proteins, as well as B-group vitamins, vitamin A and minerals such as iron, zinc, and selenium—all of which are highly bioavailable—are provided by the liver. Therefore, pork liver pâté can be a concentrated source of nutrients—even more than those provided by other foods such as yogurt or whole grain bread—but it should be consumed in moderation. On the other hand, pâtés are emulsified meat products widely consumed around the world, that are highly appreciated for their sensory attributes such as intense flavor, desirable spreadability, and smooth texture mainly provided by saturated fat. This makes them easy to consume and therefore suitable for populations with chewing difficulties, such as the elderly and individuals with mild cognitive impairment (who may suffer from deficiencies in certain nutrients such as protein and iron). Despite these advantages, one of the main reasons why consumers are reducing their regular intake of these meat products is their awareness of the relatively high amount of saturated animal fat in these products. To improve the nutritional profile of fat or reduce its quantity in processed meat products, studies have been conducted in which animal fat was reduced or replaced with other healthier fats or fat-mimetic additives.[13,18,19] However, the stability, quality, and especially the sensory acceptability of the reformulated products may be negatively affected compared to full-animal-fat meat products, which may lead to low consumer acceptance.

In this context, there is a need to explore new alternative uses of pork fat and study its potential health benefits. One possibility is to regulate the bioavailability of this fat by delaying lipid digestion after consuming meat products, which is considered an important factor in promoting satiety and reducing postprandial triglyceridemia. This could be a strategy for treating metabolic disorders such as type 2 diabetes.

Additionally, the reformulation of emulsion type meat products such as pâtés, offers a valuable opportunity to introduce bioactive compounds not naturally present in this matrix, such as silicon. Therefore, the reformulation strategy carried out in this study—on the one hand, reducing animal fat content through emulsification with biopolymers, and on the other, decreasing lipid digestibility through these biopolymers and the incorporation of silicon—may offer a new way to obtain healthier reformulated pâtés without compromising sensory acceptability, helping to improve the relationship between meat, health, and consumer well-being.

Considering all the above, pâtés have been selected for clinical studies due to their advantages in terms of widespread and easy consumption derived from the use of thermally treated products (ready to eat), make them suitable matrices for the development of functional foods— all within the framework of a balanced diet.

In a previous study, different biopolymeric pork lard emulsions without and with Si added from diatomaceous earth powder were prepared to be used as pork fat analogues in pâtés with reduced fat content. The reformulated pâtés had highly adequate physicochemical and sensory properties comparable to the control pâté that was prepared with 100% pork backfat. The addition of biopolymers and Si in the protein-stabilized emulsion caused a slowdown of the *in vitro* gastrointestinal digestion and, consequently, lower lipid bioaccessibility of the main fatty acids compared to that of the control pâté.[13] However, there is no information on the possible effects of the consumption of this type of products on human digestion, which deserves investigation considering that meat products are rich in nutrients and highly accepted and consumed by different population groups. In addition, the research team has expertise in the field of bioavailability of food components and their metabolic effects. This expertise is derived from the implementation of robust clinical trials, including the study of the effects of carbonated mineral waters

or a grape powder on postprandial lipemia in adults who present obesity or women after menopause.[20–23]

Based on the aforementioned findings, the present study aimed to investigate whether the consumption of a reformulated meat product—specifically, a reduced-fat pâté added with Si from a diatomaceous source—could attenuate the postprandial elevation of TGs, and whether this effect is associated with Si bioavailability or changes in postprandial insulin response in middle-aged adults.

## 2. Materials and methods

### 2.1. Experimental design

A randomized controlled trial with full factorial design was used. It was a postprandial four-way randomized crossover-controlled trial. Participants were randomly assigned to start with one of the four meals containing a different pâté in a random order, with an allocation ratio of 1 : 1 : 1 : 1.

### 2.2. Preparation of pâtés

Four pâtés were prepared: a control (C) pâté with a typical fat content (~30%) elaborated exclusively with pork backfat; a reduced-fat (RF) pâté (~15%), in which pork backfat was fully replaced by emulsion; the C pâté with added diatomaceous earth powder as a source of Si (C-Si); and the RF pâté containing the same Si source (RF-Si).

The source of silicon (Si) was a food-grade diatomaceous earth powder (Tierra de Diatomeas®, Vitality Gesf, Valencia, Spain). The powder was analyzed to contain 85% $SiO_2$, which corresponds to approximately 40% elemental Si. The emulsion used as pork fat replacer was prepared adding a mixture of different hydrocolloids, methylcellulose and carboxymethylcellulose in a soy protein concentrate-stabilized emulsion, in order to have a controlled lipid digestibility as previously found in *in vitro* studies.[13] The formulation of the pâtés is shown in Table 1, and details on their preparation have been previously published[13] with slight modifications since the diatomaceous earth powder was added during the preparation of pâtés instead to be incorporated into the emulsion.

The experimental pâtés were analyzed for moisture and ash contents by the AOAC methods[24] and fat content by the Bligh and Dyer method.[25] Protein content was analyzed using a LECO FP-2000 Nitrogen Determinator (Leco Corporation, St Joseph, MI, USA). All analyses were performed in triplicate. The nutritional composition of the prepared pâtés is presented in Table 2.

### 2.3. Standard meal

For the postprandial study, a standard meal was formulated based on previous experience of our research group[21,22,26] to supply approximately 75 g of fat and 1000 kcal (4184 kJ) if the C or C-Si pâtés were consumed, and approximately 50 g of fat and 800 kcal (3347 kJ) if the RF or RF-Si pâtés were consumed. The food items that were part of the standard meal (Table 3) were always purchased from the same supplier and were of the same commercial brand. Table 4 shows the nutritional composition of the meal containing each pâté. The energy profile of the meals containing C and C-Si was: fat, 68%; protein, 15%; and carbohydrate, 17%; and for the meals containing RF and RF-Si it was: fat, 60%; protein, 19%; and carbohydrate, 21%.

### 2.4. Participants

Recruitment was carried out in the Madrid region of Spain by advertisements published on websites and the study was conducted at the Institute of Food Science, Technology and

**Table 1** Ingredients of the pork liver pâtés (g per 100 g)

| | Pâté | | | |
|---|---|---|---|---|
| | C | C-Si | RF | RF-Si |
| Meat | 19.16 | 19.16 | 19.16 | 19.16 |
| Pork liver | 33.30 | 33.30 | 33.30 | 33.30 |
| Pork backfat | 27.15 | 27.15 | 0 | 0 |
| Biopolymeric emulsion[a] | 0 | 0 | 31.95 | 31.95 |
| Diatomaceous earth powder | 0 | 1.5 | 0 | 1.5 |
| Water | 14.83 | 13.33 | 10.03 | 8.53 |
| NaCl | 1.5 | 1.5 | 1.5 | 1.5 |
| Additives | 4.32 | 4.32 | 4.32 | 4.32 |

Pâtés: C, control; C-Si, control with silicon; RF, reduced fat; RF-Si, reduced fat with silicon. [a] The biopolymeric emulsion was prepared with pork lard, soy protein and a mixture of methylcellulose and carboxymethylcellulose.[12]

**Table 2** Composition of the pork liver pâtés (g per 100 g)

| | Pâté | | | |
|---|---|---|---|---|
| | C | C-Si | RF | RF-Si |
| Moisture | 52.7 | 51.8 | 67.4 | 64.5 |
| Fat | 31.7 | 30.7 | 16.2 | 17.3 |
| Saturated | 9.52 | 9.25 | 4.49 | 5.37 |
| Protein | 12.8 | 13.2 | 13.5 | 13.8 |
| Ash | 2.8 | 4.2 | 2.9 | 4.4 |
| Si | 0 | 0.6 | 0 | 0.6 |

Pâtés: C, control; C-Si, control with silicon; RF, reduced-fat; RF-Si, reduced-fat with silicon.

**Table 3** Composition of the standard meal

| Ingredient | Quantity |
|---|---|
| Pâté (g) | 150 |
| Saturated fat in C | 14.28 |
| Saturated fat in C-Si | 13.87 |
| Saturated fat in RF | 6.73 |
| Saturated fat in RF-Si | 8.05 |
| Wheat bread (g) | 80 (2 slices) |
| Olive oil (g) | 10 |
| Whole cow's milk (g) | 200 |
| Decaffeinated coffee (g) | 2 (1 sachet) |
| Raw almonds (g) | 20 |
| Saccharine (g) | 0.064 (1 tablet) |
| Mineral water (mL) | 200 |

Table 4 Nutritional composition of the standard meal containing the pâtés (per meal)

| | Pâtés included in the meal | | | |
|---|---|---|---|---|
| | C | C-Si | RF | RF-Si |
| Fat (g) | 76.8 | 74.3 | 50.1 | 50.1 |
| Carbohydrate (g) | 46.4 | 46.4 | 46.4 | 46.4 |
| Protein (g) | 37.1 | 37.4 | 37.4 | 37.4 |
| Fibre (g) | 2.9 | 2.9 | 2.9 | 2.9 |
| Energy (kcal) | 1014 | 1003 | 809 | 825 |

Pâtés: C, control; C-Si, control with silicon; RF, reduced-fat; RF-Si, reduced-fat with silicon. Pâtés C-Si and RF-Si provided 0.6 g of silicon.

Nutrition (ICTAN-CSIC). Participants were selected according to the following criteria. Inclusion criteria: adult, age >45 years for men and >50 years for women (to prevent the influence of the menopausal transition[20,21]), and ≤70 years for both men and women; body mass index (BMI) > 22 and <35 kg $m^{-2}$; without medication or taking statins and/or oral hypoglycemic drugs (melformin, sulphonylureas) and/or blood pressure control drugs. Exclusion criteria: age ≤45 years for men, ≤50 years for women and >70 years for both; BMI ≤ 20 and ≥35 kg $m^{-2}$; serum TG > 2.82 mmol $L^{-1}$ (250 mg $dL^{-1}$) due to suspected familial hypertriglyceridemia; under insulin treatment; renal disease, liver disease, Crohn disease, glycated hemoglobin >8%; allergy or intolerance to any component of the pâtés/meal of the study; avoidance to pâtés or any food item included in the meal; pregnant or lactating women; participation in another clinical assay.

Potential participants were asked about these criteria by an on-line questionnaire that included specific questions on food habits, disease diagnosis and drug treatments.

This study was conducted according to the guidelines laid down in the Declaration of Helsinki and procedures were approved by the Ethics Committee of the Spanish CSIC (Ref. 063/2019) and the Clinical Research Ethics Committee of Hospital de la Princesa, Madrid (Ref. 4002; minute CEIm 07/23). Each participant signed an informed consent form before the study begun.

### 2.5. Study design

This postprandial study was a double blinded four-way randomized crossover-controlled trial.

There were two research teams: one produced the pâtés and knew their identity (technological team), and the other recruited the volunteers and worked in the Human Nutrition Unit (HNU) (clinical team). Allocation sequence generation was performed by randomization generated by the RAND function in Microsoft Excel and was performed by a senior researcher who assigned each participant to a specific sequence (ABCD, BCDA, CDAB, DABC, each letter means a different pâté). This researcher did not know the identity of the volunteers, did not have contact with them throughout the trial, and did not know the identity of the pâtés. The clinical team asked the technological team to provide the required number of samples of each codified pâté for each day of assay, but was unaware of their composition, and assured the allocation sequence concealment. Finally, the technological team knew the composition of the pâtés and coded them for the clinical team and prepared the meals. All data and results were recorded codified and the identity of the pâtés was not revealed until the statistical analyses were complete. This ensured blinding of participants, blinding of personnel and blinding of outcome assessment.

Volunteers attended the HNU of the institute ICTAN-CSIC four times with a 2-week interval (wash-out period) each time. Participants were asked to avoid consuming whole grain cereal foods or drink beer in the 48 h prior to each visit (foods high in fiber or Si) and they could not perform intense physical activity during the previous 24 h. On the morning of each visit, fasting (for at least 10 h) and medication conditions were checked, as well as smoking habits, previous consumption of several drinks and foods, and previous physical activity.

After a cannula was inserted into a vein for blood sampling, baseline samples were obtained and the volunteers received the standard meal which contained one of the four study pâtés. The meal was eaten in approximately 30 min. Postprandial blood samples were taken at baseline (0 h) and at times, 60, 120, and 240 min after finishing the meal. During the postprandial time drinking low mineral water (Bezoya®, Madrid, Spain) was allowed.

In addition, on the first and fourth visits, blood pressure, heart rate, waist circumference, body weight and body composition were measured.

### 2.6. Silicon analysis

Si was analyzed in the diatomaceous earth powder and human serum by atomic absorption spectroscopy (AAS) and the graphite chamber technique, using a high-resolution continuous source atomic absorption spectrometer (HS CS AAS technology), model ContrAA 700 (Analytik Jena AG, Jena, Germany), equipped with Xenon short-arc lamp (GLE, Berlin, Germany). A calibration line was obtained from different Si concentrations prepared from the commercial standard Superlco, Certipur (Merck, Darmstadt, Germany) and the measurements were taken at the main atomic line 251.6110 mn. Samples were thawed and diluted 1 : 7 or 1 : 10 with type I deionized water (resistivity 18.2 MΩ cm), using a Milli-Q Integral system (Merck) before analysis. Si was analyzed in samples from 0, 120, and 240 min. Serum samples from the same subject were analyzed in the same run (12 samples per participant in duplicate). The intra-assay coefficient of variation was 3.7%.

### 2.7. Blood pressure, anthropometrics and body composition

Systolic and diastolic blood pressure (SBP and DBP), and heart rate were measured using a validated automatic digital blood pressure monitor (IHEalth KN-550BT, iHealthLabs Europe, Paris) and the mean of two consecutive readings was recorded. Body weight, height, and waist and hip circumferences were measured by a trained member of the clinical team by standardized procedures,[27] and body mass index (BMI) was calculated.

Percentages of body fat, abdominal fat, and body water, as well as total muscle mass and abdominal muscle mass, were determined by a validated body composition monitor (Tanita BC-601, Tanita Ltd, Amsterdam, The Netherlands).

### 2.8. Biochemical analyses

Blood samples were collected by venipuncture and serum was obtained after centrifugation at 1000 g for 15 min (Jouan CR-312 centrifuge, Jouan Ltd, Ilkeston, UK). TGs, total cholesterol high-density lipoprotein (HDL)-cholesterol (HDLc), low-density lipoprotein (LDL)-cholesterol (LDLc), glucose and insulin were determined by autoanalyzer in fresh serum.

Total-cholesterol/HDLc, LDLc/HDLc, and the molar ratio TG/HDLc were calculated. Insulin resistance was calculated by the homeostatic model assessment index (HOMA-IR) = [glucose (mg $dL^{-1}$) × insulin (μU $mL^{-1}$)]/405.

### 2.9. Statistical analyses

Sample size was calculated based on our previous experience.[22,26] The primary variable was TG at 120 min and 24 subjects in a 4-way crossover trial was calculated as sufficient to detect significant differences with 80% power and alpha value of 0.05.

Variable distributions were checked by the Shapiro–Wilk test and visually. The variable TG was not normally distributed and it was log-transformed before statistical analysis. Results are expressed as mean ± SD unless otherwise specified.

Generalized mixed linear models were used to study the fixed effects, pâté (C, C-Si, RF, and RF-Si), sex, age, and pâté × hour and pâté × sex interactions; the random effect, which was the order of pâté consumption (starting with C, C-Si, RF or RF-Si); and the repeated effects, which were visit (1, 2, 3, 4) and postprandial hour. The Bonferroni correction for multiple testing was used. In addition, the non-parametric independent-samples Kruskal–Wallis test was used to study the differences between pâtés within each postprandial hour.

The data were analyzed using SPSS for Windows, version 29.0.0.0 (IBM SPSS Statistics for Windows Armonk, NY, USA). The level of significance was set at $p < 0.05$.

## 3. Results

Fig. 1 shows the flow chart of the participants. From a total of 45 individuals who contacted the research group, 19 were randomized (1 refused to continue the study in visit 1) and 18 volunteers completed the study (11 women and 7 men). Table 5 shows their characteristics including the cardiovascular risk indexes total cholesterol/HDLc and LDLc/HDLc, and the diabetes risk indexes HOMA-IR and TG/HDLc. Table 6 shows the changes in anthropometric, blood pressure and heart rate measurements of the participants at the beginning and at the end of the trial. While body weight did not vary, waist circumference and percentage body fat significantly decreased ($p$ = 0.048 and 0.005, respectively), total muscle mass and body water increased (both $p$ = 0.005), and blood pressure decreased ($p < 0.001$ for SBP, and $p$ = 0.003 for DBP). However, the multivariate mixed model demonstrated no significant effects of the

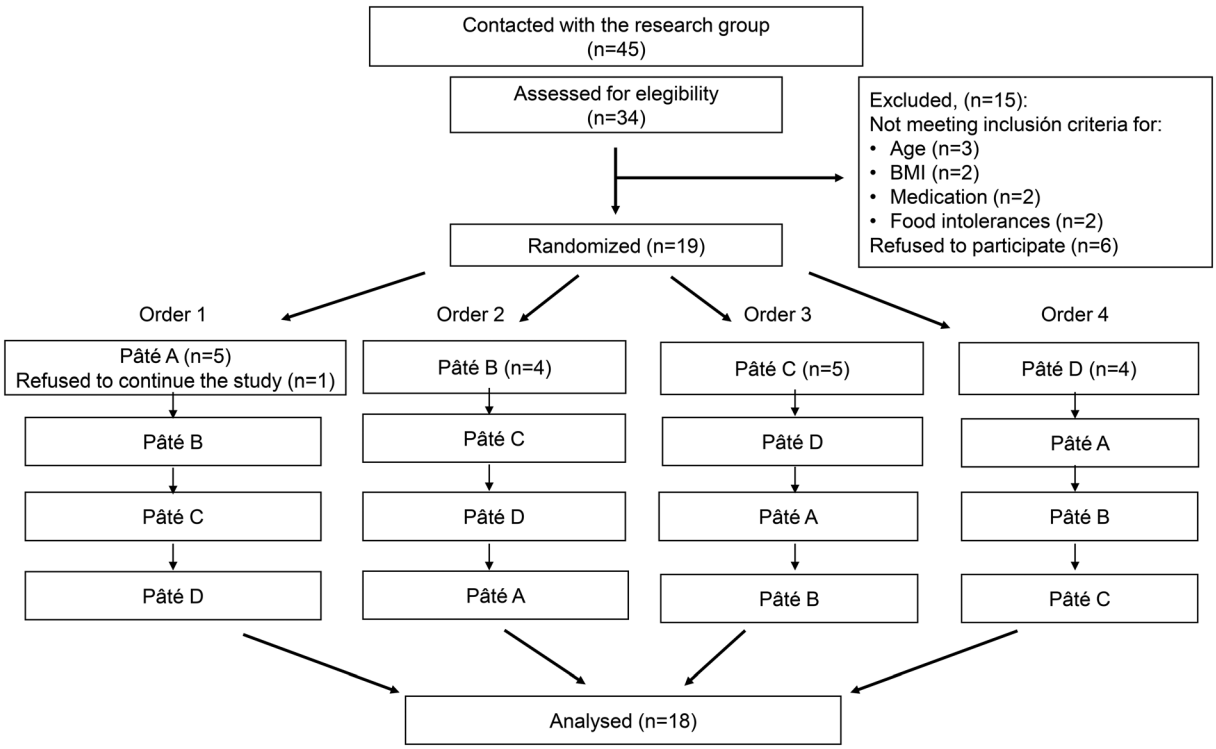


Fig. 1 Flowchart of the participants in the randomized controlled trial.

 

**Table 5** Baseline characteristics of the participants

| Parameter | Value[a] |
|---|---|
| Total participants (*n*) | 18 |
| Women (%) | 68 |
| Diabetes (%) | 11 |
| Smoking (*n*) | 1 |
| Medication for (*n*): | |
| Lipid control | 5 |
| Blood pressure control | 4 |
| Glucose control | 2 |
| Thyroid control | 3 |
| Age (years) | 58 ± 8 |
| BMI (kg $m^{-2}$) | 26.1 ± 3.5 |
| Body weight (kg) | 73.1 ± 12.0 |
| SBP (mmHg) | 126 ± 14 |
| DBP (mmHg) | 77 ± 11 |
| Glucose (mg $dL^{-1}$) | 92 ± 15 |
| Insulin (μU $mL^{-1}$) | 6.9 ± 3.8 |
| HOMA-IR | 1.64 ± 1.05 |
| Total cholesterol (mg $dL^{-1}$) | 193 ± 39 |
| LDLc (mg $dL^{-1}$) | 124 ± 29 |
| HDLc (mg $dL^{-1}$) | 61 ± 19 |
| Total cholesterol/HDLc (mg $dL^{-1}$) | 3.4 ± 1.0 |
| LDLc/HDLc (mg $dL^{-1}$) | 2.15 ± 0.67 |
| Triglycerides (mg $dL^{-1}$) | 87 (68, 108) |
| Triglycerides/HDLc (mol $mol^{-1}$) | 0.62 (0.47, 0.86) |

[a] Values are given as *n*, %, mean ± SD or median (95%CI). SBP, systolic blood pressure; DBP, diastolic blood pressure; HOMA-IR, homeostasis model assessment-insulin resistance; LDLc, LDL-cholesterol; HDLc, HDL-cholesterol.

**Table 6** Changes in anthropometric, blood pressure and heart rate between visit 1 and visit 4

| | Visit 1 | Visit 4 |
|---|---|---|
| Body weight (kg) | 73.1 ± 12.0 | 73.1 ± 12.0 |
| Waist circumference (cm) | 95.3 ± 10.2 | 93.7 ± 12.0 |
| Body fat (%) | 29.0 ± 8.9 | 27.4 ± 9.3 |
| Abdominal fat (%) | 27.5 ± 8.0 | 26.5 ± 9.9 |
| Total muscle mass (kg) | 49.3 ± 10.6 | 50.4 ± 10.8 |
| Abdominal muscle mass (kg) | 27.9 ± 5.5 | 27.9 ± 5.7 |
| Body water (%) | 51.3 ± 6.0 | 52.6 ± 6.4 |
| SBP (mmHg) | 125.7 ± 14.0 | 113.7 ± 10.9 |
| DBP (mmHg) | 77.1 ± 10.6 | 70.7 ± 7.6 |
| Heart rate (bpm) | 65.9 ± 11.1 | 66.2 ± 11.1 |

SBP, systolic blood pressure; DBP, diastolic blood pressure. The differences between visits were not significant for any variable.

type of pâté ($p$ = 0.447) or the order sequence ($p$ = 0.408) on these parameters.

Fig. 2–4 present the postprandial changes of serum TG, insulin, glucose and Si. Serum TG (Fig. 2) increased from the fasting baseline to the second postprandial hour and reached a plateau between the 2nd and the 4th hours (time effect, $p$ < 0.001), and although age had a significant effect ($p$ < 0.001), the effect of pâté was not significant ($p$ = 0.447). Insulin (Fig. 3) increased significantly during the first postprandial hour and decreased sharply after the 2nd hour ($p$ < 0.001) without any other significant effect. Glucose (Fig. 4), showed no significant effects by time, pâté, age or sex. Finally, post-

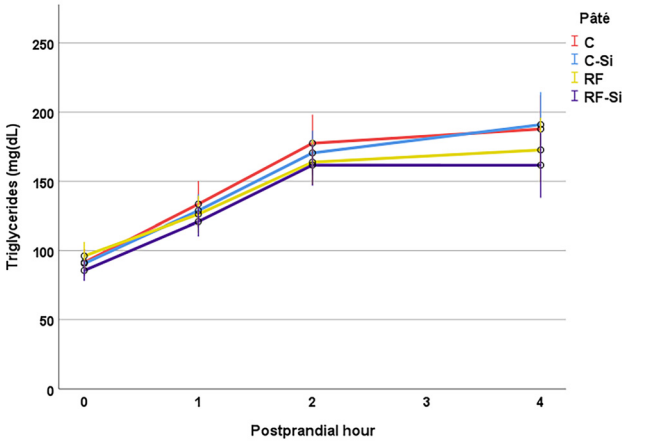


**Fig. 2** Postprandial triglycerides. Data are mean ± ESM for $n$ = 18 participants consuming standard meals with each of the four pâtés: C, control; C-Si, control with S; RF, reduced-fat; RF-Si, reduced-fat with Si.

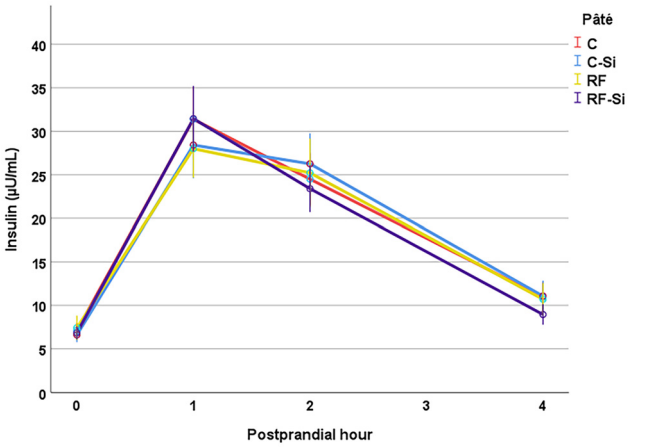


**Fig. 3** Postprandial insulin. Data are mean ± ESM for $n$ = 18 participants consuming standard meals with each of the four pâtés: C, control; C-Si, control with S; RF, reduced-fat; RF-Si, reduced-fat with Si.

prandial Si levels (Fig. 5) showed a significant time effect ($p$ = 0.015), while no significant effects of pâté type ($p$ = 0.616), sex, or age were observed. No carryover effects were detected. The absence of significant differences between pâté formulations was further confirmed by independent-samples Kruskal–Wallis tests conducted at each postprandial time point.

## 4. Discussion

This four-way randomized controlled trial demonstrates that Si, in the form of diatomaceous earth incorporated into a meat product (pâté) and consumed as part of a standard meal, does not alter the postprandial increase in triglyceride (TG) or insulin levels in humans. The results showed a slight increase in serum Si following meal ingestion, which was similar regardless of whether diatomaceous earth was included, sup-

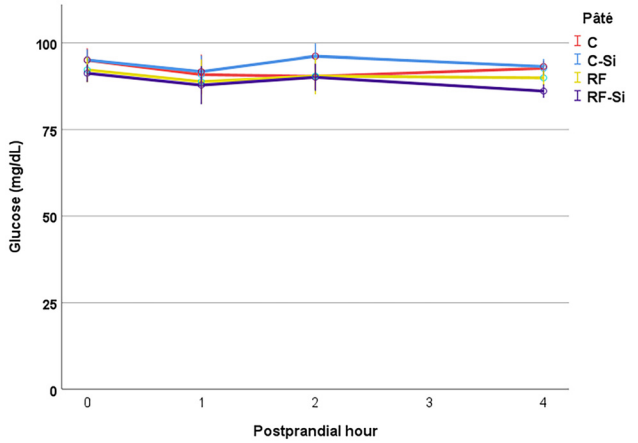


**Fig. 4** Postprandial glucose. Data are mean ± ESM for $n$ = 18 participants consuming standard meals with each of the four pâtés: C, control; C-Si, control with S; RF, reduced-fat; RF-Si, reduced-fat with Si.

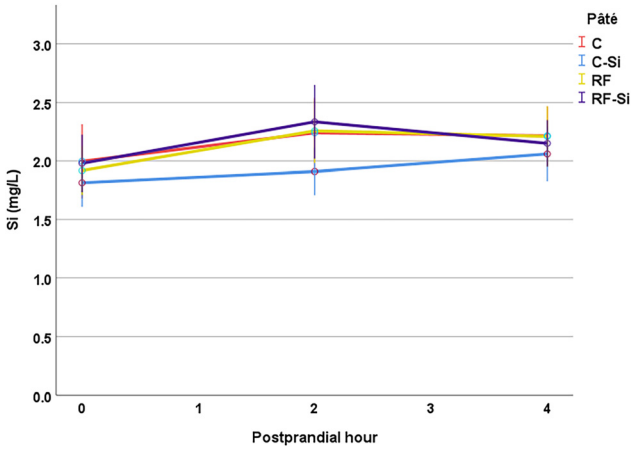


**Fig. 5** Postprandial silicon. Data are mean ± ESM for $n$ = 18 participants consuming standard meals with each of the four pâtés: C, control; C-Si, control with S; RF, reduced-fat; RF-Si, reduced-fat with Si.

porting the notion that this Si source is poorly absorbed. Furthermore, the findings suggest that unabsorbed Si does not influence postprandial lipemia or insulinemia, contrary to previous suggestions by several authors.[12,28]

Previous *in vitro* studies by our research group using diatomaceous earth incorporated in various reformulated pâtés, differing in fat content and the way of Si incorporation, have shown that the presence of Si ameliorated lipid bioaccessibility of the main fatty acids.[13] It was also observed that the substitution of pork back fat with pork fat emulsified with protein and other polymers significantly reduced lipid digestibility and resulted in a lower amount of free fatty acid (FFA) release. However, these favorable effects are not confirmed in the present human study. This discrepancy can be explained by the complexity of lipid digestion *in vivo*. After gastric digestion, the lipid fraction reaching the duodenum is transformed by bile salts and enzymes into FFA, 2-monoglycerols, and lysophospholipids. These digestion products, and not exclusively FFA, are included in mixed micelles that can enter the enterocytes by diffusion or by specific transporters (fatty acid binding proteins). Once in the enterocyte, TG, phospholipids and cholesterol esters are resynthesized, finally forming chylomicrons (QM) that leave the enterocyte through the lymphatic circulation and finally the blood circulation.[29] The determination of postprandial serum TG represents the amount of fat absorbed and carried in QM.[22]

In a type 2 diabetes mellitus rat model, chronic consumption of a Si-enriched meat product induced hypolipidemic and hypoglycemic effects, which were attributed to improvements in enterohepatic circulation, including reduced reabsorption and increased excretion of cholesterol and bile acids.[6,28,30] The discrepancy in findings compared to the present study can be mainly attributed to the form of Si used—organic Si in the aforementioned studies *versus* inorganic Si in the present one. Diatomaceous earth, the Si source used here, is a siliceous material derived from the fossilized skeletons of diatoms. Our human study suggests that the low bioavailability of Si from this inorganic source had a negligible effect on the absorption process, which may explain the absence of significant metabolic effects.

There are very few studies focused on Si bioavailability and absorption in humans. Using urinary excretion as a surrogate marker of Si absorption, the highest absorption rates have been reported for beer, followed by green beans, whole cereals, and food supplements based on orthosilicic acid.[31,32] In this context, it is well established that beer contains soluble orthosilicic acid and may contribute substantially to daily Si intake.

There are currently no established adequate intake values for Si, nor is there a consensus on normal serum levels in humans. Jugdaohsingh *et al.*[31] estimated dietary Si intake in adults to range between 13 and 62 mg day$^{-1}$. Robberecht *et al.*[33] assessed dietary Si intake using the duplicate portion sampling technique over seven consecutive 24-hour meal periods, reporting a mean intake of 18.6 ± 8.5 mg day$^{-1}$. The 600 mg of Si per 100 g of pâté used in this postprandial assay was selected based on the assumption of low Si bioavailability and to reflect a dose compatible with supplemental consumption. This amount corresponded to approximately 12 mg per kg per day body weight.

On average, our serum Si data at fasting are higher than in other human studies.[31,32] Bissé *et al.*[34] analyzed serum of healthy individuals and reported reference Si values according to sex and age. They obtained median values between 9 and 10 μmol L$^{-1}$ (*ca.* 266 μg L$^{-1}$) for the ages 45 to 74 years and reported amply ranges. Another prior study found maximum serum Si of approximately 1904 μg L$^{-1}$.[35] In the present study, we obtained that the fasting baseline serum Si ranged between 45–3233 μg L$^{-1}$ (median 1679 μg L$^{-1}$). Interestingly, the two highest values corresponded to a man who declared consumption of beer 2 days before the day of blood extraction, and a woman who declared consumption of whole grain cereals also 2 days before the day attending our Institute for the postpran-

 

dial assay (participants were instructed to refrain consumption of beers and whole cereals 48 h before the visits).

To our knowledge, this is the first time that the postprandial evolution of serum Si from diatomaceous earth is studied in humans. Moreover, most of the publications are based on the analysis of urine as the biomaterial to assess Si bioavailability[31,36] and the determination of serum samples before and after supplemental Si intake is very limited. Our findings show that serum Si increased very slightly during the postprandial period irrespective of the pâté formulation, and support the low bioavailability of the inorganic Si contained in the C-Si and RF-Si pâtés. In addition, it is possible that the relatively elevated baseline levels rendered it impracticable to detect subsequent increases. In this line, it is known that humans are exposed to significant amounts of this element due to its ubiquitous presence in nature. However, bioavailability is certainly the limiting step, and present findings demonstrate that absorption of Si from diatomaceous earth is insignificant.

The essentiality of Si is under debate because evidence of deficiency is required for an element to be considered a nutrient and this has not been demonstrated for Si in humans.[4,12] However, a growing body of research points that it plays a role in metabolic processes associated with chronic diseases. Therefore, it may be considered a bioactive element instead of a nutrient.

Concerning the results of postprandial TG, an increase in TG levels was shown with peak values after 4 h of intake (Fig. 5), in agreement with previous findings by our research group[21,22] and others who used similar fat load.[37] Consistently, insulin increased sharply during the first hour after eating the meal and declined thereafter (Fig. 3), demonstrating a fast postprandial response to the fat-rich meal, while the absence of postprandial increase in glucose should be explained by the very low sugar intake, mainly provided by the lactose in milk, in agreement with previous findings.[20,22,26] All these postprandial trends were physiological, however, the lack of influence of the type of pâté on TG and insulin was unexpected. This should be attributed to the aforementioned unavailability of Si from diatomaceous earth. In addition, the possibility that this form of Si is transformed in part to orthosilicic acid and induce postprandial metabolism changes should be ruled out.

Furthermore, the results demonstrate that the reformulated pâté exhibited negligible differences in fat absorption when compared to the control, indicating that reducing the fat content of meat products whilst incorporating a biopolymeric emulsion of fat results in a minor impact on postprandial metabolism. In contrast, factors inherent to the individual, such as age and the status premenopausal *versus* postmenopausal, exerted significant influences on the evolution of postprandial TG.[21] We here detected the age influence; however, given that all women were postmenopausal, the postprandial curves exhibited a similarity between men and women.

Participants in this trial were middle-aged men and women with overweight, some of whom were undergoing hypocholesterolemic and oral hypoglycemic treatments. The clinical trial was robust in design, as each participant served as his or her own control. However, it was considered a pilot study due to the small sample size and the limited number of parameters assessed. Nevertheless, the results clearly demonstrated that the observed postprandial changes were physiological, and there is no doubt regarding the ineffectiveness of Si under the tested conditions.

In conclusion, this randomized controlled trial demonstrated that inorganic Si form diatomaceous earth included in a reformulated meat product and consumed as part of a meal, was not bioavailable, and did not modify the normal postprandial lipemia, insulin and glucose evolutions according to the nutritional composition of the meal consumed. Further studies should be focused on high bioavailability organic Si (*e.g.* orthosilicic acid) that may be assayed included in solid food or drinks. Concerning the target population, individuals with cardiovascular risk and groups with inadequate bone resorption should be the priority.

## Author contributions

Vaquero MP: writing – original draft, conceptualization, validation, methodology, investigation, formal analysis, data curation. Álvarez MD: conceptualization, validation, methodology, writing – review & editing. Zapatera B: methodology. Saiz A: methodology. Cofrades S: conceptualization, investigation, writing – review & editing, project administration.

## Conflicts of interest

The authors declare that they have no known competing financial or personal interests.

## Data availability

Data associated to human participants are available at DIGITAL.CSIC at **https://digital.csic.es/handle/10261/400463** and **https://doi.org/10.20350/digitalCSIC/17576**.

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## References

1 M. Rondanelli, M. A. Faliva, G. Peroni, C. Gasparri, S. Perna, A. Riva, G. Petrangolini and A. Tartara, Silicon: A neglected micronutrient essential for bone health, *Exp. Biol. Med.*, 2021, **246**, 1500–1511.

2 R. Jugdaohsingh, A. I. E. Watson, P. Bhattacharya, G. H. van Lenthe and J. J. Powell, Positive association between serum silicon levels and bone mineral density in female rats following oral silicon supplementation with monomethylsilanetriol, *Osteoporosis Int.*, 2015, **26**, 1405–1415.

3 H. Rico, J. L. Gallego-Lago, E. R. Hernández, L. F. Villa, A. Sanchez-Atrio, C. Seco and J. J. Gérvas, Effect of Silicon Supplement on Osteopenia Induced by Ovariectomy in Rats, *Calcif. Tissue Int.*, 2000, **66**, 53–55.

4 A. M. Pérez-Granados and M. P. Vaquero, Silicon, aluminum, arsenic and lithium: essentiality and human health implications, *J. Nutr., Health Aging*, 2002, **6**(2), 254–162.

5 Ł. Dudek, W. Kochman and E. Dziedzic, Silicon in prevention of atherosclerosis and other age-related diseases, *Front. Cardiovasc. Med.*, 2024, **11**, 1370536.

6 A. Garcimartín, M. E. López-Oliva, A. Macho-González, S. Bastida, J. Benedí and F. J. Sánchez-Muniz, Hypoglycaemic and hypotriglyceridaemic postprandial properties of organic silicon, *J. Funct. Foods*, 2017, **29**, 290–294.

7 A. Garcimartín, J. A. Santos-López, S. Bastida, J. Benedí and F. J. Sánchez-Muniz, Silicon-Enriched Restructured Pork Affects the Lipoprotein Profile, VLDL Oxidation, and LDL Receptor Gene Expression in Aged Rats Fed an Atherogenic Diet, *J. Nutr.*, 2015, **145**, 2039–2045.

8 R. Redondo-Castillejo, M. Hernández-Martín, J. Á. Issa-García, A. Bocanegra, A. Garcimartín, A. Macho-González, S. Bastida, F. J. Sánchez-Muniz, J. Benedí and M. E. López-Oliva, Diatomaceous Earth Supplementation as a Bioavailable Silicon Source Modulates Postprandial Lipid Metabolism in Healthy Female Rats, *Nutrients*, 2025, **17**, 2452.

9 M. Rinde, N. Kupferschmidt, M. N. Iqbal, G. Robert-Nicoud, E. V. Johnston, M. Lindgren and T. Bengtsson, Mesoporous Silica with Precisely Controlled Pores Reduces Food Efficiency and Suppresses Weight Gain in Mice, *Nanomedicine*, 2020, **15**, 131–144.

10 S. N. Kunz, D. Bohrer, P. C. do Nascimento, F. W. S. Cibin and L. M. de Carvalho, Interference of Parenteral Nutrition Components in Silicon-Mediated Protection Against Aluminum Bioaccumulation, *Biol. Trace Elem. Res.*, 2024, **202**, 3662–3671.

11 S. Cofrades, A. Garcimartín, M. Pérez-Mateos, A. Saiz, R. Redondo-Castillejo, A. Bocanegra, J. Benedí and M. D. Álvarez, Stabilized soy protein emulsion enriched with silicon and containing or not methylcellulose as novel technological alternatives to reduce animal fat digestion, *Food Res. Int.*, 2023, **170**, 112833.

12 M. A. Farooq and K.-J. Dietz, Silicon as Versatile Player in Plant and Human Biology: Overlooked and Poorly Understood, *Front. Plant Sci.*, 2015, **6**, 994.

13 S. Cofrades, A. Saiz and M. D. Álvarez, Biopolymeric emulsions with added silicon as pork fat substitutes in the reformulation of healthy pâtés: Effect on technological, nutritional and sensory properties and on lipid digestibility after in vitro gastrointestinal digestion, *LWT–Food Sci. Technol.*, 2024, **210**, 116865.

14 S. Bansal, J. E. Buring, N. Rifai, S. Mora, F. M. Sacks and P. M. Ridker, Fasting Compared With Nonfasting Triglycerides and Risk of Cardiovascular Events in Women, *J. Am. Med. Assoc.*, 2007, **298**, 309.

15 Y. Zhao, Z. Zhuang, Y. Li, W. Xiao, Z. Song, N. Huang, W. Wang, X. Dong, J. Jia, R. Clarke and T. Huang, Elevated blood remnant cholesterol and triglycerides are causally related to the risks of cardiometabolic multimorbidity, *Nat. Commun.*, 2024, **15**, 2451.

16 R. Riachi, E. Khalife, A. Kędzia and E. Niechciał, Understanding Insulin Actions Beyond Glycemic Control: A Narrative Review, *J. Clin. Med.*, 2025, **16**(14), 5039, DOI: **10.3390/jcm14145039**.

17 G. Riccardi, L. Bozzetto and G. Annuzzi, Postprandial lipid metabolism, *Food Nutr. Res.*, 2006, **50**, 99–106.

18 S. Cofrades, A. Saiz, M. Pérez-Mateos, A. Garcimartín, R. Redondo-Castillejo, A. Bocanegra, J. Benedí and M. D. Álvarez, The Influence of Cellulose Ethers on the Physico-Chemical Properties, Structure and Lipid Digestibility of Animal Fat Emulsions Stabilized by Soy Protein, *Foods*, 2022, **11**, 738.

19 S. Cofrades, J. Gómez-Estaca, M. D. Álvarez, A. Garcimartín, A. Macho-González, J. Benedí and T. Pintado, Influence of the Oil Structuring System on Lipid Hydrolysis and Bioaccessibility of Healthy Fatty Acids and Curcumin, *Gels*, 2023, **10**, 33.

20 S. Schoppen, F. J. Sanchez-Muniz, A. M. Perez-Granados, J. A. Gomez-Gerique, B. Sarria, S. Navas-Carretero and M. P. Vaquero, Does bicarbonated mineral water rich in sodium change insulin sensitivity of postmenopausal women?, *Nutr. Hosp.*, 2007, **22**, 538–544.

21 S. Schoppen, A. M. Perez-Granados, S. Navas-Carretero and M. P. Vaquero, Postprandial lipaemia and endothelial adhesion molecules in pre- and postmenopausal Spanish women, *Nutr. Hosp.*, 2010, **25**, 256–261.

22 S. Schoppen, A. M. Perez-Granados, A. Carbajal, B. Sarria, F. J. Sanchez-Muniz, J. A. Gomez-Gerique and M. P. Vaquero, Sodium bicarbonated mineral water decreases postprandial lipaemia in postmenopausal women compared to a low mineral water, *Br. J. Nutr.*, 2005, **94**, 582–587.

23 E. García-Díez, M. Cuesta-Hervás, A. M. Veses-Alcobendas, Ó. Alonso-Gordo, E. García-Maldonado, M. Martínez-Suárez, B. Herranz, M. P. Vaquero, M. D. Álvarez and J. Pérez-Jiménez, Acute supplementation with grapes in obese subjects did not affect postprandial metabolism: a randomized, double-blind, crossover clinical trial, *Eur. J. Nutr.*, 2021, **60**, 2671–2681.

24 AOAC, *Official methods of analysis of AOAC International*, AOAC international, 2005.

25 E. G. Bligh and W. J. Dyer, A rapid method of total lipid extraction and purification. Canadian Journal of Biochemistry and Physiology, *Can. J. Biochem. Physiol.*, 1959, **37**, 911–917.

 

26 L. Toxqui, A. M. Perez-Granados, R. Blanco-Rojo and M. P. Vaquero, A sodium-bicarbonated mineral water reduces gallbladder emptying and postprandial lipaemia: A randomised four-way crossover study, *Eur. J. Nutr.*, 2012, **51**, 607–614.

27 International Society for Advancement of Kinanthropometry, *International Standards for Anthropometric Assessment*, International Society for the Advancement of Kinanthropometry, Potchefstroom, South Africa, 2001, ISBN 9780868037127.

28 M. Hernández-Martín, A. Garcimartín, A. Bocanegra, A. Macho-González, R. A. García-Fernández, S. De Pascual-Teresa, R. Redondo-Castillejo, S. Bastida, F. J. Sánchez-Muniz, J. Benedí and M. E. López-Oliva, Silicon-Enriched Meat Ameliorates Diabetic Dyslipidemia by Improving Cholesterol, Bile Acid Metabolism and Ileal Barrier Integrity in Rats with Late-Stage Type 2 Diabetes, *Int. J. Mol. Sci.*, 2024, **25**, 11405.

29 E. Martínez de Victoria, M. Mañas and M. D. Yago, in *Bases fisiológicas y bioquímicas de la Nutrición*, Médica Panamericana, Madrid, 3rd edn, 2017, vol. 1, pp. 27–56.

30 M. Hernández-Martín, A. Garcimartín, A. Bocanegra, R. Redondo-Castillejo, C. Quevedo-Torremocha, A. Macho-González, R. A. García Fernández, S. Bastida, J. Benedí, F. J. Sánchez-Muniz and M. E. López-Oliva, Silicon as a Functional Meat Ingredient Improves Jejunal and Hepatic Cholesterol Homeostasis in a Late-Stage Type 2 Diabetes Mellitus Rat Model, *Foods*, 2024, **13**, 1794.

31 R. Jugdaohsingh, S. H. Anderson, K. L. Tucker, H. Elliott, D. P. Kiel, R. P. Thompson and J. J. Powell, Dietary silicon intake and absorption123, *Am. J. Clin. Nutr.*, 2002, **75**, 887–893.

32 S. Sripanyakorn, R. Jugdaohsingh, H. Elliott, C. Walker, P. Mehta, S. Shoukru, R. P. H. Thompson and J. J. Powell, The silicon content of beer and its bioavailability in healthy volunteers, *Br. J. Nutr.*, 2004, **91**, 403–409.

33 H. Robberecht, R. Van Cauwenbergh, V. Van Vlaslaer and N. Hermans, Dietary silicon intake in Belgium: Sources, availability from foods, and human serum levels, *Sci. Total Environ.*, 2009, **407**, 4777–4782.

34 E. Bissé, T. Epting, A. Beil, G. Lindinger, H. Lang and H. Wieland, Reference values for serum silicon in adults, *Anal. Biochem.*, 2005, **337**, 130–135.

35 G. M. Bercowy, H. Vo and F. Rieders, Silicon Analysis in Biological Specimens by Direct Current Plasma-Atomic Emission Spectroscopy, *J. Anal. Toxicol.*, 1994, **18**, 46–48.

36 N. Boqué, R. M. Valls, A. Pedret, F. Puiggrós, L. Arola and R. Solà, Relative absorption of silicon from different formulations of dietary supplements: a pilot randomized, double-blind, crossover post-prandial study, *Sci. Rep.*, 2021, **11**, 16479.

37 C. Mihas, G. D. Kolovou, D. P. Mikhailidis, J. Kovar, D. Lairon, B. G. Nordestgaard, T. Chye Ooi, P. Perez-Martinez, H. Bilianou, K. Anagnostopoulou and G. Panotopoulos, Diagnostic Value of Postprandial Triglyceride Testing in Healthy Subjects: A Meta-Analysis, *Curr. Vasc. Pharmacol.*, 2011, **9**, 271–280.