ORIGINAL ARTICLE



Objective Evaluation Tool for Texture-Modified Food (**OET-TMF**): **Development of the Tool and Validation**

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Abstract Texture-modified diets (TMDs) should fulfil nutritional goals, guarantee homogenous texture, and meet food safety regulations. The food industry has created texture-modified food (TMF) that meets the TMD requirements of quality and safety for inpatients. To design and develop a tool that allows the objective selection of foodstuffs for TMDs that ensures nutritional requirements and swallowing safety of inpatients in order to improve their quality of life, especially regarding their food satisfaction. An evaluation tool was designed to objectively determine the adequacy of food included in the TMD menus of a hospital. The "Objective Evaluation Tool for Texture-Modified Food" (OET-TMF) consists of seven items that evaluate the food's nutritional quality (energy and protein input), presence of allergens, texture and viscosity, cooking, storage type, useful life, and patient acceptance. The total score ranged from 0 to 64 and was divided into four categories: high quality, good quality, medium quality, and low quality. Studying four different commercial TMFs contributed to the validation of the tool. All the evaluated products scored between high and good regarding quality. There was a tendency (p = 0.077)towards higher consumption and a higher overall quality of the product obtained with the OET-TMF. The product that scored highest with the tool was the best accepted; the product with the lowest score had the highest rate of refusal. The OET-TMF allows for the objective discrimination of the quality of TMF. In addition, it shows a certain relationship between the observed and assessed quality intake.

Keywords Deglutition · Deglutition disorders · Diet · Texture-modified food · Tool · Viscosity

Introduction

The choice of appropriate food is highly relevant for inpatients and hospital organisations [1]. The objective selection of food requires the study of the characteristics of the offered products by the Clinical Nutrition and Dietetics Unit (CNDU) and the Management Department of each hospital. In order to reach the minimum requirements in the selected food, it is essential to guarantee its nutritional, organoleptic, and microbiological quality, while meeting the budget objectives of the hospital.

Improvements in the provision of nutritional support and general nutritional status in hospitalised patients have been shown to be cost-effective. Malnutrition may reach a rate of 40–50 % in different hospitals and health services [1].

A study conducted in our centre by the CNDU in 2011 found that the prevalence or risk of malnutrition was 61.2 % [2]. Nowadays, in our hospital, 86 % of inpatients receive food cooked in the hospital kitchen. Hence, the characteristics of the menus should guarantee an adequate nutritional content to meet the hospitalised patients' requirements, and should reach a high level of patient acceptance.

Texture-modified diets (TMDs) are indicated for patients with swallowing problems, who usually have a higher risk of malnutrition [3]. A TMD is one of the most common therapeutic diet served in hospitals, and is currently used in 10-15 % of patients [4, 5]. Because of this, it

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is important to assure its acceptance by inpatients [6]. rheologic Therefore, TMDs should fulfil nutritional requirements, guarantee a homogenous texture and meet food safety regulations [7]. In some hospitals and long-term care

regulations [7]. In some hospitals and long-term care facilities, blended meals are cooked in a traditional way by trituration in a blender. This procedure might hinder an adequate caloric and protein intake, homogenous texture and pudding-like viscosity [4, 5].

The viscosity of a fluid is a measure that reflects the resistance of the fluid against an applied force. It is a rheological characteristic that can be measured with a rheometer or a viscometer, and can be expressed as milipascales (mPa) or centipoises (cP) [8]. In a systematic review in 2015, Steele et al. pointed out the absence of methodological conventions in the literature regarding the measurement of viscosity [9]. There is still no national consensus on the matter [10] although, in 2000, the American Dietetic Association proposed a national standardisation of terminology concerning the consistency of products for patients with dysphagia. This standardisation related to viscosity included: thin (1-50 cP), nectar-thick (51-350 cP), honey-thick (350-1750 cP), and pudding-like (>1750 cP) [11], which is also referred to as a spoon-thick viscosity [12].

The food industry has created manufactured blended foods that improve the nutritional and organoleptic quality, as well as the safety, of meals given to inpatients [7]. These products consist of lyophilised or dehydrated food (consisting of powder to reconstitute with water), and "readyto-eat" purees (previously sterilised) that have a long shelflife, are non-perishable, and do not require special storage conditions. There are also pasteurised products ready for consumption (which require storage under refrigerated conditions). The strengths of all of these products include constant nutritional value, homogeneous texture, puddinglike viscosity, and a decreased risk of contamination as they require a lower level of manipulation for preparation.

The aim of this study was to design and validate a tool that facilitates the objective selection of foodstuff for hospital diets. The objective of the tool was to improve the overall quality of the menus (in terms of nutrition, texture, viscosity, allergens, food product quality, safety, etc.), particularly regarding the main meals of TMD lunch and dinner.

Method

The CNDU designed and elaborated an evaluation tool to objectively assess the adequacy of food included in the menus of hospital TMD. It was developed by expert consensus opinion after reviewing the literature on specific foods for patients with dysphagia, (taking into account rheological characteristics, microbiological specifications, current food legislation, etc.). Five members of the CNDU comprising two registered dietitians (RDs) and three endocrinologists, agreed the parameters that should be included in the designed tool and their importance when selecting products, with nutritional intake and patient acceptance as the most important criteria.

The Objective Evaluation Tool for Texture-Modified Food (OET-TMF) consisted of seven items that evaluated nutritional quality (that is, energy and protein input), the presence of allergens, its texture and viscosity, cooking, storage type, useful life, and patient acceptance. Each item received a score; these scores were divided into three categories according to the experts' opinion, taking into account its importance for patients safety; category 1 (0, 5 or 10 points) that included nutritional inputs (energy and protein), and patient acceptance; category 2 (0, 4, 8 points) that included presence of allergens, and texture; and category 3 (0, 3, 6 points) that included preparation, storage, and useful life. The total score ranged from 0 to 64 and was divided into four categories, as seen in Fig. 1. If any product had been classified as low quality, it would have been excluded for further economic study. All patients who were receiving TMDs at the time of the study were included for subsequent analysis.

The amount eaten by patients of each product was recorded, depending on whether they had eaten the entire meal, more than half, or less than half or nothing (using the scale described in the NutritionDay) [13]. After visual assessment of consumption, all the patients who did not eat the entire meal were asked verbally why they refused the meals given. The reasons for refusal were classified as follows: lack of appetite, inadequate taste, inadequate texture, performing a medical test, or other causes.

Validation of the OET-TMF

This observational study was conducted at the Complejo Asistencial Universitario de León (Spain) between January and February, 2014. Four TMFs, (A, B, C, and D), commercialised in Spain, were evaluated for use in the hospital TMD programme and were scheduled to be dispensed over four consecutive weeks, one category per week, Monday to Friday at lunch time, to all patients requiring a TMD. Each product was available in four different flavours that were given on different days, but product acceptance was assessed regardless of the flavour consumed. Product A was a lyophilised product that had to be reconstituted with water. Product B was a sterilised product that was heated in a covered oven tray without any handling whatsoever. Product C was a dehydrated product that was reconstituted with water. Product D was a pasteurised product that needed to be heated in a steam oven. Products A and B

Caloric Input			SCORE					
<50 kcal per 100 g	rams of product ready fo	or consumption.	0					
\geq 50 and <100 kcal per 100 grams of product ready for consumption.								
\geq 100 kcal per 100 grams of product ready for consumption.								
Proteic Input								
< 5 g of proteins pe	er 100 grams of product	ready for consumption.	0					
\geq 5 g and < 6.5 g o	\geq 5 g and < 6.5 g of proteins per 100 grams of product ready for consumption.							
\geq 6.5 g of protein per 100 grams of product ready for consumption.								
Presence of Allergen	s, In accordance to th	e "Directive 2006/142/EC an	nending Annex IIIa of					
Directive 2000/13/EC	' listing the ingredients	which must under all circur	nstances appear on the					
labelling of food stuffs:								
Not reporting the a	Not reporting the absence or presence of allergens.							
More than two alle	rgens.		4					
Stating the presence	e of two or less allergens	s or the lack of them.	8					
Homogeneous texture								
Heterogeneous tex	ture or viscosity < 1750	cp at the time of consumption.	0					
Homogeneous texture and viscosity > 1750 cp at the time of consumption.								
Elaboration								
Heat-treated and di	iced		0					
Reconstituted (being a lyophilised or dehydrated) and heat-treated.								
Heat-treated for its consumption without any other added process.								
Storage								
Under refrigeration	1.		0					
At room temperature in a cool, dry place.								
Useful life								
Less than 5 days.			0					
Less than 90 days.								
More than 90 days.								
Patient's acceptance			I					
Intake >75% of rec	ceived product in < 50%	of evaluated patients.	0					
Intake >75% of received product in ≥ 50 to $< 70\%$ of evaluated patients.								
Intake $>75\%$ of received product in $>70\%$ of evaluated patients.								
HIGH QUALITY	GOOD QUALITY	MEDIUM QUALITY	LOW QUALITY					
> 80% 51–64 points	80–60% 38–50 points	40–60% 26–37 points	< 40% 0–25 points					
Cp: centipoises	50–50 points	20-37 points	<u> </u>					

Cp: centipoises

Fig. 1 OET-TMF

were already available at the hospital as part of the TMD; the other two products (C and D) were obtained free of charge for this study, as they were not normally available at the centre.

The technical specifications provided by the product's manufacturer were used to assess its energy, protein, and allergens content, characteristics of the texture and viscosity value, cooking, storage type, and useful life.

In the absence of a rheometer, visual assessments were performed by the study's expert committee of the products' adequacy of adhesion and cohesion. Before this assessment, the products were reconstituted and heated (according to the manufacturer's instructions), and the evaluation was performed by looking for the absence of lumps, no phase separation, and the absence of surface film. A viscometer, the Brookfield DVII + Pro[®], was used to measure viscosity under the following conditions: a sample temperature of 70 °C, spin of no. 6, and at 100 rpm. The viscosity of the product was analysed immediately before its consumption to ensure that it met the conditions of food security for the patient. In the absence of clear standards for TMDs, the results were compared with the standards provided by the American Dietetic Association and the National Diet Task Force [5, 8], which considered a viscosity of >1750 cp to be a spoon-thick viscosity; this was expected for the TMF and accepted by our CNDU as safe for the patient.

Each type of TMF was provided for lunch for a week. For the evaluation of acceptance, all inpatients older than 18 years with a prescribed TMD were included. An RD, who was informed about the study, helped patients to complete the satisfaction questionnaire related to each product.

Statistical analysis was conducted using SPSS 15.0. Data were expressed as absolute values and absolute frequencies. Categories were compared with χ^2 tests; the level of statistical significance was set at p < 0.05.

The Ethics and Clinical Investigation Committee of the hospital approved the study protocol, and patient anonymity was preserved.

Results

The four products were objectively evaluated. The technical specifications of the energy, protein, and allergens content, characteristics of the texture and viscosity value, cooking, storage type, and useful life are shown in Table 1.

The validation was performed in 204 patients; 504 meals were evaluated. Each inpatient consumed only one of the four products because they were hospitalised for <2 weeks.

The distribution of the four products was: 93 units of product A (18.45 %), 160 units of product B (31.74 %), 110 units of product C (21.82 %), and 141 units of product D (27.98 %). The oral intake of the evaluated products is detailed in Fig. 2. Fifty-four percent of the patients ate all the TMF they received; 10 ate >50%; 15 ate 50 %; 9 ate <50 %; and 12 % ate nothing. In the specific analyses of each product, it was seen that product B had the highest acceptance rate while product D had the lowest. The differences between their acceptance were statistically significant (p = 0.033). The main reason that led to the refusal of the evaluated products was caused by inadequate taste (product A: 10 %; B: 18 %; C: 21 %; and D: 35 %). The other parameters are described in Fig. 3. There were significant differences among products and reasons for refusing them (p < 0.001).

The energy and protein input of the four products ranged from 219 to 435 kcal/100 g and 15 to 21.9 g/100 g. Only product D had less than two allergens. All the evaluated products had adequate adhesion and cohesion, and a viscosity value >1750 cp [8]. Products A and C needed to be reconstituted with water, while B and D did not need any handling whatsoever. Of all evaluated products, only D needed to be stored under refrigeration. Their useful life ranged from 60 days to 24 months. These values are detailed in Table 1.

There was a weak and non-significant association (p = 0.077) between consumption and the overall quality as measured by the OET-TMF of the four evaluated products (Fig. 4); product B, which obtained the highest

Table 1 Characteristics of the products selected

Product	Energy (kcal/100 g)	Protein (g/100 g)	Allergens	Texture and viscosity	Cooking	Storage type	Useful life (months)
A	219–229	15	More than 2 but specified	Homogeneous >1750 cp	Reconstituted with water	No special conditions	18 months
В	306–314	15	More than 2 but specified	Homogeneous >1750 cp	No handling	No special conditions	24 months
С	435	21.9	More than 2 but specified	Homogeneous >1750 cp	Reconstituted with water	No special conditions	18 months
D	255–333	19.5	<2	Homogeneous >1750 cp	No handling	Under refrigeration	60 days

Cp centipoises

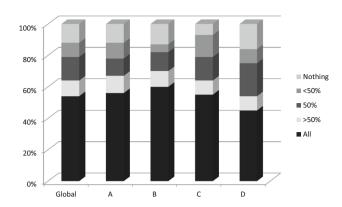


Fig. 2 Qualitative intake of the evaluated products

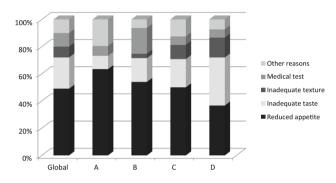


Fig. 3 Reasons for not consuming the evaluated product

score on the OET-TMF, was the best accepted. Product D obtained the highest rate of refusal. Product A obtained the lowest score on the OET-TMF, mainly because it had the lowest energy input.

The full results of the evaluation of the four products using the OET-TMF are shown in Table 2.

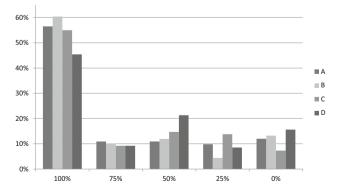


Fig. 4 Relationship between consumption and overall quality from data recorded on the OET-TMF (p = 0.077)

Discussion

The purpose of the tool developed in this study is to facilitate the objective selection of food products for a TMD. To our knowledge, this is the first study that aims to objectively select TMF taking into account the nutritional needs and organoleptic expectations for inpatients with TMDs, while ensuring homogeneous texture, pudding-like viscosity, patient safety, and acceptable qualities regarding storage and cooking.

At the time of the study, there were 11 TMDs available at our centre intended for patients with dysphagia and other diseases (diabetes, diarrhoea, kidney disease, etc.), that included two types of TMF (Products A and B). The energy contribution ranged from 700 to 1400 kcal (10-20 kcal/kg of body weight), while the protein contribution ranged from 30 to 45 g (0.43-0.64 g of protein/kg of body weight), which was clearly below the patients' nutritional needs. Considering a hypercaloric and high-protein diet for the average patient weighing 70 kg, the caloric needs would be 30-35 kcal/kg of body weight, and 0.8-1.5 g of protein/kg of body weight [14]. Moreover, the texture of the meals was heterogeneous (e.g., toasted bread with puree, biscuits with a glass of milk, etc.); only the main meals of lunch and dinner were lyophilised and "ready-toeat" purees. These two issues regarding nutrition and texture led to the development of the OET-TMF in this study.

The manufacturers provided sufficient documentation regarding all the necessary parameters except for viscosity; therefore, this was evaluated with a viscometer by an expert RD. The techniques used by the manufacturers were not the same. The viscosity of products A and C was expressed by the manufacturers in terms of cm/30 seg, tested by a Bostwick® viscometer; the same technique was used to evaluate the viscosity of product D; but there was no information regarding the viscosity measurements of product B. We suggest that manufacturers should inform consumers about the viscosity of their products and the techniques used to determine it, as not all centres have the necessary equipment and staff to carry out their own evaluations. Knowledge of the characteristics of the products in terms of energy and protein content, texture and viscosity, allergens, storage, cooking, etc., could simplify and improve the prescription of TMDs.

When evaluating TMF intake, it should be noted that the characteristics of the food were not the only important factors for its acceptance. There were no striking differences in consumption among the four evaluated TMFs; the organoleptic characteristics of the products strongly affected its consumption or rejection. This observation was detected in product D, which had the highest rate of refusal. As seen in the literature, patients receiving TMDs usually

Product	Energy (kcal/ 100 g)	Protein (g/ 100 g)	Allergens	Texture and viscosity	Cooking	Storage type	Useful life	Acceptance	Total score	Quality
A	5	5	4	8	3	6	6	5	42	GQ
В	10	5	4	8	6	6	6	10	55	HQ
С	10	10	4	8	3	6	6	5	52	HQ
D	10	5	8	8	6	3	3	5	48	GQ

GQ good quality, HQ high quality

suffer from a condition that forces them to rely on their caregiver in order to eat. Often, this situation directly affects the amount of food ingested, regardless of what has been offered [15–17]; if a lack of appetite is factored in with inadequate product taste, the rate of rejection of the product increases.

Velasco et al. evaluated two products, a lyophilised product and a "ready-to-eat" product. Although the acceptance of both was similar, the second had a slightly better result in terms of acceptability [18]. These findings are similar to those obtained in our study in which product B, which was also a "ready-to-eat" meal, had the higher acceptance rate. Considering that the ingredients were similar, these differences might be explained by variations in lyophilised product preparation, such as variability in the ratio of water to product, and also the procedure to reconstitute it according to the particular practice of the chef in charge. The "ready-to-eat" product does not need any handling whatsoever. The variability in the reconstitution procedure may result in failure to achieve the optimal characteristics of the reconstituted product, which might affect patient acceptance. In this regard, De Luis et al. [19], in a study evaluating the acceptance of TMDs by comparing lyophilised with traditional cooking of TMF, noted that the first was better accepted by patients. This suggests that more variations in the preparation could mean an overall lower acceptance rate.

According to the results obtained with the OET-TMF, none of the products was of such low quality that would lead to rejection; thus, all should be studied to assess their economic suitability for inclusion in hospital diets. Despite having adequate characteristics determined by the expert committee of the CNDU in terms of nutritional value, viscosity, storage, preparation, etc., it should be taken into account that product D was the most rejected, because of inadequate taste. This observation might be relevant when determining the appropriate use of resources and cost-effectiveness in the hospital organisation and budget.

The strengths of the OET-TMF were that the use of this tool did not imply any additional cost to the centre; it was innovative, objective, and easy to use, although the analysis of the acceptance and consumption of the products might need to be made by a trained RD.

One of the limitations of this study was that the homogeneity was evaluated visually by two expert RDs because the centre does not have a rheometer. Another limitation was the lack of international consensus about the criteria involved when selecting the parameters and scores used in this tool to evaluate TMFs. After several meetings among the professionals of the CNDU (that included dietitians and endocrinologists), seven items were considered to be the most important, in fulfilling all the criteria for food safety and acceptance within the hospital.

This study aimed to increase the quality of TMDs in a hospital, by an objective selection of an adequate TMF that ensures the nutritional requirements and swallowing safety of inpatients in order to improve their quality of life, especially with regard to their food satisfaction. This tool should be validated for use in other centres and with other food products.

In conclusion, the OET-TMF allows for the objective discrimination of the quality of TMF, and shows a relationship between the observed and assessed quality intake.

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Author Contributions ACF was responsible for the conception and design of the study, the acquisition of data, the viscosity evaluation, the analysis and interpretation of the data, and drafting of the article. AVC was also responsible for the analysis and interpretation of data, as well as critically revising the paper for important academic content. BPM was responsible for the acquisition of data, the viscosity evaluation, and drafting the paper. ICR was responsible for the conception and design of the study, as well as critically revising the paper for important academic content. MDBP supervised all the procedures, critically revising the paper for important academic content, and offering the final approval of the version to be submitted.

Compliance with Ethical Standards

Conflict of interest The authors have no competing financial interests in relation to the work described herein.

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