THE EVALUATION OF THE NUTRITIONAL OUTCOMES OF ADVANCED NUTRITIONAL CARE FOR THE TREATMENT OF DYSPHAGIA IN THE ELDERLY

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NUTRITIONAL OUTCOMES OF A DYSPHAGIA DIET IN THE ELDERLY

In memory of

Maria Pezzano Crisafi

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ABSTRACT

Undernutrition and dysphagia in the institutionalized elderly are well documented in the literature. However, the clinical efficacy of diets to treat dysphagia have not been established. To offer a better understanding of the textural characteristics of the new Sainte-Anne's Hospital (SAH) modified texture reformed foods, rheological evaluations were performed. Apparent viscosity, consistency coefficient, flow behavior index and yield stress values were calculated for the thickened beverages. Texture profile analyses were performed on the reformed foods. Secondly, to evaluate the impact of SAH's reformed foods on nutritional intake and weight, a 12-week clinical trial was undertaken. Dysphagic frail elderly subjects (n = 17) of a long-term care facility of Montréal were randomly assigned to receive SAH reformed foods or traditional care. The experimental group demonstrated a significant increase in nutritional intake resulting in significant weight gain. These findings suggest that dysphagic frail elderly could reach healthy weight when adequately fed.

RÉSUMÉ

La malnutrition et la dysphagie chez la personne âgée sont bien documentées dans la littérature. Toutefois, l'efficacité clinique des diètes pour le traitement de la dysphagie demeure inconnue. Des évaluations rhéologiques ont été effectuées afin de connaître les caractéristiques de texture des nouveaux aliments fabriqués par l'Hôpital Sainte-Anne (HSA). La viscosité apparente, le coefficient de consistance, l'indice de flot et la force d'activation ont été calculés pour les breuvages épaissis. Des analyses de profil de texture ont été réalisées pour les aliments reformés HSA. Une étude clinique de 12 semaines a également été menée. Des sujets âgés dysphagiques (n = 17) d'un centre de soins de longue durée ont reçu aléatoirement les aliments HSA (traitement) ou l'alimentation traditionnelle (contrôle). Le groupe traité a vu son apport nutritionnel augmenter significativement engendrant un gain de poids. Ces résultats indiquent que des personnes âgées dysphagiques peuvent atteindre un poids santé lorsque nourries adéquatement.

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INTRODUCTION

Recent demographic studies show the aging of the North American population. This may ultimately result in the increase of several degenerative diseases associated with old age such as strokes, Dementia, Parkinson's and Alzheimer's diseases. *Dysphagia*, the difficulty to swallow, is a secondary condition frequently observed as a result of these ailments in the elderly. Dysphagia is known to affect up to 60% of the institutionalized elderly population[1,2]. Furthermore, undernutrition has been reported in the institutionalized elderly[3-5] with a prevalence as high as 76%[3,6-8]. Providing an appropriate oral food intake to elders affected by dysphagia is a challenge and undernutrition has frequently been observed in dysphagic individuals. Other problems include confusion, constipation, dehydration, pressure ulcers, infections and decreased quality of life[3,7,9].

Modification of food texture to minced or pureed consistency and thickening of the liquids are generally required to increase food intake of individuals affected by dysphagia. These changes in the diet too often result in foods that are less appealing, and nutritionally diluted. Several dysphagia diets have been published[9-14]. The dysphagia diets generally present lists of suggested foods that are described qualitatively in terms of texture and viscosity. Several professionals are involved in the diagnostic and treatment of dysphagia. Interpretation of vocabulary and terminology could result in potential clinical mistakes. Also, no study of increased nutritional intake or amelioration of clinical outcomes associated to the use of these dysphagia diets has been reported.

At Sainte-Anne's Hospital (SAH), dysphagia was also a clinical challenge that brought the elaboration of a Dysphagia Program associated to the development of a dysphagia diet which included thickened beverages and reformed minced and pureed foods (Pictures 1 to 4).

SAH is a long-term care institution that serves a clientele (97% male) composed of veterans of the 2nd World War or the Korean War. The age average of the residents is 80.4 years old and 50% of the patients receive a modified texture diet (minced or puree) and 10% of the patients receive thickened liquids.

A Dysphagia Program for screening and intervention in dysphagia was adopted and implemented throughout the hospital in 1991. During that same year, the first intervention of the clinical nutrition team was to thicken all the beverages and the supplements offered in three standardized consistencies named *Nectar*, *Honey* and *Pudding* to ensure a better hydration of the dysphagic patients. These beverages became part of the regular menu. They were elaborated along with the occupational therapy department to associate the specific consistency levels with various problematic swallowing conditions. The dietary department thereafter elaborated consistency standards (Picture 4).

In a retrospective analysis[15], the weights of the patients receiving thickened beverages were evaluated. Six months before the introduction of the thickened beverages, all categories of patients (Parkinson, Alzheimer, Strokes, Dementia, Other) demonstrated weight loss. Following the introduction of the thickened beverages, stabilization or an increase of the weight was observed in the categories of Parkinson, Alzheimer, Strokes and Dementia diseases. Several observational reports from SAH's interdisciplinary teams remarked that those better hydrated patients presented less pneumonia cases, less constipation cases, less decubiti ulcers, and needed less tube feedings, IV's or clysis used for hydration.

After such encouraging clinical results, an evaluation of the reasons related to the lack of weight gain of certain groups was done. Items present on the tray were surveyed. Most of these individuals were receiving modified texture diets (minced, pureed or a combination of both) and the overall look of the tray was not very attractive or appetizing. SAH opted for the improvement of the look to their pureed and ground foods. New recipes were elaborated. The new formulations took into consideration the nutrient density and the appearance of the food. Foods were pureed or minced and were shaped back into a more normal looking item, very similar to the regular texture counterpart.

Clinical results observed following the introduction of the reformed foods were positive. Although the production method was standardized for each recipe, the foods were evaluated qualitatively for their texture characteristics – tenderness, stickiness, and brittleness - without precise quantitative measures. In addition, these clinical results were not obtained under a scientific protocol. Therefore, a first study was designed to better evaluate the rheology – quantitative evaluation of deformation and flow of foods – of the foods developed at SAH for the treatment of dysphagia. Secondly, a randomized clinical trial was designed to study the impact of the texture-controlled foods on the nutritional status of dysphagic elderly.

The following text comprises three main sections. Initially, a literature review will provide the most recent information on the situation of malnutrition in the elderly, dysphagia and its outcomes as well as the possible treatments available to the medical profession to overcome the vicious cycle of malnutrition and dysphagia. The literature review will also present the theoretical concepts associated with *rheology* – the study of deformation and flow of foods.

Secondly, results of the first quantified rheological analyses of SAH's thickened beverages and reformed modified texture foods will be presented to provide quantification of certain texture parameters of the SAH specialized foods.

The final section will present the randomized clinical trial that took place from June 1999 to December 1999 at the long-term care facility Marie-Rollet (MR) and the results obtained after the 12-week protocol. This randomized clinical trial evaluated the impact of providing SAH advanced nutritional care to institutionalized elderly on their nutritional and medical status.

LITERATURE REVIEW

1. INTRODUCTION

Canadians are growing older. The 1997 Canada Year Book[16] published by Statistics Canada mentions that the older Canadians gradually become a larger portion of our population. In 1993, there were already 3.4 million Canadian seniors. Numbers suggest that by 2016, there will be 6.3 million seniors in Canada, and between 9 and 11 million by 2041. Life expectancy at birth for a baby boy is about 73 years of age and 80 years for baby girls. Canada is not the only industrialized country that faces this phenomenon. According to US Census Bureau, the US elderly population has grown substantially in this century. In 1994, the population aged 65 or over made up 33.2 million (12.5%) adults. By 2050, this number will increase to 80 million (30%)[17].

Heterogeneity is increased as humans grow older. With age, individuals differ more and more in their health and activity levels. In addition, physiological and physical changes occur in the body. Different age groups of the elderly population have been stratified to better describe those 65 and older. The word *elderly* identifies the individuals above 65 years of age. The expression *young old* describes the group of 65-74, the term *old-old* is used for the 75-84 group and the *oldest-old* is representative of the 84 and over. In addition, the expression *frail elderly* is used to describe the segment of the elderly population that requires support for the activities of daily living[18].

2. NUTRITIONAL STATUS OF THE INSTITUTIONALIZED ELDERLY

The adequate energy requirement for the very old population is not well defined. A decrease in the need of energy intake is mainly associated to reduced activity level since basal metabolism is known to remain unchanged when muscle mass is unaffected. However, Morais and Chevalier[19] suggested that a loss in efficacy of the metabolism could result in a high need for energy and require more substrate to provide equal energy. Therefore, some researchers have suggested that the protein intake should be increased with age to a 1.0 to 1.3 g per kg daily[19].

Undernutrition in the institutionalized elderly population has frequently been reported over the years. Values on prevalence of malnutrition varying between 39% and 76% can be found in the literature[3,6-8]. The World Health Organization (WHO) considers malnutrition to be either undernourishment resulting from insufficient food intake, or specific nutrient deficiencies, and imbalance due to disproportionate dietary intake[20]. Overnutrition caused by excess food intake is also considered as malnutrition but will not be addressed in this document.

In Canada, Keller[3] reported on a cross-sectional survey of 200 elderly subjects in long-term care hospitals. Severe undernutrition was found in 18% of this population and 27.5% of mild/moderate undernutrition. The results also suggested that factors determining overall malnutrition in the elderly included environmental conditions and disease processes that affect the ability to consume food. Dysphagia, feeding dependency, and number of feeding impairments were noted as predictors of poor intake. In 1994, Abbasi and Rudman[4] found that for the institutionalized American elderly intakes were frequently low for both energy and protein. In nursing homes, 30 to 50% of the residents had substandard body weight, mid-arm muscle circumference, and serum albumin level, indicators of protein-energy undernutrition. Blood levels of both water and fat-soluble vitamins were frequently low. A publication by Winograd and Brown[21], based on 3 case reports, suggested that aggressive oral refeeding is underutilized with hospitalized elderly.

In a review of the literature done in 1989, Rudman and Feller[5] compared the results of 14 surveys on institutionalized elderly. They concluded that elderly living in nursing homes showed an unfavorable nutritional profile. A prevalence of protein-energy undernutrition varying between 30-60% was observed in this population. Although the energy intake estimates indicate that only 5-18% of nursing home patients are below the 'Recommended Dietary Allowance' (RDA), up to half of these individuals are underweight and have substandard adipose mass. These observations concur with the possible increase in energy requirements expressed by Morais and Chevalier[19]. Up to 30% ate less than 0.8g protein/kg body weight per day and 15-60% had substandard midarm muscle circumference or serum albumin level, or both. Estimates of mineral and micronutrient intakes showed 20% or more individuals were below the RDA for one or usually several micronutrients such as iron, vitamin D, ascorbic acid, riboflavin, and pyridoxine.

Several causes of malnutrition in institutionalized elderly have been established. They have been divided by Abbasi and Rudman[4] into two categories: 1) those which cause inadequate intake like unappealing environment, disability, poor oral health, dysphagia, medication, and 2) those which cause increased nutritional requirements such as agitation, involuntary movements and infections.

The large variability in the observed prevalence rates could be related to the fact that the evaluation and the parameters used to estimate and establish the presence of malnutrition differ greatly from one study to the other. Different parameters are commonly used to evaluate the nutritional status of individuals. Among them, we can find food intake, anthropometric measures such as weight, weight/height, Quetelet index (Body Mass Index), skin folds, arm-muscle circumference and biochemical measures such as serum albumin and hematocrit.

The Body Mass Index (BMI) is one of several anthropometric measures used to evaluate nutritional status and perhaps the most accessible to evaluate nutritional status for institutionalized elderly. BMI is the ratio of the weight (kilograms) of an individual over his or her height squared (meters)[22]. A healthy BMI for adults has been estimated to range between 20 to 25 kg/m^2. In the geriatric population, this range is questioned, more specifically for the individuals reaching 75 years of age or older. For the elderly population, the recommended BMI varies according to the reference consulted (Table 1). Although Kushner indicated that BMI became less and less associated with mortality as age increased[23], it has been observed that BMI values of less than 25 kg/m^2 were associated with decreased survival rates in institutionalized elderly[24-28]. In fact, the nadir of mortality for BMI was reported to vary between 27 to 30 kg/m^2 for men and 30 to 35 kg/m^2 for women over 70 years of age[25,26,29]. Often, BMI values lower than 28 kg/m^2 are related to higher mortality rate. These studies show that BMI well above the 20 to 25 kg/m^2 range, as suggested for younger healthy adults, were found to be protective in the elderly population and consequently, moderately high weight could be considered beneficial for the elderly population. Furthermore, recent weight loss (within the past year) was also linked with an increase in morbidity[30,31] and mortality[28].

As early as 1976, Bistrian and colleagues[6] reported the prevalence of protein-energy malnutrition to vary between 44 and 76% in medical and surgical services of a municipal hospital, depending on the anthropometric or biologic parameter considered. The difference in the prevalence rates of malnutrition in the elderly can be attributed to the variety of methods used to assess malnutrition or the categorization of the groups under study. Nevertheless, these figures remain impressive and establish the need to better quantify and interpret the nutritional status of the elderly institutionalized population.

3. Risk Factors of Undernutrition in the Institutionalized Elderly

The death rate and incidence of infections are more prevalent in malnourished individuals compared to the well-nourished patients[7,30,32]. Undernutrition has also been linked with many incapacitating conditions in the elderly population such as decreased functional status[33] and decreased wound healing[31,34,35]. These conditions increase the need for care, the costs of Medicare and decrease the quality of life of these patients.

The decrease in wound healing capacity caused by the lack of adequate dietary intake results in an increase in pressure ulcer development. In *Treatment of Pressure Ulcers: Clinical Practice Guidelines*[36], pressure ulcers are defined as any lesion caused by unrelieved pressure resulting in damage of underlying tissue and usually occur over a bony prominence. The group of experts responsible for the elaboration of the guidelines mentioned that a high correlation existed between malnutrition, more specifically dietary protein intake and hypoalbuminemia, and the appearance of pressure ulcers.

Prevalence of pressure ulcers in the institutionalized elderly population is known to vary between 4.7% and 7.3% according to different studies[37,38]. Incidence rates of pressure ulcers (stage II or more) of 12.9% and 38.5% were observed in 2 cohort studies[39,40]. The presence or the apparition of pressure ulcers was associated with age, dietary protein intake[40,41], weight loss (> 10% of baseline weight) over the past 6 months[39] or low body weight[37] and overall malnutrition[38]. From these results, we can observe that nutritional status plays an important role in the evolution of pressure ulcers and general health of the frail elderly.

In addition to the numerous ailments affecting the frail elderly, certain socio-psychological, physiological and physical factors could be detrimental to the nutritional status of the elderly[3,42].

Among them are diet modifications, dental and chewing capacity, swallowing skills, dementia or mental disorders and medication[42]. Dependency for feeding, poor appetite, slow eating/feeding, dysphagia, number of feeding impairments and energy and protein intake are all factors significantly associated with overall malnutrition. Moreover, undernutrition was specifically associated with dysphagia, slow eating, poor protein intake, poor appetite, poor position for eating and presence of a feeding tube[3].

4. DYSPHAGIA

4.1 DEFINITIONS

In its literal sense, dysphagia means *difficulty* (dys- from the Greek) *to eat* (-phagos also from the Greek). In the medical domain, dysphagia is considered a swallowing dysfunction. Logemann[43] describes the term "swallowing" as the entire act of deglutition from placement of food in the mouth through the oral and pharyngeal stages of the swallow until the material enters the esophagus through the cricopharyngeal juncture. Furthermore, Groher[44] defines this dysfunction as an abnormality to transfer a bolus from the mouth to the stomach and which may involve the oral, pharyngeal or esophageal stage of the swallowing sequence and includes misdirection of transferred material. Buchholz[45], includes concepts such as pleasure, nutrition and hydration when qualifying a safe-swallow. These three elements should be provided reasonably, efficiently and safely to insure an adequate deglutition.

A normal deglutition sequence is known to happen in four principal stages[43,44]. In the mouth, food is held by the tongue, chewed and mixed with saliva and transformed into a moist bolus ready to be swallowed. The nostrils are usually opened and the lips are closed. This is recognized as the *oral preparatory* phase. After adequate mastication, the tip of the tongue is elevated and the bolus is compressed against the hard palate. This is the *oral transport* phase. Then mastication is halted, respiration is inhibited, the tongue is retracted and elevated against the hard palate and the veli palatini is elevated to close the nasal route. This portion of the swallowing process is voluntary. The bolus is transferred into the upper part of the pharynx and the swallowing reflex is triggered. The *pharyngeal* stage begins. The larynx moves upward and front, the epiglottis is tipped downward and peristalsis is initiated permitting the descent of the bolus. Airway protection is provided by contraction of the intrinsic laryngeal muscles that shorten and widen the arytenoepiglottic folds and vocal and vestibular (false vocal) folds. Once the bolus has entered the esophagus, at the *esophageal* phase, peristaltic waves are initiated and bring the bolus to the stomach. The pharyngeal and esophageal phases are not voluntary.

Dysphagia is often seen as a secondary condition in strokes, Parkinson's Disease, Alzheimer's Disease and dementia. The swallowing process can be altered differently according to the type and severity of the primary diagnosis. For example, Veis et al.[46] evaluated swallowing disorders with a videofluoroscopy in individuals with cerebrovascular accident (n = 38). They classified the individuals according to the location of their injuries (left hemisphere, right hemisphere or brainstem) and found that overall, the most frequent disorders were delayed swallowing reflex, reduced pharyngeal peristalsis and reduced tongue control. Although patients presenting an injury located in the right hemisphere were found to have a higher tendency to one component swallowing problem, one patient demonstrated as many as four different type of dysfunction related to his condition.

To establish a diagnosis of dysphagia, different approaches are possible: clinical or bedside evaluation, videofluoroscopy, endoscopy, manometry, manofluorography, scintigraphy or ultrasounds[43,47-51]. Various test materials will be used to perform these evaluations. For example, the clinical evaluation would involve water and other food products of different consistency whereas the videofluoroscopy will require barium pastes or liquids, administered with or without food. More protocols presenting a precise quantified consistency or viscosity of these test materials need to be developed for these investigations[43,52,53].

Dysphagia is a complex symptom. By its effect on the intake of fluids and solid foods, it has a definite impact on the physiological and psychological aspects of an individual's life.

4.2 Prevalence of Dysphagia in the Institutionalized Population

In the institutionalized elderly population, prevalence of dysphagia is reported to vary from 11 to 65.9%[1,2]. In a study evaluating the prevalence of dysphagia, Groher and Bukatman[1] determined that swallowing dysfunction could be screened with specific criteria. Among them were the criteria of difficult oral intake, frequent choking and excessive coughing, no oral intake, need for a diet modified in texture, need for non-oral nutritional support, history of aspiration pneumonia and need for individual meal time supervision. In the two Centers they surveyed, they observed a prevalence of 11% and 12% of swallowing dysfunction and nearly a third of the total population screened presented some condition preventing them from receiving adequate oral nutrition. Using the Fleming Index for the assessment of dysphagia, Layne et al.[2] found a prevalence of 65.9% in a nursing home care unit (n = 129).

The wide range of prevalence values observed could be explained by the various definitions of dysphagia (oro-pharyngeal, esophageal, dysphagia to liquids and/or solids) and by the screening process used to determine the presence of dysphagia. In addition, the clientele and their conditions must be considered carefully.

4.3 Consequences of Dysphagia

4.3.1 Aspiration

One of the main consequences observed with swallowing dysfunction is aspiration. Aspiration is present when some of the bolus being swallowed penetrates the airway. In fact, aspiration is the process during which matter present in the oro-pharynx is carried through respiration (inhalation) into the lower trachealbronchial tree. It is more properly thought of as several aspiration syndromes, implying different etiologies and pathophysiologic mechanisms, and requiring different modes of therapy[54]. The result of aspiration depends on the type and amount of material aspirated as well as the host's lung clearance mechanisms [43,54]. Aspiration of inert fluid or particulate matter (partially digested food, hot dogs or peanuts) may produce mechanical obstruction but secondary bacterial pneumonia may also occur[54,55]. Langmore[55] presented four principal sources of material that can be found on the folds: food, liquids, gastric content or oro-pharyngeal secretions.

Three valves protect the larynx. They are 1) the epiglottis and the aryepiglottic folds, 2) the false vocal folds and 3) the vocal folds. Also, three types of aspiration can be observed: before swallowing (due to a lack of control of the tongue or a delay in swallowing reflex), during swallowing (due to the improper closure of the valves) and after swallowing (due to an inadequate peristalsis or hypertonicity of the cricopharyngeal muscle creating residues dripping after the swallow)[43].

Although Huxley et al. stipulated in1978 that 45% of normal adults aspire during their sleep (cited in Groher[56]), pulmonary complications in healthy individuals seldom occur[54]. The aspiration-prone patient presents the following picture: 1) reduced level of consciousness (e.g. stroke victims, anesthesia subjects, patients with seizure disorders); 2) dysphagia secondary to esophageal or neurological disorders (e.g. esophageal carcinoma or scleroderma); or 3) mechanical disruption of the esophageal sphincter due to a nasogastric tube. Individuals with poor dental hygiene have increased areas of anaerobiosis and consequently may aspirate larger numbers of anaerobic bacteria than those with adequate oral hygiene. Gingivodental disease seems important in pathogenesis. In addition, patients who develop bacterial pneumonia following aspiration frequently have impairment of the normal lung clearance mechanisms[54] or present undernutrition[13].

4.3.2 Pneumonia

Aspiration pneumonia is a typically polymicrobial pulmonary infection which commonly follows aspiration of a suspension in saliva of the oropharyngeal bacterial flora[54]. The oropharyngeal flora of hospitalized patients differs from that of normal subjects since these individuals commonly become colonized with facultative anaerobic pathogens, such as enteric gram-negative rods, pseudomonads, or Staphylococcus aureus. Consequently, aspiration pneumonia acquired in the hospital frequently involves these facultative anaerobic bacteria, often in combination with the usual obligate mouth anaerobes[54]. Also, individuals that are undernourished have greater difficulty in clearing the respiratory tract of the aspirated material therefore, in time, this might imply a higher incidence of aspiration pneumonia[13]. Cot[48] also mentions that aspiration pneumonia can be caused by food material or contaminated saliva due to gingivitis or gastric reflux. Indications of deleterious effects of the aspiration of oropharyngeal secretions have been expressed. Nevertheless, Logemann[43] indicates that few conclusive data exist as of how much aspirated material is too much and would trigger pneumonia.

Acute pneumonia may also follow aspiration of many toxic agents, the most common of which is gastric acid. The injury to the lung is virtually instantaneous, resulting in marked hypoxemia and a significant mortality of 30% to 60%[54].

4.4 Nutritional Impact of Dysphagia in the Institutionalized Elderly

For different reasons such as fear of choking, fatigue and unappealing meals, dysphagic elderly individuals generally decrease their food intake, which puts them at nutritional risk. Figure 1 summarizes several interrelationships present when dysphagia is present in the elderly clientele. The different feeding alternatives for dysphagic patients are enteral feeding, total parenteral nutrition (TPN) or modified consistency diets and thickened beverages. Dysphagia was highly associated with overall malnutrition and undernutrition[3]. The presence of a feeding tube was also significantly related to undernutrition [3].

4.4.1 Total Parenteral Nutrition and Enteral Feeding

Dysphagia raises questions concerning the risks and benefits of mainly oral feeding *vs* enteral feeding since total parenteral nutrition (TPN) is usually not part of the debate in the treatment of dysphagia in long-term care settings. TPN can and should be used in acute care following a stroke for example but preferably not as a long-term solution. Risks of complications during the surgery or risk of infections following the intervention makes TPN a less acceptable solution for the institutionalized elderly. The loss of quality of life is also a major negative impact resulting from TPN[57].

Enteral feeding bypasses the respiratory tract and avoids penetration or aspiration of food material originating from the oral cavity. This method demands generally less time at the meal time from nursing staff but can be difficult to accept for the patient when it becomes a long term solution. Enteral feeding is not hazard free. Jacobs and associates[58] found that 54% of their 24 ventilated patients on continuous enteral feeding developed pneumonia. Johnson et al.[59] also found 17 of 22 stroke patients fed through tube feeding developed aspiration pneumonia compared to 13 of the 38 orally fed patients.

In 1987, Campbell-Taylor and Fisher[60] presented their position against enteral feeding for patients in terminal phase of a neurodegenerative disease (ALS, Alzheimer's Disease, Huntington's Chorea, Multi-infarct, Multiple sclerosis, Parkinson Disease). The patients presented generally an impossibility to communicate, in recumbent position most of the time and were known to aspirate liquids or purees. The authors listed many factors that can provoke aspiration during enteral feeding in this population. In fact, the recumbent position, the lack of verbal communication, the diminution oral and hypopharyngeal sensations, dysphagia and non diagnosed aspiration, the reduction of the upper and lower esophageal sphincter competence, the diminution of the esophageal peristalsis, the delayed gastric emptying and the gastric reflux exacerbated by the recumbent position were all considered to be risk factors. Spoon-feeding multiple meals high in energy and supplements high in proteins was the suggested alternative. According to this report, the risk of aspiration-pneumonia during enteral nourishment can be as high as careful spoon-feeding.

Moreover, a meta-analysis of the literature done by Finucane and Bynum[61] suggested that the data on dysphagia, enteral feeding and aspiration pneumonia did not indicate that enteral feeding reduced the risks for aspiration pneumonia for patients with neurological dysphagia. Certain studies proved the opposite and, the consequences of placing a tube were considered complex. The security aspect of enteral feeding was non-conclusive. Therefore, quality of life should be considered as an important part of the decision. Others argue that the goal of enteral nourishment is to feed not to avoid aspiration[62].

4.4.2 Modified Consistency Diets and Thickened Beverages

The oral route for feeding dysphagic individuals should be privilege as much as possible for stimulation and satisfaction during mealtime. For dysphagic patients, the experience of eating can be facilitated if the foods are modified in consistency.

The National Dysphagia Diet Task Force (NDDTF), an interdisciplinary team composed of dietitians, speech therapists and food scientists, received the mandate to assess the different aspects of the feeding considerations of dysphagic individuals. In 1997, the Task Force had reviewed over 200 American dysphagia diets. They have denoted 40 different names for the solid food diets and 18 different names for the consistency (referred to as viscosity) altered liquids. Many modified texture diets have been elaborated in hopes of a standardization of the clinical approach and, consequently, achieve proper oral feeding of this population.

Among the different diets available, we can find the American Dietetic Association *Dysphagia Diet*[10] which is mainly based on a descriptive evaluation of the consistency of the solids and the liquids, the *Multistage Diet for Dysphagia*[11] with 5 stages of solid foods and 3 levels of beverages, the *Aspiration Risk Reduction Diet*[9] with a constant semi-solid consistency and 3 types of beverages, the *Dysphagia Diet Plan*[12] with 4 levels and the *Dysphagia Diet* developed at the *Institut universitaire de gériatrie de Montréal*[13]. The NDDTF along with the American Dietetic Association and the Dietitians of Canada have developed, in 1999, the *North American Dysphagia Diet*, in order to offer a more uniform approach to dietary intervention with the dysphagic population[63]. Recently, the Quebec Order of Dietitians has also reviewed its *Modified Texture Diet*[14], which should be released by the end of the year 2000.

When an individual experiences problems swallowing thin liquids, the increase in fluid thickness is often required for a safe swallow of beverages in the treatment of dysphagia. This generally helps in reducing the seepage of the liquid from the mouth or by decreasing the speed at which the liquid will pass from the mouth to the pharynx to the esophagus. The liquids are generally described with 3 illustrative terms: Nectar-like products, Honey-like products, Pudding or spoon-thick products[9,48,63,64]. Table 2 shows different thickeners used to increase the consistency of liquids. The thickened beverages could be prepared for the patient by the staff and family members or they could be purchased. When prepared for the patient, the use of commercial thickeners and other thickening agents such as baby cereals is fairly common[65-67]. The palatability, the consistency and the costs of the resulting thickened beverages can differ greatly[65].

Glassburn and Deem (1998) [68] have evaluated the capacity of 23 experienced speech-language pathologists (SLP) to repeat mixes of thickened beverages. A commercial thickener (*Thick It* - Milani Foods, Melrose Park, IL) was used to thicken tap water according to what SLPs believed to be Nectar, Honey and Pudding consistency beverages. The SLPs were asked to repeat the experiment 3 times with a 2-4 minute break between each set of consistencies. The Nectar and Honey products were evaluated for their viscosity using a Brookfield viscometer (cone/plate model, LVDV II). No correlation was found for the intersubject results ($r = -0.03$ for Honey; $r = +0.02$ for Nectar) and intrasubject correlation was weak ($r = +0.67$ for Honey; $r = +0.33$ for Nectar). The authors have concluded that subjective judgment is not a valid method in the treatment of dysphagia and suggest that a standardized method for mixing consistencies be adopted.

The modification of the texture of the solids is often suggested to facilitate bolus formation and swallow. The diet requirements will be expressed as soft, minced or pureed foods. The desired texture is usually obtained with a blender or a food processor. The addition of a liquid is frequently required to produce a pureed product that is smooth and without lumps or big particles. However this dilution technique is thought to reduce the nutrient density[69]. The resulting products have been qualified by many as not appealing and bland. Special efforts should be made to improve the taste and the appearance[69-71]. Once more, the description of the texture modified diets is usually qualitative. A number of cookbooks have been published to help in the realization of adapted foods for dysphagic individuals[72-74].

Consequently, the dysphagia diets usually take the form of forbidden or allowed foods[9-12]. They use descriptive terms such as sticky, smooth, soft or homogeneous to discuss the foods that are permitted or forbidden. This list of terms creates an interpretation dilemma in the clinical management of the diets offered to the dysphagic patients. Clinical trials evaluating specifically the efficacy of the various dysphagia diets and quantification of the textural parameters of a nutritious minced or pureed diet have not yet been published.

All of the dysphagia diets published are mainly based on a descriptive evaluation of the consistency of solids and liquids and very little is said about nutritional efficacy or quantitative textural characteristics of the foods permitted for the patients. The dysphagia diets usually take the form of forbidden and allowed foods and are qualitative in their descriptions of what is acceptable versus what is not. Many professionals such as doctors, nurses, radiologists, speech-language pathologists, occupational therapists, physiotherapists and dietitians may be required to participate in the clinical evaluation of the dysphagic individual. The multidisciplinary approach required for the treatment of dysphagia necessitates communication and coordination. It is essential to insure that what is clinically observed as problem during the evaluation of the patient is what is conveyed via the dietetic prescription. It is believed that dysphagic individuals able to handle specific test material during clinical evaluations such as videofluoroscopy should be able to swallow foods of similar texture. Thereafter, a qualitative description of the appropriate foods will be given and a subjective evaluation of what the prescribed diet should be is done. A lack of objectivity in the transmission of the clinical information could lead to clinical errors.

Published clinical trials evaluating the efficacy of these diets are still to come. Also, due to the qualitative and descriptive approach of the dysphagia diets developed thus far, the nutritional values of the foods offered would potentially vary from one center to the other depending on the modifying technique and the recipes used. This is the reason why the food industry has been developing several new ready-to-serve modified texture products. Companies such as *Cliffdale Farm*, *Campbell*, *Travis*, *Mon Jardin*, *Hormel* and *Nestlé* have products to facilitate the production of the modified texture items.

Evaluations of dysphagia diets based on commercial or institutionalized products have been published in the recent years. In 1996, Cassens et al.[71] published the results of a study evaluating the effects of a 3-dimensional pureed diet on the taste, texture, appearance and presentation of pureed food on 18 elderly residents receiving a pureed diet for a total period of 32 days. Although, the authors mention that they use standardized recipes containing texture enhancers and using a food processor to obtain the desired texture, no precise information is given on the nutritional composition or textural characteristics of the new diet offered. They observed an increase in the food intake of 15% with an overall 41% increase in energy and 36% increase in protein. They observed that patients were easier to feed.

Although commercial products were also evaluated with similar results in unpublished documents[75-78], the information provided thus far in the literature does not include studies of individuals requiring a minced texture diet nor do they quantify the nutritional composition of these diets.

5. Rheology

On a daily basis, people all around the world consume a wide range of liquids and solids to sustain their energy and hydration requirements. These foods vary in chemical and physical composition. In general, the texture is an organoleptic characteristic that is used to distinguish if foods are ripe, well-cooked or still acceptable for consumption. One would squeeze a peach to evaluate its firmness and decide if it is ready for consumption. Vegetables are often cooked until they become tender. Also, when bread has hardened and is brittle, one will decide to discard it.

Dysphagia is a complex symptom affecting the intake of fluids and solid foods. Modifications of the texture of food is necessary to permit a transfer and transport of the bolus from the mouth to the stomach. When dysphagia is not well treated, it has a definite impact on the physiological and psychological aspects of life. Weight loss, pressure ulcers and pulmonary infections are often reported as correlating with a dysphagia diagnosis[3,56]. Therefore, the treatment of dysphagia has brought forward the importance of food texture and consistency but in a much different context. In the treatment of dysphagia, the texture and consistency of foods is considered from a medical viewpoint. A liquid that would be too thin or a dry and crumbly cookie could separate into particles and descend in the pharynx, enter the airway and cause choking.

Thus far, a qualitative and descriptive approach has been used to discuss the food texture in the clinical management of dysphagia. This approach is being intensively questioned and a quantified approach to better describe the food items provided to dysphagic individuals has been requested by several experts involved in the treatment of dysphagia[9,11,12,68,79]. A description of textural characteristics of foods is prone to become an integral part of the clinical management of dysphagia. Few publications have reported quantified food texture in relation to its importance in the health care of dysphagic individuals[53], but rheology is thought to offer a promising avenue in a more objective treatment of dysphagia[80].

Rheology is the study of the deformation and flow of foods[81]. It offers vocabulary and specific terminology to discuss foods and their textural characteristics. Foods vary greatly in composition and show a vast array of textural characteristics. Liquids could be viscous and thick like molasses or fluid and thin like water. They could be suspensions like salad dressings or pure solutions like salty water. Solids also vary in texture. Crackers and baked pie crust could be brittle and dry. Foods could be hard like Parmesan cheese or soft like Ricotta. Solids could be adhesive like peanut butter or slippery like butter and margarine. Rheology also offers several instruments such as viscometers and texturometers which permit quantification of these textural characteristics.

5.1 RHEOLOGY OF FLUIDS

Fluids could be characterized by their viscosity and their consistency. In the literature discussing dysphagia management and modification of food textural characteristics, the terms viscosity and consistency are sometimes used interchangeably[12,53,65,66,68]. For the purpose of this thesis, both concepts were evaluated. Therefore, a clarification of the definition of each term will be presented.

5.1.1 Theoretical Concepts

Davis defined *consistency*[82] as a quality of food which is perceptible to touch. The term 'body' was also used to express consistency. Smith[82] used a broader definition when he referred to consistency as a characteristic of a mixture of fluid and solid foods. Szczesniak[82] referred to consistency as the mouthfeel characteristics of semi-solids or liquids. Hence, sensory concepts such as mouthfeel and body could be associated with consistency. Consistency could be empirically evaluated with apparatus such as the Adams consistometer or the Bostwick consistometer. The measure of consistency is usually presented as centimeters per 30 seconds when the Bostwick consistometer is used.

Viscosity is defined as the rate of flow per unit of force and is expressed in centiPoise or milliPascal*second[83,84]. Finney[85]also defines viscosity as the internal friction of a fluid or its resistance to flow. It is a textural parameter that could be evaluated by fundamental testing which quantifies the flow of fluids. Instrumental devises such as capillary flow, Couette or Searle flow, parallel-plate or cone-and-plate viscometers could be used[83]to determine viscosity.

Isaac Newton was the first to express the law of ideal liquids. He described the flow behavior of ideal liquids as

$$\eta = \sigma / \gamma \qquad \text{(Equation 1)}$$

where η is the viscosity (Pa·s), σ is the shear stress (Pa) and, γ is the shear rate (s^{-1}).

Ever since, fluids are mainly classified as Newtonian or non-Newtonian. A linear relationship of the shear stress (σ) expressed in Pascal as a function of shear rate (γ) expressed in s^{-1} illustrates the flow behavior of ideal liquids (Figure 2). A Newtonian liquid will have a constant slope that will express viscosity (η). The Newtonian liquids present flow characteristics that are influenced only by temperature and food composition. The Newtonian foods are not affected by shear rate and shear history. Typical Newtonian foods are egg products, most honeys, corn syrups and milk[83].

Non-Newtonian liquids are affected by temperature, food composition and shear rate. The apparent viscosity (η_a) is then used to express the viscosity and is specific to the shear rate at which the product is tested. Non-Newtonian foods could further be divided as *time-independent* or *time-dependent*. The latter, contrary to time-independent fluids, will show an apparent viscosity that will be affected by the length of time for which the shear is applied. Time-independent fluids could be either *pseudoplastic* (i.e. shear-thinning, losing viscosity with time at a varying shear rate) or *dilatant* (i.e. shear-thickening, gaining viscosity over time) which is rarely encountered. Shear-thinning could be explained by re-orientation, stretching, deformation or disaggregation of molecules, which compose the tested product, following shear[84,86]. Therefore, important decrease in viscosity could be observed in products after the shearing. Some pseudoplastic foods are concentrated fruit juices, french mustard and fruit and vegetable purees[87]. Figure 2 also presents the typical curves of non-Newtonian fluids.

Time-dependent flow characteristics are further divided into *thixotropic* and *rheopectic* liquids. The former displays a decrease in viscosity when a constant shear rate is applied for a certain period of time.

The latter presents an increase in viscosity over time when the shear rate is maintained constant. Examples of thixotropic foods are mayonnaise and condensed milk. Rheopectic foods have never been reported[83,84].

Most foods do not follow the ideal liquid law expressed by Newton. Time-independent type of fluids have been described according to different rheological models. The Power Law (Equation 2) and the Herschel-Bulkley models (Equation 3) are most often used in the literature to describe the rheological parameters of foods[86,88-91]. The Herschel-Bulkley model was developed to mathematically express products for which a yield stress (σ_o) is found at the initial application of the shear rate. Therefore, the product will act similar to a solid. It will require a certain level of shear prior to beginning its deformation[89].

$$\sigma = m\,\gamma^n \qquad \text{(Equation 2)}$$

$$\sigma - \sigma_o = m\,\gamma^n \qquad \text{(Equation 3)}$$

where n = flow behavior index, m = consistency coefficient (also referred to as K) , σ_o = yield stress factor.

The Casson model is also used when describing flow behavior of foods and was chosen as the official method for the interpretation of chocolate flow data by the International Office of Cocoa and Chocolate (Equation 4)[83,88].

$$\sigma^{0.5} - m_o = m\,\gamma^{0.5} \qquad \text{(Equation 4)}$$

These models relate shear stress and shear rate in conjunction with the specific flow behavior index (n), consistency coefficient (m) and yield stress factor (σ_o). The flow behavior index will be equal to 1 for Newtonian liquids, greater than 1 for shear-thickening foods and less than 1 for shear-thinning non-Newtonian fluids. The yield stress factor will be 0 for Newtonian fluids. The consistency coefficient will be greater than 0 and will vary according to the product[83,86].

The Bingham model was used to describe the flow behavior of apricot puree and minced fish paste[83] (Equation 5). It expresses the plastic viscosity (η').

$$\sigma - \sigma_o = \eta'\gamma \qquad \text{(Equation 5)}$$

This model is applicable when shear-thinning products are evaluated at medium to high shear rate. At low shear rate, the shear-thinning fluids will demonstrate a Newtonian behavior (zero shear viscosity) and the Power Law model will not be able to evaluate the viscosity. Other models have been developed to overcome this problem. They are the Cross model (Equation 6) and the Powell-Eyring model (Equation 7) where η is the apparent viscosity, η_0 is the limiting viscosity at zero rate of shear, η_∞ is the limiting viscosity at infinite rate of shear, and α and β are constants.

$$\eta = \eta_\infty + \frac{\eta_0 - \eta_\infty}{1 + \alpha\gamma^{2/3}} \qquad \text{(Equation 6)}$$

$$\sigma = \eta_\infty\gamma + \frac{\eta_0 - \eta_\infty}{\beta} \sinh^{-1}(\beta\gamma) \qquad \text{(Equation 7)}$$

Specific mathematical models have also been developed for the time-dependent thixotropic fluids. As previously mentioned, thixotropic foods will experience a viscosity decrease over time when maintained under a steady shear rate. These various models integrate structural breakdown parameters which quantify the loss of viscosity. Higgs and Norrington[83] measured the coefficient of thixotropic breakdown with time (B) at constant shear rate (Equation 8). They also provided a coefficient of thixotropy due to increase of shear rate (M) which indicates the loss in shear stress per unit increase in shear rate (Equation 9).

$$B = \frac{\eta_1 - \eta_2}{\ln(t_2 - t_1)} \qquad \text{(Equation 8)}$$

$$M = \frac{\eta_1 - \eta_2}{\ln(N_2 / N_1)} \qquad \text{(Equation 9)}$$

where η_1 and η_2 are viscosities measured after time 1 and time 2 and viscosities evaluated at angular speeds N_2 and N_1, for equations 8 and 9 respectively.

A kinetic rheological model was used by Tiu and Boger[83] to characterize the thixotropic behavior of mayonnaise. Based on the Herschel-Bulkley model, this model also considered a decay structural parameter (λ) which ranged between 1 for zero shear time to equilibrium value (less than 1; Equations 10 and 11).

$$\sigma = \lambda(\sigma_0 + m\gamma^n) \quad \text{(Equation 10)}$$

$$\frac{d\lambda}{dt} = -K_1(\lambda - \lambda_e)^2 \qquad \text{for } \lambda > \lambda_e \quad \text{(Equation 11)}$$

where σ_0, m, n, K and λ_e are determined by experimental evaluations. Following the obtention of these data, the thixotropic behavior of a food product could be completely expressed.

Two more mathematical models were developed to describe the flow behavior of thixotropic fluids: the Weltman's model and the Hahn model[83] (Equations 12 and 13, respectively).

$$\sigma = A_1 - B_1 \log t \quad \text{(Equation 12)}$$

$$\log(\sigma - \sigma_e) = A_2 - B_2\, t \quad \text{(Equation 13)}$$

where σ_e is the equilibrium shear stress, t is the time in seconds, and A_1 and A_2 are constants that indicate the initial shear stresses and B_1 and B_2 are constants indicating the rates of structural breakdown.

Temperature is another factor that also affects the viscosity of fluids[88,92]. Generally, the effect of temperature on viscosity could be expressed by the Arrhenius relationship (Equation 14). Rao[83,87] has collected values of activation energy for a certain number of foods such as diluted fruit juices, egg products, concentrated fruit juices and pureed fruits.

$$\eta_a = \eta_\infty^{\,Ea/RT} \quad \text{(Equation 14)}$$

where Ea is the activation energy in kcal/(g·mol), R is the gas constant and T is the temperature in Kelvin.

It is also recognized that the concentration of a product influenced the viscosity. It was observed that an increase in concentration will induce an increase in viscosity. Concentration could convey an exponential relationship or a power type relationship on apparent viscosity. In the latter, the effect of temperature and concentration on viscosity can be combined into one equation (Equation 15):

$$\eta_a = \alpha \exp\left(\frac{E_a}{RT}\right) c^{\beta} \qquad \text{(Equation 15)}$$

5.1.2 Instrumental Evaluation

Several fundamental and empirical methods have been developed over the years to permit the quantification of viscosity of fluids. A brief overview of these methods follows[81,83].

Mostly used for Newtonian liquids, the *capillary flow method* uses a viscometer usually made of glass which requires gravity or pressure force (piston) to allow standard quantity of liquid to flow through a capillary section. Two points are identified on the capillary and the pressure drop between them is calculated. Certain considerations have to be controlled for: a) the product must run with a steady flow, b) no end effect must be present and c) velocity must only be a function of axial distance. Several designs of capillary viscometers exist.

Concentric cylinders are also used to determine viscosity. Two types of viscometers are available: Couette or Searle type. The former presents a stable inner cylinder placed within a rotating outer cylinder. The outer cylinder is stable in the latter. The gap between both cylinders is very narrow which permits one to consider that the liquid is moving according to a steady and laminar flow (streamline flow). The force with which the liquid travels within the gap is recorded by a torque sensor. This type of equipment allows for continuous measurements at varying shear rates. A well known instrument of this type is the *Haake Rotovisco* viscometer.

The *Cone and Plate* viscometer is an instrument on which the sample is placed between a plate and a cone of small angle. Again, the torque created by the fluid as it turns is recorded. This system is particular for its stable shear rate at any point in the fluid. This is interesting when testing non-Newtonian liquids. Certain advantages of this instrument are quite interesting: 1) it provides no end-effect (no distortion due to rims or geometry), 2) a very small quantity of liquid is required (2 mL) and 3) it is quite easy to maintain the desired testing temperature due to the thin surface of contact.

Quantification of the consistency of thickened beverages and modified texture foods could be obtained using different apparatus. In 1996, Mann and Wong[93] presented an objective and simple method to assess consistency of thickened beverages and pureed foods offered to the dysphagic population. The line spread test measures the flow of 50 ml of a given product when placed on a flat surface. The product is placed in a hollow cylinder of 3,5 cm high and 5 cm of internal diameter. This cylinder is placed at the center of a Plexiglass sheet. The latter is positioned on a chart presenting concentric rings drawn every 5 cm. The tube is lifted and the product is allowed to flow for 1 minute. The distance traveled by the product is measured at each 90° angle and averaged to give the line spread reading. The line spread test was strongly correlated ($r = 0.90$ to $0,96$) with the sensory panel evaluation of the scaling of various products. The authors concluded that the line spread test was reliable, valid, objective and an inexpensive tool to assess consistency. Other methods such as the Bostwick consistometer are available to evaluate flowability of semi-solid products[94] and is currently used as a quality control tool in Sainte-Anne Hospital[15]. Ranges of clinically efficient consistencies have not been published and each hospital or medical center is bound to standardize internally to insure quality control.

Several studies report the viscosity of fluids or semi-solid foods such as regular juices, juice concentrates, stirred yogurts or pureed fruits [86,87,89,90,92]. However, the analysis of the viscosity of thickened beverages used in the clinical treatment of dysphagia is rarely reported in the literature[53,79]. Mills[79] suggested 'wide range upper and lower viscosity' boundaries to quantify and standardize the thickened beverages used in the treatment of dysphagia. The viscosity ranges were expressed in centiPoise and stated for a shear rate of 50 s^{-1} : 1 to 50 mPa·s for the thin liquids, 51 to 350 mPa·s range for the Nectar-like liquids, 351 to 1750 mPa·s for the Honey-like liquids and not less than 1751 mPa·s for the spoon-thick liquids. According to Tymchuck[95], a wide range system of viscosity for thickened liquids would provide standards to which the industry will have to comply and would provide thickened beverages that correspond to a wide range of patients' needs.

5.2 RHEOLOGY OF SOLIDS

5.2.1 Theoretical Concepts

Solids are usually described by their textural characteristics. Texture is defined by the Collins English dictionary[96] as 'the surface of a material especially as perceived by the sense of touch' and as 'the general structure and disposition of the constituent parts of something'. Food texture is generally characterized as the way in which the structural components of a food are arranged in a micro- and macro- structure and the exterior manifestations of this structure[94]. The International Organization for Standardization (Standard 5492/3, 1979) has also defined texture as all the rheological and structural parameters of foods perceived by the mechanical, tactile and when possible, visual and audiologic receptors. Texture is a complex and multi-factorial food characteristic and should be considered for its overall attributes and not as an independent element[81].

5.2.2 Instrumental Evaluation

Over time, several imitative tools were created to relate the sensory evaluation of the texture of foods and a more mechanical and objective measure. Friedman et al.[97], Bourne[81] and Szczesniak[98] reported the existence of many instruments such as the shear-press, gelometers, viscometers, penetrometers, compressimeters, consistometers and tenderometers. They stated that these instruments were of interest but could only derive the values of a limited number of textural characteristics and did not integrate the totality of the textural profile of the evaluated foods. These limitations were taken in consideration when Friedman and colleagues[97] developed the texturometer, an instrument based on the MIT denture tenderometer. The tenderometer was an instrument imitating the masticatory action of the human mouth. The chewing action and penetration force were monitored and recorded. Other structures such as cheeks and gums were also simulated on this instrument. The tenderometer was the prototype used to develop the texturometer.

The texturometer was elaborated by replacing the dentures by a plunger and plate unit, providing several chewing speeds and adding a viscosity measurement unit. Other mechanical modifications such as the strain-gauge displacement and the adding of the strip-chart recorder were done. This instrument would provide profiles based on a force-distance relationship of food products correlated to definitions of mechanical texture characteristics elaborated by Szczesniak[82].

This new instrument was now able to evaluate certain physical characteristics of foods and generate a texture profile analysis (TPA) (Figure 3). A correlation between instrumental and sensory evaluation of foods[99] was obtained when using the texture profile method[100]. The TPA would provide information on several textural parameters such as hardness, brittleness, adhesiveness, cohesiveness, springiness, gumminess and chewiness of the product. In 1963, Szczesniak[82] described for the first time these textural parameters. They were presented in 3 main categories : 1) primary and secondary mechanical characteristics, 2) geometrical characteristics and 3) other characteristics. The definitions of most of the textural characteristics are presented below :

Primary Mechanical Characteristics (Presented on the TPA - Figure 3)

Hardness or **Firmness** is defined as the energy necessary to attain a given deformation (A_1). It is expressed in Newton (N).

Cohesiveness is defined as the strength of the internal bonds making up the body of the product (A_2/A_1). It is a ratio and is dimensionless.

Viscosity is defined as the rate of flow per unit of force. It is expressed in centiPoise or Pascal-second.

Elasticity or **Springiness** is defined as the rate at which a deformed material goes back to its undeformed condition after the deforming force is removed. It is expressed in % of recovery or in millimeters (mm).

Adhesiveness is defined as the work necessary to overcome the attractive forces between other materials with which the food comes in contact (e.g. tongue, teeth, palate, etc.) (A_3). It is expressed in Newton (N).

Secondary Mechanical Characteristics

Brittleness is defined as the force with which the material fractures. It is related to the primary parameters of hardness and cohesiveness. It is expressed in Newton.

Chewiness or Elasticity is defined as the energy required to masticate a *solid* food product to a state ready for swallowing. It is related to the primary parameters of hardness, cohesiveness and elasticity. It is expressed in Newton.

Gumminess is defined as the energy required to disintegrate a *semi-solid* food product to a state ready for swallowing. It is related to the primary parameters of hardness and cohesiveness. It is expressed in Newton.

Geometrical characteristics :

Size and shape of the particles

Shape and orientation of the particles

Other characteristics :

Moisture content

Fat content.

Breene[101] and Bourne[102] have reported several instrumental texture profiles of foods. In 1987, Szczesniak[99] stated 4 main reasons for desiring a correlation between sensory evaluation and instrumental readings: 1) the need for quality control; 2) the desire to predict consumer response; 3) the desire to understand what is being perceived in sensory texture assessment and 4) the need to develop improved/optimized instrumental test method to ultimately construct the texture testing instrument that will duplicate the sensory evaluation. All these reasons remain fundamental when dysphagia treatment in considered. Knowing that the complex sensory system present in a healthy mouth is altered by neurological and/or muscular impairments renders the correlation of the sensory evaluation and the instrumental evaluations even more difficult but nonetheless essential in the treatment of dysphagia.

In 1993, Robertson and Pattillo[53] presented 3 ranges of viscosities using the Brookfield DV-1 rotary viscometer to describe liquids as well as solids. The ranges suggested were 250 to 800 mPa·s for thickened liquids, 800 to 2000 mPa·s for thin purees such as cream soups with pureed vegetables and over 2000 mPa·s for thick purees such as meats, casseroles and puddings in order to correlate the clinical investigation to the dietary prescription. No clinical trial has been associated with these ranges; therefore, the clinical efficacy of this approach remains to be demonstrated. Also, the ranges suggested include solids and liquids and differ from the ones suggested by Mills[79].

No study has been published relating the TPA or any other textural evaluation to the modified texture food items required in the dysphagia diet. Rheology offers a standardized terminology that is generally used in the food industry to establish standard recipes and to assess quality control and could benefit the dysphagia diet interpretation. The modified texture foods would also benefit of a quantification of the food texture parameters. A better understanding of the textural characteristics of the foods, a better control of the rheological parameters and an association with clinical impairments in dysphagia patients would allow a standardization and better application of the prescribed diet.

6. Sainte-Anne Hospital's Dysphagia Diet

At Sainte-Anne's Hospital (SAH), specialized modified texture foods were developed to provide nutritious foods, adequate hydration and quality of life to those patients presenting dysphagia. The thickened beverages are prepared in 3 consistencies named Nectar, Honey and Pudding (Picture 4). The solid foods are modified to ground or pureed texture and reformed, using molds, into their normal counterpart shapes. The meats are offered in ground or pureed textures whereas the fruits, vegetables and cakes are offered in pureed texture only (Pictures 1 to 3).

6.1 Thickened Beverages

Although certain commercial thickened beverages are available, the production of thickened liquids is usually assumed by the health center where patients reside for cost and quality control reasons. Therefore, the methods of production and the resulting products will not only vary among hospitals, but also among therapists and from batch to batch as it was well pointed out by Glassburn and Deem[68]. To limit this variability, SAH opted for a single production center where all the beverages were to be prepared and controlled for consistency reliability.

Introduced in 1991 at SAH, the thickened liquids were developed to allow individuals with oro-pharyngeal dysphagia to maintain a healthy level of hydration. This condition affects approximately 10% of SAH's clientele. The thickened liquids are made from any regular liquid, cold or hot, and thickened with a commercial thickener such as modified pre-gelatinized starch or a combination of different thickeners. The selection of thickened beverages comprises cranberry, apple, orange and prune juices, milk, milkshakes along with banana, chocolate, vanilla and strawberry supplements. Carbonated beverages, coffee and tea are also offered. On special occasions such as Christmas, Easter, Remembrance Day, Father's day and BBQ parties, wine, beer and fruit punch are available.

Originally, the thickened beverages were developed with the Dietary Department and Occupational Therapy department of SAH. Both departments had to evaluate the proper consistency required to adequately hydrate patients presenting several possible oro-pharyngeal dysfunctions.

The thickened beverages were developed in 3 consistencies named **Nectar, Honey** and **Pudding** to respond to various clinical needs. The **Nectar** consistency represented liquids with a certain body but still able to flow or be sipped from the cup. It is thicker than a regular fruit nectar and usually used to diminish the risk of premature leakage of the liquid in the pharynx or seepage from the mouth. The **Honey** consistency is thicker than the Nectar consistency and could be visualized as liquid honey at room temperature (23°C). It will flow but at a slower pace than the Nectar beverage. This beverage is easier to hold on the tongue and allows more control during the oral phase of the swallow. The **Pudding** consistency is the thickest. It was formulated to look like a milk-based pudding dessert. It keeps its shape and requires a spoon to be eaten. It is usually offered to individuals who cannot hold a thin liquid on the tongue to propel it into the pharynx safely or to individuals with a slow swallowing reflex. Due to lack of demand, certain beverages are not offered in all consistencies: BoostÔ, banana flavor, Nectar consistency; liquid supplement, chocolate flavor, Nectar consistency; Vegetable juice, Nectar consistency.

These particular consistency ranges were standardized using the Bostwick consistometer *(CSC Scientific Company, Co, Fairfax, VA, 22031)*. This stainless steal instrument presents 2 cavities. A reservoir portion is separated by a guillotine gate from a longer portion. The longer cavity is graduated in half-centimeter sections which begin at the gate. The thickened beverages were first thickened by the clinicians according to what they believed was the proper consistency and than measured via the consistometer. The measures were made after the instrument was leveled and 90 ml of thickened beverage, at 8°C, was placed in the reservoir. The gate was lifted and the distance traveled by the thickened beverage was noted after 30 seconds.

To reduce variability in the consistency of the thickened beverages served to the patients, it was decided that the beverages would be prepared by the Dietary Service, in the main kitchen, according to a fixed schedule and method.

To insure standardization of the final products, the ingredients are verified, weighed and identified at the Ingredients and Standardization Center of SAH's kitchen. The ingredients are given to a cook of the Specialized Food Production Center. Most of the thickened beverages are produced in bulk in a vertical cutter *(Stephan, UM 44A)*. Quantity of lesser volumes are produced with a Braun hand mixer. The beverages are refrigerated in a walk-in refrigerator for 18 to 24 hours at 4°C. This waiting period allows for complete hydration of the thickeners and permits quality control and modification of inadequate batches. The thickened beverages are portioned in 125 ml cups using an automatic rotary filler (*Vitality Rotary System RS3, Lykes Pasco, Florida, US*). A plastic lid is put on and each cup is identified according to the type and consistency of the product.

Several of the thickened beverages are produced using a pre-gelatinized modified starch at different concentration levels according to the initial product and the consistency desired. To increase efficiency in the production of these products and to reduce repetition, a certain number of smaller batches' volumes were augmented and standardized to support freezing. To obtain a freeze-thaw stable thickened product, other thickening agents were introduced in the formulation. The production method remains the same but the products are sent to a walk-in freezer (-8°C) until further use. Formulations are constantly re-evaluated to maintain the consistency within SAH's standard ranges and to compensate for the lack of control of the original beverage being thickened.

6.2 Reformed Modified Texture Foods

In 1995, SAH's dietary team decided to evaluate the foods most frequently offered to its dysphagic population: the foods of the minced and pureed diets. The traditional preparation methods included cooking the food, mincing or pureeing it and serving it with a ladle as several bowls in the plate (Picture 5). To increase nutrient density and to add to the appearance, the meats, vegetables and fruits were molded back into shape. Cakes were also pureed and reformed to provide a better selection of foods available to the dysphagic population and increase their quality of life. This approach was believed to stimulate appetite, increase recognition of the food and offer a meal that was interesting to eat or to feed to someone else (Pictures 1 to 3).

Therefore, these foods were developed within the Dietary Department with the help of the food production team, the clinical dietitians and dysphagic clients. Qualitative descriptions of what was needed as texture profiles for various population presenting various clinical profiles were established and the reformed foods' recipes were formulated according to these 2 general statements: 1) the pureed foods had to be tender, cohesive without any grains or lumps and moist without letting water or fluids trickle out and 2) the minced foods had to be cohesive and offer a ground texture that would be felt on the tongue. Several formulations were developed and the foods were standardized using highly descriptive and qualitative descriptors. Still today, the developing team functions with the qualitative organoleptic evaluations to elaborate new foods but feels the need for a more uniform vocabulary and descriptions that could be quantified.

Clinically, the foods are used mainly in 3 diets to provide safe-to-swallow nutritious meals to dysphagic individuals. Each of these diets requires individualization to consider personal taste and physical capacity. The three diets could be defined as :

Minced diet : this diet offers meats and combined dishes of minced texture. Also, soft dishes such as omelets, pasta dishes and shepherd's pie could be offered. Vegetables are usually of regular texture and well cooked. Desserts are tender but certain particles could be present such as fruit morsels or tapioca pearls. This diet will help with a dentition problem or will allow to reduce fatigue during a meal. At SAH, the minced diet will offer reformed minced meats with sauce of nectar consistency, soft regular vegetables and tender desserts.

Minced-Pureed diet : As its name stipulates, this diet will offer minced meat and soft combined dishes but the vegetable will also have a pureed texture. Desserts have to be tender and present no particles. Again, this diet will reduce fatigue induced by mastication. The texture will help with the formation of a cohesive bolus. At SAH, the Minced-Pureed diet will offer reformed minced meats with sauce of nectar consistency, reformed pureed vegetables and reformed pureed desserts without any particle such as milk puddings and applesauce.

Pureed diet : the pureed diet will have meats, combined dishes, vegetables and desserts of pureed texture. This type of feeding will help in the formation of a cohesive bolus and will reduce the energy required to eat and swallow. The pureed diet also reduces the mouth residues that could end up in the sulci, valleculea and the pyriform sinus. This diet will permit reformed pureed meats with nectar consistency sauces, reformed pureed vegetables, reformed pureed desserts or desserts that are soft and without any distinct particles.

To insure a good control of the final products, all the ingredients entering a reformed food recipe are verified, weighed and identified at the Ingredients and Standardization Center of SAH's kitchen. The ingredients are given to a cook of the Specialized Food Production Center to be prepared. The reformed foods are can be separated in two main groups: 1) recipes requiring cooking period and 2) recipes made from cold products. The recipes requiring cooking are prepared as a regular recipe in a steam-jacketed pot. All the initial ingredients are in ground form or a finer texture. Cooking time will vary according to the recipes' needs. The mixture will be transferred into a vertical cutter (*Stephan*, 52L) and processed until a pureed consistency is reached. For the meat recipes, part of the cooked mixture is not be pureed and will be portioned directly into the molds, sealed and quick frozen (-20°C). This provides the ground reformed meats. The ingredients for the recipes requiring no heating (fruits, Chef's salad and cakes) are blended directly in the vertical cutter (*Stephan, 52L*) and processed until the pureed consistency is obtained. The mixture is placed into molds, sealed, quick-frozen (-20°C) and stored.

PART I : RHEOLOGICAL EVALUATION OF SAINTE-ANNE HOSPITAL'S MODIFED TEXTURE PRODUCTS

1. INTRODUCTION

Several modified texture diets have been developed to offer better tools for the treatment of dysphagia[9-13]. With the exception of the work done by Robertson and Patillo[53] and Mills[79], rheology has rarely been used for the analysis of modified texture foods used in the clinical treatment of dysphagia.

In this section, the rheological parameters of the foods offered as SAH's dysphagia diet were evaluated. The apparent viscosity, the consistency coefficient, the flow behavior index and the yield stress of the thickened beverages were evaluated with a Searle type viscometer. Seven (7) textural parameters of SAH's modified texture foods were evaluated to provide the first quantitative evaluation of thickened beverages and modified texture foods used in a clinical setting. For each sub-section, the results are presented followed by a discussion which highlights previous work published in the area of rheology and dysphagia. Conclusions are drawn and placed in the perspective of the clinical treatment of dysphagia.

2. THICKENED BEVERAGES

2.1 GOAL AND OBJECTIVES

To obtain a better understanding of the rheological variables affecting the viscosity and consistency of thickened beverages used in the clinical treatment of dysphagia, rheological analysis were performed on SAH's thickened beverages. This study of SAH cold thickened beverages had 2 main objectives :

a) Describe, measure and quantify objectively the cold, non-carbonated, thickened beverages used in the clinical treatment of dysphagia at SAH

b) Evaluate possible correlation between the 3 consistency groups and rheological parameters such as apparent viscosity, consistency coefficient, flow behavior index and yield stress values

2.2 METHODS

SAH's thickened beverages were prepared according to their usual method and formulation and kept in a refrigerator for 24 hours at 6°C. They were evaluated for their viscosity with the Haake Rotovisco RV2 (*Haake, Germany*) coaxial cylinder sensor system. The Searle type viscometer was fitted with the M5 OSC measuring head and the MV1 rotor system (Ro = 20.04 mm; h = 60 mm) was placed within a cyiindrical cup (Ri = 21 mm). The temperature was maintained at 8°C using a circulating waterbath (*Haake, Fk-2 Model*). This measuring head and rotor system were used because of the wide range of viscosity it could measure. The instrument was linked to a computer for control and constant data collection. The Rotovisco RV20 Software (*Version 2.3.15, Haake, Germany, 1990*) was used to determine the best mathematical model for the evaluation of these thickened beverages.

Three (3) samples of each cold, non-carbonated, thickened beverage produced with the usual production method at SAH were evaluated. The consistency of the samples was monitored, at 8°C, using the Bostwick consistometer. The samples had to be within acceptable HSA clinical range to be evaluated for viscosity. An up-cycle varying the shear rate from $0s^{-1}$ to $100s^{-1}$ in 5 minutes followed by a stable period of 5 minutes at $100s^{-1}$ shear rate and a down-cycle of $100s^{-1}$ to $0s^{-1}$ of 5 minutes were performed to give a complete description of the various beverages studied.

First, the flow curves - also known as rheograms - of the increasing shear rate cycle were plotted. For each product, a linear regression was performed in order to obtain the value of the yield stress. Secondly, the log transformed data of the value resulting from the subtraction of the yield stress from the shear stress and the log transformed data of the shear rate were then calculated and plotted. Thereafter, a second linear regression was performed to obtain the slope and the intercept values. The slope and the antilog value of the intercept correspond to the n-value and the m-value respectively. Lastly, the apparent viscosity (η_a) at a shear rate of 50 s^{-1} was determined for each product tested according to the H.-Bulkley model.

2.3 Statistical Method

Student unpaired t-tests were performed for each rheological parameter (m- and n-values, yield stress and apparent viscosity) to compare the 3 different consistency groups. The consistency groups were further divided into high-protein content items and juice items. Student unpaired t-tests were calculated to compare both sub-groups within each consistency level. Probability of $p < 0.05$ was considered statistically significant. A linear regression analysis was done to evaluate the correlation between the apparent viscosity, consistency coefficient, flow behavior index as well as the yield stress values and the consistency levels.

2.4 RESULTS

The Bostwick consistency of each sample evaluated respected the clinical standards developed at SAH. Figures 4a and 4b show typical rheograms of HSA thickened beverages. The first portion of the graphs (upward cycle) showed an increase in shear stress as shear rate in augmented whereas the down-cycle show a decrease in shear stress with reduced shear rate. The center portion demonstrated the time independence of the thickened products. Therefore, based on these rheograms, the products can be described as non-Newtonian and pseudoplastic with a yield stress. They demonstrated a shear-thinning behavior. The products best fitted the Herschel-Bulkley model.

Table 3 presents the average values of the consistency coefficient (m), flow behavior index (n), the yield stress (σ_o) and the values of the apparent viscosity (η_a) at a shear rate of $50s^{-1}$ of the upward portion of the curve for each product of each consistency group. The results of the upward and downward cycles were similar therefore, only the data of the first cycle are presented.

At each consistency level - Nectar, Honey and Pudding - the consistency coefficient, yield stress and viscosity values were found to be statistically different ($p < 0.05$). The average values show high standard deviations demonstrating the wide range of physical composition of these products.

The consistency coefficient values of all test samples were greater than 1. They were statistically different for the 3 consistency levels ($p < 0.05$). The Nectar products presented an average of 2.75 ± 0.76 $Pa{\cdot}s^n$ (mean ± SD) and ranged from 1.61 to 3.60 $Pa{\cdot}s^n$. The Honey liquids presented an averaged m-value of 7.77 ± 4.22 $Pa{\cdot}s^n$ with a range passing from 1.96 to 16.48 $Pa{\cdot}s^n$. The Pudding beverages showed a 15.95 ± 10.12 $Pa{\cdot}s^n$ consistency coefficient value that ranged from 5.07 to 36.24 $Pa{\cdot}s^n$. The m-value increased almost 3-fold from the Nectar consistency to the Honey consistency whereas it doubled from the Honey consistency to the Pudding consistency.

All products demonstrated a yield stress. The yield stress values were of 3.44 ± 2.92 Pa for the Nectar consistency, 13.48 ± 9.83 Pa for the Honey consistency and 44.06 ± 26.92 Pa for the Pudding consistency. The yield stress augmented 4-fold from the Nectar consistency to the Honey consistency and more than 3-fold from the Honey consistency to the Pudding consistency.

The flow behavior index values of all test samples were below 1. They presented an average of 0.57 ± 0.09 and ranged from 0.40 to 0.65 for the Nectar products. The Honey products presented an averaged n-value of 0.52 ± 0.18 with a range going from 0.21 to 0.76. The Pudding beverages showed an averaged n-value of 0.54 ± 0.11 which ranged from 0.35 to 0.68. The flow behavior index did not differ statistically from one consistency to the other ($p > 0.05$).

At a shear rate of $50s^{-1}$ and temperature of 8°C, the average viscosity values of the Nectar products was of 615 ± 260 mPa·s, the Honey products had a viscosity of 1480 ± 790 mPa·s and the Pudding products presented a 3340 ± 1240 mPa·s viscosity. The viscosity values for the Nectar group ranged from 239 ± 17 mPa·s for the cranberry juice to 1030 ± 42 mPa·s for the strawberry supplement. Within the Honey consistency, the viscosity values ranged from 427 ± 18 mPa·s for the vegetable juice to 2700 ± 44 mPa·s for the prune juice. The Pudding consistency level displayed viscosity values of 1600 ± 51 mPa·s for the orange juice up to 4880 ± 400 mPa·s for the prune juice. Figures 5a to 5f describe typical flow curves of certain thickened products evaluated whereas Figure 6 shows the high variability of the apparent viscosity ranges for different consistency products.

Since concentration and formulation are known to affect the apparent viscosity, each consistency group (Nectar, Honey and Pudding) was further divided into high-protein content products and juice products. It was found that only the consistency coefficient of the pudding consistency products displayed a statistically higher value for the high-protein product when compared to the juice products ($p < 0.04$) but this could be due to the high standard deviations observed. Therefore, each consistency level was considered as 2 sub-groups: high-protein products and juices.

To verify the level of correlation between Bostwick consistency and apparent viscosity, we plotted the m-values, n-values, yield stress and apparent viscosity values as a function of the consistency levels

(Figures 7a to 7d). Linear regressions were performed for each sub-group of products of Nectar, Honey and Pudding consistency.

The correlation coefficient between the consistency coefficient and the Bostwick consistency levels (Nectar, Honey and Pudding) was found to be r = 0.74 and r = 0.60 for the high-protein products and the juices, respectively. The apparent viscosity and the Bostwick consistency levels showed correlation coefficients of r = 0.83 for the high-protein products and r = 0.72 for the juices. The correlation coefficients were different for juice products with coefficients of r = 0.85 than the high-protein products with r = 057 when yield stress and the Bostwick consistency values are compared. The flow behavior index demonstrated no correlations.

2.5 Discussion

Clinically, the thickened beverages were developed with the objective of reducing their speed of flow and thereby reducing seepage from the lips and/or to avoid precocious spillage of liquid into the oro-pharynx region prior to airway protection. To obtain such results, SAH thickened beverages are produced with a standardized procedure and verified for their consistency with the Bostwick consistometer. A retrospective study realized in 1993 following the introduction of the SAH thickened beverages revealed that the patients at SAH had stopped losing weight and, in some cases, regained enough weight to reach their usual pre-illness weight[15].

The use of thickened beverages was found to be a positive alternative to hydrate the dysphagic population safely but it was observed that thickening agents varied greatly in their thickening power and in overall quality results[65,66]. Furthermore, the nomenclature used to describe the thickened beverages is not standardized in clinical practice and this complicates medical follow-up and increases possible medical errors. In order to standardize the terminology, authors have suggested a ranking of various consistencies mentioned in the literature and a quantification of the rheological parameters according to the consistency levels used with the thickened products. The North American Dysphagia Diet[63] (to be published by the end of 2000) will be suggesting a 4-level scale for the beverages used in the treatment of dysphagia. The terminology will be referring to Thin liquids and Nectar-like, Honey-like and Spoon-thick for the thickened fluids. Thus, the terminology used during this protocol was very similar to what is found in the literature except for the thickest samples to which the name Pudding was given. The latter might have a food connotation rather than a beverage connotation and could be re-evaluated for its name.

Mann and Wong[93] suggested the line spread test as an objective, valid and reliable evaluation of consistency. Ste-Anne Hospital uses the Bostwick consistometer to evaluate the flowability of the thickened beverages offered to dysphagic individuals. This method grants results in centimeter per 30 seconds and appears to be more direct with less calculations and does not require averaging of a circular spread of liquid as needed for the line spread test.

Hoffman et al.[103] presented results supporting Mann and Wong's findings. They also related consistency values obtained on the line spread test to apparent viscosity values of certain products obtained via Brookfield HVT Rotational Viscometer. They studied Newtonian products (castor oil, motor oil and glycerin) and non-Newtonian liquids (Novartis pre-thickened apple Honey, Lemon Honey, Orange Nectar and Orange Honey). Results granted values ranging from 100 to 1300 mPa s. The Pearson correlation coefficient between the line spread test and viscosity values was of r = 0.99 (n=3) and r= 0.85 (n=5) for the Newtonian and the non-Newtonian liquids respectively.

The results obtained with this study show that pre-determined consistency levels obtained with the Bostwick consistometer for a much varied selection of thickened products granted a wide range of apparent viscosity values at a given temperature and shear rate. Contrary to what was found by Hoffman[103], the results of this study showed a moderate correlation between apparent viscosity (r = 0.83 for high-protein products and r = 0.72 for juices) and the consistency levels established with the Bostwick consistometer. As well, the consistency coefficients (r = 0.74 for the high-protein products and r = 0.60 for the juices) have weaker trend and the flow behavior index showed no correlation with the Bostwick consistency. These results could be partially explained by the wide range of products evaluated (5 types of juices, 2 milk-based products and 4 supplements) which rendered large standard deviations within each sub-groups.

Mills[79] suggested a 'wide-range' approach for the quantification of the viscosity for the 3 levels of consistency. He suggested viscosity ranging from 1 to 50 mPa·s for thin liquids, 51 to 350 mPa·s for Nectar-like beverages, 351 to 1750 mPa·s for Honey-like beverages and not less than 1751 mPa·s for Spoon-thick products.

The results of this study do not entirely comply with the viscosity ranges suggested by Mills. In fact, the less viscous products were less comparable when compared to the lower range. Within the Nectar consistency group, only the cranberry juice corresponded to the suggested standard of less than 351 mPa·s. All other products show a higher viscosity. Seven products out of 11 (64%) (banana supplement, milkshake, 2% milk and the vegetable, orange, apple and cranberry juices) met the range suggested by Mills for the Honey-like products (351 to 1750 mPa·s). When the Pudding consistency group is considered, all but the orange juice and the vegetable juice meet the 1751 mPa·s boundary. It is possible that the range of viscosity suggested for the Nectar-like products is too low to comply with SAH's clinical standard of Nectar consistency.

These findings lead back to the definitions of viscosity and consistency and their relevancy to thickened liquids in the clinical context of dysphagia. When standardized for clinical treatment at SAH, the thickened beverages were identified as products that would demonstrate a pre-determined consistency and form a cohesive bolus on the tongue to permit a safe swallow. As new products were introduced on the menu, they were formulated for the 3 clinical standards of consistencies. A wide range of products became available from juices to milk-based products to supplements. Certain production limitations required the development of freeze-thaw stable products. This demanded formulations with several thickening agents and the concentration of each ingredient varied within each consistency level. It is possible that Hoffman observed a correlation between consistency and viscosity due to the limited number of non-Newtonian samples evaluated.

Viscosity is the physical property of a liquid to resist shear induced flow[84] and it is related to 5 independent parameters : physical-chemical nature of a substance, temperature, pressure, shear rate and time. Therefore, the various formulations of SAH's thickened beverages will affect the viscosity readings under specific testing environments. Consistency, on the other hand, is more broadly defined as the mouthfeel impression of a product or its 'body'. It is a measure of flowability of liquid and semi-liquid products. Also related to certain parameters such as pressure, time and temperature, consistency might reveal the presence of other rheological parameters. For example, as the product flows on the apparatus, the adhesiveness might slow it down and result in a less flowable product. An important cohesiveness level could also prevent the product from running easily and reduce the flowability accordingly.

Limitations of the study would comprise the fact that the beverages were evaluated at only one temperature.and the fact that the thickened beverages analyzed were specific to SAH. The temperature of evaluation was set at 8°C. Although, it was believed to be the optimal serving temperature, a mealtray might be served between 15 to 30 minutes after it was assembled. Therefore, it is possible that the temperature of the thickened beverage is actually higher than 8°C when consumed. The viscosity and consistency at several temperatures should be evaluated to provide true clinical results of viscosity and consistency ranges. Also, SAH's thickened beverages were designed to respond to the clientele needs and the production center limitations. Although the production methods are well established and controlled, the formulation of these beverages varies regularly. It is possible that these results reflect SAH's reality and are not representative of other thickened beverages offered commercially or prepared.

2.6 CONCLUSION

Thickened beverages have been used at SAH's since 1991 as a safe and positive method to maintain adequate hydration for dysphagic individuals while maintaining quality of life. This study was the first exhaustive evaluation of the rheological parameters of thickened beverages used in a clinical setting.

When analyzed for their rheological parameters, the SAH thickened beverages were found to be non-Newtonian, pseudoplastic, time-independent products. They all presented a yield stress and could be best described by the Herschel-Bulkley model.

Although various types of products composed each consistency group, no statistical difference was observed between the high-protein products and the juice products - except for the consistency coefficient in the Pudding group ($p < 0.05$). The 3 consistency groups were statistically different for their consistency coefficient, yield stress and apparent viscosity ($p < 0.05$) despite sometimes high standard deviation values.

When separated as high-protein and juice products, correlation between consistency coefficient, apparent viscosity, yield stress values and the Bostwick consistency could not be clearly established. The flow behavior index had no correlation with the consistency level.

Apparent viscosity could be an essential parameter when formulating new thickened beverages but no apparent viscosity ranges have yet been published demonstrating their clinical efficacy. Taking in consideration the positive health results observed at SAH with individuals receiving thickened beverages and the standardized approach used to produce the thickened beverages, we conclude that consistency is a critical and essential parameter to control in the treatment of dysphagia. The Bostwick method is relatively inexpensive, accessible to most and time efficient.

Future research should consider temperature and concentration of the constituents as possible factors influencing the apparent viscosity and consistency of thickened fluids in the clinical management of dysphagic individuals.

3. REFORMED FOODS

3.1 GOAL AND OBJECTIVES

Using rheological instrumental methods, the first quantitative evaluation of reformed minced and pureed foods was performed to provide a better understanding of their textural characteristics and eventually, help in the development of better tools for the treatment of dysphagia. This study has evaluated the texture profile analyses (TPA) of SAH modified texture reformed foods with 2 main objectives :

1- Describe, measure and quantify objectively SAH's reformed modified texture foods within the clinical food groups

2- Evaluate possible similarities of textural profiles of the solids within food groups

3.2 METHODS

The reformed foods were tested using the Tensile Testing machine - texturometer (Lloyd Model LRX, Fareham, Hans UK) fitted with a 50N cell and a 50 mm diameter disk-shaped probe. All the samples (Width: 30 mm x Length: 30 mm x Height: 15 mm) were individually heated and tested at normal serving temperature (65°C). Each sample of meat, taken from the center of a reformed item, was heated to 65°C using a microwave oven (*Goldstar, LG Electronics Inc, Kyungsangnam-Do, Korea; 2450mhz; 600W*) at an intensity of 60% for 60 seconds. Each sample of vegetable were heated 65°C using the same microwave oven at an intensity of 40% for 40 seconds. The reformed cakes were tested at 8°C. A 2-cycle TPA compression test at a speed of 150 mm per minute was performed on 8 replicates of each reformed food available. The data were gathered via the RControl Data Analysis Software (version 3.2, 1995).

3.3 Statistical Methods

Reformed foods were classified by family of products. Means and standard deviation (SD) were calculated for all rheological parameters resulting from the TPA for each reformed food tested. Means, standard deviations and variability coefficients were calculated for each family of reformed foods. Maximum and minimum values are also presented.

3.4 Results

The foods have been grouped in 4 main categories : 1) minced hot meats, 2) pureed hot meats, 3) hot pureed vegetables and 4) pureed cakes.

Tables 4a to 7 present 7 textural characteristics of SAH's reformed foods. Firmness 1 is the firmness found after the first compression of the sample whereas Firmness 2 is the value of the firmness found after the second compression. Other mechanical parameters were evaluated : elasticity, cohesion, adhesion, gumminess and chewiness. The tables present the average values of these rheological parameters for each food tested and their standard deviations. The bottom section of each table shows the global average and the standard deviation of each food category. A coefficient of variation has been calculated for each textural parameter for the whole group (absolute value of the global standard deviation of a group divided by the global average of the group). Minimal and maximal values have also been highlighted to better describe the top and bottom rheological boundaries of each group. The range provided for each textural parameter is the difference between the minimal value and the maximal value of the group.

3.4.1 Variability within the groups

Minced Heated Meats (Tables 4a and 4b): When individually evaluated, the minced meats showed a highly variable profile for most of the textural parameters. As a group, the variability was also high but two mechanical textural characteristics showed a lesser standard deviation: cohesiveness and springiness. It was also observed that the Lamb Chop and Turkey Slices in Table 4a) presented outlying values for most of the textural parameters. Table 4b) presents the group's rheology data after the omission of the Lamb Chop and Turkey Slices. The standard deviations are reduced. Cohesiveness and springiness remain the parameters with the lesser standard deviation.

Pureed Heated Meats (Table 5): The pureed meats also presented a high variability within the group. Here again, the Lamb Chop and the Turkey Slices presented the most extreme textural profiles for most of the textural characteristics. When eliminated from Table 5, the variability within the group was reduced.

Pureed Hot Vegetables (Table 6): The hot vegetables presented a less variable profile of texture than the other groups. However, the Cauliflower presented 6 of the maximum values. When omitted from the group, the variability is reduced and the group became more homogeneous in its textural characteristics. Cohesiveness and springiness were still the parameters with the lesser standard deviation.

Pureed Cakes (Table 7): The texture profiles of the cakes were obtained at 8°C. The peach cake had 6 of the minimal values for the textural parameters evaluated. Therefore, Table 7 was elaborated without the values of the Peach Cake and the variability was more acceptable. Also, the cohesiveness and springiness parameters were the parameters with the lesser standard deviation.

Figures 8a to 8d show typical TPA curves for minced beef, pureed beef, pureed asparagus and pureed apple cake.

3.4.2 Comparison of the groups

All groups presented coefficients of variability ranging from 4.7% (adhesivess in the pureed cakes) up to 91% (chewiness of the minced meats). Generally texture profile analyses are done on products of the same type[104,105] as for cheeses or specific beef meats profiling. In this study, various types of meats or vegetables or cakes were grouped together to form a group of minced or pureed products in order to provide a clinical answer to dysphagia. The variability normally found in studies of food samples of the same products was potentially enhanced by the presence of several types of food. It is also important to mention that the food items in those food groups were representative of only one production batch. Since these products are made manually and have little automation in the process, it is possible that the coefficients of variability were increased by the handling.

When discussing dysphagia diets, several authors will refer to softness and the tenderness[53] of the food items offered on the menu. It is actually intended to describe foods of reduced firmness. This mechanical characteristic could be quantified using the Texture Profile Analysis (TPA). The TPA will provide a first value of firmness (Firmness 1) which correspond to the initial force required to first compress the food and a second firmness (Firmness 2) is obtained on the second portion of the compression cycle. The second firmness value will indicate the force required to compress the same sample a second time (second bite). Ultimately, for dysphagic individuals, the initial force required to chew or to manipulate the food in the mouth should be kept to a minimum in order to limit the fatigue that could result from the eating activity. The pureed reformed vegetables showed a Firmness 1 of 0.708 ± 0.21 Newtons (N), the reformed minced meat present a Firmness 1 of 2.87 ± 0.87 N, the reformed pureed meats had a Firmness 1 of 3.04 ± 0.99 N and the pureed cakes displayed an averaged Firmness 1 of 4.59 ± 1.6 N.

A low firmness 2 (firmness sensed at the second compression) should be seen as important since it could imply that the first compression of the food was successful and the food item required less chewing. The pureed reformed vegetables showed a Firmness 2 of 0.586 ± 0.17 N, the reformed minced meat present a firmness 2 of 2.18 ± 0.66 N, the reformed pureed meats had a firmness 2 of 2.57 ± 0.90 N and the pureed cakes displayed an average firmness 2 of 3.97 ± 1.30 N.

Firmness 1 and firmness 2 are integrated into the cohesion ratio. In fact, cohesiveness is the result of the ratio of the firmness 2 by the firmness 1. A low cohesion ratio indicates that the first compression had strongly damaged the macro-structure of the food and that the following compression encountered much less resistance the second time down on the food. Clinically, a low cohesion ratio could imply the initial macro-structure of the food is greatly affected by the first compression therefore less energy will have to be deployed by the patient, on the second compression, to transform the food into a cohesive and ready-to-swallow bolus. The pureed reformed vegetables presented a cohesiveness of 0.220 ± 0.04, the reformed minced meat had a cohesiveness of 0.238 ± 0.04, the reformed pureed meats had a cohesiveness of 0.274 ± 0.06 and the pureed cakes displayed an averaged cohesiveness of 0.495 ± 0.04.

Springiness is the capacity of a solid to go back to its original shape after a force has been applied. For dysphagic individuals, elasticity should be maintained to a minimum considering that the energy required to chew should be kept to a minimum. A food having great springiness would bounce back to its original shape, requiring many strokes of the jaw before being appropriate in texture to swallow. The group of foods presenting the lowest springiness level is the pureed vegetables at 1.41 ± 0.19 mm followed by the minced meats and the pureed meats with 2.06 ± 0.39 mm and 1.94 ± 0.35 mm, respectively. The group presenting the highest springiness is the pureed cakes category with 3.81 ± 0.18 mm which is twice as high as the pureed vegetables.

The cakes are generally used with the reformed pureed meats and reformed pureed vegetables as part of the Pureed diet. The discrepancy was questioned further. The reformed pureed cakes were evaluated at a temperature of 8°C which was believed to be the optimal serving temperature. A potential explanation for these high springiness values is the presence of a cold-stable binder in the formulations of the cakes. Therefore, it is possible that TPA values obtained at 8°C would generate high springiness values. Also, it was observed that the cakes remained in the patient tray for a certain amount of time - reaching temperatures as high as 12 to 15°C - before the reformed pureed cake is eaten. It is possible that a TPA performed at such temperatures would generate lower springiness values due to a softening of the binder at higher temperature.

Another mechanical rheological parameter to be considered when developing foods for dysphagic individuals is adhesiveness. Adhesiveness corresponds to the force or energy necessary to break the attraction of the foods with the structures of the mouth (teeth, palate, tongue, etc.). For dysphagic individuals, food items presenting high adhesiveness such as peanut butter should be avoided. Diminished tongue motion and mouth sensitivity will reduce the capacity of the patient to clean food particles clinging to the mouth's structures. When the results of the adhesiveness parameter are evaluated, it is observed that the reformed pureed vegetables present the least adhesion with a sensed resistance force of 0.395 ± 0.14 N. The reformed minced meats and the reformed pureed meats present an adhesion force of 0.505 ± 0.24 N and 0.734 ± 0.26 N respectively. The reformed pureed cakes have the highest adhesiveness with 0.773 ± 0.38 N. The high content of water in the vegetable products might explain their low adhesiveness results whereas the high starch content might translate into elevated values for the cake products.

Chewiness is the force required to reduce a solid to a ready-to-swallow bolus. Although these products are soft solids, the chewiness – the force necessary to reduce a solid product to a ready-to-swallow bolus - remains a factor of interest. In fact, if chewiness became too important, the re-shaping of the reformed foods might be harmful. The hot pureed vegetables showed 0.223 ± 0.07 N for the chewiness parameter. The minced meats and the pureed meats demonstrated chewiness values of 2.07 ± 1.9 N and 2.35 ± 2.0 N. The reformed pureed cakes present the highest chewiness with 8.94 ± 3.8 N which is almost 10% of the 50 N cell load used to perform the tests. Where the pureed cakes are concerned, it is possible that chewiness could be reduced by the increase in temperature. Again, tests at higher temperature values would be necessary to better understand the discrepancy of the rheological values of the cake category versus the other pureed items.

The reformed foods are soft foods and could be considered as semi-solids. Therefore, the gumminess was also a rheological parameter evaluated. This last parameter evaluated the force required to reduce a semi-solid to a ready-to-swallow bolus. Here again, the pureed vegetables show the least gumminess with a value of 0.154 ± 0.04 N. Minced meats and pureed meats had a gumminess value of 0.692 ± 0.27 N and 0.837 ± 0.35 N, respectively. The pureed cakes displayed a gumminess of 2.32 ± 0.94 N. Once more, the pureed cakes have a much greater value than the other pureed products and it is believed that warmer products would have granted lower values of gumminess.

3.5 DISCUSSION

Dysphagia treatment requires an interdisciplinary approach to ensure that the patients receive the best care from all professionals involved in the diagnosis and treatment of their condition. Therefore, communication and coordination of the proper clinical care is essential and could be improved by more objective methods to describe the optimal dietetic prescription. Dysphagic individuals will consume minced or pureed foods and liquids modified in consistency on a daily basis. They risk health hazards if the adequate diet is not respected. Several authors have described dysphagia diet foods in qualitative terms and attempted a standardization of the dysphagia diet vocabulary[9,11,12,69,70].

In 1993, Robertson and Pattillo[53] introduced the first dysphagia diet which included a more objective description of the foods included in the dysphagia management approach. Apparent viscosity, obtained via the Brookfield DV-1 rotary viscometer was implemented as an objective measure for the appropriate texture and consistency for pureed foods and thickened beverages in relation to what was observed during the videofluoroscopic examination. Although, the minced/chopped and the soft diets remained qualitatively described, the main objective was to relate the clinical information obtained during the clinical examination of the patient and the foods that were actually delivered to the patient. They also wanted to reinforce the interdisciplinary approach between doctors, speech-language pathologists, dietitians and the dietary service staff by using a uniform language and having a range of foods corresponding to specific viscosity and identifying certain viscosity-specific foods. The food items suggested by Robertson and Pattillo were different from the ones studied here since they were of a semi-liquid form and did not hold a specific shape.

Reformed foods are commercially available for dysphagic individuals. They are aimed at increasing quality of life by offering more appealing foods while also providing the patient with a well balanced and nutritious diet. The reformed foods have been studied for their acceptability and nutritional impact on dysphagic individuals[71,75,77] and but they have not yet been evaluated for rheological parameters.

Ultimately, the association of the TPA profiles and the clinical profiles of groups of patients would provide a more objective and standard dietetic prescription. One has to remember that the TPA technique presents its share of limitations. It is an imitative test that will bring to light various textural characteristics of the foods but when the association with the sensory evaluation is attempted (or a clinical profile), one should remember that saliva is not taken into account with this apparatus. The heat transfer is also different on the testing plate of the instrument when compared to the oral cavity.

Authors refer to a 'cohesive bolus' when discussing proper ready-to-swallow boluses for dysphagic individuals. The cohesiveness of the ready-to-swallow bolus was not evaluated with this series of TPA evaluations of SAH's reformed foods. The evaluations granted results comparable to the first and second bites in a food sample. Another important factor to remember is that most of the meats are served with Nectar consistency sauces. Once the food is masticated in the mouth, the textural profile observed under TPA would be different.

Generally, texture profile analysis of foods are done within specific families of foods such as cheeses or restructured beef products[104,105] for example. In dysphagia treatment, the texture profile analysis should be looked at as being a means to categorize various types of foods according to clinical needs in function of textural characteristics.

3.6 CONCLUSION

This is the first series of TPA evaluations of the reformed foods of Ste-Anne Hospital. This evaluation granted objective and quantified results on 7 mechanical texture parameters (firmness at the first bite, firmness at the second bite, cohesiveness, adhesiveness, elasticity, chewiness, gumminess) at optimal serving temperatures for reformed minced meats, reformed pureed meats, reformed pureed vegetables and reformed pureed cakes. Large variation coefficients were observed in each family of products. This variability could be partially explained by the large diversity of products within each group.

Cohesiveness and springiness were two parameters granting lower variability coefficients. The hot pureed vegetables presented the less intense profile whereas the cakes were on the superior extremes for most rheological parameters.

Future studies should involve organoleptic evaluations of these products and evaluations of the rheological parameters at different temperatures. Establishing a correlation of the TPA results and sensory evaluations of normal swallowing individuals and dysphagic individuals would allow the complete circle of product development to occur. A quantified value of what is clinically required for a certain clinical profiles would render a quicker and more precise development of modified textured foods.

PART II: RANDOMIZED CLINICAL TRIAL AT MARIE-ROLLET (MR)

1. INTRODUCTION

Given the high prevalence of dysphagia and malnutrition in the institutionalized elderly population and the limited information concerning the clinical efficacy of the various dysphagia diets, a randomized clinical study was planned by Sainte-Anne Hospital (SAH). The goal of the study was to evaluate the impact of the SAH's reformed modified texture foods and thickened beverages on the dietary intake and health of dysphagic frail elderly.

Therefore, an investigation took place from June 1999 to December 1999 at Marie-Rollet Center (MR), a Quebec Long Term Care Facility of the Montreal region. This was a 12-week randomized clinical trial where dysphagic individuals with a recent history of weight loss and/or low BMI were randomly assignment to an experimental or a control group. After an evaluation of their swallowing ability, the subjects of the experimental group were provided with SAH reformed foods and thickened beverages whereas the control group continued receiving the menu offered at MR. Food intake, weight, BMI, number and type of prescriptions, presence of pressure ulcers and development of other infections were monitored for both groups.

The following section will provide the results and discussion resulting from this trial.

2. Goal and Objectives

The goal of this randomized clinical trial was to improve the dietary intake in dysphagic frail elderly as a mean of improving health. Two objectives were also established for this investigation:

- To assess whether a change dietary intake will occur, over a period of 12 weeks, in dysphagic frail elderly receiving SAH's dysphagia diet and Marie-Rollet modified texture diet.
- To measure weight changes and compare both groups as a result of the consumption of these 2 diets.

3. Methods

3.1 Subject Selection

Marie-Rollet Long Term Care Center (MR) is a Quebec long-term care facility where 93 elderly individuals and 32 young adults with important physical handicaps reside. Individuals between 60 and 90 years of age who had been at the Center for more than 3 months and suffered an involuntary weight loss > 7.5% of usual weight in the past 3 months or presented BMI of less than 24 were considered potential candidates to included in the protocol. Type of diet and diet consistencies were not exclusive. Individuals with an active cancer, a chronic intestinal disease such as Crohn Disease or in agony were excluded. Also, individuals who would have required an amputation during the course of the protocol would have been excused.

In June and July 1999, all 93 medical files of the geriatric population at MR were evaluated to determine which patients corresponded to the inclusion criteria. Two previous weight recordings - usually taken every two months for each individual at MR - and the height of each subject were obtained from the medical charts. The two last weights noted in the charts were compared and the change in weight was calculated.

After the preliminary chart screening, a list of the potential subjects from each ward was made and the head nurse contacted the family - or the person with power of attorney - to obtain consent and sign the consent form (Appendix A). Individuals who were competent to sign the consent forms on their own were met with individually. The principal investigator requested to meet patients at their convenience, read the consent form to the patient, explain the procedure of the protocol and then ask for their signature on the consent form. The consent form permitted the evaluation for dysphagia using the *RIC Clinical Evaluation of dysphagia* (Appendix B) by a professional dietitian. If dysphagia was observed, the patient was included.

The bedside evaluation for dysphagia was done using the *RIC Clinical Evaluation of dysphagia* to confirm the presence of oro-pharyngeal dysphagia. Subjects who were alert enough to participate were observed in their room. Pre-feeding skills, dentition status, phonation and volitional cough were assessed. Positioning was observed. Patients were asked to drink water, eat vanilla commercial pudding and chew on a graham crackers, in a pre-determined order. They were evaluated for oral and pharyngeal stages of the swallowing process. Dysphagia was identified when an individual presented difficulties eating or swallowing solids or liquids.

3.2 RANDOMIZATION

This was a randomized clinical trial of two treatments at Marie-Rollet long-term care center. The allocation of the subjects to the experimental (reformed foods and thickened beverages supplied by SAH) or control group (Marie-Rollet traditional foods) was done according to a predetermined randomization protocol. Dr. Gray-Donald, supervisor for this clinical trial, prepared randomization. Thirty (30) envelopes containing either a *Treatment* or a *Control* label were prepared, sealed and numbered. The sequence of group allocation was unknown to the dietitian performing the screening evaluations. As subjects were positively screened for dysphagia, they received the next study number and the corresponding envelope was opened. The subjects were then allocated to the specified group. Figure 9 presents the allocation of the subjects to the groups.

3.3 MEASUREMENTS

Weights were recorded in the charts every two months for most patients. Height and smoking status were present in either Social and Physical Evaluation chart (CTMSP) or in the initial medical evaluation. Medications were usually prescribed for an approximate 3 month-period (105 days) and adjusted as needed. Nursing staff would amend the medical chart when a change in medication took place. The prescription data were computerized which ensured legibility. The dietitian noted every intervention on the Dietary Services form and completed the report deriving from in the annual multi-disciplinary evaluation of the patients. No biochemical data were gathered for this study.

During the course of the study, change in medical status, absence/presence or evolution of pressure ulcers and development of infections were documented daily in the medical charts by the nursing staff and/or by the doctor responsible for the ward.

At baseline, medical assessment information such as age, principal diagnosis, height, smoking status (prior and current) was collected. When a subject presented more than one diagnosis, the diagnosis leading to institutionalization was retained as the primary diagnosis.

The nursing staff was instructed to weigh subjects with interior clothes and without shoes on a pedestal scale. Individuals who could not stand were weighed on a scale lift or on a chair scale. For the latter, the weight of the chair was subtracted subsequently. For individuals with incontinence, the diaper had to be new. At weeks 6 and 12, subjects were weighed again according to the protocol.

Heights from the charts were confirmed by knee height measurements. The knee height measurement was obtained by using the *Ross Caliper*. The subjects were lying on their back, the left knee and ankle were bent at a 90° angle. The fixed band of the caliper was placed under the heel whereas the mobile band was placed on the thigh, 5 cm from the patella. Each subject was measured for height twice (results had to be within 0.5 cm otherwise a third measure was obtained when needed). The average of the two nearest values, within 0.5 cm, obtained by knee-height measurements was used for the study. BMI was calculated by dividing weight (kg) by the value of the height-squared (m^2).

Two-day dietary intakes were measured at baseline at mid- (6 weeks) and end- (12 weeks) points. The same days of the menu cycle were evaluated to facilitate the comparative analysis and to limit the variation due to food diversity alone. The dietary intakes were completed by the dietitian in charge of the project for both groups. Each item served on the trays for these 2 days was weighted before and after the service of the meal. Differential weights (before and after) of each container were considered to be the eaten portions. The trays were also marked with a special reminder card to insure that nothing was mistakenly thrown away and that all empty containers were kept.

When items were stirred together (meat, potato and the sauce for example), the weight of the remaining portion was evaluated according to a *pro-rata* ratio as compared to the original quantity of each food items served (weight of the meat, the potato and the sauce). The subtraction was performed and the nutritional value was calculated for each item accordingly. When the original weight of each item was not available, as for the *Campbell TrePuree*'s meat, vegetable and potato fractions for example, the remaining portion was considered as a fraction of the original total weight. The nursing staff listed snacks. The 2-day dietary intakes were repeated at week 6 and week 12.

Dietary analyses were performed by the NutriWatch Software package (*NutriWatch, Nutrient Analysis Program, Version 6.1.4F - Delphi 1 for Windows, 2000, PEI, Canada*). Nutritional values absent from the Canadian food file were manually entered following the values provided by the manufacturer whenever possible. Nutrient composition of certain recipes were also added to the Canadian food files according to existing recipes at SAH and MR Center for items such as thickened soups, salmon pie and shepherd's pie. The laxative puree (prune/bran cereal mixture) offered daily at MR was prepared on site and the recipe was added to the Canadian Food File. The quantity of laxative puree received by each patient was entered in the nutrient analysis program as indicated on the prescription chart.

On both days of dietary intake, the dietitian in charge of the project monitored the time required to complete the breakfast, lunch and supper meals. The feeder was also identified as being an orderly, the patient or a family member.

3.4 INTERVENTION

To help in feeding individuals with oro-pharyngeal dysphagia to solids, the texture of the foods offered to the patients had to be altered. Individuals could suffer - independently of their capacity to handle solid foods - from oro-pharyngeal dysphagia to liquids. When dysphagia to liquids was identified, patients received beverages modified for their consistency: thickened beverages.

The 3 week-cycle menu was maintained and the modification of the texture was adjusted, when needed, according to the bedside assessment results (*RIC Evaluation of Dysphagia*) and the clinical evaluation of the dietitian at MR. It would have been unethical to maintain a diet consistency believed to be inadequate considering the dysphagia evaluation results. All subjects continued to receive their MR menus and remained under the care of the dietitian on duty 2 days a week at the Center.

3.4.1 Intervention related to the Control Group

The menus were computerized according to the patients' nutritional needs, specific diet, allergies, preferences, and aversions on *MicroGesta Software*. The *MicroGesta Software* was programmed with a menu of 21 days which was fragmented into different choices according to various diet profiles required (diabetic, no salt added, high fiber, soft, etc.). The diet prescription of each patient was identified with a code and the system took into consideration the likes and dislikes of the patient, previously entered by the clinical dietitian. The menu was then generated by deduction by the software according to the preset menu items. In general, the menu could be presented as follows: 1 soup was offered daily in its regular consistency and a thickened version (E.g.: chicken noodle soup and thickened and blended noodle soup); 1 choice of main dish, different for each meal; 3 alternative items *À la carte* were also available at each meal: sliced ham, hamburger steak or sandwiches; 2 choices of vegetables were offered at each meal but only one was modified in texture (E.g.: broccoli and pureed carrots); 4 choices of desserts were available at lunch and dinner. They included normal texture items such as cakes and canned fruits and more soft texture choices such as ice cream and puddings. The menu cards were printed periodically and used to assemble the tray according to the patients' needs.

At MR, modified textured diets were of three types: Minced 70, Minced 3 and Pureed diet. Cooks at MR prepared the minced foods. The Minced 70 diet allowed all minced foods - originating from the regular texture diet menu (E.g.: Minced salmon pie) to be offered to the patients. It also offered certain soft foods such as meat loaf, poached fish, muffins and omelets. The soft desserts such as soft cakes without nuts, mousse cakes or firm yogurts were also permitted for these patients. The Minced 3 diet was used to identify the diet where all the foods - again derived from the regular texture diet menu - were presented on a minced form to the patient (meats, stews, pasta and vegetables) or softer texture such as pureed foods (pureed fruits and puddings). No soft foods were included. The Pureed diet consisted of mainly *Campbell TrePuree* foods as main entrees and desserts and other foods offered were of the pureed texture. This dish comprises the pureed meat, vegetable and potato in three parallel 'sausage-looking' portions. The dishes come in an assortment of 12 pre-determined menus. The pureed diets also offered traditional pureed foods (Picture 5).

MR offered one level of thickened consistency beverages designated *Honey*. The beverages were prepared using a commercial instant thickening agent named *Consistaid* (Berthelet, Montreal, Canada), 24 hours before service. A description of this consistency would be that it was almost as thick as a commercial pudding; it did not flow readily when poured. The consistency did not compare to SAH's 'Honey' consistency as it was more similar to SAH's consistency named 'Pudding'. No other consistency was available. Although the recipes were standardized, the consistency obtained sometimes varied with production due to production changes (measurements of ingredients, type of ingredients, etc.). The consistency was not systematically controlled. Six varieties of thickened beverages were offered at MR: apple juice, orange juice, cranberry juice and tropical juice, 2% milk or vanilla supplements. The daily production schedule for the thickened beverages offered 2 types of juices along with milk and vanilla supplement.

3.4.2 Intervention related to the Experimental Group

For the duration of the study, the nutritional care of the subjects in the treated group was shared by the 3 clinical-dietitians from Sainte-Anne's Hospital. They were instructed to use SAH's nutritional approach to care for the nutritional needs of the treated group. The dietitian in charge of the project was responsible for transmitting the daily information concerning each patient and insuring meal delivery.

SAH's nutritional approach is highly individualized and aimed at using foods dense in energy, SAH's reformed foods (pureed fruits, vegetables and deserts along with pureed and minced meats), thickened beverages as pertinent, and supplements when necessary. The SAH enriched-milk (milk added of skimmed milk powder) was also available.

The menus were revised for each subject of the treated group. Two subjects were able to inform us of their food preferences and dislikes. Their menus were adapted accordingly. The *MicroGesta Software* did not allow the inclusion of SAH 'à la carte' items. Therefore, to reduce perceivable changes on the tray and possible bias, 63 menu cards (3 meals x 7 days x 3 weeks) were reproduced using *Microsoft Excel Software* for each treated subject to match the menu cards usually printed for MR patients.

SAH also offered three types of modified texture diets: Minced diet, Minced/Pureed diet and Pureed diet. For the Treated group, the SAH's reformed foods were introduced and a new 3-week cycle menu was developed. This new menu reflected the regular texture menu normally offered at MR.

The new selection offered a variety of 9 reformed meats in minced or pureed texture (beef, veal, ham - cold or hot - and turkey slices, chicken breasts, pork and lamb chop), 5 cube-shaped dishes in minced or pureed texture (Stroganoff Beef, Soukiaki Beef, Bourguignon Beef, Vegetable Stew and Fall Stew) and 3 reformed dishes in pureed texture only (meat pie, salmon pie and lasagna). Nine (9) vegetables were also available in the reformed shapes. The selection of vegetables included baby carrots, asparagus, waxed beans, green beans, broccoli, cauliflower, green peas, cold salad and cold marinated beets (Pictures 1 and 2).

Reformed desserts were offered mainly as cakes or fruits. The cakes were shaped as a disc of approximately 1-inch of height and always dressed with either fruit sauce or whipped toppings. The cakes made available were carrot cake (cheese topping), peach cake (peach sauce), apple cake (applesauce), choco-moka cake (vanilla whipped topping), *Bagatelle* cake (cranberry topping), vanilla cake (chocolate whipped topping), chocolate cake (vanilla whipped topping) and Black Forest cake (vanilla whipped topping). The fruits included reformed quarters of peaches, half pears, strawberries and pineapple slices. Other soft desserts such as puddings and applesauce were available and offered as patients' tolerance and acceptability permitted (Picture 3).

At each meal, the patient had a choice of 2 types of reformed meats (menu of the day or a substitute), 2 reformed vegetables and a choice of reformed cake and/or reformed fruit and other regular items when possible for their condition. The overall menu followed the 3-week-menu already offered at MR as closely as possible. If these choices were not to their liking, the patient could receive an item from the *À la carte* menu that remained the same daily: reformed pork cutlet, reformed beef or ham slices and pureed sandwiches (egg and ham).

SAH's thickened beverages were offered in their 3 consistencies named *Nectar*, *Honey* and *Pudding* (Picture 4). The recipes were standardized and the products were controlled at SAH using the Bostwick consistometer to insure conformity to pre-established standards as part of the regular Q/A assessments. When a batch did not meet the standard, the production team was made aware of the problem and the thickened beverages were corrected. If a beverage did not meet the standard after the re-evaluation of the batch, it was discarded. The selection of SAH's thickened beverages included thickened milk, milkshake, vanilla, chocolate, strawberry or banana supplements, apple, orange, prune and cranberry juices.

3.4.3 Providing SAH's Foods to MR

The reformed foods (main dish plates, desserts) and thickened beverages and supplements were assembled at SAH by kitchen staff, following a compilation order, and delivered daily (Monday through Friday) in a cart using the SAH's patient transportation bus in a Cambro isothermal-cart. The cart was left at the reception desk at MR at 7:00 AM and was then send to the walk-in refrigerator soon after. Each individually labeled item was refrigerated until serving time on an pre-identified tray, rethermalized for 45 minutes in a Combi-Oven by SAH staff and served at the same time and with the same equipment usually used at MR to deliver the trays. One extra plate was heated at every meal to assure conformity and quality control for temperature, texture and appearance. The menu cards were reproduced to match the original ones to limit the influence of the overall tray aspect. The diet texture was highlighted with a yellow marker to ease the recognition of these plates and allow for proper service.

3.5 STATISTICAL METHODS

The data obtained at baseline were compared using unpaired Student's t-test to assess any difference between the groups at Baseline. This procedure was repeated with the data gathered at week-6 and week-12. An assessment of change over time was done to measure the change in nutritional intake (paired t-test) (Table 8). The change in weight and dietary intake from baseline to midway evaluations and from baseline to final assessments was compared between the groups using Student's unpaired t-test. Data analysis was completed using the SAS software package (SAS, version 6.12 for Windows). Probability of $p < 0.05$ was considered as statistically significant.

3.6 ETHICS

Ethical approval for this 12-week randomized clinical trial protocol was given in January 1999 by Mme Pauline Marois, Minister of the Health and Social Services Department of the Quebec Government according to the terms of article 21 of the Quebec Civil Code. McGill University also issued a Certification of Ethical Acceptability For Research Involving Human Subjects in July 1999. Both these approvals were issued for competent and incompetent individuals. Consent to conduct this study was also obtained by the professional Services Director of Marie-Enfant Hospital, Dr. J. Leblanc, Marie-Rollet Long Term Care Center being a section of this hospital at the time of the project.

4. Results

4.1 Screening and Evaluations

The evaluation of the medical charts identified 39 individuals fitting our inclusion criteria (39/93; 41.9%) and for whom consent was requested. In total, 27 consents were obtained (27/39; 69.2%). Of these, two consents were obtained from the Quebec Curator (2/27; 7.4%; 100% of the requested list). 24 consents (24/27; 88.8%) were obtained by family members or the individual responsible for the individuals i.e. the legal proxy. They had been contacted by the head nurse of each ward. One (1) consent (1/27; 3.7%) was obtained from a resident capable of providing consent. Seventeen individuals (17/27; 63%) were identified as being dysphagic and included in the protocol. The remaining 10 subjects were not dysphagic according to the bedside *RIC Clinical Evaluation of dysphagia* and were at a low BMI or losing weight for other reasons not investigated here (Figure 9).

Reasons for refusal to participate to the study included: 1) the family members or the proxy could not be reached during this time of the year - summer season; 2) family members were unsure of the necessity of their loved ones participating in such a study, therefore they refused; 3) competent patients refused to see their menu modified or to undergo the screening evaluation for dysphagia.

The random assignment of the 17 dysphagic individuals resulted in the allocation of 8 patients (3 men) to the treatment group whereas 9 patients (4 men) were assigned to the control group. The medical profile of the subjects was similar in both groups where principal diagnoses were Alzheimer's Disease (Controls: 55.6% and Treated: 37.5%) and Dementia (Controls: 22.2% and Treated: 50%). No one needed tube feeding or amputation. No statistical difference was observed when we compared both groups for sex, age and smoking status. Table 9 describes the principal characteristics studied for each group.

4.2 Participation Ratio and Prevalence of Malnutrition and Dysphagia

After the screening, 17 of the 39 individuals (43.5%) were found to be dysphagic. This is not a true prevalence of dysphagia since the pre-screening and consent process potentially eliminated certain dysphagic individuals who were not losing weight, were at a BMI > 24 or who refused to participate in the study.

4.3 Incidence of Death during the Time of the Protocol

Unfortunately, one individual in each group (2/17; 11.8%) died before the 12-week assessment (Figure 9).

4.4 Pre-Protocol Dietetic Prescriptions

Before the bedside evaluation for dysphagia was performed, 1 individual was receiving a Pureed diet with thickened beverages and 2 subjects were receiving the Minced-70 diet with thickened beverages. Two (2) individuals were on the Pureed diet, 1 individual was on the Minced-3 diet, 9 individuals were on the Minced-70 diet and 2 individuals received the Regular texture diet (Table 10).

To insure that subjects in both groups were receiving the texture most adapted to their physical capacity, modifications of the texture of the foods and the consistency of the beverages were done according to the results of the dysphagia screening evaluation for all subjects. The results of the oro-pharyngeal evaluations for dysphagia led us to suggest modifications for food texture or beverage consistency for 4 individuals in the control group and 1 individual in the treated group. This approach was used to diminish the possible impact of having individuals in either group who would receive a diet that was not adequate for their needs.

4.5 Baseline Characteristics

The average weight of the control group was 54.3 ± 7.49 kg whereas the average weight for the treated group was 55.9 ± 12.06 kg (Figure 10). The average BMI values for the treated group was 22.4 ± 3.93 kg/m^2 and for the control group 21.2 ± 2.31 kg/m^2. Both groups had mean BMI values below the 24 value desired for a geriatric population (Figure 11).

The high variability noted could be explained by the presence of both males and females in each group and the heterogeneity of the geriatric population. When the data is considered more closely, we can see that 2 individuals in the treated group and 1 subject in the control group were above the Canadian recommended weight values for individuals over 75 years of age which are 64 kg for women and 69 kg for men (Figures 12 and 13).

The analysis of the dietary intakes revealed no statistical difference between the subjects of both groups (Table 11). At baseline, the treated group had an initial intake of 5748 ± 985 kJ (1374 ± 235 kCal) whereas the control group received 6551 ± 1352 kJ (1566 ± 323 kCal). We can see a high variability in energy intake, which could be explained by the heterogeneity of the health status and appetite of these geriatric patients. Although both groups are similar for energy intake, it is important to mention that the Nutrition Recommendations of Health Canada[106] for the energy intake of the healthy individuals, presenting a low activity level, in the age group of 75 and over is of 7113 kJ (1700 kCal) for women and 8368 kJ (2000 kCal) for men. Therefore, both group averages are below the recommended values. When the individual data of the dietary intake are considered, we could see that only two individuals of the control group surpassed the suggested energy intake.

In addition, according to the Nutrition Recommendations of Health Canada, the average energy requirements for elderly individuals should be approximately 33 kCal per kilogram[106]. The energy intakes observed at baseline were 24.6 kCal/kg and 28.8 kCal/kg for the treated group and the control group, respectively.

Initially, the macronutrient intake were as follows for the control group: 14% of energy was obtained from proteins, 60% of energy from carbohydrates and 27% of energy from lipids. For the treated group, the macronutrient intake was similar: 15% from proteins, 60% from carbohydrates and 26% from lipids. These results showed no statistical differences between the groups but inform us that both groups were receiving a well balanced diet at baseline.

Proteins are important to maintain the integrity of the immune system and in preventing or improving skin damage such as pressure ulcers[78]. The baseline evaluations of the dietary intakes show that the treated group received a daily average of 52.5 g ± 14.6 g of proteins (0.97g/kg per day) and that the control group consumed 56.0 g ± 16.8 g of proteins (1.00g/kg per day).

At baseline, calcium, phosphorus, zinc, vitamin D, folacin and vitamin E were all below the RNI values for both groups. The calcium, phosphorus and vitamin D intakes were lower than suggested values and this is corroborated by a low intake of dairy products such as milk, cheese and yogurt in both groups. This population is at high risk of osteoporosis and osteomalacia and therefore, the vitamin D and calcium intake should be maintained at or above the suggested values for this age group. The reduced intake of phosphorus could be also exacerbated by the regular consumption of anti-acid or mineral laxatives due to the capacity of these compounds to reduce absorption. Low intake of folacin was also noted which may induce a megaloblastic anemia or an organic brain syndrome characterized by periods of confusion and loss of memory, which are two common symptoms observed in this population. Most other minerals and vitamins were consumed in adequate quantity. The vitamin C content of these dietary intakes was high. They are 2 to 6 times higher than suggested RNIs.

4.6 Comparison of Nutritional Status at 6 Weeks

At the midway evaluation, we could see that the mean energy intake for both groups was now above 6200 kJ (1480 kCal). The treated group had an intake of 8105 ± 2050 kJ (1937 ± 490 kCal) whereas the control group received 6223 ± 2116 kJ (1487 ± 506 kCal). The treated group presented a higher energy intake and the change in intake was statistically different when compared to baseline (Table 12).

Six weeks after the beginning of the protocol, the control group had a macronutrient intake of 15% of energy from proteins, 57 % from carbohydrates and 28% from lipids which was similar to the original values. The treated groups showed a slightly different picture. In fact, 17% of the energy was provided by proteins, 56% by carbohydrates and 27% by lipids. At six weeks, the protein intake was significantly higher in the treated group than the intake of the control group (Table 12). No other macronutrient showed a noticeable augmentation. Both diets remained well balanced.

When comparing the intake of the two groups after 6 weeks, potassium, magnesium, calcium, phosphorus, zinc and vitamins B_2, B_3, B_6, B_{12} and vitamin E where higher in the treated group. SAH's diet provided individuals with an increased quantity of milk and enriched milk, reformed pureed cakes, reformed purred vegetables and reformed pureed meats. This new diet composition coincides with foods providing the micronutrients that demonstrated an increase.

The average change in weight for the control group was -0.61 ± 2.23 kg whereas the experimental group demonstrated a weight change of 1.31 ± 2.85 kg (Table 13). Although the Figure 14 shows a trend toward an increase for the treated group, the weight changes observed in both groups (Figures 14 and 15) were not significantly different at week 6 ($p < 0.14$).

4.7 Comparison of Nutritional Status at 12 Weeks

At the end of the protocol, the macronutrient intake continued to show a well balanced diet for each group. The control group had 14% of the total energy intake provided by proteins, 62 % by carbohydrates and 24% by lipids. The treated group had a diet of 17% proteins, 55% carbohydrates and 29% lipids. The protein intake was significantly higher in the treated subject meals than the intake of the control for at total protein intake of 1.39 g per kg and 1.06 g/kg, respectively. After 12 weeks, the quantity of lipids consumed by the treated group was significantly higher than the control group (Table 14). However, the percentage of energy provided by lipids remained below the 30% recommended by Health Canada. Both diets continued to be well balanced.

The treated group gained 3.90 ± 2.30 kg which is significantly higher than the weight decrease of 0.79 ± 4.18 kg observed in the control group ($p < 0.02$; Table 15). Energy, protein, lipid, total saturated fat and monounsaturated fat intake increased significantly (Table 15; $p < 0.05$). The increase in micronutrients was statistically significant for potassium, magnesium, calcium, phosphorus, zinc, vitamin D, vitamin B2 and vitamin B12.

4.8 Information on Feeder and Feeding Time Required

Table 16 indicates the various feeding approaches used with the subjects. At baseline, most subjects were helped to perform the various tasks related to meal consumption (opening of the containers, preparing the meat, pouring the beverage, etc.).

The control group had 3 individuals partially helped during the meals. This implies that an orderly had to open containers and prepare part of the meal for the patient (for example: cut the meat or vegetables, pour in the milk for the cereals, prepare the coffee and/or tea) and also, a certain amount of verbal stimulation was needed for the patient to perform the task. Four (4) patients had to be completely taken care of during the total meal period. Therefore, the orderly had to prepare the meal, stimulate verbally and feed the resident. Two patients had to be partially fed or totally fed certain days or meals. No subject could entirely eat on their own.

The treated group had 3 subjects that could eat on their own once the tray was prepared for them (for example: milk cartons or jam containers opened for them). Two (2) individuals were partially helped during the meals and 3 patients had to be completely taken care of during the total meal period. Most subjects were receiving their meals in the dining room of the ward or in their room. One individual in the treated group was well enough to receive his lunch and dinner meals at the cafeteria on the main floor of MR Center.

At the midway evaluation, 1 control subject had lost some abilities and was now fed with complete help. The treated group had only 2 subjects who could self-feed by that time. Most subjects were still receiving their meals in the dining room of the ward or in their room and 1 individual in the treated group remained well enough to receive his lunch and dinner meals at the cafeteria.

The final evaluation showed no change in the way individuals of the control group were being fed. On the other hand, the treated group had only 2 subjects who could partially fed themselves at that point in time. Two (2) individuals were now partially or totally dependent on the orderly for feeding. No statistical difference could be established.

Time necessary to feed the subjects under evaluation at baseline is presented in Table 17. Length of the average meal required a minimum of 22 minutes (Range for control group: 10 to 40 min. and range for treated group: 10 to 50 min.) We can observe that the treated group seems to be slower for the feeding process but due to high variability, the difference is not statistically significant for any of the meals. This considerable variability can be explained by each patient varying alertness and health status at each meal (fatigue, side effects of medications such as drowsiness and sleepiness, overall health of the moment) and/or the rhythm and the personality of the feeder taking care of the individual.

Recording the time required to feed the individuals was used to evaluate if the increase in total energy intake was associated to a longer meal period. It appears that the change in length of time was not significant in either group. We could therefore say that the increase in total energy obtained in the treated group was not achieved at the expense of a longer feeding time.

4.9 Variety of Food Choices

Although the number of food servings per food group did not change significantly by the end of the trial (Table 18) when both groups are compared, it is possible to notice that the food choices (Tables 19a and 19b) were different between both groups. The menu provided by SAH was designed with respect to the regular texture menu and considered the choices of meat and vegetable available on any given day. The puree diet and the minced diet offered an extensive choice and permitted many permutations varying the meats and the vegetables as needed. The Campbell *TrePuree* were pre-established combination of dishes and offered reduced versatility.

4.10 CHANGE IN MEDICAL STATUS AND COST EFFECTIVENESS OF SAH'S ADVANCED NUTRITIONAL CARE

The parameters used to evaluate the change in cost of care and the modification in overall health status of the subjects of this study were the development/evolution of pressure ulcers, bronchitis, pneumonia or other infections. Using the medical charts allowed for monitoring of the development of such conditions, as they were clearly identified in the nurses' notes of the medical section of the chart. The pressure ulcers were usually described by size and color. Bronchitis and pneumonia were also noted in the medical section along with the antibiotherapy, when prescribed.

Comparing the baseline and the final results for these parameters did not provide a statistical evidence of change in either group (Table 20). Also, at the final assessment, the treated group did not demonstrate a lesser prevalence of infections or pressure ulcers when compared to the control group. Therefore, a statistically significant improvement in overall health for these patients could not be established when these parameters were considered. The mean number of prescriptions did not differ significantly. Excluding the latter, all these parameters are considered as counts and, unlike the continuous parameters, would require a larger sample to show a significant difference. The mean number of prescriptions currently administered demonstrated a large standard deviation rending statistical significant results impossible to observe in this small sample. Again, a larger group would be helpful in establishing a correlation between improvement of health status and the advanced nutritional approach suggested by SAH.

The costs of medication and nursing time were not precisely evaluated but it could be inferred as unchanged since no change in health status for either group was observed. Also, the time required to feed was not significantly modified with the use of SAH advanced nutritional care when compared to the regular modified textured diet foods offered at MR. Consequently, the costs of feeding were unchanged. Importantly, although present in the advanced nutritional care approach of SAH, use of dietary supplements did not show statistical difference among the groups (Table 18).

4.11 Anecdotal Results

Quality of life was not directly addressed in this randomized clinical trial but certain anecdotal results could be mentioned for their informative aspects:

- An individual in the treated group had a major reduction in laxative therapy after the introduction of thickened beverages. The staff of the ward was intrigued and wanted to know what was added to the SAH thickened beverages. We explained that the increase in total liquid intake was possibly the reason for this increase in bowel movement since no fiber is added to the liquids.
- The same subject received thickened coffee daily. Although reputedly confused, this subject opened his eyes when coffee was given to him the first time. It was used as stimulation later to motivate him to eat.
- One alert subject was quite aware of the changes taking place on his menu. Although he did not mention it greatly when his food was originally changed to SAH's foods, he quickly asked what had happened to the new food he was getting once protocol period was over. He complained that the MR food was bland and did not have much taste.
- The reformed pureed deserts (Black Forest and Mocha cakes and fruits) were appreciated by staff members and residents. They created discussion and interaction during the meals.

4.12 Feasibility of Realizing a Clinical Trial with the Special Food Items Developed at SAH's

One of the objectives of this study was to evaluate the methods chosen. Feasibility was confirmed and several organizational and operational data were gathered. The delivery of the food carts was done successfully, within the expected time limits, on 100% of the scheduled delivery days.

Human Resources: The number of working hours and cost evaluation of the human resources is presented in Table 21. The screening of the charts for the geriatric population required 30 hours. The dysphagia evaluation procedure was done by 2 dietitians and requested 1 hour per subject (physical screening and completion of the RBC Evaluation grid). Twenty-seven (27) subjects were evaluated. The initial complete re-evaluation and modification of the menus of the 8 treated subjects required 1 hour for the clinical dietitian in charge of the subject. The adaptation of the 21 days of chart menus on Excel required and additional 2 hours per treated subjects. After approximately 15 hours of evaluation and trial of the food system and kitchen facility used at the MR Center, we were able to provide for the treated subjects with a highly individualized and complete menu elaborated from the reformed foods and thickened beverages for a period of 16 weeks (gradual beginning and ending of protocol period of the selected individuals).

The preparation of the meals and supervision of the service required the presence of a member of SAH staff, usually the dietitian in charge of the study, from 6:15 AM to 6:00 PM, 7 days a week for 16 weeks.

Various tasks had to be performed, as part of the dietary service routine, during the course of the typical day in the production center at MR. The dietitian in charge of the project would have to insure preparation and rethermalisation of the specialized foods, establish/maintain inventory, make a compilation of the requested food items and send the order of the necessitated food items for the future deliveries, receive and verify the delivered goods (Monday through Friday) by SAH transportation team, identify the various plates according to day it had to served and the subject it had to be served to, print, cut and mark (with yellow marker) of the menu cards, as well as insert the new menu cards and suppress the non valid one. On the wards, the daily or weekly data collection was taking place.

During the days where dietary intakes were being completed, a second member of SAH was present to assure the daily routine and to perform the dietary intakes as well as verifying the weighing of the subjects and the completion of the snack form. This necessitated an additional 210 hours of labor.

Equipment: The food was delivered Monday through Friday in a Cambro isothermal-cart. It was kept in the walk-in refrigerator on a trolley. Some freezing space was also needed to keep a small inventory of frozen goods and frozen thickened beverages (approx. 2 feet^3). The food was rethermalized in a Combi-oven 45 minutes before service. Shelve space was required to keep an inventory of supplements at room temperature (approx. 2 feet^3). No supplementary kitchen equipment was needed to provide SAH's foods to the clients at MR.

5. DISCUSSION

Several dysphagia diets have been published [9,11-13,53,64] and cookbooks have been developed[72-74] to prepare modified texture foods but no clinical outcomes have been discussed in the literature. This study is the first detailed analysis of nutrient intake and weight changes of dysphagic institutionalized elderly receiving traditional and reformed pureed and/or minced foods along with thickened beverages when needed. Dysphagia is defined as a difficulty to form and to transfer safely a cohesive bolus from the mouth to the stomach. Therefore, contrary to other studies[71,75-77], this intervention included individuals presenting a dysphagia profile requiring minced or soft foods as well as subjects in need of pureed foods.

Undernutrition in the institutionalized elderly population has been reported on several occasions[32,107] and malnutrition is also known to be correlated with dysphagia[3,108]. Our results show that 39 of the 93 (41,9%) older individuals of MR were at low BMI (< 24) or losing weight (> 7,5% in 3 months). This concurs with other studies, which report undernutrition in the institutionalized elderly to vary between 10 and 60 % in nursing homes and hospitals[3,6-8].

At baseline, total energy intake was less than 5748 ± 985 kJ per day with an averaged intake of protein of 55 g per day (Table11). Frisoni and colleagues[109] showed similar findings when evaluating 72 elderly institutionalized subjects. This group also demonstrated that low energy and protein intake were associated with decreased rate of survival. Johnson and associates[110] evaluated the energy intake of 20 elderly women on pureed diet to be a little over 5400 ± 586 kJ in their institution and 56 ± 7 g of protein a day. The smaller standard deviations in this study might be the result of a more homogenous group.

The dysphagia prevalence found in the 27 participating subjects was of 63%, which correlates, with highest results of prior findings[1,111]. This prevalence is not an absolute prevalence of the integral population at MR and was potentially increased by the selection process. Eventhough, requesting consents only for individuals presenting weight loss and/or having BMI < 24 and soliciting acceptance to participate prior to the dysphagia screening evaluation could have resulted in excluding potential dysphagic subjects and disregarded potential dysphagic subjects, the first screening for weight lost or low body weight might in turn have increased the prevalence within the subgroup. This high prevalence leads us to believe that a recent important weight loss and low BMI are good predictors of dysphagia in this age group.

A possible way to obtain true prevalence would have been to suggest the evaluation of all patients as an incentive to participate. Screening and selection would have been longer and more expensive and could be difficult in a larger study.

The reformed foods developed by SAH's dietetic team brought a 44% increase in total energy intake where proteins improved by 54%, carbohydrates by 28% and lipids by 47% (Table 15). This agrees with the increase of 15% food intake resulting in an increase of 41% total energy intake and 36% of protein reported by Cassen[71] et al. in 1996. Quantified composition of the meals or the foods and the characteristics of the studied population were not disclosed in this publication.

An unpublished study reported by Sun[76] used the *Menu Magic Products* to evaluate weight gain and intake in a matched-paired group of 19 individuals. The experimental group received the commercial pureed products whereas the controls were served the institutionalized pureed foods. The period of the study was of 9 weeks and no change in weight was observed at the end of the trial. In a similar report, Sun[75] observed an increase in food intake of shaped pureed meats and vegetables but was not able to document a statistically significant weight gain after 4 weeks of intervention. This study had used *Travis Pureed Foods* to feed 8 residents and compared their weight gain and food intake to those of 8 residents receiving institutionally prepared pureed foods. The 2 groups were from two different Centers and it is possible that exterior and independent factors such as difference in feeding environment, staff or level of care present at these Centers affected the results. The short period of evaluation could also have been a detrimental factor in that aspect.

Amunrud[77] reported results of the impact of using *Cliffdale Puree* shaped foods on intake, weight gain and decubiti ulcers healing. The intervention included 29 individuals receiving pureed diets and lasted 8 weeks. The intake was statistically increased but weight gain and decubiti ulcers did not show any change.

These 3 prior reports used an estimated percentage of intakes to evaluate the amount of food eaten by the subjects and these percentages were recorded by the nursing staff or by the principal investigator. This method did not permit consistent recording of the food intake. Therefore, certain days or meals had to be excluded for the final analysis and thereby might have reduced the statistical significance of the results. Our results were obtained via differential weight measures have insured a better quantification of the food ingested. This method is believed to be more time consuming and expensive[110] but precision is an important factor when evaluating change in nutrient intake in a small sample.

At MR, the reformed foods had a positive impact on personnel. Many comments were gathered throughout the project. Nurses and orderlies appreciated being able to recognize the foods they were serving. Although the appreciation of the appearance of the foods was not specifically evaluated, these comments might reflect a preference for the feeder to give the entire serving and support the increased intake. A pilot study attempted to evaluate the appreciation of molded fruits[112]. An initial group of 12 dysphagic and 12 non-dysphagic individuals were chosen to rate the shaped pear and peaches. Due to health reasons, only 2 dysphagic individuals were able to complete the study. The preliminary results showed a lower rating of the molded fruits than the conventional products. A larger sample size would be required to confirm this information.

The experimental subjects received SAH's reformed foods and thickened beverages for 12-weeks resulting in a daily increase of 2357 kJ ± 1794 kJ at 6 weeks (Table 13), and of 2556 kJ ± 1709 kJ at 12 weeks (Table 15). This resulted in a statistically significant weight gain of 3.9 kg ± 2.3 kg at the final evaluation (Table 15). The dietary intake increase was confirmed by a rise in weight in the treated group. This also confirms that the days of food intake monitored were representative of usual intake and that the orderly staff were not over enthusiastic in their feeding habit the days of evaluation (potentially due to the presence of the study supervisor). An increase of more than 2200 kJ per day (500 kCal) is believed to generate an increase of 450g of fat per week[113]. Theoretically, an intervention of 12 weeks would have potentially increased the weight of the experimental group by 5.4 kg. Body composition was not assessed, therefore it is not clear at this point whether the subjects gained fat, water or muscle mass. Future studies are needed to evaluate and describe the change in body composition in elderly subjects following weight gain.

The final assessments also show that RNI in the treated group were met for all nutrients (Table 14). These results are encouraging since an increase in weight was possible after 12 weeks of intervention with the use of these new reformed foods. The number of supplements was not different from one group to the other (Table 18). An average BMI of 24.5 ± 4.14 kg/m^2 was also reached by the end of the 12th week for the treated group (Table 14).

A larger group would have been necessary to evaluate the cost effectiveness with the established parameters: development/evolution of pressure ulcers, bronchitis, pneumonia or other infections. Being closely related to a state of undernutrition, these indicators remain important for a future study. The mean number of prescriptions demonstrated a large standard deviation rendering statistically significant results unlikely (Tables 13 and 15). In addition, a larger group would be helpful in establishing a correlation between improvement of health status and the advanced nutritional approach suggested by SAH. Both groups lost a subject to death during the 12-week period (treated: 12.5% and control: 11.1% death rate). While this variable needs to be considered, it cannot be used as an outcome variable owing to the very large sample size that would be needed to detect differences in death rates.

The costs of care were not precisely evaluated but could be inferred as unchanged since no change in the critical indicators or health status was observed. In addition, the time required to feed was not significantly modified with the reformed foods therefore keeping the costs of feeding unchanged (Table17). Contrary to most medical parameters, the overall qualitative appreciation of the food by the subjects was somewhat more difficult to obtain. Dementia and confusion were highly prevalent in this group. The appreciation of the menu was indirectly evaluated by the feeder, which could have been biased. In a larger study, potentially more lucid subjects (as established by a Mini-Mental assessment) could be asked to participate in a discussion and tasting panel to generate more information on the appreciation of these products.

Although all aspects of the study were under the care and supervision of SAH's staff, it was observed that the feasibility of providing SAH's foods in the regular setting of MR center, without major modification of the kitchen routine and equipment, was possible. The staff at MR often commented on the simplicity of preparing the reformed foods.

This study should not be generalized to all the *old-old* or the *very-old* population due to its small sample size and the high variability observed in the standard deviations. The notorious heterogeneity of the elderly population requires judgment when interpreting data. The results also do not provide a prevalence of dysphagia in the elderly population and could not inform us on change in overall health status provided by the SAH's advanced nutritional care.

6. CONCLUSION

Malnutrition, and more specifically, protein-energy malnutrition is very common in the institutionalized elderly population[3,6-8]. Dysphagia is also an exacerbating factor of malnutrition and is a secondary condition in several degenerative diseases developing with old age[3,70].

A 12-week clinical trial using the SAH's reformed foods and thickened beverages was conducted. All the variables were successfully collected. Our results show a statistically significant change in energy intake and weight using SAH advanced nutritional care with a group of 8 treated individuals compared to 9 controls. Since the implementation of SAH's nutritional approach was meant to increase variety of foods, augment high-density foods and maintain a well balanced diet, these changes confirmed the expected results of the application of SAH's approach. Furthermore, all the established parameters were readily obtained during the clinical trial. The SAH's reformed foods were successful in providing appealing texture modified foods to the elderly dysphagic clientele.

Future studies should consider:

1) Enrolling a larger number of individuals to allow for the gathering of subjective information and evaluate certain parameters such as development of pressure ulcers, infections, pneumonia or bronchitis and permit the evaluation of a change in the number of prescribed medications,

2) Allowing the dietary service to prepare the foods and provide further information on how adaptable these products are in different kitchen settings.

3) Evaluating the dietary intake with a percentage of consumption method to save time and money as it is clear that subjects will eat more if given these foods.

4) A protocol to better document the pressure ulcers (according to stages) and the infections

It is crucial that we find a nutritive and appealing dietary solution to help the elderly dysphagic population. The correlation of textural studies and nutritional and clinical assessment of the subject must be at the core of the dysphagia treatment.

CONCLUSION

Undernutrition is a common reality seen in the institutionalized elderly and dysphagia is a condition affecting up to 60% of the elderly population. Both conditions are known to be associated. To facilitate the treatment of dysphagia and standardize the various clinical procedures, several dysphagia diets have been published in the literature but their clinical efficacy have not been established.

Test material used for diagnosis of dysphagia and the food presented in most dysphagia diets are qualitatively described[9-13]. In the clinical management of dysphagia, a multi-disciplinary approach is often required and demands a great deal of communication. It is believed that this affluence of terminology increases the challenge in providing an efficient clinical treatment for dysphagia and could lead to inadequate treatment and medical errors.

The lack of quantified standards has been commented on in the literature. Consequently, viscosity was used to describe certain foods offered in dysphagia diets. Robertson and Pattillo[53] used viscosity as a mean of quantification of the foods listed on the dysphagia diet they presented. Solids as well as liquids were included in this categorization. Mills[79] is the first to suggest a quantification of texture modified liquids using a 'wide-range' classification of viscosity obtained at a shear rate of $50s^{-1}$.

Although recognized as important, a quantification and classification of modified texture foods has not yet been published[80]. No study reported Texture Profile Analysis (TPA) of the modified texture solids offered to dysphagic individuals. In order to reach a standardized dysphagia diet that is clinically efficient, the quantification of textural characteristics of foods is necessary.

The first segment of this study evaluated the rheological parameters of Sainte-Anne Hospital's thickened beverages and reformed minced and pureed foods used in the clinical management of dysphagia. It was established that a moderate correlation between the Bostwick consistency values and the apparent viscosity values was present. The apparent viscosity values observed for the thickened beverages (shear rate of $50s^{-1}$ at 8°) did not correspond to the 'wide-range' viscosity classification suggested by Mills[79]. Nevertheless, a retrospective study of SAH thickened beverages had shown clinical effectiveness in 1993[15]. Associated to the use of reformed modified texture foods in the clinical randomized trial conducted at Marie-Rollet long-term care center, the beverages assisted in the increase in food intake and weight augmentation of the treated subjects.

Texture profile analyses were performed on all SAH's modified texture foods. The foods were evaluated for 7 of their textural parameters: firmness, chewiness, cohesiveness, springiness, elasticity, gumminess and firmness of the second bite. Our results show that cohesiveness and springiness have the lowest variability coefficients within each group of products. Consequently, these 2 parameters might be important rheological parameters to consider when discussing food profiles in the treatment of dysphagia. Future studies are required to clearly establish the link between various medical profiles of dysphagic individuals and the textural parameters of the TPA that would most benefit the appropriate clinical treatment.

The present study evaluated the rheological parameter of only the new reformed foods offered as SAH's dysphagia diet. For many subjects, other regular foods were used in conjunction with SAH's reformed foods and thickened beverages. Future studies should also include the assessment of those foods and beverages. In addtion, a correlation between the diagnostic tools such as barium and the actual food used in the treatment of dysphagia should be documented with quantitative rheological comparison parameters. Such a correlation would permit a better continuity between diagnosis and treatment.

In addition, a randomized clinical trial was undertaken with 17 elderly dysphagic individuals at Marie-Rollet long-term care center. This study was aimed at evaluating the impact of SAH's dysphagia diet on nutritional intake and weight over a period of 12 weeks. The results concurred with the current literature and showed a depleted nutritional status for institutionalized dysphagic elderly. The dietary composition of the modified texture diet was higher in energy, protein and lipids. It was demonstrated that high-density reformed foods could bring statistically significant weight gain, within a 12-week period, in frail elderly dysphagic subjects. Using these reformed foods did not involve longer feeding period and was appreciated by personnel.

The aging of the population and the increasing development of major illness such as Parkinson's Disease, strokes and Alzheimer's Disease bring us to question the quality of care given to the institutionalized elderly. Given the high prevalence of undernutrition and dysphagia in this segment of the population, it is undeniable that the constant evolution of these ailment calls for a vigilant and comprehensive follow-up for all professionals involved with institutionalized dysphagic individuals. The effect of an inadequate nutritional intake has important repercussions on the physical, psychological and overall quality of life of the patient. Although the small sample size did not permit the observation of changes in medical condition, this randomized clinical trial provides clear evidence that modified texture foods result in better intake and weight gain when compared to the traditional pureed foods.

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LIST OF TABLES

Table 1: Recommended BMI (kg/m^2), according to age
Adapted from Kushner et al., 1993[23], Cot et al., 1996[48] and Allison et al., 1997[25]

Organizations	Sex	Age (years)	Recommended BMI
US Departments of Agriculture and Health and Human Services (USDA/DHHS)	Both	35	21 - 27
National Academy of Science (NAS)	Both	65	24 - 29
National Center for Health Statistics (NCHS)	Male	20 - 74	20.7 - 27.8
	Female	20 - 74	19.1 - 27.3
World Health Organization (WHO)	Both	Adults	20 - 25
Gaudreault et Sanscartier[13]	Both	65 65 - 80 80	20 - 25 23 - 27 24 - 29
Allison et al.[25]	Male	70 - 99	27 - 30
	Female	70 - 99	30 - 35
Ministry of National Health and Welfare Canada (Canadian)	Both	20 - 65	20 - 27

Table 2: Common Food Items and Commercial Thickeners
adapted from Stanek et al., 1992[66] et Pelletier, 1997[65]

Domestic Products	Commercial Products
Baby rice cereal	Thick It[1]
Baby apple flakes	Nutra Thik[2]
Strained applesauce	Thick'N Easy[3]
Applesauce	Thicken Right[2]
Canned pudding	Thicken Up[4]
Instant pudding	Quik Thick[5]
Bread crumbs	
Graham crackers crumbs	
Yogurt	
Tofu	

1- Milani Foods
2- Menu Magic, Division of NALCO
3- American Institutional Products
4- Sandoz Nutrition
5- Gage Food Products Co.

Table 3: Consistency Index. Flow Behavior Index, Yield Stress and Apparent Viscosity of Thickened Beverages, shear rate of $50s^{-1}$ at 8°C

Products of Nectar Consistency									
	m Index[a]	**SD**	**n Index[b]**	**SD**	R^2	**YS[c]**	**SD**	**Viscosity[d]**	**SD**
Vanilla Supplement	2.93	0.50	0.65	0.03	0.96	7.67	0.50	904	36.25
Strawberry Supplement	3.58	0.66	0.64	0.04	0.95	7.69	1.55	1033	42.07
Milkshake	2.28	0.44	0.61	0.04	0.96	0.69	0.18	513	12.56
Milk 2%	3.34	0.52	0.57	0.03	0.95	1.82	1.67	654	19.35
High Protein Group Average	*3.03*		*0.62*		*0.96*	*4.47*		*776*	
High Protein Group Std Dev	*0.56*		*0.04*		*0.00*	*3.74*		*235*	
Prune Juice	1.88	0.06	0.59	0.01	0.96	2.11	0.21	425	13.04
Orange Juice	3.60	0.22	0.47	0.01	0.97	0.28	0.24	463	9.55
Apple Juice	2.76	0.37	0.62	0.02	0.96	2.76	0.34	684	20.12
Cranberry Juice	1.61	0.39	0.40	0.03	0.92	4.52	0.14	239	17.32
Juice Group Average	*2.46* ♀ ☼		*0.52* ♀ ☼		*0.95*	*2.42* ♀ ☼		*453* ♀ ☼	
Juice Group Std Dev.	*0.90*		*0.11*		*0.02*	*1.75*		*182*	
Group Average	***2.75***		***0.57***		***0.96***	***3.44***		***615***	
Std Dev.	***0.76***		***0.09***		***0.02***	***2.92***		***261***	
Products of Honey Consistency									
	m Index[a]	**SD**	**n Index[b]**	**SD**	R^2	**YS[c]**	**SD**	**Viscosity[d]**	**SD**
Banana Supplement	1.96	0.73	0.66	0.07	0.94	15.32	2.26	807	9.20
Vanilla Supplement	9.16	1.95	0.53	0.04	0.94	29.56	4.38	2024	130.89
Strawberry Supplement	5.96	1.05	0.68	0.04	0.98	23.39	1.72	2129	54.23
Chocolate Supplement	9.20	0.29	0.60	0.00	0.97	23.26	1.30	2359	41.13
Milkshake	8.18	0.29	0.51	0.00	0.97	5.73	0.50	1307	17.70
Milk 2%	16.48	0.18	0.42	0.00	0.98	1.68	0.76	1749	53.29
High Protein Group Average	*8.49*		*0.57*		*0.96*	*16.49*		*1729*	
High Protein Group Std Dev	*4.77*		*0.10*		*0.02*	*10.96*		*578*	
Prune Juice	7.28	0.70	0.71	0.02	0.98	18.42	0.75	2701	44.05
Vegetable Juice	2.97	0.68	0.44	0.06	0.94	4.88	1.28	427	17.45
Orange Juice	10.28	1.74	0.25	0.02	0.88	4.14	0.68	617	50.94
Apple Juice	3.14	0.22	0.76	0.02	0.97	18.46	0.53	1593	60.72
Cranberry Juice	10.90	0.80	0.21	0.01	0.88	3.40	0.95	560	8.02
Juice Group Average	*6.91*		*0.47*		*0.93*	*9.86*		*1180*	
Juice Group Std Dev.	*3.78*		*0.26*		*0.05*	*7.85*		*969*	
Group Average	***7.77*** ♀ ✚		***0.52*** ♀ ✚		***0.95***	***13.48*** ♀ ✚		***1479*** ♀ ✚	
Std Dev.	***4.22***		***0.18***		***0.04***	***9.83***		***790***	
Products of Pudding Consistency									
	m Index[a]	**SD**	**n Index[b]**	**SD**	R^2	**YS[c]**	**SD**	**Viscosity[d]**	**SD**
Banana Supplement	10.76	2.11	0.47	0.04	0.93	41.96	3.21	2184	46.83
Strawberry Supplement	20.27	3.33	0.47	0.06	0.92	113.75	1.29	4793	226.98
Vanilla Supplement	25.06	2.11	0.51	0.01	0.95	49.56	3.04	4693	194.55
Chocolate Supplement	9.34	1.84	0.64	0.05	0.98	51.79	3.67	3254	11.21
Milkshake	26.72	3.29	0.48	0.02	0.99	21.71	1.65	3896	188.62
Milk 2%	36.24	4.22	0.35	0.02	0.98	7.43	4.01	3015	58.48
High Protein Group Average	*21.40* †		*0.49*		*0.96*	*47.70*		*3639*	
High Protein Group Std Dev	*10.21*		*0.09*		*0.03*	*36.64*		*1016*	
Vegetable Juice	6.64	0.16	0.48	0.02	0.94	43.18	1.97	1748	42.21
Prune Juice	16.05	0.94	0.66	0.01	0.98	27.36	3.66	4880	404.17
Orange Juice	5.19	1.00	0.50	0.03	0.92	43.77	1.79	1602	50.63
Apple Juice	5.07	1.79	0.68	0.06	0.92	51.13	1.25	2397	197.77
Cranberry Juice	14.14	4.95	0.66	0.07	0.99	33.00	14.72	4272	47.73
Juice Group Average	*9.42* †		*0.60*		*0.95*	*39.69*		*2980*	
Juice Group Std Dev.	*5.26*		*0.10*		*0.03*	*9.44*		*1503*	
Group Average	***15.95*** ☼ ✚		***0.54*** ☼ ✚		***0.96***	***44.06*** ☼ ✚		***3339*** ☼ ✚	
Std Dev.	***10.12***		***0.11***		***0.03***	***26.92***		***1240***	

[a]: Consistency Index [b]: Flow Behavior Index [c]: Yield Stress [d]: Viscosity calculated according to the Herschel Bulkley equation

♀ Products of Nectar Consistency versus Honey Consistency; $p < 0.05$

☼ Products of Pudding Consistency versus Nectar Consistency; $p < 0.05$

✚ Products of Honey Consistency versus Pudding Consistency; $p < 0.05$

† High Protein group versus Juice group, Pudding Consistency; $p < 0.05$

Table 4a : Texture Profile Analysis of the Reformed Minced Meats offered at SAH at 65°C

	Firmness 1		Springiness		Cohesiveness		Adhesiveness		Gumminess		Chewiness		Firmness 2	
	N		mm		Ratio		N		N		N		N	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Meat Balls	1.705	0.32	2.190	0.30	0.244	0.06	-0.377	0.19	0.424	0.14	0.957	0.39	1.300	0.32
Chicken Breasts	3.459	0.45	1.725	0.20	0.198	0.03	-0.264	0.18	0.695	0.18	1.224	0.44	2.883	0.44
Pork Chop	4.452	0.62	2.466	0.12	0.274	0.03	-0.563	0.27	1.226	0.26	3.042	0.76	3.198	0.42
Lamb Chop	17.040	1.26	2.802	0.13	0.393	0.03	-2.453	0.85	6.708	0.89	18.859	3.11	13.885	1.09
Fall Stew	1.669	0.47	1.471	0.29	0.186	0.06	-0.430	0.08	0.302	0.09	0.456	0.22	1.316	0.35
Bourguignon Stew	2.516	0.23	1.953	0.37	0.202	0.02	-0.823	0.29	0.508	0.05	7.234	2.57	1.843	0.14
Chicken Brochette	3.800	0.64	1.526	0.26	0.178	0.04	-0.893	0.25	0.682	0.22	1.077	0.51	2.973	0.55
Soukiaki Stew	2.536	0.42	1.995	0.11	0.231	0.00	-0.395	0.21	0.588	0.11	1.179	0.26	1.876	0.35
Stroganoff Stew	2.361	0.24	1.895	0.10	0.237	0.01	-0.825	0.48	0.561	0.08	1.069	0.21	1.791	0.05
Beef slices	3.421	0.42	2.366	0.18	0.299	0.01	-0.221	0.11	1.027	0.17	2.445	0.52	2.682	0.35
Turkey slices	10.078	0.98	2.485	0.26	0.339	0.04	-0.842	0.28	3.433	0.60	8.648	2.22	8.315	0.77
Ham slices (hot)	2.525	0.51	2.686	0.33	0.290	0.06	-0.416	0.08	0.729	0.19	1.999	0.71	1.948	0.55
Veal slices	3.140	0.45	2.360	0.18	0.272	0.04	-0.348	0.14	0.870	0.27	2.086	0.79	2.183	0.40
Group Mean	4.516		2.148		0.257		-0.681		1.366		3.867		3.553	
Standard deviation	4.33		0.43		0.06		0.58		1.79		5.15		3.59	
Variation coefficient (%)	96		20		24		86		131		133		101	
Minimum value	1.669		1.471		0.178		-2.453		0.302		0.456		1.300	
Maximum value	17.04		2.802		0.393		-0.221		6.708		18.86		13.89	
Range	15.37		1.33		0.215		2.23		6.41		18.40		12.58	

Table 4b : Texture Profile Analysis of the Reformed Minced Meats offered at SAH at 65°C (excluding the lamb chop and the turkey slices)

	Firmness 1		Springiness		Cohesiveness		Adhesiveness		Gumminess		Chewiness		Firmness 2	
	N		mm		Ratio		N		N		N		N	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Meat Balls	1.705	0.32	2.190	0.30	0.244	0.06	-0.377	0.19	0.424	0.14	0.957	0.39	1.300	0.32
Chicken Breasts	3.459	0.45	1.725	0.20	0.198	0.03	-0.264	0.18	0.695	0.18	1.224	0.44	2.883	0.44
Pork Chop	4.452	0.62	2.466	0.12	0.274	0.03	-0.563	0.27	1.226	0.26	3.042	0.76	3.198	0.42
Fall Stew	1.669	0.47	1.471	0.29	0.186	0.06	-0.430	0.08	0.302	0.09	0.456	0.22	1.316	0.35
Bourguignon Stew	2.516	0.23	1.953	0.37	0.202	0.02	-0.823	0.29	0.508	0.05	7.234	2.57	1.843	0.14
Chicken Brochette	3.800	0.64	1.526	0.26	0.178	0.04	-0.893	0.25	0.682	0.22	1.077	0.51	2.973	0.55
Soukiaki Stew	2.536	0.42	1.995	0.11	0.231	0.00	-0.395	0.21	0.588	0.11	1.179	0.26	1.876	0.35
Stroganoff Stew	2.361	0.24	1.895	0.10	0.237	0.01	-0.825	0.48	0.561	0.08	1.069	0.21	1.791	0.05
Beef slices	3.421	0.42	2.366	0.18	0.299	0.01	-0.221	0.11	1.027	0.17	2.445	0.52	2.682	0.35
Ham slices (hot)	2.525	0.51	2.686	0.33	0.290	0.06	-0.416	0.08	0.729	0.19	1.999	0.71	1.948	0.55
Veal slices	3.140	0.45	2.360	0.18	0.272	0.04	-0.348	0.14	0.870	0.27	2.086	0.79	2.183	0.40
Group Mean	2.871		2.058		0.238		-0.505		0.692		2.070		2.181	
Standard deviation	0.87		0.39		0.04		0.24		0.27		1.87		0.66	
Variation coefficient (%)	30		19		18		47		39		91		30	
Minimum value	1.669		1.471		0.178		-0.893		0.302		0.456		1.300	
Maximum value	4.452		2.686		0.299		-0.221		1.226		7.234		3.198	
Range	2.784		1.215		0.121		0.671		0.924		6.778		1.898	

<u>Table 5</u> : Texture Profile Analysis of SAH Reformed Pureed Meats at 65°C (excluding the lamb chop and the turkey slices)

	Firmness 1		Springiness		Cohesiveness		Adhesiveness		Gumminess		Chewiness		Firmness 2	
	N		mm		Ratio		N		N		N		N	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Meat Balls	1.35	0.21	1.99	0.27	0.270	0.06	-0.562	0.24	0.371	0.12	0.766	0.34	1.122	0.20
Chicken Breast	4.39	0.29	1.69	0.59	0.265	0.10	-0.901	0.17	1.146	0.40	2.097	1.36	4.053	0.53
Pork Chop	4.58	0.71	2.38	0.20	0.340	0.03	-0.729	0.19	1.567	0.36	3.761	1.07	3.886	0.65
Brouguignon Stew	4.02	0.76	1.28	0.17	0.166	0.02	-0.528	0.14	0.667	0.17	0.874	0.35	3.281	0.55
Fall Stew	2.58	0.40	1.76	0.32	0.212	0.05	-0.840	0.24	0.560	0.20	7.836	4.64	2.091	0.38
Chicken Brochette	3.19	0.59	2.43	0.19	0.332	0.03	-0.440	0.22	1.058	0.19	2.591	0.59	2.790	0.48
Soukiaki Stew	2.24	0.28	1.75	0.49	0.244	0.08	-0.568	0.14	0.552	0.22	1.037	0.62	1.909	0.35
Stroganoff Stew	2.41	0.34	1.84	0.15	0.228	0.03	-1.380	0.26	0.543	0.02	0.999	0.07	1.838	0.19
Beef slices	3.33	0.21	1.85	0.21	0.275	0.04	-0.712	0.29	0.916	0.14	1.706	0.40	2.721	0.16
Ham slices (hot)	2.40	0.43	2.05	0.23	0.327	0.05	-0.792	0.10	0.792	0.19	1.649	0.49	2.085	0.35
Veal slices	2.90	0.40	2.36	0.41	0.360	0.07	-0.620	0.20	1.040	0.24	2.520	1.02	2.502	0.29
Group Mean	3.04		1.94		0.274		-0.734		0.837		2.349		2.571	
Standard deviation	0.99		0.35		0.06		0.26		0.35		2.03		0.90	
Variation coefficient (%)	33		18		22		35		42		87		35	
Minimum value	1.350		1.282		0.166		-1.380		0.371		0.766		1.122	
Maximum value	4.576		2.434		0.360		-0.440		1.567		7.836		4.053	
Range	3.225		1.152		0.194		0.940		1.195		7.070		2.931	

Table 6 : Texture Profile analysis of the SAH Reformed Pureed vegetables at 65°C

	Firmness 1		Springiness		Cohesiveness		Adhesiveness		Gumminess		Chewiness		Firmness 2	
	N		mm		Ratio		N		N		N		N	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Asparagus	0.740	0.12	1.55	0.14	0.210	0.04	-0.229	0.06	0.157	0.04	0.244	0.07	0.612	0.12
Broccoli	1.030	0.11	1.32	0.11	0.202	0.01	-0.505	0.08	0.209	0.02	0.278	0.05	0.877	0.08
Baby Carrots	0.621	0.20	1.48	0.21	0.266	0.09	-0.476	0.12	0.164	0.07	0.252	0.13	0.565	0.15
Waxed Beans	0.603	0.17	1.09	0.09	0.162	0.03	-0.256	0.06	0.095	0.02	0.105	0.03	0.459	0.11
Green Beans	0.428	0.04	1.61	0.23	0.257	0.04	-0.337	0.09	0.111	0.02	0.182	0.05	0.370	0.07
Green Peas	0.826	0.12	1.43	0.21	0.224	0.07	-0.570	0.11	0.188	0.07	0.280	0.15	0.634	0.12
Group Mean	0.708		1.41		0.220		-0.395		0.154		0.223		0.586	
Standard deviation	0.21		0.19		0.04		0.14		0.04		0.07		0.17	
Variation coefficient (%)	29		13		17		36		28		30		30	
Minimum value	0.428		1.09		0.162		-0.570		0.095		0.105		0.370	
Maximum value	1.030		1.61		0.266		-0.229		0.209		0.280		0.877	
Range	0.602		0.518		0.105		0.341		0.113		0.175		0.508	

Table 7 : Texture Profile Analysis of the SAH Reformed Pureed Cakes at 8°C

	Firmness 1		Springiness		Cohesiveness		Adhesiveness		Gumminess		Chewiness		Firmness 2	
	N		mm		Ratio		N		N		N		N	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Choco-Moka cake	3.90	0.64	3.83	0.11	0.481	0.08	-0.538	0.12	1.91	0.58	7.29	2.11	3.43	0.58
Banana cake	6.49	0.33	3.70	0.29	0.521	0.04	-1.455	0.18	3.39	0.36	12.6	2.03	5.13	0.50
Carrot cake	4.97	0.35	3.90	0.21	0.536	0.07	-0.993	0.05	2.66	0.35	10.4	1.87	4.50	0.30
Black Forest cake	6.29	0.65	4.12	0.16	0.530	0.10	-0.506	0.25	3.32	0.58	13.6	2.34	5.59	0.50
Orange cake	3.22	0.39	3.61	0.23	0.456	0.07	-0.608	0.15	1.45	0.07	5.23	0.54	2.76	0.32
Apple cake	2.69	0.32	3.73	0.16	0.446	0.05	-0.540	0.12	1.20	0.20	4.50	0.88	2.40	0.26
Group Mean	4.59		3.81		0.495		-0.773		2.32		8.94		3.97	
Standard deviation	1.6		0.18		0.04		0.38		0.94		3.83		1.30	
Variation coefficient (%)	35		4.7		7.9		49		41		43		33	
Minimum value	2.69		3.61		0.446		-1.45		1.20		4.50		2.40	
Maximum value	6.49		4.12		0.536		-0.506		3.39		13.6		5.59	
Range	3.80		0.508		0.090		0.949		2.18		9.12		3.19	

Table 8: Significance Levels for Changes in Nutrient Intake in Treated and Control Subjects for 6-week *versus* Baseline and 12-week *versus* Baseline using paired *t*-test

	Baseline *versus* Week 6		Baseline *versus* Week 12	
Variables	Treated	Controls	Treated	Controls
	P-Value	P-Value	P-Value	P-Value
NB Prescriptions	< 0.01			
Weight			< 0.01	
BMI			< 0.01	
Energy	< 0.01		< 0.05	
Protein	< 0.01		< 0.05	
Carbohydrate	< 0.05		< 0.05	
Lipid			< 0.05	
Cholesterol	< 0.05			
Total Fiber (g)				
Sodium	< 0.05			
Potassium	< 0.05		< 0.05	
Magnesium	< 0.01		< 0.05	
Calcium	< 0.01		< 0.01	
Phosphorus	< 0.01		< 0.01	
Iron				< 0.05
Zinc	< 0.05		< 0.05	
Carotene				
Vitamin A	< 0.05			
Vitamin C				
Vitamin D	< 0.01		< 0.01	
Vitamin B_3	< 0.05			
Vitamin B_2	< 0.01		< 0.01	
Vitamin B_1	< 0.05		< 0.05	
Vitamin B_6	< 0.05			
Vitamin B_{12}	< 0.01		< 0.05	
Ac. Pantotenic	< 0.05			
Folacin	< 0.05			
Total Saturated Fat (g)	< 0.01	< 0.05	< 0.01	
Monounsaturated Fat (g)	< 0.05		< 0.05	
Polyunsaturated Fat (g)				
Vitamin E	< 0.05		< 0.05	
Copper				
Manganese				

Table 9: Principal Characteristics for the Individuals Entering the Protocol (Baseline Values)

Characteristics	Control Group (n = 9)	Treated Group (n = 8)	p-Value
Number of females	5	5	
Time post admission (Years ± SD)	4.8 ± 1.90	3.9 ± 1.66	
Age (Years ± SD)	84.6 ± 3.81	82.5 ± 4.41	0.3186
Weight (kg ± SD)	54.3 ± 7.49	55.9 ± 12.09	0.7434
BMI (kg/m^2 ± SD)	22.4 ± 3.93	21.2 ± 2.31	0.4471
Primary Diagnostics			
Alzheimer's Disease	5 (55.6%)	3 (37.5%)	
Parkinson's Disease	1 (11.1%)	0 (0%)	
Other dementias	2 (22.2%)	4 (50%)	
Stoke	1 (11.1%)	1 (12.5%)	
Number of Prescriptions	5.0 ± 2.55	8.6 ± 5.07	0.0772
Number of smokers	0	1	

No statistical difference was noted when comparing the baseline parameters of both groups

Table 10: Diet Prescriptions Prior and During the Protocol Period

Pre-Protocol Diet Prescription

Control Group	Pureed	Minced 3	Minced 70	Regular	*Treated Group*	Pureed	Minced 3	Minced 70	Regular
Clear liquids	2		5	1	Clear liquids		1	4	1
Nectar liquids					Nectar liquids				
Honey liquids			1		Honey liquids	1		1	
Pudding liquids					Pudding liquids				

First Dietary Intake Evaluation

Control Group	Pureed	Minced 3	Minced 70	Regular	*Treated Group*	Pureed	Minced 3	Minced 70	Regular
Clear liquids	3		2	1	Clear liquids		1	4	1
Nectar liquids					Nectar liquids				
Honey liquids	2		1		Honey liquids	1		1	
Pudding liquids					Pudding liquids				

Midway Dietary Intake Evaluation

Control Group	Pureed	Minced 3	Minced 70	Regular	*Treated Group*	P/F HSA	MP/F HSA	M/F HSA	Regular
Clear liquids	3		2	1	Clear liquids	1	1	4	
Nectar liquids					Nectar liquids				1
Honey liquids	2		1		Honey liquids				
Pudding liquids					Pudding liquids	1			

Final Dietary Intake Evaluation

Control Group	Pureed	Minced 3	Minced 70	Regular	*Treated Group*	P/F HSA	MP/F HSA	M/F HSA	Regular
Clear liquids	1	1	1	1	Clear liquids	2	2	2	
Nectar liquids					Nectar liquids				1
Honey liquids	2		2		Honey liquids				
Pudding liquids					Pudding liquids				

Table 11: Energy Intake and Nutrient Composition of the Groups at the Baseline Assessment

	Control (n = 9)		Treated Group (n = 8)		*t*-test
Variables	Mean	SD	Mean	SD	p-Values
Weight (kg)	54.3	7.50	55.9	12.1	0.7434
Number of Prescriptions	5.00	2.50	8.60	5.00	0.0772
BMI	21.2	2.30	22.4	3.90	0.4471
Energy (kJ)	6551	1352	5748	985	0.1864
Protein (g)	56.0 (14%)	16.8	52.5 (15%)	14.6	0.6574
Carbohydrate (g)	238 (59%)	45.2	211 (59%)	23.4	0.1466
Lipid (g)	47.4 (27%)	13.7	39.3 (26%)	12.2	0.2177
Cholesterol (mg)	131	70.8	123	15.4	0.7912
Total Fiber (g)	16.9	6.78	12.6	4.68	0.1553
Sodium (mg)	2519	624	2580	820	0.8629
Potassium (mg)	2885	625	2704	637	0.5631
Magnesium (mg)	256	50.8	240	76.2	0.6129
Calcium (mg)	757	209	639	312	0.3683
Phosphorus (mg)	1107	251	975	299	0.3382
Iron (mg)	13.5	4.97	12.2	2.84	0.5199
Zinc (mg)	8.88	3.50	7.90	4.16	0.6061
Carotene (RE)	136	117	167	258	0.7654
Vitamin A (RE)	1150	387	1339	531	0.4121
Vitamin C (mg)	155	51.4	136	74.9	0.5503
Vitamin D (μg)	4.45	1.81	3.39	2.46	0.3230
Vitamin B_1 (mg)	1.63	0.74	1.39	0.58	0.4638
Vitamin B_2 (mg)	1.93	0.97	1.38	0.47	0.1623
Vitamin B_3 (NE)	22.3	6.54	23.0	7.52	0.8582
Vitamin B_6 (mg)	1.36	0.33	1.53	0.60	0.4845
Vitamin B_{12} (μg)	2.57	1.39	2.82	1.49	0.7298
Pantothenic Acid (mg)	4.53	1.42	3.80	1.56	0.3314
Folacin (μg)	193	61.0	176	70.6	0.5967
Total Saturated Fat (g)	11.3	4.95	11.7	6.03	0.8828
Monounsaturated Fat (g)	10.8	4.87	13.2	7.46	0.4429
Polyunsaturated Fat (g)	5.84	2.67	6.72	3.39	0.5605
Vitamin E (mg)	2.22	1.04	1.62	0.92	0.2313
Copper (mg)	0.98	0.25	1.01	0.40	0.8581
Manganese (mg)	3.17	1.22	2.75	1.20	0.4898

Table 12: Energy Intake and Nutrient Composition of the Groups at the Midway Assessment

	Control (n = 9)		Treated Group (n = 8)		*t*-test
Variables	Mean	SD	Mean	SD	P-Value
Weight (kg)	53.7	8.23	57.2	10.7	0.4559
Number of Prescriptions	5.67	3.12	7.63	4.50	0.3092
BMI	20.9	2.40	23.0	3.61	0.1832
Energy (kJ)	6223	2116	8105	2050	0.0831
Protein (g)	54.8 (15%)	23.7	84.4 (17%)	26.3	**0.0273**
Carbohydrate (g)	222 (57%)	66.0	275 (56%)	68.2	0.1262
Lipid (g)	45.9 (28%)	24.8	59.1 (27%)	15.6	0.2140
Cholesterol (mg)	125	88.7	191	71.0	0.1137
Total Fiber (g)	17.6	9.97	10.8	4.27	0.0864
Sodium (mg)	2475	974	3338	1396	0.1560
Potassium (mg)	2726	861	3885	1142	**0.0310**
Magnesium (mg)	255	121	377	112	**0.0493**
Calcium (mg)	701	287	1331	671	**0.0353**
Phosphorus (mg)	1087	369	1651	606	**0.0331**
Iron (mg)	13.6	7.26	15.4	4.93	0.5667
Zinc (mg)	8.72	5.96	14.5	4.97	**0.0486**
Carotene (RE)	124	114	322	349	0.1623
Vitamin A (RE)	1199	672	1716	611	0.1191
Vitamin C (mg)	162	68.0	174	43.2	0.6751
Vitamin D (μg)	4.73	2.36	8.89	5.85	0.0930
Vitamin B_1 (mg)	1.56	1.00	2.00	0.77	0.3344
Vitamin B_2 (mg)	1.73	0.84	2.91	1.24	**0.0345**
Vitamin B_3 (NE)	22.4	11.5	37.4	12.5	**0.0209**
Vitamin B_6 (mg)	1.26	0.65	2.68	0.85	**0.0014**
Vitamin B_{12} (μg)	3.08	2.06	6.23	2.23	**0.0084**
Pantothenic Acid (mg)	4.56	3.33	5.56	2.25	0.4832
Folacin (μg)	203	141	298	87.4	0.1223
Total Saturated Fat (g)	9.37	6.00	18.0	6.66	**0.0132**
Monounsaturated Fat (g)	9.21	6.39	18.4	6.21	**0.0092**
Polyunsaturated Fat (g)	4.85	3.54	7.77	2.78	0.0808
Vitamin E (mg)	1.78	0.75	6.64	4.87	**0.0258**
Copper (mg)	0.92	0.49	1.15	0.53	0.3594
Manganese (mg)	3.22	2.12	2.75	1.25	0.5913

Table 13: Change in the Energy Intake and Nutrient Composition of the Groups (Baseline *vs* Midway Assessment)

	Control (n = 9)		Treated (n = 8)		*t*-test
Variables	Mean	SD	Mean	SD	p-Values
Weight (kg)	-0.61	2.23	1.31	2.85	0.1396
BMI	-0.29	0.97	0.57	1.12	0.1147
Energy (kJ)	-329	1239	2357	1794	**0.0025**
Protein (g)	-1.22	14.4	31.9	23.4	**0.0028**
Carbohydrate (g)	-16	45	64	62	**0.0078**
Lipid (g)	-1.51	13.0	19.9	14.8	**0.0062**
Cholesterol (mg)	-6.44	27.5	67.4	65.1	**0.0150**
Total Fiber (g)	0.70	3.98	-1.88	4.98	0.2539
Sodium (mg)	-44.0	517	758	815	**0.0269**
Potassium (mg)	-159	498	1181	978	**0.0025**
Magnesium (mg)	-0.78	78.7	137	107	**0.0081**
Calcium (mg)	-56.1	187	692	455	**0.0018**
Phosphorus (mg)	-19.8	266	675	423	**0.0009**
Iron (mg)	0.16	1.83	3.26	4.16	0.0889
Zinc (mg)	-0.17	6.43	6.57	5.40	**0.0348**
Carotene (RE)	-12.2	124	155	336	0.2174
Vitamin A (RE)	48.4	463	378	400	0.1400
Vitamin C (mg)	6.67	46.5	37.5	48.9	0.2026
Vitamin D (μg)	0.28	2.44	5.50	4.02	**0.0050**
Vitamin B_1 (mg)	-0.07	0.40	0.61	0.55	**0.0101**
Vitamin B_2 (mg)	-0.20	1.39	1.53	0.87	**0.0085**
Vitamin B_3 (NE)	0.05	7.33	14.5	12.1	**0.0089**
Vitamin B_6 (mg)	-0.11	0.54	1.15	1.01	**0.0052**
Vitamin B_{12} (μg)	0.51	1.45	3.41	2.35	**0.0071**
Pantothenic Acid (mg)	0.03	2.24	1.76	1.82	0.1030
Folacin (μg)	9.75	93.0	122	124	**0.0507**
Total Saturated Fat (g)	-1.92	2.14	6.31	4.47	**0.0002**
Monounsaturated Fat (g)	-1.60	2.51	5.19	5.14	**0.0070**
Polyunsaturated Fat (g)	-0.10	2.01	1.05	3.40	0.1482
Vitamin E (mg)	-0.44	1.31	5.01	4.53	**0.0110**
Copper (mg)	-0.07	0.28	0.14	0.37	0.2107
Manganese (mg)	0.56	1.10	0.00	0.76	0.9064

Table 14: Energy Intake and Nutrient Composition of the Groups at the Final Assessment

	Control (n = 8)		Treated Group (n = 7)		*t*-test
Variables	Mean	SD	Mean	SD	P-Value
Weight (kg)	53.4	5.87	59.9	13.0	0.2213
Number of Prescriptions	4.13	2.36	7.71	4.75	0.0807
BMI	21.2	2.00	24.5	4.14	0.0642
Energy (kJ)	6708	1533	8148	1324	0.0755
Protein (g)	56.6 (14%)	19.8	83.1 (17%)	21.2	**0.0265**
Carbohydrate (g)	254 (63%)	66.8	272 (56%)	44.5	0.5458
Lipid (g)	43.3 (24%)	11.1	62.3 (29%)	11.2	**0.0058**
Cholesterol (mg)	165	120	209	97.9	0.4614
Total Fiber (g)	16.2	4.57	12.2	4.01	0.0980
Sodium (mg)	2781	927	3270	915	0.3236
Potassium (mg)	3095	689	3913	665	**0.0364**
Magnesium (mg)	253	74.0	366	92.2	**0.0204**
Calcium (mg)	865	257	1347	644	0.1024
Phosphorus (mg)	115	270	1640	450	**0.0345**
Iron (mg)	13.9	3.95	15.6	4.34	0.4491
Zinc (mg)	7.69	3.44	14.6	4.42	**0.0047**
Carotene (RE)	138	93.3	293	305	0.2438
Vitamin A (RE)	1258	427	1517	544	0.3214
Vitamin C (mg)	182	76.1	175	44.4	0.8223
Vitamin D (μg)	5.19	2.01	10.1	5.35	0.0526
Vitamin B_1 (mg)	1.54	0.40	1.92	0.68	0.1982
Vitamin B_2 (mg)	1.78	0.56	3.00	1.22	**0.0248**
Vitamin B_3 (NE)	22.2	8.01	36.2	10.9	0.0135
Vitamin B_6 (mg)	1.40	0.51	2.50	0.81	**0.0070**
Vitamin B_{12} (μg)	2.80	1.53	6.12	1.82	**0.0020**
Pantothenic Acid (mg)	4.66	1.35	5.79	2.08	0.2308
Folacin (μg)	204	66.6	295	104	0.0604
Total Saturated Fat (g)	10.9	6.21	19.0	2.76	**0.0068**
Monounsaturated Fat (g)	9.75	6.64	20.1	5.39	**0.0060**
Polyunsaturated Fat (g)	5.27	4.45	8.51	2.64	0.1164
Vitamin E (mg)	2.70	1.58	5.89	4.70	0.1291
Copper (mg)	1.01	0.33	1.18	0.30	0.3136
Manganese (mg)	2.94	1.40	2.71	0.81	0.7172

Table 15: Change in the Energy Intake and Nutrient Composition of the Groups (Baseline *vs* End Assessment)

	Control (n = 8)		Treated (n = 7)		*t*-test
Variables	Mean	SD	Mean	SD	p-Values
Weight (kg)	-0.79	4.18	3.90	2.30	**0.0208**
BMI	-0.27	1.46	1.63	1.01	**0.0127**
Energy (kJ)	340	707	2556	1709	**0.0252**
Protein (g)	2.14	10.0	28.6	26.0	**0.0366**
Carbohydrate (g)	18.1	32.3	59.3	51.1	0.0808
Lipid (g)	-0.75	7.34	21.1	18.4	**0.0195**
Cholesterol (mg)	26.3	64.7	76.1	107	0.2875
Total Fiber (g)	1.19	2.53	0.61	1.95	0.6315
Sodium (mg)	322	488	583	768	0.4401
Potassium (mg)	261	435	1139	815	**0.0198**
Magnesium (mg)	5.94	53.3	112	110	**0.0306**
Calcium (mg)	108	161	674	480	**0.0199**
Phosphorus (mg)	100	187	628	410	**0.0059**
Iron (mg)	1.76	1.92	3.27	3.97	0.3557
Zinc (mg)	-0.83	3.50	5.93	4.65	**0.0069**
Carotene (RE)	-5.88	107	110	195	0.1682
Vitamin A (RE)	150	499	169	412	0.9379
Vitamin C (mg)	38.1	53.7	38.4	62.1	0.9923
Vitamin D (μg)	0.71	1.93	6.48	3.97	**0.0029**
Vitamin B_1 (mg)	0.12	0.27	0.48	0.73	0.2586
Vitamin B_2 (mg)	-0.16	0.79	1.54	0.86	**0.0015**
Vitamin B_3 (NE)	0.99	3.80	11.7	12.4	0.0642
Vitamin B_6 (mg)	0.06	0.46	0.84	1.03	0.0729
Vitamin B_{12} (μg)	0.28	0.77	2.98	2.37	**0.0229**
Pantothenic Acid (mg)	0.51	1.22	1.69	1.92	0.1708
Folacin (μg)	26.0	54.9	103	128	0.1768
Total Saturated Fat (g)	-1.18	2.70	5.99	3.71	**0.0008**
Monounsaturated Fat (g)	-1.75	3.32	5.18	5.58	**0.0109**
Polyunsaturated Fat (g)	-0.92	2.97	0.91	4.26	0.3460
Vitamin E (mg)	0.65	1.56	4.16	4.11	0.0684
Copper (mg)	0.09	0.22	0.10	0.35	0.9342
Manganese (mg)	0.65	1.56	4.16	4.11	0.0684

Table 16: Characteristics of the Feeding Approach During Meals

Control Group	Baseline	Midway	Final	Treated Group	Baseline	Midway	Final
SF	0	0	0	SF	3	2	2
FP	3	2	2	FP	2	3	2
FP-T	2	2	2	FP-T	0	0	1
FT	4	5	5	FT	3	3	3

SF: Mostly independent for feeding (opening of certain containers might be necessary)
FP: Partially dependent for feeding (opening of containers. verbal stimulation needed)
FP-T: Partially or totally dependent for feeding (will vary according to patients health status)
FT: Totally dependent for feeding

Table 17: Time Required to Feed

	Baseline Values - Feeding Time				
	Control (n = 9)		Treated Group (n = 8)		T-test
Variables	Mean	SD	Mean	SD	P-Value
Time for Breakfast (min.)	28.56	25.14	31.19	24.39	0.7594
Time for Lunch (min.)	25.00	14.15	32.81	15.06	0.1288
Time for Supper (min.)	22.78	7.92	32.06	17.71	0.0675
	Change in Feeding Time (Baseline vs Midway)				
	Control (n = 9)		Treated (n = 8)		
Variables	Mean	SD	Mean	SD	P-Value
Time for Breakfast (min.)	-1.89	22.73	8.13	13.84	0.1366
Time for Lunch (min.)	4.83	18.83	8.06	15.64	0.5930
Time for Supper (min.)	3.78	16.23	1.00	18.99	0.6487
	Change in Feeding Time (Baseline vs End)				
	Control (n = 8)		Treated (n = 7)		
Variables	Mean	SD	Mean	SD	P-Value
Time for Breakfast (min.)	-5.89	17.37	-5.75	23.61	0.9844
Time for Lunch (min.)	1.22	17.40	-2.69	21.86	0.5659
Time for Supper (min.)	6.39	17.21	-5.81	28.66	0.1514
	Change in Feeding Time (Midway vs End)				
	Control (n = 8)		Treated (n = 7)		
Variables	Mean	SD	Mean	SD	P-Value
Time for Breakfast (min.)	-2.50	25.02	-13.00	18.88	0.2103
Time for Lunch (min.)	0.69	14.65	-5.36	17.37	0.3100
Time for Supper (min.)	5.50	15.33	-2.79	21.35	0.2281

Table 18 : Averaged Number of Portions Consumed per Food Group at Final Assessment

	Treated Group			Control Group			P-Values
	Average	SD	Range	Average	SD	Range	
Dairy Products	3	2.24	0 - 6.5	2.83	2.33	0 - 6	0.8868
Vegetables	3.43	1.95	0 - 6	1.83	1.56	0 - 3.5	0.1034
Fruits	3.71	1.98	0 - 6.5	4.11	2.26	0 - 7	0.7141
Meats	1.21	0.7	0 - 2	0.67	0.66	0 - 1.5	0.136
Grains	1.71	0.95	0 - 3	1.28	0.75	0 - 2	0.3407
Combined dishes	1.43	1.43	0 - 3	2.44	1.31	0 - 4	0.168
Baked Goods	0.79	0.7	0 - 2	0.72	0.83	0 - 2.5	0.8708
Oil and Fats	1.21	0.91	0 - 3	0.44	0.53	0 - 1	0.0762
Sweets	1.29	0.95	0 - 2.5	1.11	0.65	0 - 2	0.6862
Supplements	0.93	1.24	0 - 3	0.61	1.05	0 - 3	0.5978
Miscellaneous	3.43	1.99	0 - 6	2.5	2.49	0 - 8	0.4206

Table 19a : Menu Selection Specific to SAH:

Dairy Products	Enriched Milk	
9 Pureed Vegetables	Broccoli P/F	Asparagus P/F
	Carrots P/F	Green beans P/F
	Cauliflower P/F	
	Green Peas P/F	Lettuce P/F
	Waxed beans P/F	Fresh tomato P/F
5 Pureed Fruits	Halves of Pear P/F	Pineapple slices P/F
	Slivers of Peach P/F	Applesauce
	Strawberries P/F	
Meats / Main Entrees	Bourguignon Beef P/F M/F	Beef slices P/F M/F
	Fall Stew P/F M/F	Chicken Breasts P/F M/F
17 Pureed Items	Soukiaki Stew P/F M/F	Cold ham slices P/F M/F
	Stroganoff Stew P/F M/F	Hamburger Steak P/F M/F
14 Minced Items	Vegetable Stew P/F M/F	Hot ham slices P/F M/F
	Meat Pie P/F M/F	Lamb cutlet P/F M/F
	Lasagna P/F	Pork cutlet P/F M/F
	Salmon Pie P/F	Turkey slices P/F M/F
	Shepherd's Pie P/F	Veal slices P/F M/F
9 Sweets / Desserts	Carrot cake	Apple cake
	Choco-Moka cake	Bagatelle cake
	Oatmeal cookies	Black Forest cake
	Peach cake	Chocolate cake
	Vanilla cake	
7 Supplements	Banana (liquid)	Butterscotch (pudding)
	Chocolate (liquid)	Chocolate (pudding)
	Strawberry (liquid)	Vanilla (pudding)
	Vanilla (liquid)	

P/F: Pureed Reformed M/F : Minced Reformed

Table 19b : Menu Selection Specific to MR:

6 Pureed Vegetables	Carrots Green beans Green Peas Waxed beans	Carrot and Turnip Mixed vegetables
5 Pureed Fruits	Fruit cocktail sauce Peach sauce Pear sauce	Pineapple sauce Apple sauce
Meats / Main Entrees 11 Pureed Items 4 Minced / Soft Items	***When the main dish could not be served*** ***Minced / Soft Substitutes*** Hamburger Steak Minced Beef Minced Pork Minced Turkey	***Campbell TrePuree*** Coriander Pork Honey Mustard Ham Lemoned Chicken Old Fashion Beef Roast Beef Roast Chicken Roast Turkey Stroganoff Beef Tarragon chicken Turkey à la King White Fish Newburg
Sweets / Desserts	Ice Cream and Puddings	Jell-O
6 Supplements	Chocolate (liquid) Fieldberries (liquid) Vanilla (liquid)	Butterscotch (pudding) Chocolate (pudding) Vanilla (pudding)

Table 20: Development of Pressure Ulcers or Other Infectious Diseases

	Pressure Ulcers		Bronchitis / Pneumonia	
Group	# of Cases	Subjects	# of Cases	Subjects
Treated (n=8)	1	# 11	2	# 7, 10
Control (n=9)	1	# 9	2	# 8, 9

Table 21: Costs of Human Resources

Tasks	Professional	Number of hours required	Rate ($/hour)	Total ($)
Chart screening	DIT-01	30	25.64	769.20
Dysphagia evaluation	DIT-01	27	25.64	692.28
Re-evaluation of menus	DIT-01	8	25.64	205.12
Creation of Excel menus	DIT-01	16	25.64	410.24
Kitchen evaluation	DIT-01	15	25.64	384.60
Overall supervision	DIT-01	1284	25.64	32921.76
Overall supervision (weekends)	EG-03	60	18.46	1107.60
2nd person for dietary intakes	EG-03	210	18.46	3876.60
Total				40704

DIT-01: Dietitian without employee supervision
EG-03: Administrative technician

LIST OF FIGURES

Figure 1: Dysphagia in the Elderly

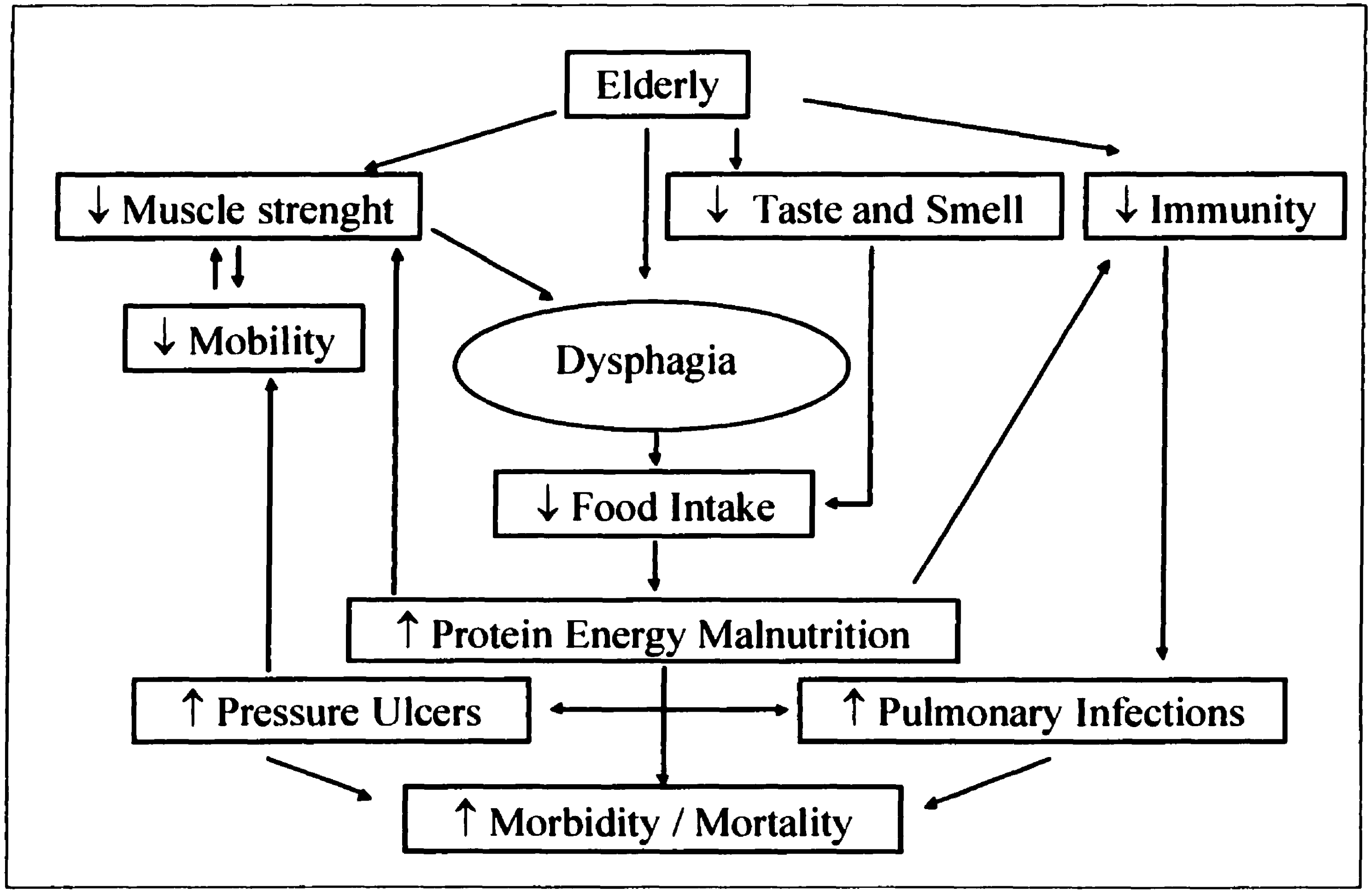
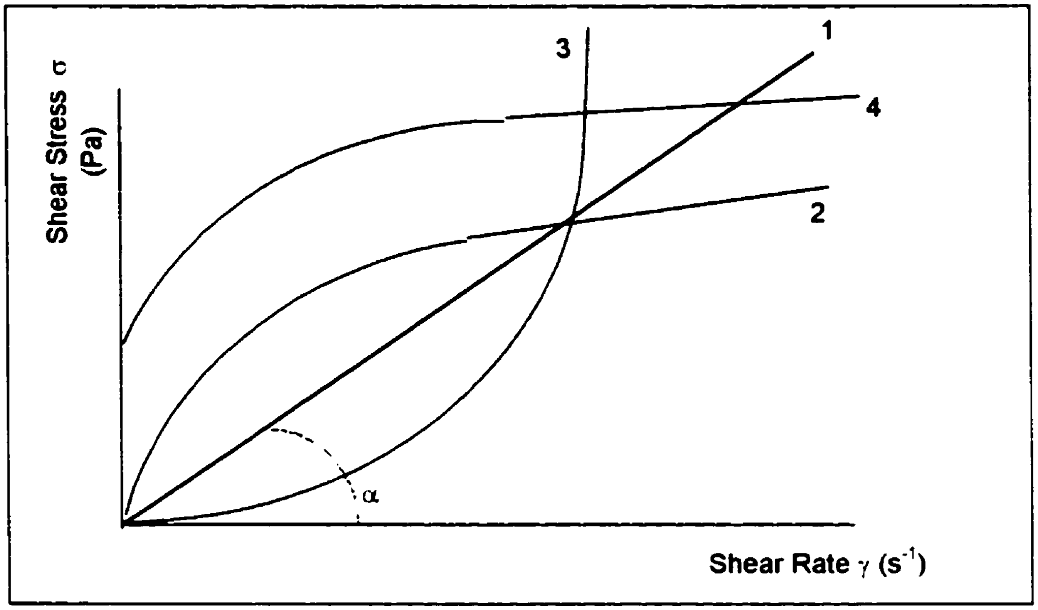


Figure 2: Typical Flow Curves of Newtonian and non- Newtonian Fluids



1: Newtonian fluids
2: Pseudoplastic fluids
3: Dilatant fluids
4: Pseudoplastic fluids with a yield point

Figure 3: Typical Texture Profile Analysis

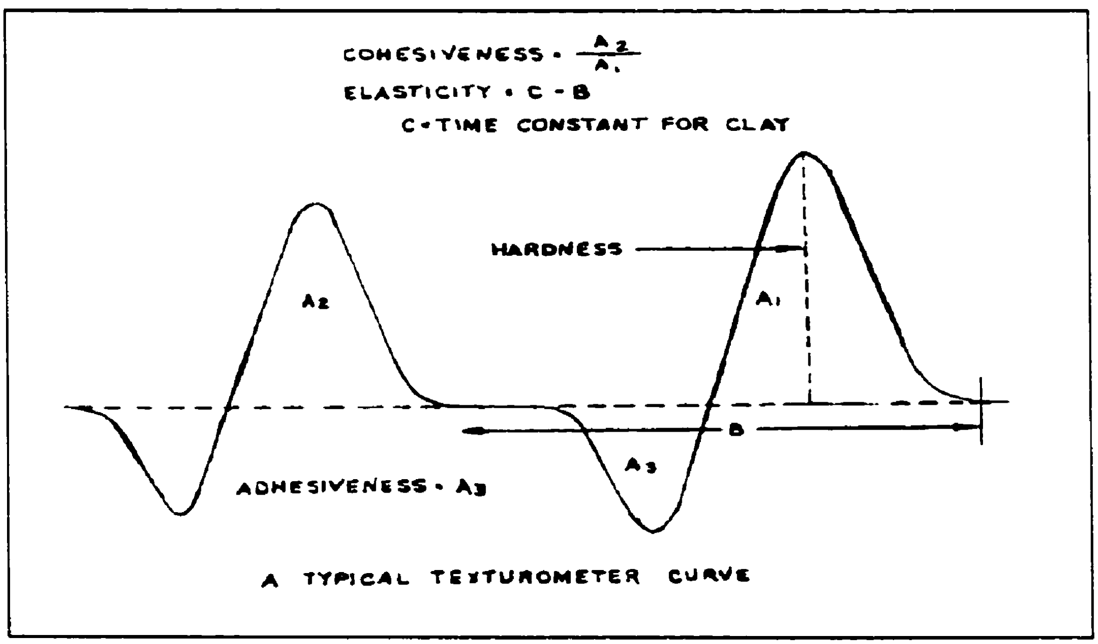


Figure 4a)

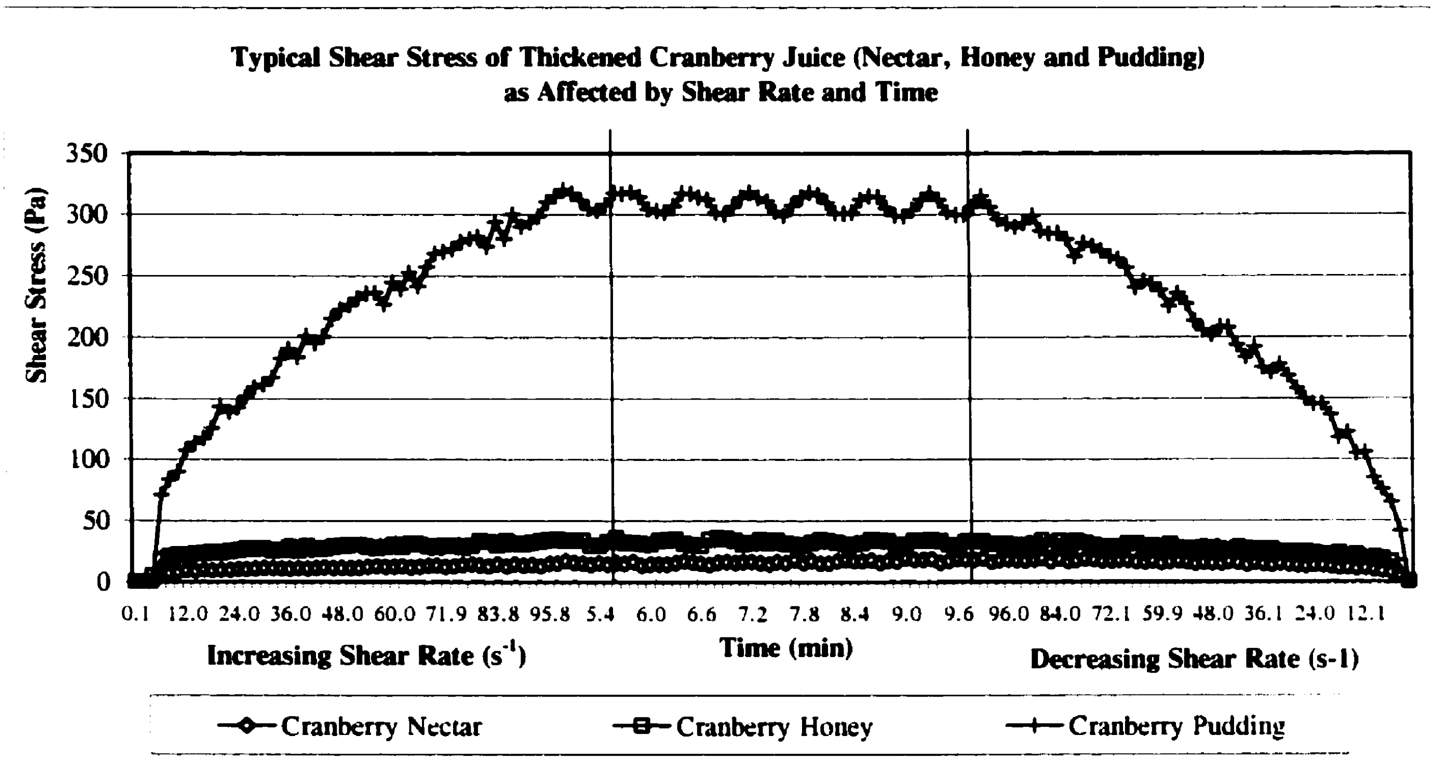


Figure 4b)

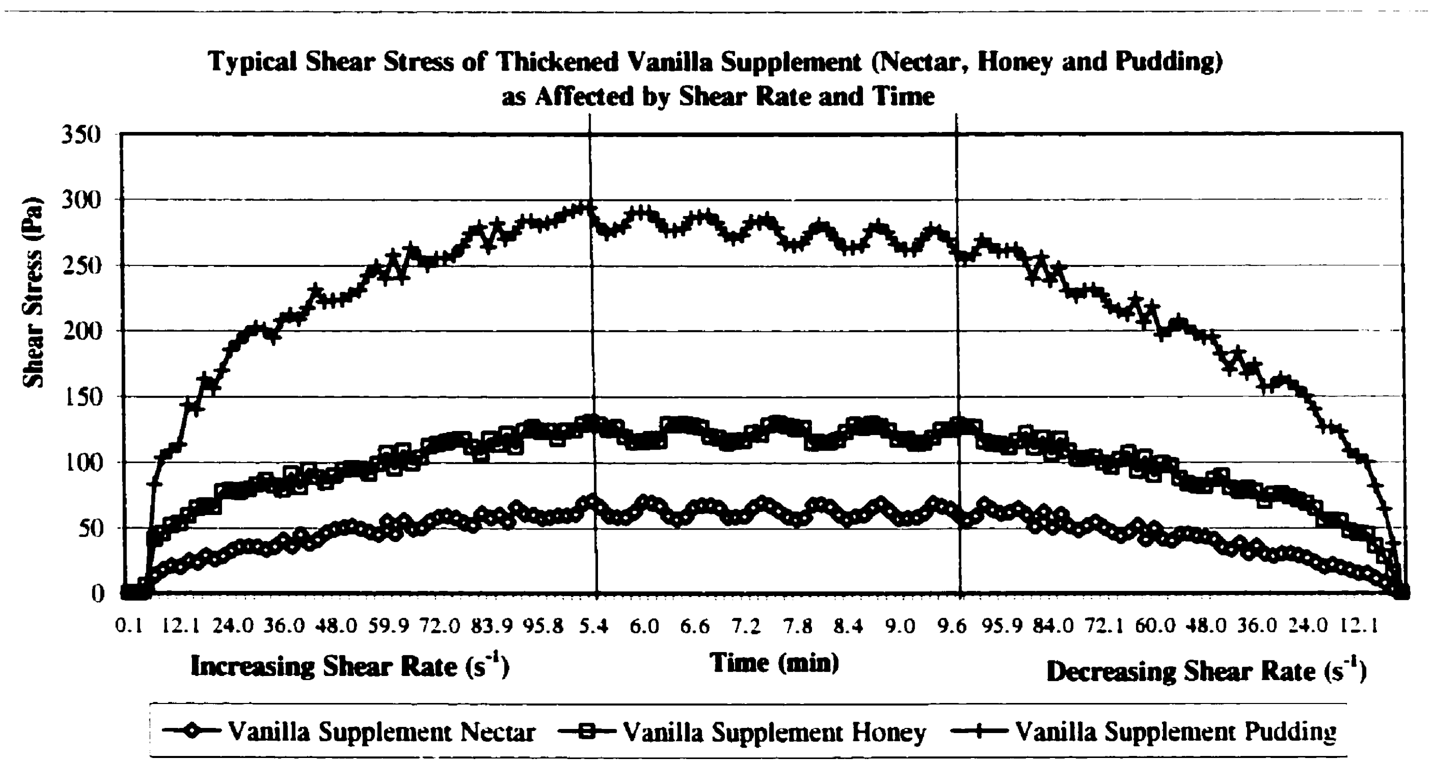


Figure 5a)

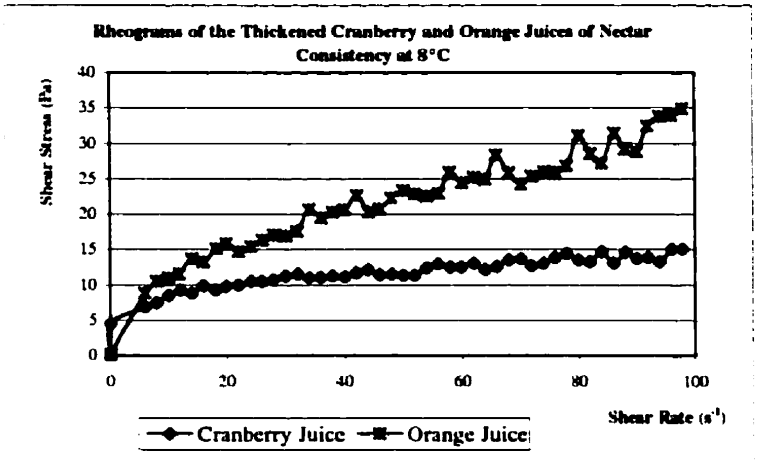


Figure 5d)

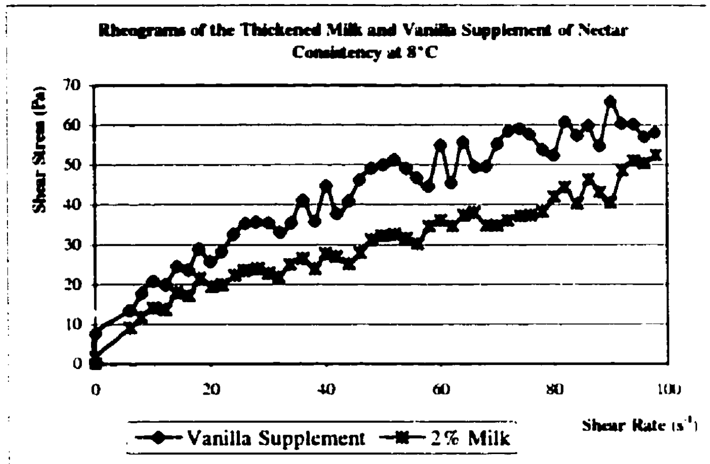


Figure 5b)

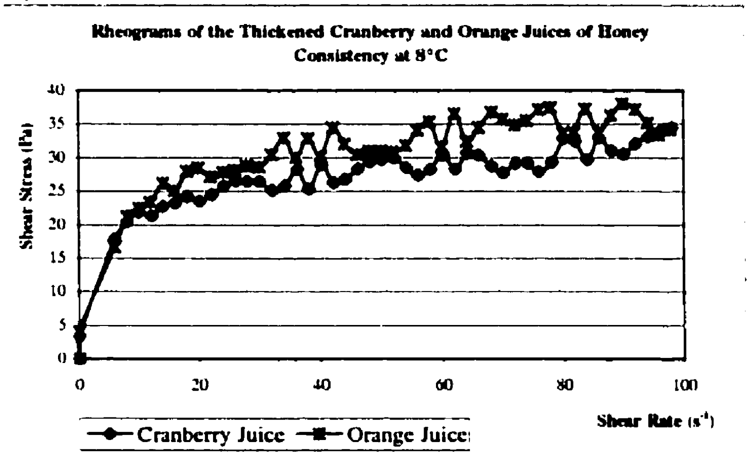


Figure 5e)

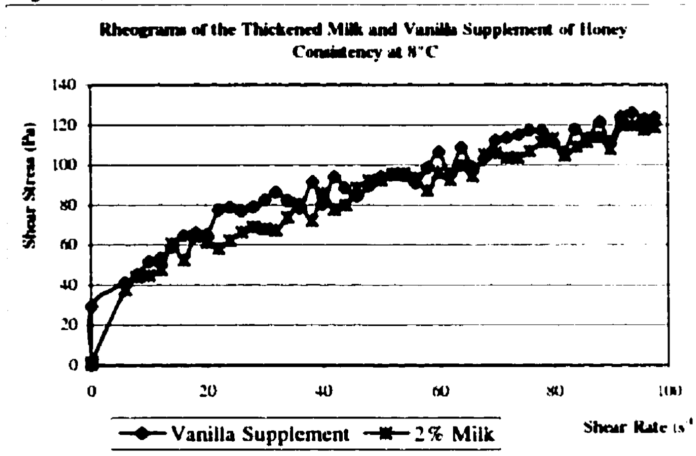


Figure 5c)

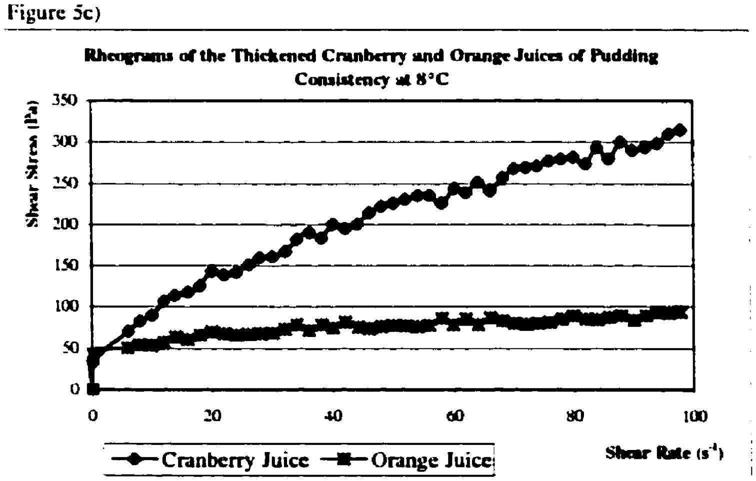


Figure 5f)

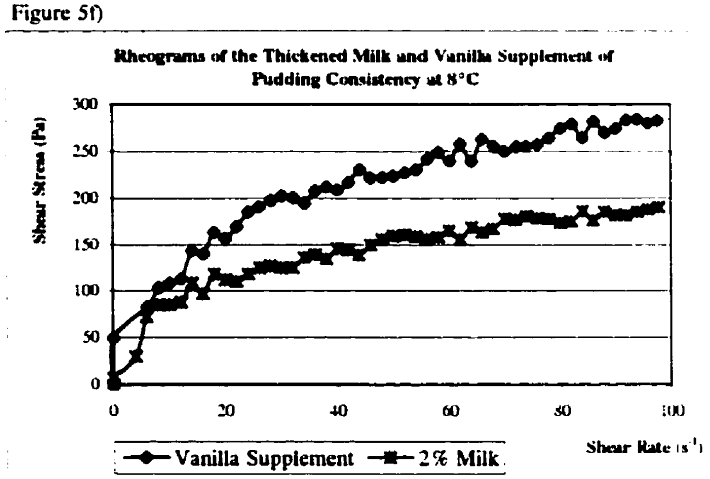


Figure 6: **Apparent Viscosity of the Cold Thickened Beverages Offered at SAH (shear rate of 50 s^{-1}; 8°C)**

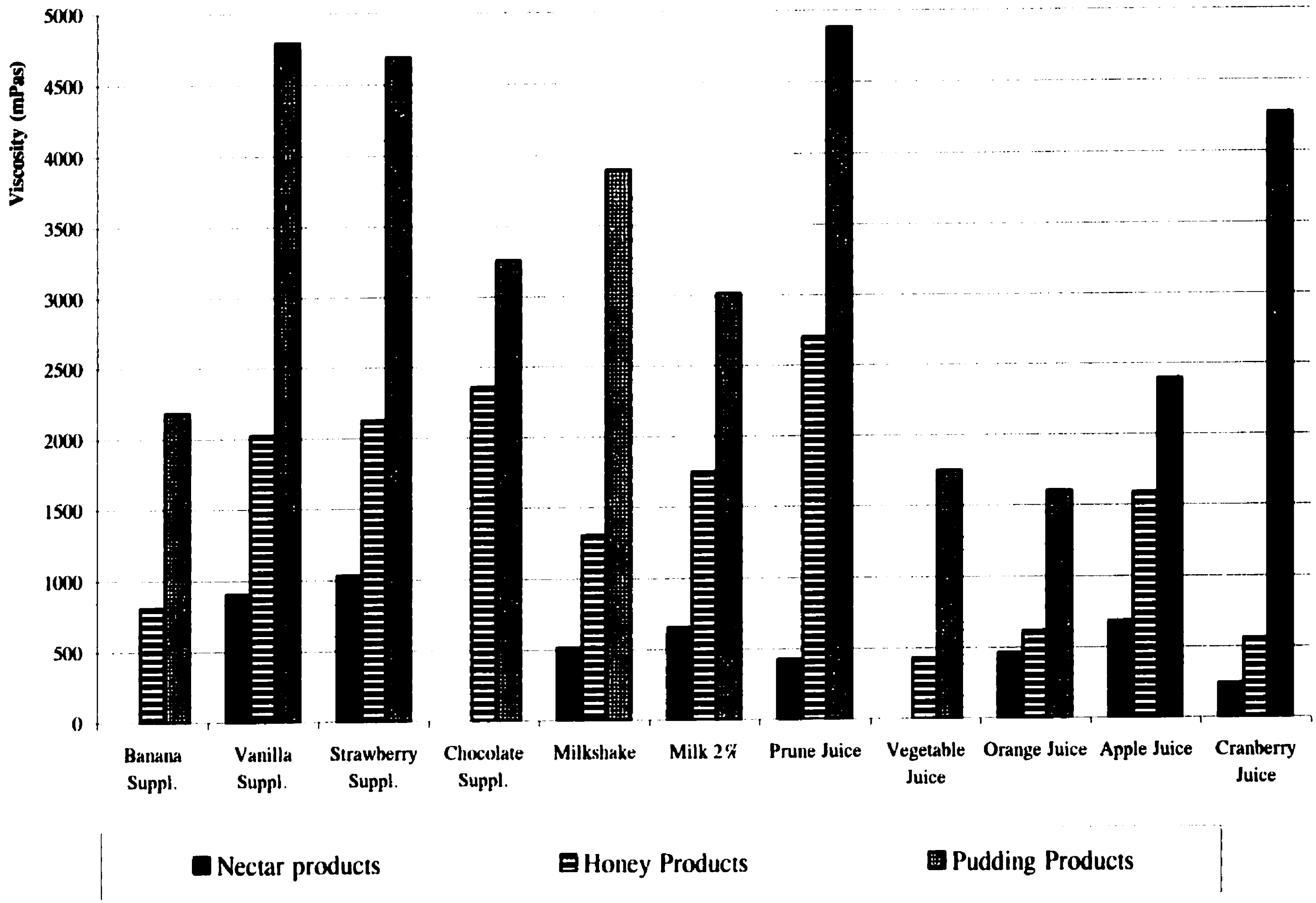


Figure 7a: Correlation between Consistency Coefficient and Consistency Grouping

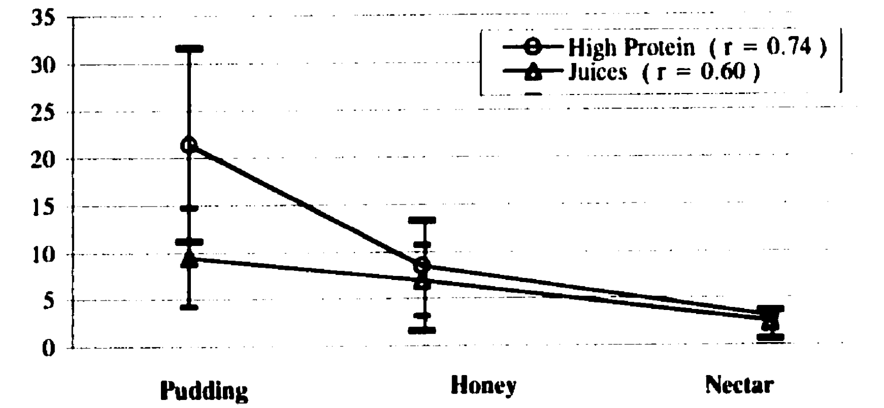


Figure 7b: Correlation between Apparent Viscosity and Consistency Grouping

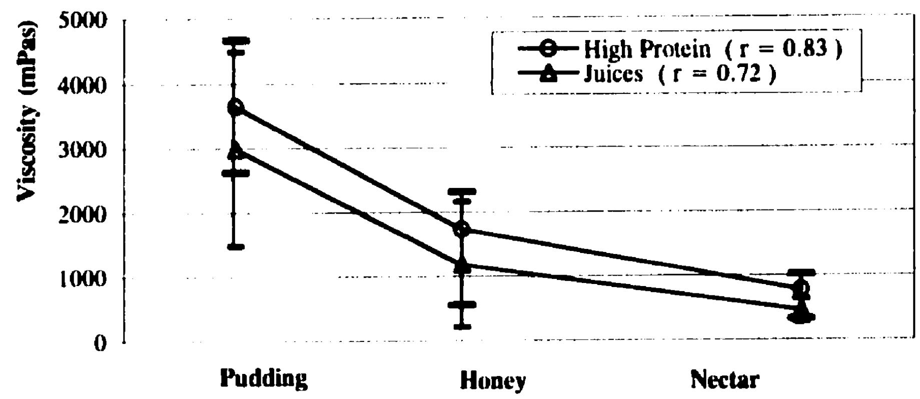


Figure 7c: Correlation between Flow Behavior Index and Consistency Grouping

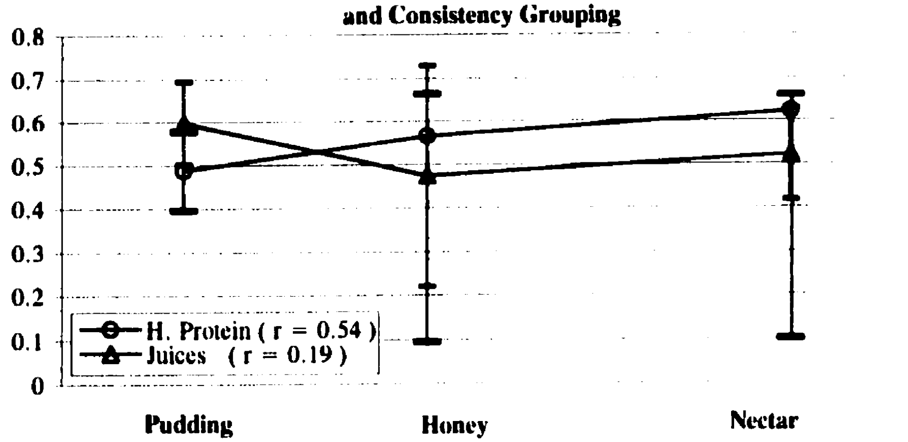


Figure 7d: Correlation between Yield Stress and Consistency Grouping

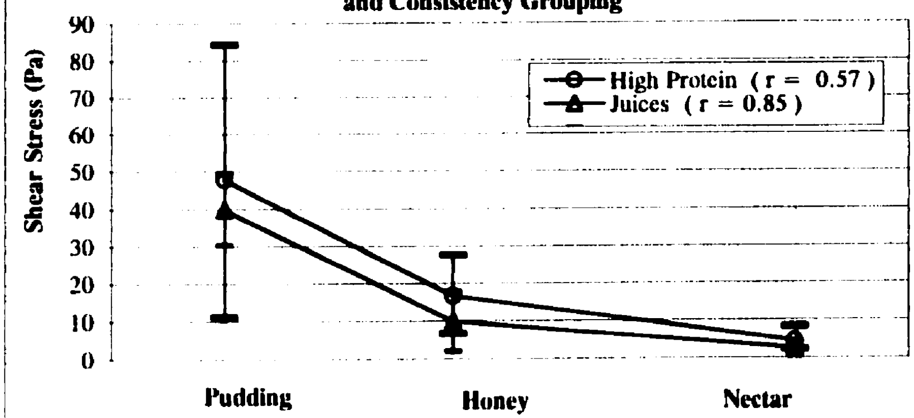


Figure 8a:

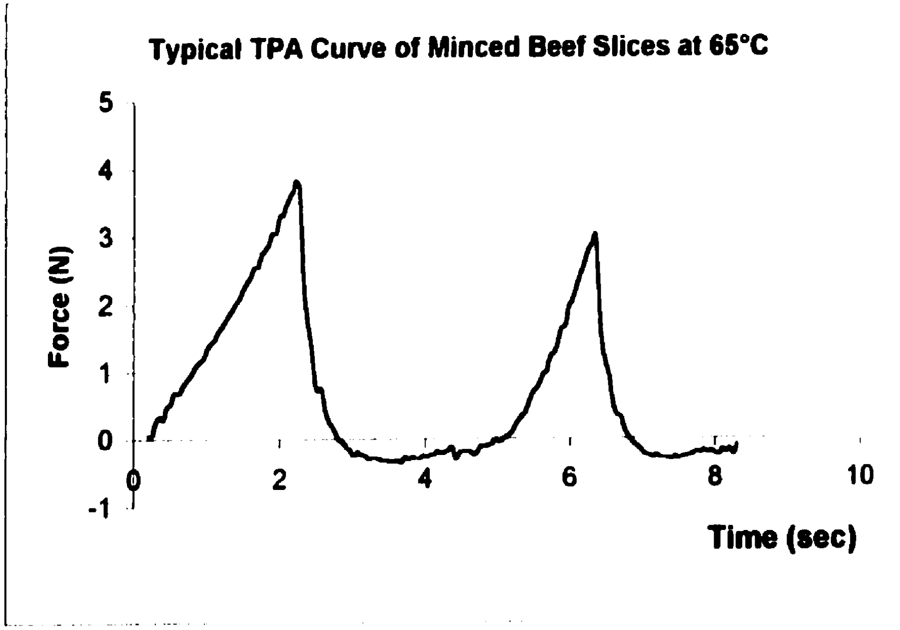


Figure 8b:

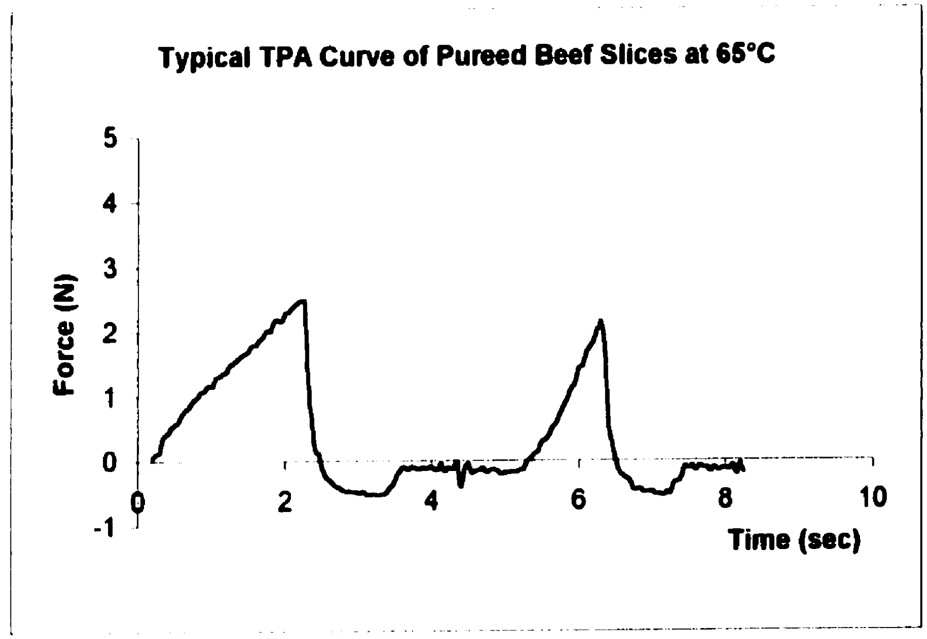


Figure 8c:

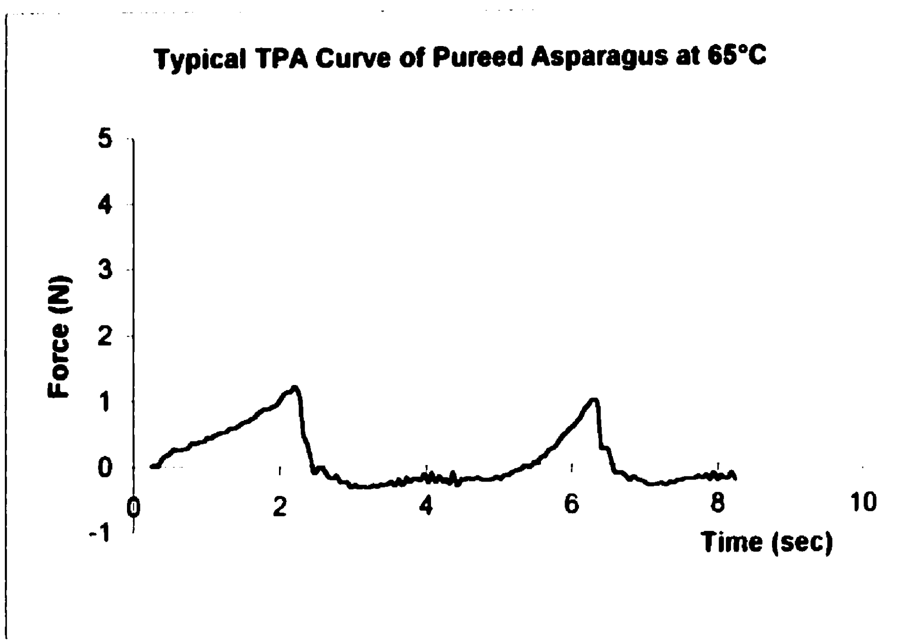


Figure 8d:

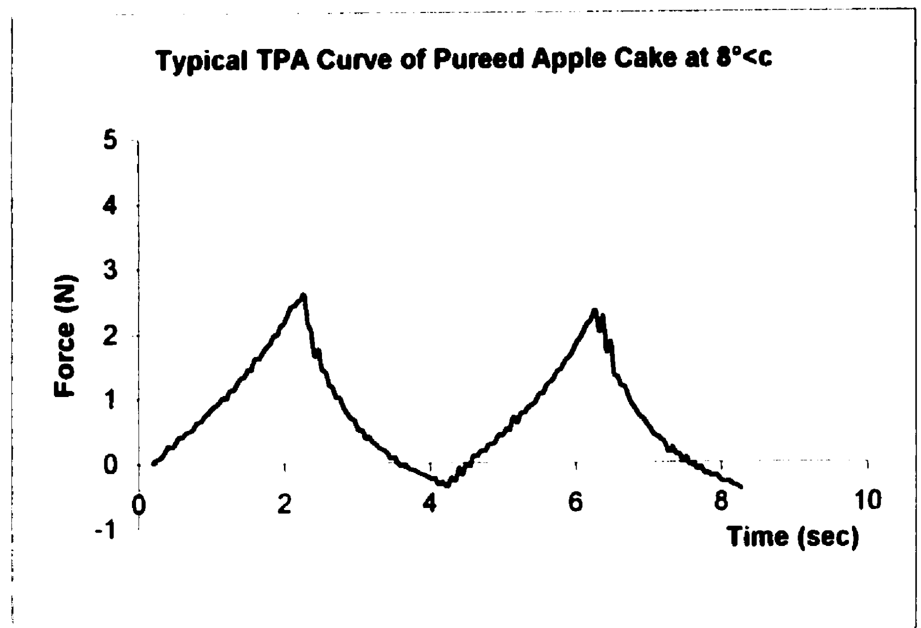


Figure 9: Selection of Subjects

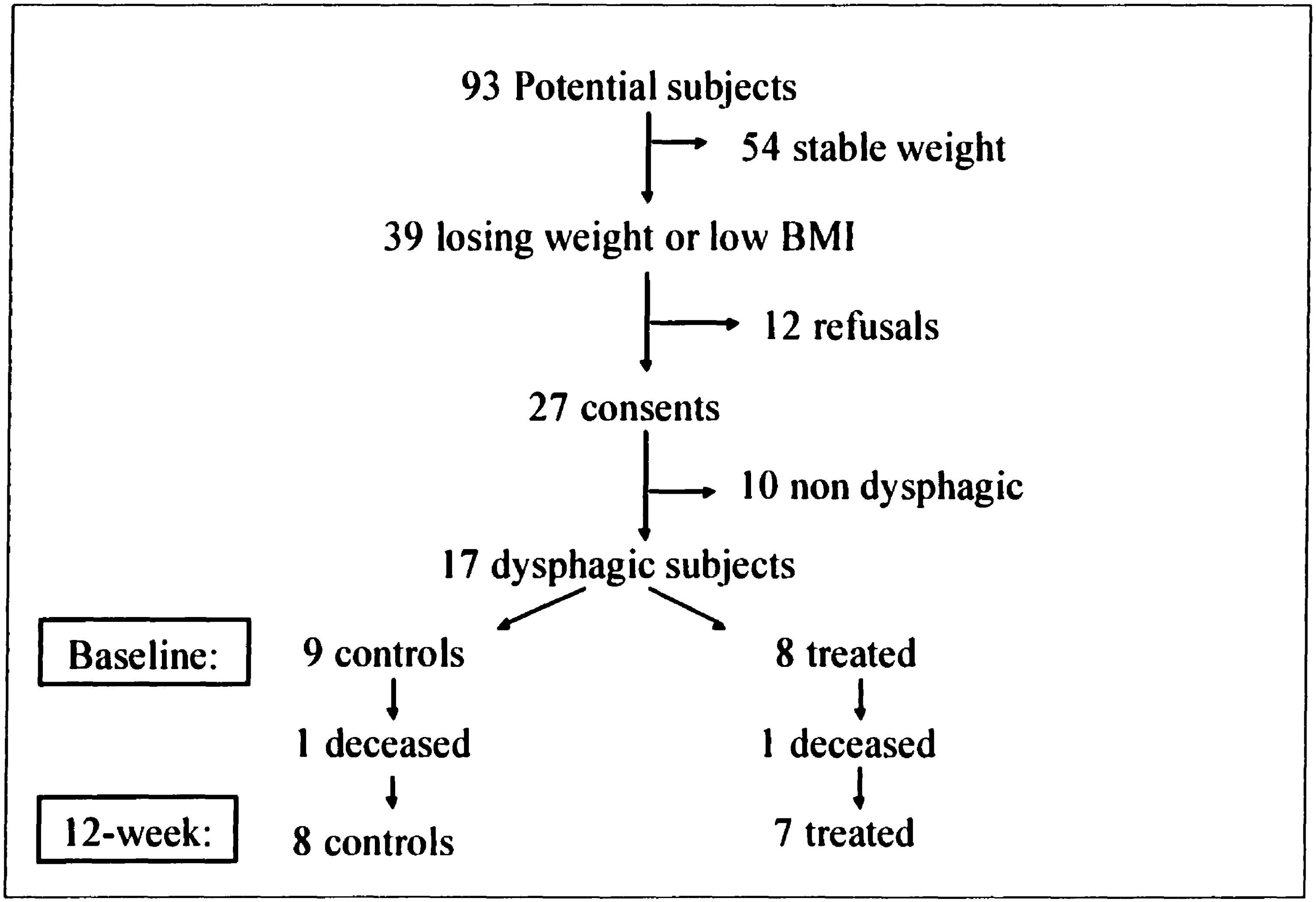


Figure 10: Average Weight at each Time Point for Both Groups during the Protocol

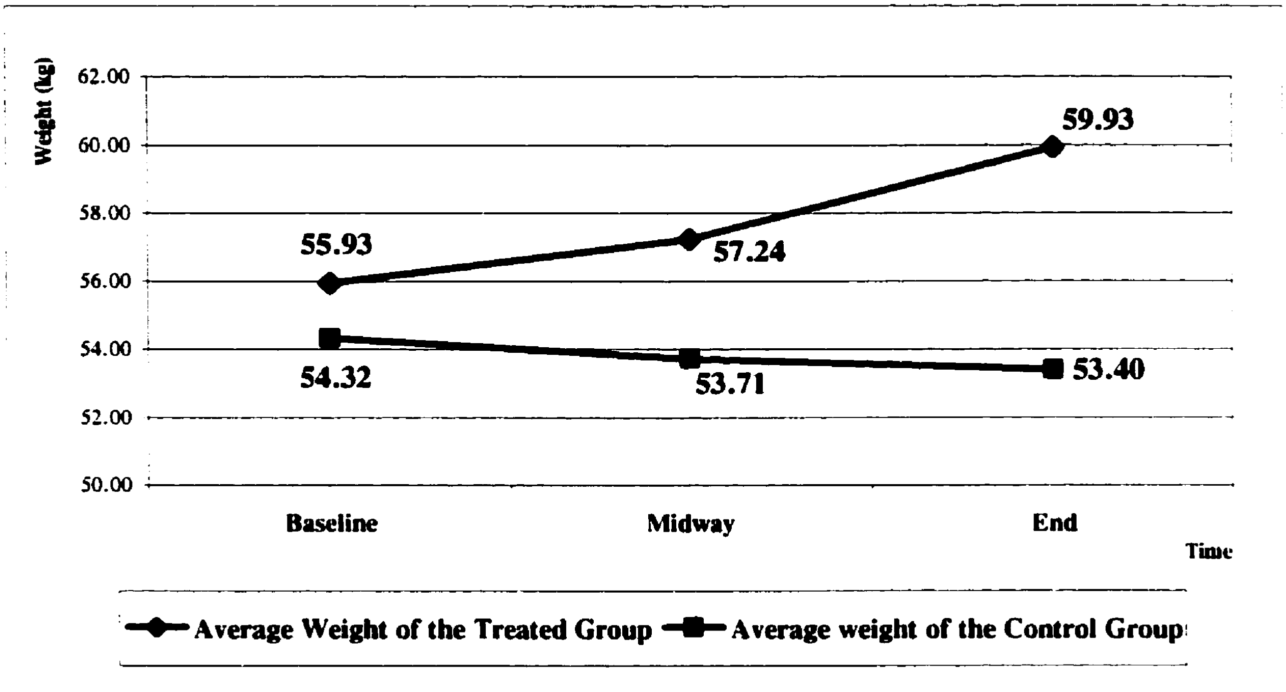


Figure 11: Average BMI at each Time Point for Both Groups during the Protocol

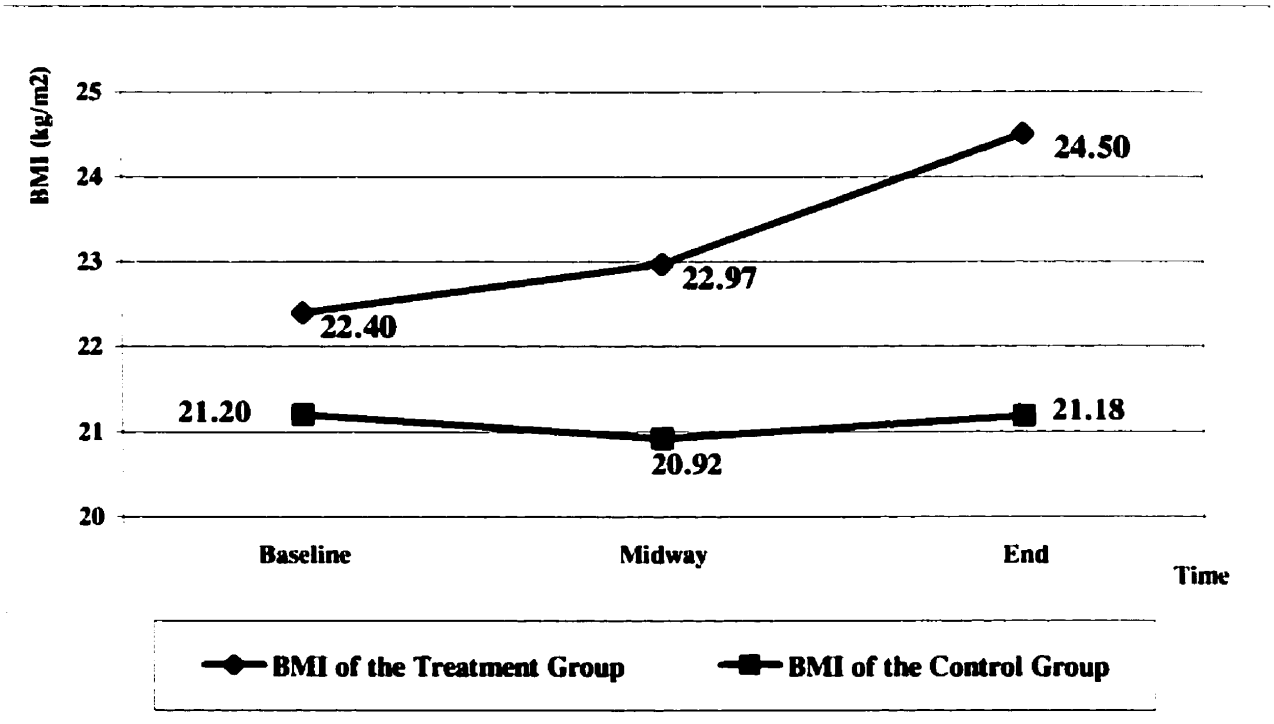


Figure 12: Evolution of Weight of each Individual in the Control Group during the Protocol

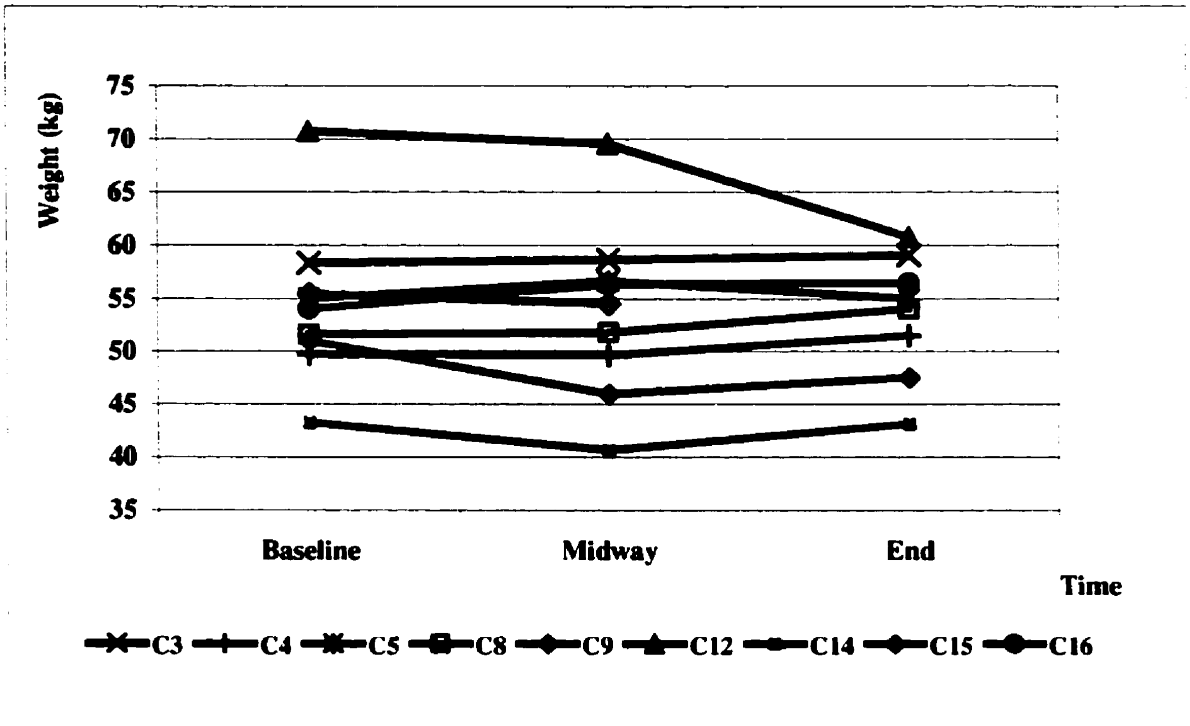


Figure 13: Evolution of Weight of each Individual in the Treated Group during the Protocol

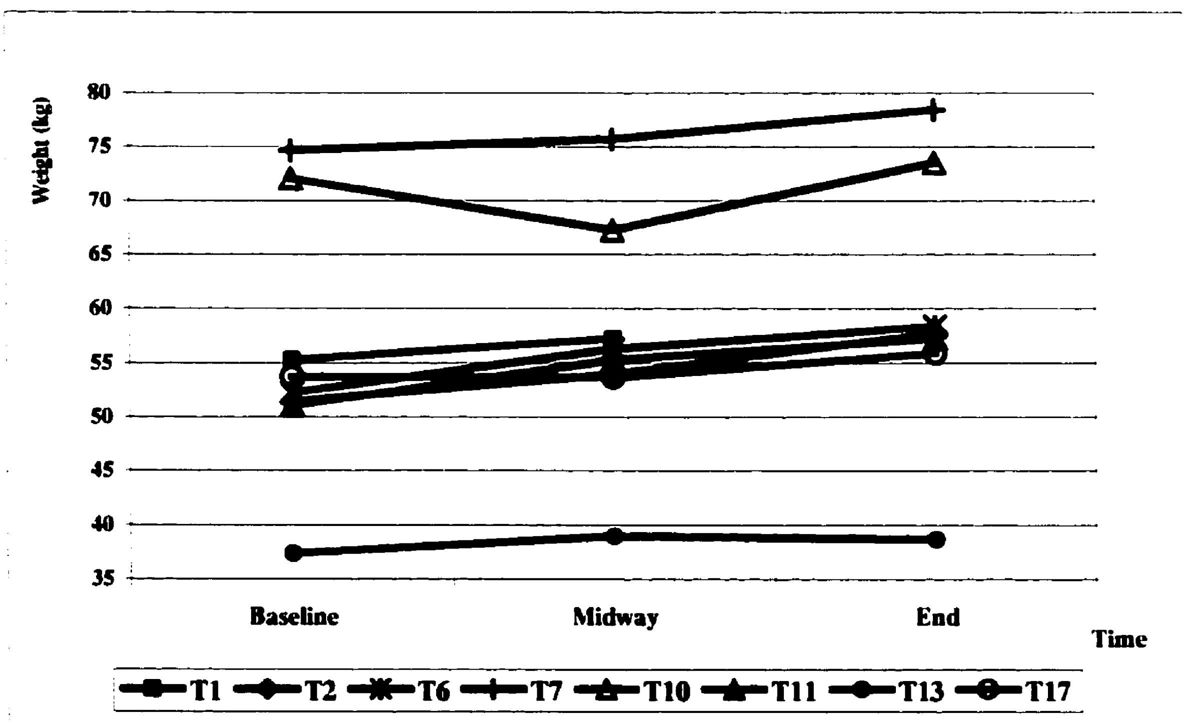


Figure 14: Weight Change of the Control Group over Time (n = 9)

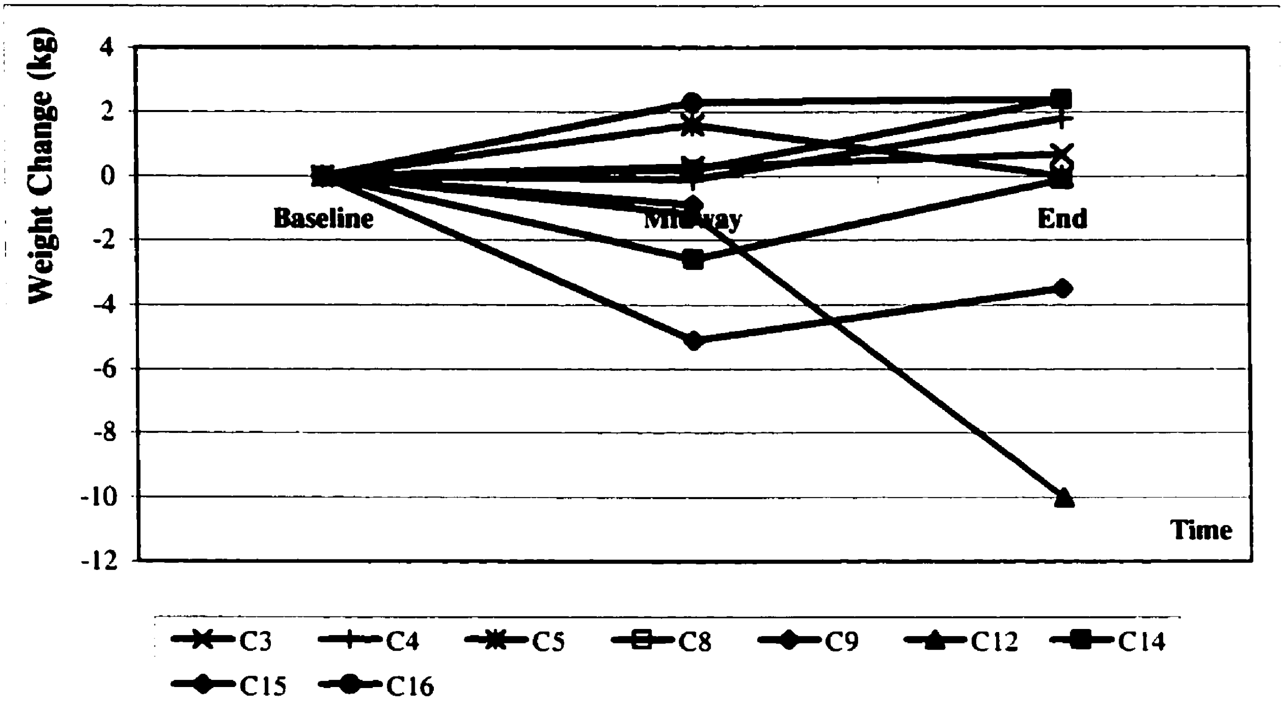
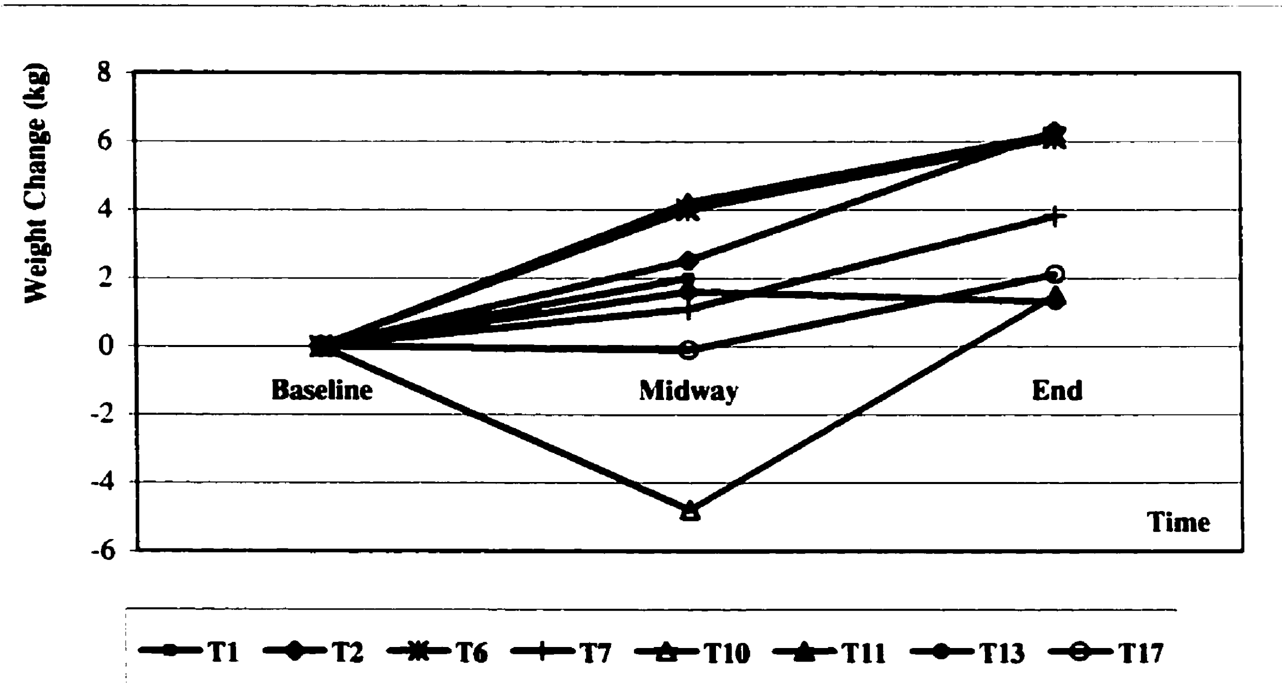
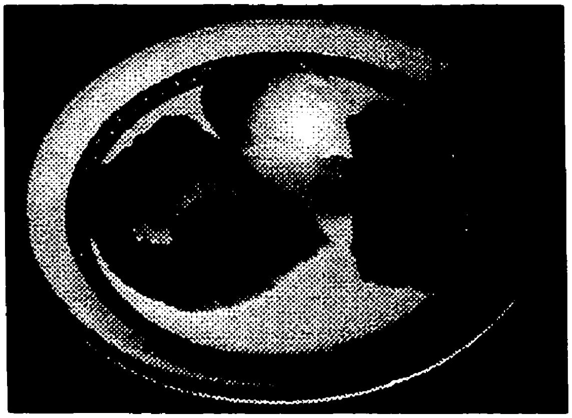


Figure 15: Weight Change of the Treated Group over Time (n = 8)



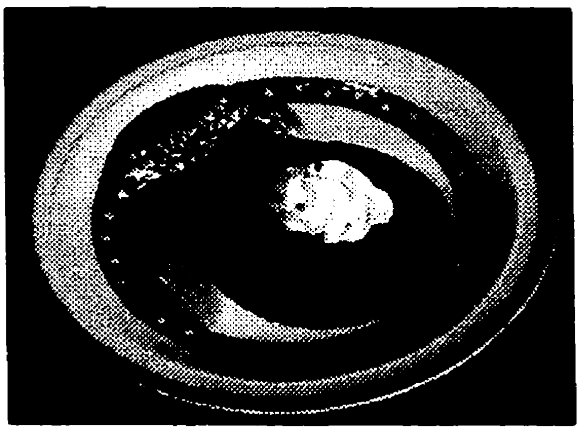
LIST OF PICTURES

Picture 1: SAH's Reformed Minced Ham Slices Served with Reformed Pureed Asparagus

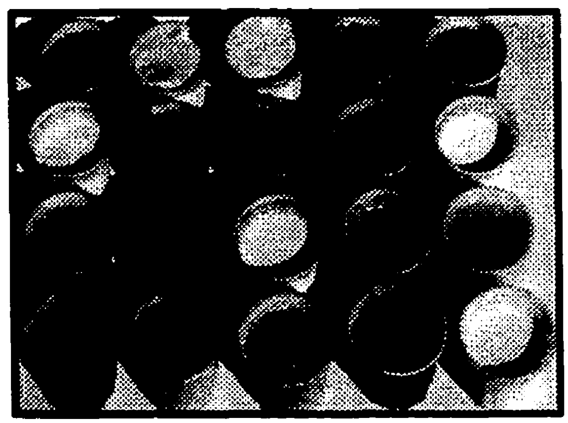


Picture 2: SAH's Reformed Pureed Chicken Breast Served with Reformed Pureed Broccoli

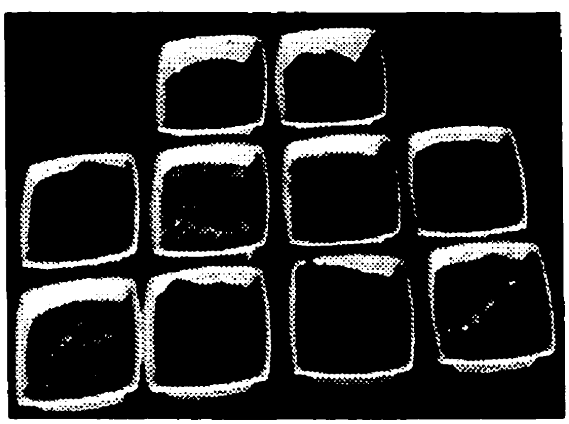
Picture 3: SAH's Reformed Pureed Peach Cake Served with Reformed Pureed Peach Quarters



Picture 4: SAH's Thickened Beverages



Picture 5: Traditional Pureed Foods



APPENDICES

McGill

APPENDIX A

School of Dietetics and Human Nutrition
Faculty of Agricultural and Environmental Sciences
McGill University
Macdonald Campus

École de diététique et nutrition humaine
Faculté des sciences de l'agriculture et de l'environnement
Université McGill
Campus Macdonald

Tel.: (514) 398-7842
Fax: (514) 398-7739
Website: http://www.agrenv.mcgill.ca/dietetic

21,111 Lakeshore
Ste-Anne-de-Bellevue
Québec, Canada H9X 3V9

CONSENT BY SUBJECT OF RESEARCH PROTOCOL (PILOT STUDY)

Benefits and cost-effectiveness of advanced nutritional care for the treatment of Dysphagia

I, ______________________, the undersigned, hereby consent to participate in this study.

or

I,______________________, the undersigned, person duly authorized to take decisions for ______________________, consent to the participation of the person I represent in this study.

1. GOAL AND NATURE OF THE STUDY :

Ste.Anne's Hospital has developed special foods in order to help patients who have difficulty eating (a condition called *dysphagia)*. These special foods consist of liquids that have been thickened and solid foods that have been minced or puréed but that look, taste and are as nourishing as their normal counterpart.

Ste.Anne's Hospital, together with McGill's School of Dietetics and Human Nutrition, is doing this pilot study in order to gather information essential to better specify the research methods of a large scale research study that will be held next year. This «big study» will measure the benefits and cost-effectiveness of a nutritional treatment done with these new foods.

At the beginning of the study, you will be examined by a specialist in dysphagia, to identify precisely your difficulty eating. Then, ***if dysphagia is detected***, you will be weighed and measured and your meals and snacks will be analyzed for two days. This analysis will be done by a dietitian, who will measure all the foods that you will have eaten. The dietitian will also interview you or the person who feeds you in order to get your opinion on the foods that you receive.

The study will last **12 weeks**. At weeks 6 and 12, you will again be weighed and your meals and snacks will be analyzed again for two days.

You may be assigned to the group of «***control***» persons or to the group of «***treated***» persons. The assignation to either group will be done randomly. If you are assigned to the «***control***» group, you will be served the same food as presently.

On the other hand, if you are assigned to the «***treated***» group, you will be served Ste-Anne's Hospital specialized foods adapted to your condition for a period of 12 weeks. These foods will be served in the same way as the foods you are served presently (same time, same tray, same dishes, same delivery cart, etc..). At the end of the study, that is after 12 weeks, you will revert to the foods that you receive presently.

2. POTENTIEL RISKS :

There are no known hazards associated with :

- Intake of Ste.Anne's foods specialized for the nutritional treatment of Dyphagia
- Dysphagia evaluation procedure
- Weighing procedure

3. ADVANTAGES :

Although there are no monetary or personal benefits to be gained from participating in this study, the results of this pilot study will allow us to further define the research methods for the large research study which will be done next year and which will attempt to measure the impact (on the quality of life and on cost of care) of a specialized dietary approach for elderly who experience a difficulty in eating.

4. PERMISSION TO CONSULT MEDICAL CHART :

If needed to obtain certain information pertinent to the study, the members of the research team will consult your medical chart.

5. PERMISSION TO USE INFORMATION :

The data and information collected during this study may be used for various reports or publications. However, your name will never be mentioned.

6. RIGHT TO WITHDRAW :

Your participation in this study is voluntary. You may change your mind at any time and stop participating at any time without prejudice to the quality of any further care or food service.

7. RESEARCH STUDY TEAM :

This study is financed by Veterans Affairs Canada. The members of the research team are :

- Therese Dufresne, P.DT., Study Coordinator. She is head of Dietary Services at Ste.Anne's Hospital. For more information on this study, you can contact her at : Dietary Services, Ste.Anne's Hospital, 305, boul. des Anciens-Combattants, Ste-Anne-de-Bellevue, Qc., H9X 1Y9, tel. : (514) 457-3440, ext. 2177, fax : (514) 457-8793
- Katherine Gray-Donald, PH.D., Consultant for Research Methods. She is Director of the School of Human Nutrition and Dietetics of McGill University
- Isabelle Germain, P.DT., Researcher assigned to data collection, analysis and quality control. She is a dietitian in research at Ste.Anne's Hospital
- Karina Marie Tomasino, P.DT. Research Assistant for data collection and quality control. She is a dietician in research at Ste.Anne's Hospital
- Louise Landry, Sonia Yeghiayan et Sophie Brousseau, Dietitians, are assigned to the screening and the clinical interventions. They are Clinical Dietitians at Ste.Anne's Hospital.

Signature : ______________________ Date : ________________________

Witness : ____________________________

I, Isabelle Germain, hereby certify that I have explained to the above mentioned person (or to the person authorized to take decisions in her or his place) the goal of this study, the known risks involved in participating in the study and the option of withdrawal at any time.

Signature : _____________________________

RIC Clinical Evaluation of Dysphagia (CED)

Leora Reiff Cherney, Ph.D., CCC-SP
Carol Addy Cantieri, M.A., CCC-SP
Jean Jones Pannell, MA., CCC-SP

AN ASPEN PUBLICATION®

Clinical Evaluation of Dysphagia
Face Sheet

Patient: ______________________________ Date: ______________

Case #: ____________________ Therapist: ______________________

Overall diagnosis: ____
____

Dysphagia severity: _______________________________________
____

Suggestions for feeding: ___________________________________
____
____
____
____
____
____
____
____

Recommended diet: ____
____
____

Precautions: ____
____
____
____
____
____
____
____
____
____

Name: ______________________
Case #: ______________________
Date: ______________________

Evaluation of Prefeeding Skills

Medical/Nutritional Status ____

____

____

Respiratory Status ____

History of Aspiration ____

Tracheostomy _____ yes _____ no Type ____________________ Size _________

Position of Cuff _____ Inflated _____ Partially Inflated_____ Deflated

Suctioning Required _____ yes _____ no Frequency ____________________

Other Relevant Information ______________________________________

Level of Responsiveness ____

Behavioral Characteristics ____

Current Feeding Method Oral _____ Alternate ____________________

Intake Amount ____________________ Frequency of Intake ____________________

Other ____

Positioning

Habitual ____

Interfering Patterns ____

Trial/Optimal Position ____

____

Observations of Oral, Pharyngeal, and Laryngeal Function

Lips ____

Tongue ____

Mandible ____

Name: ____________________
Date: ____________________

Dentition ____________________

Phonation ____________________

Articulation ____________________

Hypernasality ____________ Hyponasality ____________

Cough (involuntary and volitional) ____________________

Gag Reflex ____________________

Voluntary Swallow ____________________

Other Observations ____________________

Response to Stimulation

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Recommendations

_____ Swallowing Evaluation Deferred: Patient NPO

_____ Clinical Evaluation of Swallowing

_____ Videofluoroscopy

_____ ENT

_____ Other ____________________

____

Goals:

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Patient/Family Counseling:

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____

THIN LIQUIDS	THICK LIQUIDS	PUREED	GROUND SOLIDS	CHOPPED SOLIDS	REGULAR SOLIDS

Name: ______________________

Case #: ______________________

Date: ______________________

General Impressions: ____

____

I. *ORAL STAGE*

A. *Lips*

1. Protrusion
   - _____ Initiates protrusion
   - _____ Maintains protrusion
2. Closure
   - _____ Initiates Closure for Retrieval from Utensil
   - _____ Maintains Closure for Retrieval from Utensil
   - _____ Maintains Closure throughout Oral Stage
   - _____ Leakage ______________________

Spoon	Cup	Straw

3. Interpretation of Lip Function
   - _____ Adequate
   - _____ Adequate but Reduced
   - _____ Interferes with Function
   - _____ Nonfunctional
   - Problems due to
     - _____ ↓ ↑ Tone
     - _____ ↓ Sensation
     - _____ ↓ Strength
     - _____ ↓ Range of Motion
     - _____ ↓ Rate
     - _____ Inaccurate Direction
     - _____ Other ______________________

B. *Tongue*

1. Bolus Formation and Transport
   - _____ Adequate
   - _____ Adequate but Reduced
   - _____ Interferes with Function
   - _____ Nonfunctional
   - _____ Pumping Action of Tongue
   - _____ Tongue Thrust
2. Food Remaining in Mouth
   - _____ None
   - _____ Left Side
   - _____ Right Side
   - _____ Anterior
   - _____ Roof of Mouth
   - _____ Midline of Tongue
   - _____ On Lips

THIN LIQUIDS	THICK LIQUIDS	PUREED	GROUND SOLIDS	CHOPPED SOLIDS	REGULAR SOLIDS

Name: ______________________________
Date: ______________________________

A. *Summary*

Overall Pharyngeal Phase

_____ Adequate
_____ Adequate but Reduced Function
_____ Interferes with Function
_____ Nonfunctional

Problems due to ____
____
____
____

Patient Appears Able/Unable to Protect Airway

Additional Comments (e.g., medical or behavioral status that *compensates* or *interferes* with performance) ______________________
____
____
____

III. *ADDITIONAL TEST RESULTS*

Videofluoroscopy Test Results/Recommendations

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____
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____
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____

ENT Test Results ____
____
____

Other ____

IV. *OVERALL FUNCTIONAL SEVERITY LEVEL AND INTERPRETATION OF UNDERYLING NEUROMUSCULAR CHARACTERISTICS*

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____
____
____
____