

Effect of Bolus Viscosity on the Safety and Efficacy of Swallowing and the Kinematics of the Swallow Response in Patients with Oropharyngeal Dysphagia: White Paper by the European Society for Swallowing Disorders (ESSD)

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Abstract

Background Fluid thickening is a well-established management strategy for oropharyngeal dysphagia (OD). However, the effects of thickening agents on the physiology of impaired swallow responses are not fully understood, and there is no agreement on the degree of bolus thickening.

Aim To review the literature and to produce a white paper of the European Society for Swallowing Disorders (ESSD) describing the evidence in the literature on the effect that bolus modification has upon the physiology, efficacy and safety of swallowing in adults with OD.

Methods A systematic search was performed using the electronic Pubmed and Embase databases. Articles in English available up to July 2015 were considered. The inclusion criteria swallowing studies on adults over 18 years of age; healthy people or patients with oropharyngeal dysphagia; bolus modification; effects of bolus modification on swallow safety (penetration/aspiration) and efficacy; and/or physiology and original articles written in

English. The exclusion criteria consisted of oesophageal dysphagia and conference abstracts or presentations. The quality of the selected papers and the level of research evidence were assessed by standard quality assessments.

Results At the end of the selection process, 33 articles were considered. The quality of all included studies was assessed using systematic, reproducible, and quantitative tools (Kmet and NHMRC) concluding that all the selected articles reached a valid level of evidence. The literature search gathered data from various sources, ranging from double-blind randomised control trials to systematic reviews focused on changes occurring in swallowing physiology caused by thickened fluids. Main results suggest that increasing bolus viscosity (a) results in increased safety of swallowing, (b) also results in increased amounts of oral and/or pharyngeal residue which may result in post-swallow airway invasion, (c) impacts the physiology with increased lingual pressure patterns, no major changes in impaired airway protection mechanisms, and controversial effects on oral and pharyngeal transit time, hyoid displacements, onset of UOS opening and bolus velocity—with several articles suggesting the therapeutic effect of thickeners is also due to intrinsic bolus properties, (d) reduces palatability of thickened fluids and (e) correlates with increased risk of dehydration and decreased quality of life although the severity of dysphagia may be an confounding factor.

Conclusions The ESSD concludes that there is evidence for increasing viscosity to reduce the risk of airway invasion and that it is a valid management strategy for OD. However, new thickening agents should be developed to avoid the negative effects of increasing viscosity on residue, palatability, and treatment compliance. New randomised controlled trials should establish the optimal viscosity level for each phenotype of dysphagic patients

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and descriptors, terminology and viscosity measurements must be standardised. This white paper is the first step towards the development of a clinical guideline on bolus modification for patients with oropharyngeal dysphagia.

Keywords Deglutition · Deglutition disorders · Review · Viscosity · Rheology · Kinetics

Introduction

Oropharyngeal dysphagia (OD) is a prevalent condition which is recognised by the World Health Organisation (WHO) in the International Classification of Diseases (ICD). The 9th ICD revision classifies dysphagia under symptoms involving the digestive system. The ICD code for OD in this version is 787.2. In the more recent 10th revision, dysphagia is classified under symptoms and signs involving the digestive system and abdomen, and the code is R13. It is described as a disorder or symptom characterised by difficulty in swallowing. OD is also recognised by many scientific societies and professional bodies including (among others) dysphagia organisations such as the European Society of Swallowing Disorders (ESSD), Dysphagia Research Society (DRS), the Japanese Society of Dysphagia Rehabilitation (JRDS), the UK Swallowing Research Group (UKSRG) and the Turkish Dysphagia Research Society; and the national professional bodies such as Royal College of Speech and Language Therapists (RCSLT) and the American Speech-Language-Hearing Association (ASHA). There are many other national groups and societies, and these are mentioned simply as examples.

The phenotypes of patients in which OD develops varies significantly and includes the older people [1] with OD affecting approximately 15–40 % [2, 3], and neurodegenerative diseases where data relating to prevalence of OD vary greatly: In Parkinson's disease, prevalence of OD ranges between 52 and 82 % [4]; in Alzheimer's, between 57 and 84 % [5, 6] and in motor neuron disease, depending on the stage of the disease, between 30 and 100 % of individuals are affected by OD [7]. Prevalence of OD following stroke varies between 37 and 78 % depending on the diagnostic method used [8, 9] whereas the incidence of OD in traumatic brain injury is approximately 25 % [10]. Between 44 % and 50 % of head and neck cancer patients are reported to present with OD either as a symptom of their disorder or following chemotherapy [11–13].

Approximately 50–75 % of patients with OD present impaired safety of swallow with bolus penetration into the laryngeal vestibule, and 20–25 % of these result in aspiration into the airway [11, 14]. Without appropriate treatment, OD is known to be associated with severe

nutritional and respiratory complications including aspiration pneumonia and may result in an individual's (often repeated) hospital readmission and eventual mortality [15]. Previous studies showed that OD is an independent risk factor for malnutrition and for one year mortality in frail older patients with both conditions [16]. Impaired efficacy of swallowing is reported to cause malnutrition and/or dehydration in up to 25 % of post-stroke patients [14].

A well-established management strategy for OD is the modification of liquid viscosity by adding a thickening agent in an attempt to reduce risk of penetration to the airway. Based on clinical studies and on accepted best practice, increasing bolus viscosity has been widely introduced in the treatment of OD irrespective of the phenotype of the dysphagic patients, the specific impairment in the swallow physiology and the degree of bolus thickening [17–19]. In addition, the reasoning behind *how* and *why* such risk is reduced (if at all) is unknown by many clinicians who routinely recommend increasing the viscosity of liquids in the management of dysphagia. The underlying nature of any dysphagia will vary depending on the phenotype of the patient (stroke, older, neurodegenerative, head and neck cancer, etc.), and therefore, its management should also vary. Nonetheless, thickening liquids continues to be the practice of choice for many clinicians in an attempt to manage dysphagia [20, 21].

Logemann [22] stated that modification of bolus viscosity should only be attempted when all other treatment options have been exhausted, although no 'risk of thickening' was addressed. Campbell-Taylor [23] stated that the practice of thickening liquids was "contentious", and also cited research by Brandt et al. [24] which showed that a high percentage of aspiration of thickened liquids still occurred in their large randomised control trial. However, Campbell-Taylor's report was found to be significantly flawed [25], and finally there is quite limited evidence to either support or dispute the efficacy of thickening liquids to increase the safety and efficacy swallowing [18, 19, 26–28].

Therefore, the principal aim of this study is to examine the evidence base within peer-reviewed literature to ascertain what biomechanical changes in swallowing physiology occur as a result of modifying liquid viscosity, including the level to which these changes extend, and if indeed modifying viscosity of oral intake improves swallowing safety and reduces risk to a patient's airway. A further aim is to identify areas needing further research.

This is a white paper produced by the European Society of Swallowing Disorders (ESSD), intended to assist investigators and clinicians in making informed decisions on the safety and efficacy of utilising increased viscosity in patients with oropharyngeal dysphagia. This paper is not a

systematic review, nor it is empirical research; it is the presentation of information gathered from the literature. The information was reviewed by ESSD experts, discussed by stakeholders (industry and rheologists) and subsequently approved by the ESSD board and thus represents the position of the society. It also provides an overview of data highlighting the effect of, and differences between, various thickening agents. The ESSD promotes the development of a consensus of definitions and standardisation of textures and nutritional adaptations for liquids and solids between nutritional companies, scientific associations and other stakeholders based on scientific evidence. However, this white paper is not intended to create or suggest uniform terminology of the numerous viscosities frequently used in clinical practice but will describe the safety and efficacy of utilising increased viscosity in oropharyngeal dysphagia.

The aim of the document is therefore to review the evidence of the effect or impact that changes in viscosity have on swallowing function by examining the biomechanical changes in the human swallowing mechanism, in particular in swallowing physiology, efficacy and safety, thereby assessing bolus thickening as a valid and evidence-based management strategy for dysphagia and suggesting areas for future research.

Methodology

The searches were carried out in the databases PubMed and Embase. No time limits were used and all appropriate journal articles up to July 2015 were included. The PubMed search used the following terminology: viscosity or rheology combined with deglutition or deglutition disorders, while the Embase search used flow kinetics or viscosity combined with dysphagia or swallowing. The search located 554 abstracts, but 92 were duplicated between databases leaving 462, all of which were from peer-reviewed journals.

The abstracts were read by two independent reviewers (RN and NV) using the following inclusion criteria: swallowing studies on healthy persons or patients with oropharyngeal dysphagia; adults (>18 years); bolus modification; effects of bolus modification on swallow safety (penetration/aspiration) and efficacy; and/or physiology and original article written in English. The exclusion criteria consisted of oesophageal dysphagia, and conference abstracts or presentations. Differences of opinion between abstract reviewers were settled by group discussion reaching consensus.

Following the reading, a further 424 abstracts were excluded for not meeting the inclusion criteria or for having insufficient published data. The original articles of the

remaining 38 abstracts were retrieved and reviewed for inclusion. A further five articles were withdrawn as they did not focus on the actual swallowing mechanism or any aspect of human biomechanical analysis. All five articles focused on the quantification of rheological properties and methods of rheological measurement, and were deemed inappropriate to be included. Finally, 33 articles met all inclusion criteria—see Fig. 1.

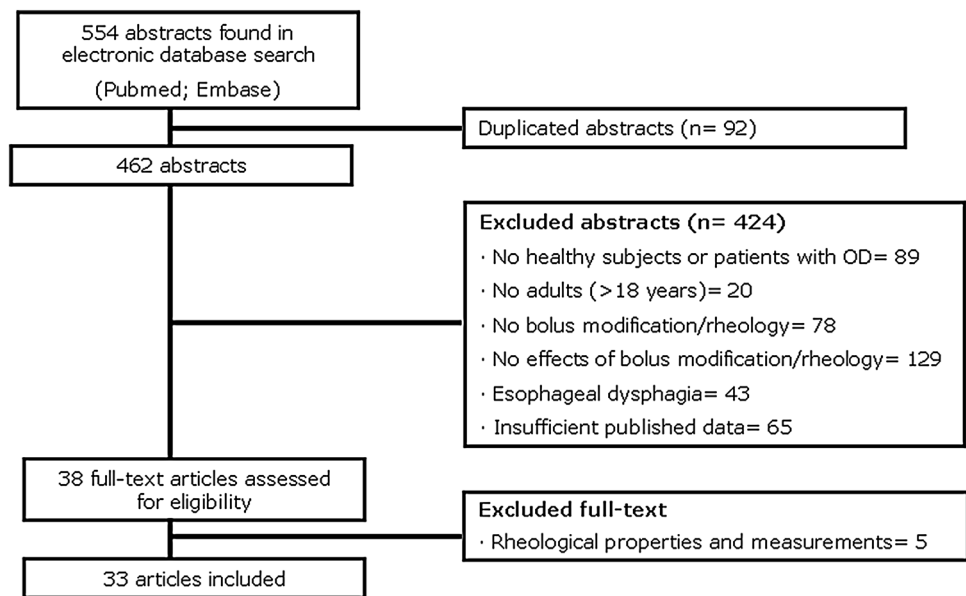
Results

The quality of the studies included in the white paper was assessed using standard quality assessment criteria for evaluating primary research papers [29]. This critical appraisal tool (CAT) or QualSyst provides a systematic, reproducible and quantitative means of assessing the quality of research over a broad range of study designs to include only studies that meet a minimum quality standard.

Completion of the CAT confirmed that all but one of these studies were of sufficiently high methodological quality as they demonstrated clear, precise and unbiased results applicable to the question of whether altering bolus viscosity increased the safety of swallowing. Of the 33 studies retrieved and included as valid evidence in the white paper, seven were not analysed with the CAT as they were not empirical or quantitative studies (for example, systematic reviews). The level of evidence of all the included articles was also assessed by using the National Health and Medical Research Council Levels of Evidence [30]. Finally, a total of 26 studies were analysed via the QualSyst and the NHMRC criteria. The results are found in the table of Appendix 1.

In summary, the CAT showed that 65.4 % ($n = 17/26$) of the studies included in the white paper were of strong quality as they scored >80 %. Those scoring between 60 % and 79 % and deemed to be of good quality totalled 23.1 % ($n = 6/26$), and 7.8 % ($n = 2/26$) scored between 50 % and 59 % meaning they were of adequate quality. One study was scored poor methodological quality (<50 %) and was therefore excluded from further discussion in this white paper. NHMRC Levels of Evidence were also included in the CAT. The NHMRC hierarchy has four levels, each having different interventions, diagnostic accuracy, prognosis, aetiology and screening intervention, with Level I being systematic reviews, and Level IV case series of test outcomes. The levels of evidence of the data included within the white paper showed both level II evidence and Level III evidence, whereby Level II consisted of randomised control trials to test accuracy via the use of an independent, blinded comparison and a valid reference standard, and Level III included either pseudorandomised control trials or comparative studies either with or without

Fig. 1 A summary of the reviewing process showing inclusion and exclusion criteria



concurrent controls. The NHMRC grading resulted in 19.2 % ($n = 5$) of the articles being designated into the Level of Evidence II and 80.8 % ($n = 21$) into Level III.

The subtopics for the white paper identified from the literature are as follows: bolus modification and an overview of rheology including terminology; objective rheological measurements; instrumental assessment used in the examination of the swallowing function where the impact of bolus viscosity was being measured; signs upon swallowing assessment; physiological changes in the swallowing mechanism and palatability of oral intake with modified viscosity.

Bolus Modification in Terms of Rheology

Rheological and physical bolus properties may affect swallowing performance. Rheology is defined as the study of the deformation and flow properties of materials. One of these rheological properties is *shear viscosity*, defined as liquids' resistance to flow under an applied force calculated as the ratio of shear stress (the shear force required for flow) and shear rate (related to the flow rate) [31]. Fluids also resist extension, e.g. when forced to flow through a contraction, and then exhibit an extensional viscosity which is always larger than the shear viscosity. To date, extensional flow is rarely considered, and the term "viscosity" generally refers to the "shear viscosity" only. Most fluid food is shear thinning which means that the viscosity decreases with the increasing shear rate, i.e. it appears thinner the faster it flows. This applies to all thickeners to a varying extent with xanthan solutions being most shear thinning and modified starch to a lesser extent. A few fluids, called Newtonian fluids, have constant viscosity irrespective of shear rate, e.g. honey, oil

and pure water. In addition, other less-studied physical properties such as density, and rheological parameters like yield stress (the level of force required to initiate flow) and slip flow (flow without sticking to the walls) may also play an important role in the swallowing process. Increased *density* has been shown to impair swallowing function [32], and the *yield stress* of a bolus is intrinsically linked to the flow of the material [33].

In experimental conditions, viscosity measurements are performed with a viscometer or rheometer applying either a constant force or a constant velocity to a contained test liquid. The units of viscosity considering the International System (IS) of Units are Pascal-second (Pa s), (N s)/m² or kg/(m s). According to the Centimetre–Gram–Second System of Units, Poise (P) or 0.1 Poiseuille (PI) is more commonly expressed as centipoise (cP). One cP is equivalent to 0.001 Pa s [34].

For products more viscous than water (e.g. nectar, honey and spoon thick), viscosity depends on several properties such as temperature and shear rate. Nowadays, there is no consensus on which range of shear rates constitutes the most representative conditions with respect to mastication and swallowing processes although a shear rate value of 50 s⁻¹ represents a reasonable order of magnitude with respect to in-mouth handling of the bolus [35]. However, other studies suggest that shear rate values during swallowing can be higher and have described shear rate variations from 1 to 1000 s⁻¹ for the whole swallowing process [36]. The ESSD recommends further research to assess the shear rates in the oropharynx during swallowing in healthy people and patients with OD.

In the management of OD, thickening agents are used to modify fluid properties. Traditionally, thickeners are usually composed of modified starch (MS) granules, composed

of carbohydrates that have the capacity to absorb water and swell, causing an increase in liquid viscosity. MS thickeners are associated with some limitations such as a starchy taste and grainy texture [37]. Research shows that MS thickeners provide a *decrease* in viscosity due to the starch settling over a 30-min period [38] or conversely an *increase* in viscosity over time due to continued absorption of water [39]. MS granules are also affected by amylase hydrolysis and are therefore broken down during the oral preparatory and oral phases of deglutition. A new generation of thickening agents is now starting to be used. These new molecules are composed of hydrocolloids, such as xanthan gum thickeners (XG). XG molecules are mixed up with water, creating new stable networks which maintain viscosity levels over time. One of the enzymes present in saliva is amylase which breaks down starch [40]. While XG offers improved palatability, it is not degraded by amylase and could potentially affect hydration by reduced extraction of water from XG-thickened liquids [17].

Preparation of the thickened liquids was said to be as per the manufacturer's guidelines, but the way in which viscosity was measured in the papers chosen for the review varied in their rheometric measuring tool. For example, Garcia et al. [39] used a Brookfield RVDV-II viscometer which measures resistance against flow. This device has a spindle which rotates in the liquid and the resistance of its viscosity calculates the shear rate within the range of 0.1 to 50 s⁻¹. This device was also used by Bogaardt et al. [41]. A Rheometric Expansion System (ARES) was used by Cichero et al. [42], consisting of a 50-mm cone and a plate. The plate rotates at a constant speed with the liquid on top of it, with the torque generated by the test liquid measured by the fixed cone above it. A similar device was used to measure viscosity by Glassburn and Deem [43]. A Brookfield Viscometer cone or plate model LDVD-II uses 1 cc samples of a solution (nectar or honey), and the viscosity rating is determined by the amount of force required to rotate the cone through the material. In addition to a viscometer similar to those described above, Taniguchi et al. [44] used a creep meter, also known as a controlled-stress rheometer. This device applies constant shear stress onto a sample of thickened liquid to observe the resulting 'flexible twist' and/or viscous flow. Interestingly, no paper used a simple line spread test (LST), and, as Kim et al. [45] showed, the LST may be limited in its ability to determine viscosity values at increased concentration.

Independent of the thickening agent used, there is no consensus with respect to the terminology used to describe the different levels of viscosity for thickened liquids. Various experts and international societies use different terminology and definitions, and there is currently no international standard regarding the levels of viscosity and their corresponding descriptors.

Some examples of the terminology describing various viscosities of liquids in the studies sourced for this document include the following:

- Nectar; thin honey; thick honey [46],
- Thin bolus; thick bolus; paste [47],
- Nectar-like; honey-like [48],
- Thin fluid; thick fluid [49],
- Liquid; syrup; thin paste; thick paste [44],
- Liquid; Nectar; Pudding [19] and
- 0.5 % xanthan; 0.75 % xanthan; 1.00 % xanthan [41]

Some national associations have developed standardised levels of viscosity and their descriptors:

- Mildly thick (150 cP); Moderately thick (400cP); Extremely thick (900cP) (Australian Standardised Terminology and Definitions for Texture Modified Foods and Fluids. Dietitians Association of Australia and the Speech Pathology Association of Australia Ltd. Nutrition and Dietetics, 64 (Suppl 2), May.
- Thin liquid (1-50cP); Nectar (51-350 cP); Honey (351-1750 cP) and spoon-thick viscosity (>1750 cP) measured at 25 °C and 50 s⁻¹ of shear rate (National Dysphagia Diet Task Force. National dysphagia diet: standardisation for optimal care. American Dietetic Association).

Further details on terminology and definitions for texture modified foods and fluids can be found in several papers published by national professional organisations [50–53].

Instrumental Assessment Used in the Examination of the Swallowing Function where the Impact of Bolus Viscosity is Being Measured

Following initial screening and clinical assessment, further assessment by means of instrumental techniques is performed to obtain a more accurate and objective diagnosis. The instrumental techniques considered to be the *gold standard* in the examination of the swallowing mechanism are videofluoroscopy (VFS) and fiberoptic endoscopic evaluation of swallowing (FEES). VFS and FEES can also be used to assess the effect of thickeners on clinical signs although some studies used other instrumental techniques or validated clinical methods such as the volume-viscosity swallow test (V-VST) [54].

VFS is a dynamic radiographic assessment based on the analysis of swallowing function where the patient swallows a radiopaque contrast medium (RCSLT, 2013). The variables examined during the VFS (visuoperceptual dynamic signs and physiological measurements of swallowing) are related to the efficacy (presence of oral and pharyngeal residue and piecemeal deglutition) and safety (presence of

penetration and aspiration) impairments of swallow [24]. Martin-Harris and Jones [55] suggested the following fifteen variables or physiologic factors to be observed during VFS: lip closure; lingual elevation; tongue to palatal seal; bolus preparation/mastication; bolus transport/lingual motion; initiation of pharyngeal swallow; soft palate elevation and retraction; laryngeal elevation; anterior hyoid excursion; laryngeal closure; pharyngeal contraction; pharyngo-oesophageal segment opening; tongue base retraction; epiglottic inversion and oesophageal clearance. In addition, radiopaque contrast makes bolus residue visible with VFS [56], an important factor when assessing efficacy of swallowing with varying viscosities. Other physiological analyses include measuring the time a bolus takes to travel from one point to another, the action of selected groups of muscles and the effect that varying viscosity has upon such action. This involves measurements such as (among others) anterior and posterior tongue pressure [44], pharyngeal response time and pharyngeal delay time [17], anterior and superior range of hyoid displacement [57], time to laryngeal vestibule closure [19] and duration of upper oesophageal sphincter (UOS) opening [58]. Despite the fact that VFS is seen to be one of the gold standards in the assessment of dysphagia, it has not been standardised [59], and a protocol to support current or new practice is urgently needed. FEES involves a nasoendoscopic evaluation by means of a fiberoptic rhinolaryngoscope passed through the nares to the pharynx to obtain images of the base of the tongue, pharynx and larynx. Coloured boluses are administered to visualise the events before and after swallowing. Variables studied during FEES are related to efficacy (pharyngeal residue) and safety (penetration and aspiration) of swallow [48, 60].

Both VFS [49] and FEES [61] enable comparisons between subjects with and without OD and allow the effects of therapeutic strategies to be assessed, including the use of thickening agents [19]. The recommendation of the ESSD is to develop an agreement on the metrics (VFS/FEES signs and measurements of swallow response) that describe the normal/impaired swallow response. Another strategy used to evaluate swallowing function, particularly muscle activity, is electromyography (EMG). This enables the timing of each swallowing event to be measured such as the onset of anterior tongue and posterior tongue movements and lingual peak amplitude, using electric sensors placed intra- or extra-orally. EMG also enables recording of variations between viscosities during the initiation, duration and completion of the movements of swallowing [44]. A tool for measuring tongue strength and endurance is the IOWA Performance Instrument (IOPPI). It is a handheld pressure transducer that measures peak tongue pressures in kilopascals (kPa) by means of a tongue bulb [62].

This review also includes newer techniques for swallowing assessments such as scintigraphy and 320-Row area detector computed tomography (320-ADCT). Scintigraphy is a radiographic procedure whereby the patient swallows a radioactive agent, enabling quantitative measurements to be taken by a gamma camera. Bogaardt et al. [41] used scintigraphy to evaluate the presence of oral and pharyngeal residue. Finally, in 2013, 320-ADCT was reported as the latest computed tomography scanner in the world [63]. It is equipped with 320 rows of 0.5 mm detectors along the body axis and the reconstruction of the three dimensional images obtained allow objective and detailed kinematic measurements of the oropharyngeal swallow.

Our list of instrumental techniques is not complete but represents those most frequently used to assess the timing, strength and efficacy of the swallowing mechanism. Most of the studies included in the white paper (60 %) used either VFS or FEES to assess the effect that increased viscosity had on swallowing.

Signs on Assessment

Across the reviewed data, the effect of bolus modification during the evaluation of the oropharyngeal swallow was considered. The items included in the swallowing assessment as bolus viscosity was modified were the presence of safety impairments of swallow such as prevalence of laryngeal penetration and aspiration and changes in penetration–aspiration scale (PAS) score, indicative of the depth of bolus invasion into the airway during swallowing [64]. Overall, the presenting data were examined for a reduction (or elimination) of laryngeal penetration or aspiration through the use of various thickening agents to modify viscosity, i.e. measuring the prevalence of safe swallows secondary to increased bolus viscosity.

Laryngeal penetration is defined as the entrance of swallowed material into the laryngeal vestibule (LV) above the level of vocal folds [22]. A VFS performed with 46 patients with OD due to a non-progressive brain damage and in 46 patients with OD associated with neurodegenerative diseases showed a significant reduction in the prevalence of laryngeal penetration associated with increased bolus viscosity, confirmed by maximal improvement at spoon-thick viscosity [19]. In a further study, Clavé et al. [54] showed that penetration into the laryngeal vestibule was the most common indicator of unsafe swallowing and was most prevalent with liquid boluses (21.6 mPa·s), subsequently decreasing when subjects were given nectar viscosity (295.0 mPa·s) and further decreasing with pudding viscosity (3682.2 mPa·s). In a subsequent study, Rofes et al. [65] also recorded statistically significant results whereby increasing bolus viscosity from liquid to pudding reduced the prevalence of

penetration and aspiration in 98.9 % of patients. These results are similar to those obtained by Kuhlemeier et al. [66] who studied 190 patients with VFS with mild or moderate dysphagia associated with different aetiologies, particularly stroke. They reported a higher prevalence of laryngeal penetration when thin liquids were delivered by a cup than when ultra-thick boluses were given from a spoon. Similar results regarding improving the safety of swallowing were obtained when xanthan gum was used as a thickening agent during VFS studies, showing a significant reduction in prevalence of penetrations from 35.3 % at thin liquid, to 13.7 % at nectar and up to 9.3 % at spoon-thick viscosity [67]. Moreover, the VFS study on adults with unilateral vocal cord paralysis performed by Bhattacharyya et al. [18] reported prevalence of liquid penetration in up to 34.5 % of the patients and it decreased for paste boluses to 21.8 %. By performing fiberoptic endoscopic evaluation of swallowing (FEES) on 61 post-stroke patients, a significant reduction in the prevalence of laryngeal penetration was also detected by Diniz et al. [60]. As bolus viscosity increased from thin liquid to spoon-thick viscosity, none of the patients exhibited laryngeal penetration. However, increased bolus *volume* has been shown to increase the risk of penetration and aspiration secondary to increased post-swallow residue [19].

The effect of increasing bolus viscosity on the prevalence of patients with laryngeal penetration is depicted in Fig. 2.

Aspiration is defined as the passage of swallowed material below the vocal folds [22]. The most prevalent physiological characteristics leading to aspiration during swallowing are delayed LV closure time, thereby decreasing airway protection, and prolongation of the UOS opening, thereby increasing the bolus volume in the

pyriform sinuses leading to greater potential for overspill into the airway [19, 67–69].

Swallowing assessments performed on patients with OD, mainly associated with stroke and neurodegenerative diseases, described an increase in the safety of swallowing as bolus viscosity also increased. A significant reduction in the prevalence of aspiration was detected via VFS [19, 49, 66, 67, 69, 70] and FEES [48, 60] at higher levels of bolus viscosity in comparison to thin liquid boluses. Moreover, Leder [48] reported the success of ingestion of nectar and honey thickened liquid consistencies in a FEES study of participants who swallow puree consistency without aspiration but aspirate with thin liquid consistency. Furthermore, Kuhlemeier et al. [66] confirmed a higher incidence of aspiration of thin liquids when these were delivered by a cup rather than by a spoon. Similar results were noted in one study involving 55 patients with unilateral vocal fold paralysis who were found to be more likely to aspirate liquid viscosity than paste Bhattacharyya et al. [18]. Chen et al. [71] studied 41 patients with various neurological diseases and found that aspiration was significantly associated with low-viscosity boluses in comparison to paste. Prevalence of patients with aspiration according to the level of viscosity is depicted in Fig. 3. It should be noted that increasing bolus *volume* was reported (by—among others—Clavé et al. [19]) to significantly reduce the safety of deglutition at all viscosities.

Data reported an improvement in the safety of swallowing by reducing the prevalence of penetration and aspiration in a bolus viscosity-dependent manner, i.e. there was improved safety of swallowing associated with the *increased* viscosity. Differences between thickening agents (modified starch and xanthan gum) during the swallowing assessment do not represent major nor significant

Fig. 2 Prevalence of patients with laryngeal penetration (measured by VFS or FEES) according to the viscosity levels cited in the literature. Note the viscosity-dependent reduction in the prevalence of penetration in the prevalence of penetration with maximal therapeutic effect at spoon-thick viscosity

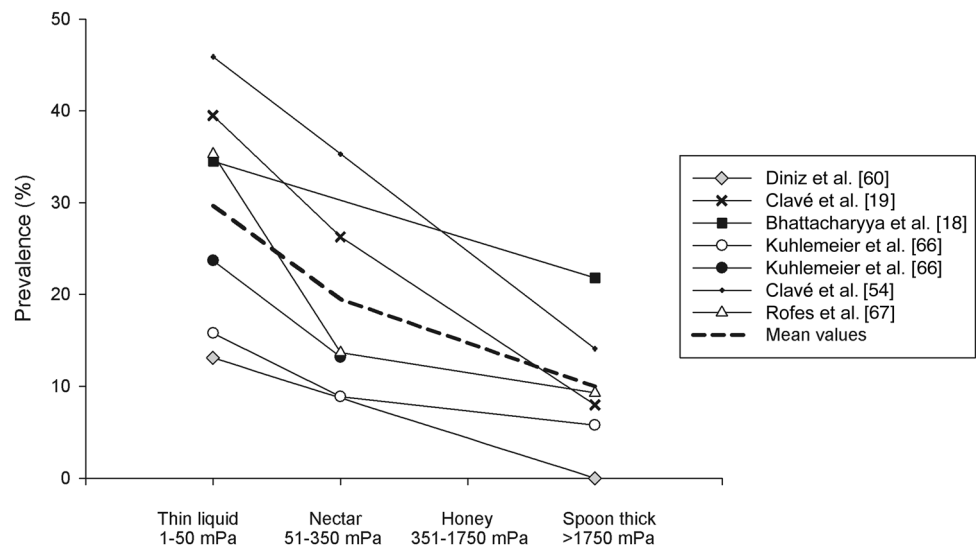
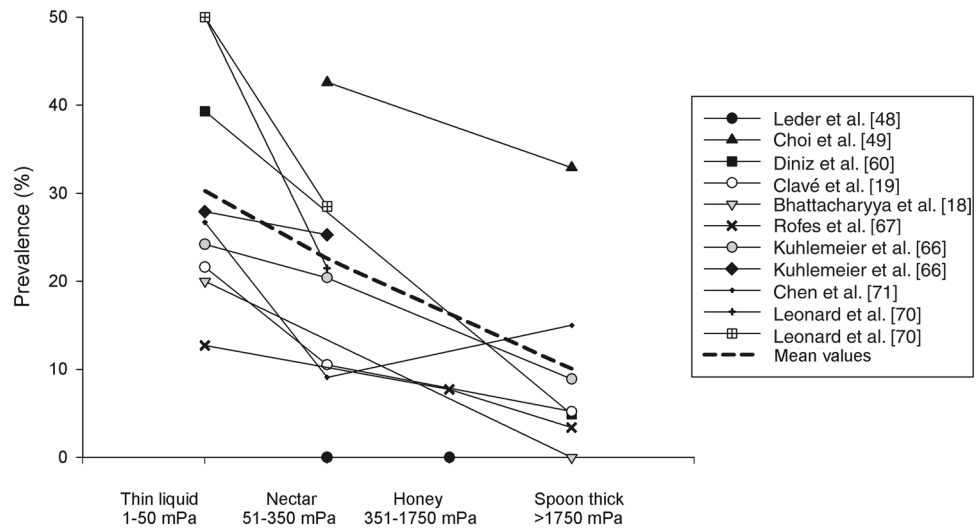


Fig. 3 Prevalence of patients with aspiration (measured by VFS or FEES) according to the level of viscosity cited in the literature. Note the overall viscosity-dependent reduction on the prevalence of aspiration with maximal therapeutic effect at spoon-thick viscosity



differences in terms of improvements of safety of swallow. Prevalence of safe swallow according to bolus viscosity level was extracted from the selected articles and is depicted in Fig. 4. Some of the data also reported that increasing bolus volume decreased the safety and efficacy of swallowing. We can conclude from this that safety mainly depends on both bolus volume and bolus viscosity. The therapeutic effect of thickeners is very high as they can greatly improve safety of swallowing in many different phenotypes of patients with OD.

The Penetration Aspiration Scale (PAS) is an 8-point clinical observation scale which determines the invasion

to the airway during swallowing and the capacity of the swallower’s response to eject bolus [64]. Reviewed studies showed a significant reduction in PAS score severity as viscosity increased from thin liquid to spoon-thick viscosity. This was evident in a study of 120 patients with dysphagia associated with ageing or neurological diseases [67] and also in a study of patients with unilateral vocal cord paralysis of various aetiologies [18]. Leonard et al. [70] studied thin and thickened boluses (starch versus gum) and noted a reduction in PAS score with the thickened ones although statistical differences were only detected when nectar gum and thin boluses

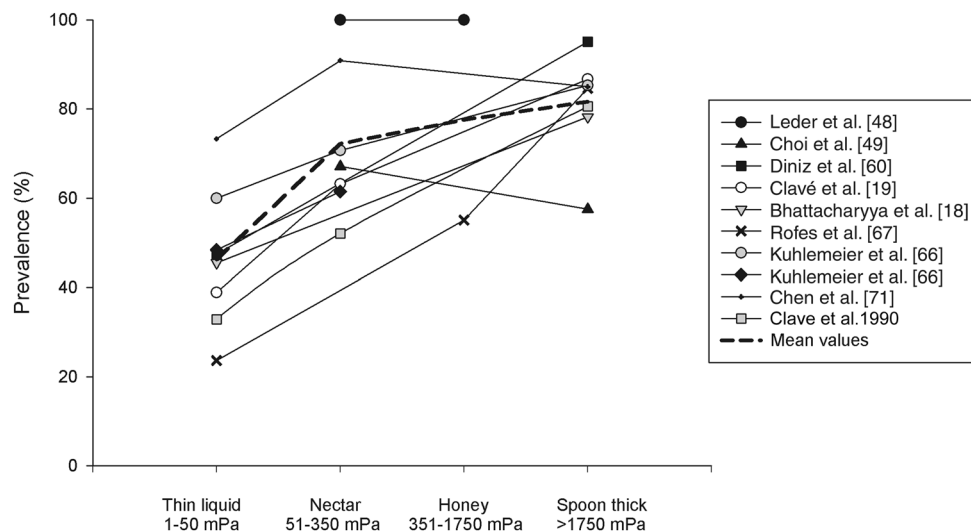


Fig. 4 Effect of bolus viscosity on the prevalence of safe swallows in patients with OD cited in the literature. **a** the viscosity-dependent increase in the safety of swallow; **b** the strong therapeutic effect of spoon-thick viscosity. The patient phenotypes in this group varied widely and included healthy volunteers; older persons; stroke patients; and patients with neurological tumour; neurodegenerative

diseases; unilateral vocal cord palsy secondary to malignancy, surgery or intracranial causes; and general illness including urinary tract infection, respiratory disorders, heart failure, chronic renal failure and cerebrovascular disease; **c** various agents were used to modify the viscosity of the fluid boluses in each study, including XG, MS and barium sulphate

were compared. The PAS score according to bolus viscosity is depicted in Fig. 5.

The presence of residue in the oral cavity and pharynx after swallowing was assessed by VFS. Different results were found for the effect of bolus modification on the prevalence of residues. Pudding viscosity resulted in increased vallecular residue in neurodegenerative patients [19] and patients with unilateral vocal fold paralysis [18]. Oral residue and pharyngeal residue were not so affected by bolus viscosity in other phenotypes of OD patients mainly post-stroke [19]. This tendency was also detected by Kuhlemeier et al. [66] who studied a group of stroke patients with OD and reported no significant difference in the prevalence of pharyngeal retention among most viscosities, but a significantly higher degree of residue was evident with 'ultra-thick' viscosity in comparison with thin liquids. Rofes et al. [67], however, reported that the amount and location of residue depends not only on the type of thickener but also on the phenotype of dysphagia. In addition to this, in the original study of the determination of the accuracy of the volume-viscosity swallow test (V-VST) for clinical screening, Clavé et al. [54] showed that the percentage of patients with OD (a mixture of ENT diseases, neurodegenerative diseases older people and post-stroke patients) showing post-swallow pharyngeal residue was seen to increase as bolus viscosity increased; likewise, an increase in fractional swallowing was also noted secondary to this residue.

In summary, bolus *volume* is reported to increase oral residue in patients with both non-progressive brain damage and neurodegenerative diseases, but only liquid thickened to pudding viscosity (with XG) increased pharyngeal residue in neurodegenerative diseases [19]. Similarly, pharyngeal residue (particularly with pudding-thick viscosity) was found to be more prevalent than penetration or

aspiration, regardless of patient phenotypes and thickening agent [18, 66].

Physiological Changes

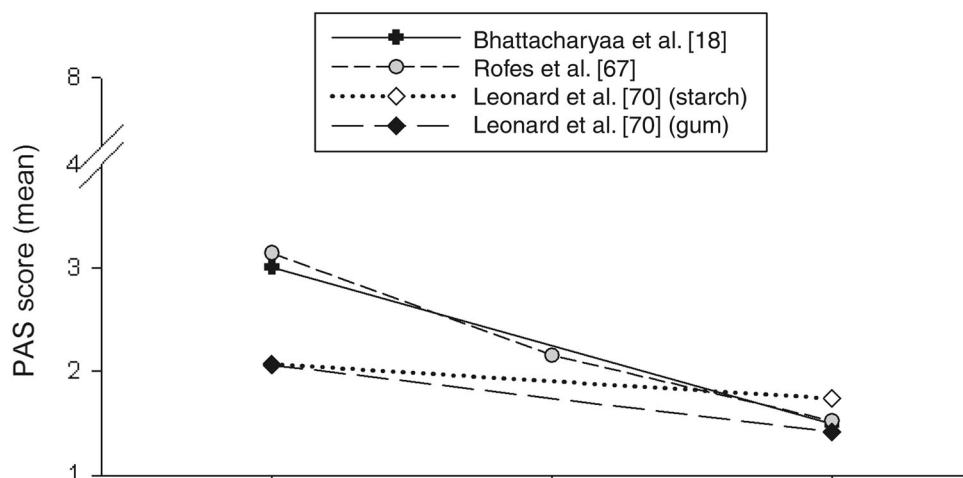
The literature included in the study showed that there are various biomechanical and kinematic variations in the swallowing mechanism when bolus viscosity is altered. In addition, variations in the timing of the onset of certain features of the swallow were also documented. The physiological changes analysed included the following: oral transit time (OTT); lingual pressure; hyoid displacement; pharyngeal transit time (PTT); time to laryngeal vestibule closure (LVC); duration of UOS opening and bolus velocity.

The impaired kinematics of the swallowing mechanism in patients with OD varies depending on the nature of the primary disorder. For ageing patients, the following characteristics have been reported: general delays in initiating the oropharyngeal swallow [72], reduction in strength and range of hyoid movement [73], increased pharyngeal residue [74] and increased laryngeal penetration [75].

In patients with a more specific reason for the onset of OD, such as stroke, traumatic brain injury, neurodegenerative disease, and head and neck cancer, there are common features reported although specific factors may be related to one patient group. These common features include reduced lingual pressure, reduced extent of superior and/or anterior hyoid excursion, increased latency of epiglottic contact, changes in the speed of bolus transition, increased rates of laryngeal penetration and aspiration, and increased pharyngeal residue [76].

When healthy subjects' swallowing was measured in a joint videofluoroscopic-manometric study, Dantas et al. [58] reported an increase in oral and pharyngeal transit time when bolus viscosity was increased from nectar

Fig. 5 This graph shows the mean value of PAS score at each viscosity. We can see that increasing bolus viscosity significantly reduced PAS scores; lower PAS scores refer to less impaired swallowing, whereas higher scores indicate increased risk of penetration and/or aspiration of boluses



(viscosity: 200 cP) to paste (viscosity: 60,000 cP). This was noted across all the volumes of intakes (2, 5, 10 and 15 mL) with no significant effect of bolus volume between both bolus types. These data suggest that increasing bolus viscosity to paste reduces bolus velocity and increases pharyngeal transit times at these very high levels of viscosity (60,000 cP). Secondary to this, it may also suggest *decreased* prevalence of laryngeal penetration and/or aspiration.

In addition, Taniguchi et al. [44] collected data from intra-oral pressure sensors placed on the anterior and posterior hard palate to measure tongue pressure and also external surface electrodes measuring suprahyoid muscle activity when swallowing four different viscosities (liquid, syrup, thin paste and thick paste) with yield stresses of 22, 28, 181 and 894 mPa respectively. The results showed that increased bolus viscosity increased the pressure patterns of the anterior tongue (AT) and posterior tongue (PT) muscles. The peak EMG bursts for the AT ranged from 0.95 s with liquid, to 2.32 s with thick paste. Similarly, the peak EMG bursts for the PT ranged from 1.18 s with liquid to 2.72 s with thick paste. Conclusions were drawn that not only does increasing viscosity lead to a longer swallowing time secondary to longer bolus ejection time, but also that lingual pressure increased from liquid to syrup, and to thin and thick pastes. In their study, no differences between healthy male and female participants were apparent. As they found, this suggests that increasing viscosity causes an increase in bolus propulsion pressure, upward hyoid displacement and overall reduction in bolus velocity [44]. Moreover, tongue-palate pressures were studied in healthy volunteers by Steele et al. [76] with a lingual manometry module when thickened liquids (190, 250 and 380 mPa·s) were administered. They reported higher tongue-palate pressure when swallowing nectar and honey-thick xanthan gum boluses in comparison with pressures used when swallowing water. Additionally, the temporal profile of tongue-palate pressures changes detecting more rapid pressure decay as liquids become thicker.

The extent of hyoid displacement during swallowing is a variable which may be considered a key element in the safety of deglutition due to its impact on the success of airway closure and also of opening of the UOS. In their study, Choi et al. [49] examined the swallowing mechanism of 132 participants via VFS. All adult subjects had previously been diagnosed with OD of unspecified origin. Their study documented that upon trialling thin fluid and thick fluid aspirators while measuring all physiologic variables of the swallow, they found that pharyngeal contraction and UOS opening were reduced for the thick fluid aspirators, both of which have a common cause, i.e. reduced extent of hyolaryngeal elevation. The results of

this study showed a decrease in hyoid excursion with increased bolus viscosity. Conversely, Zu et al. [57] reported that in their study of 122 post-treatment cancer patients whose swallowing function was analysed via VFS, anterior and superior displacement of the hyoid was in fact greater for paste than for liquid bolus.

With regard to the pharyngeal phase of swallowing, Lee et al. [47] analysed the swallowing mechanism with both thin and thick fluid boluses. They found that in thin fluid aspirators and non-aspirators in their study the latency of epiglottic contact-defined as the interval between the initiation of pharyngeal phase and bolus contact with the epiglottis was significantly prolonged for thick bolus viscosity compared with thin bolus in both groups.

Bisch et al. [17] measured the effect of bolus viscosity on pharyngeal delay time and pharyngeal response time comparing 1 mL liquid bolus and 1 mL pudding bolus. They found that healthy persons displayed significantly *shorter* pharyngeal delay time (PDT) when bolus viscosity was increased from liquid to pudding. However, it was noted that patients with severe neurologic impairments exhibited the following changes associated with increasing viscosity from liquid to pudding: significantly *shorter* pharyngeal delay time; *longer* pharyngeal response time; significantly *shorter* pharyngeal transit time; no change noted on the mean duration of laryngeal elevation and duration of laryngeal closure and *longer* duration of cricopharyngeal opening. Overall, it can therefore be concluded from this study that increasing bolus viscosity in patients with severe neurologic impairments results in an increase in the complete duration of the swallow.

Rofes et al. [67] reported on the effect of increasing viscosity of fluids on laryngeal vestibule closure (LVC) time in a study of 134 participants (120 patients with oropharyngeal dysphagia of varying nature and 14 healthy volunteers). They concluded that in patients with OD, LVC time was prolonged when compared with controls but was not affected when bolus viscosity was increased from thin liquid to nectar or spoon thick using xanthan gum. This finding coincided with Clavé et al. [19] who previously reported that increasing bolus viscosity with starch-based thickener to nectar and more so to pudding improved the safety of swallow by reducing penetration and aspiration without affecting LV closure time nor bolus transfer. Rofes et al. [67] also reported that patients with impaired safety of swallow (with evidence of penetration or aspiration) presented a significantly delayed LV closure time compared with those with a safe swallow at all three viscosities. These results indicate that OD patients presented slow oropharyngeal reconfiguration which correlates with impaired safety of swallowing.

In a report by Dantas et al. [58], ten healthy adult male volunteers with an average age of 26 years were examined. Their combined VFS-manometric study indicated that both bolus volume and viscosity had a direct effect on the timing and duration of UOS relaxation. They showed that the mean flow rate through the UOS for liquid viscosity barium sulphate was significantly faster than for the contrast medium with paste viscosity (60,000 cP). Both of their measurement tools (VFS and manometry) provided the same result of longer duration of UOS opening with increased viscosity.

This evidence was corroborated by Bisch et al. [17] in their study comparing various physiological parameters of three groups: healthy persons, stroke patients and known severely dysphagic patients secondary to neurological disorders of various origins. They showed a significant increase in the duration of UOS opening in known severely dysphagic patients compared with healthy persons and stroke patients when they radiographically compared the three groups swallowing thin liquid viscosity compared with pudding viscosity.

In contrast, in their study of healthy volunteers using a 320-row area detector CT, Inamoto et al. [63] reported no variation in the onset, termination or duration of UOS opening when comparing thin liquid and thick liquid viscosities. In addition, Lee et al. [47] reported similar findings whereby they found that despite the fact that thin fluid aspirators showed a delay in the onset of UOS opening when swallowing thick liquids, the duration of UOS opening was not affected by bolus viscosity. This was compounded by Choi et al. [49] in their evaluation of 132 patients who underwent a VFS evaluation of their swallowing. They concluded that swallowing a thick liquid viscosity resulted in a shorter duration of UOS opening when compared with thin liquid.

When considering the question of comparing bolus velocity with bolus viscosity, the use of the 320-row area detector CT by Inamoto et al. [63] regarding the timing of the onset and duration of the swallow with thin versus thick liquid showed that the speed of transition of a thicker viscosity is slower than that of a thinner viscosity. The opening of the posterior oral seal was seen to be slower with thick liquid viscosity, and in turn, this had effects on the hypopharyngeal stages of the swallow. Soft palate elevation was twice as slow with thick liquid viscosity, and in addition to thin liquid reaching the hypopharynx earlier, interestingly, it remained in the hypopharynx for longer. Further results were reported by Inamoto et al. [63] with reference to true vocal fold movement, whereby complete true vocal fold closure was reported to occur later and secondary re-opening occurred sooner with thick liquid than with thin liquid, meaning that the duration of true vocal fold closure was in fact longer with thin liquid. These

findings led to their suggestion that the rapid flow of thin liquid into the pharynx (compared with the reduced velocity of thick liquid bolus flow) may elicit an anticipatory response for increased duration of airway closure at the level of the true vocal folds in an attempt to prevent aspiration.

A statistically significant difference was reported by Stachler et al. [77] between the total speed of bolus transition of thin liquids, pastes and cookies. Their study of patients with head and neck cancer of various origins and healthy controls showed that for both groups the mean speed of bolus transition measured in seconds increased with viscosity. Contrasting results were reported by Clavé et al. [19]. They showed that in healthy volunteers and in patients with OD secondary to non-progressive brain diseases and degenerative brain diseases, bolus velocity was not affected by increasing bolus viscosity from liquid to pudding viscosity. However, they go on to qualify this by showing that patients with OD presented significantly reduced bolus velocity when swallowing thin and thickened boluses when compared with healthy volunteers. They also reported that the rate of laryngeal penetration reduced as viscosity increased [19]. Similar results were also reported by Leonard et al. [70], Rofes et al. [67, 69] whereby the prevalence of aspiration according to the PAS score [64] reduced as bolus viscosity increased. Moreover, Rofes et al. [67] noted no changes in bolus velocity or timing of the oropharyngeal swallow response at nectar using XG, compared with thin liquids. However, at spoon-thick viscosity, bolus velocity was reduced. These results suggest that the therapeutic effect of XG thickeners depends not only on its effects on swallow physiology but also on additional intrinsic texture properties. The investigators also state that in this study, increasing bolus viscosity with a XG thickener did not significantly alter the prevalence of residue in the mouth, valleculae or pyriform sinuses, Rofes et al. [67].

Varying velocity of bolus flow relating to its viscosity was also examined by Matsuo et al. [78]. They suggested that the trigger point of the swallow shifts depending on its viscosity from between the valleculae and hypopharynx for thin liquid to between the oropharynx and valleculae for thicker liquids. They also noted an impact of the speed at which each viscosity travels into the pharynx, i.e. thick liquid velocity is decreased compared with that of thin liquid. This was further hypothesised to be a potential therapeutic strategy by Bisch et al. [17] who show that increased bolus viscosity led to decreased speed of flow into the pharynx and could potentially be beneficial to patients neurologically compromised, although individual assessment would still be required.

In summary, Bisch et al. [17], Inamoto et al. [63] and Matsuo et al. [78] all proposed that the use of a thickening

agent would be beneficial for dysphagic patients with delayed swallow due to the decreased velocity of bolus flow in comparison to thin liquid. However, other studies found that increasing bolus viscosity did not affect bolus velocity [19, 67]. In addition, the results from these studies may also give rise to the need for consideration of the type of thickener used in patients with impaired swallowing function and the effect of other intrinsic bolus properties.

Table 1 shows a summary of these physiological changes in swallowing and also changes in bolus velocity associated with increased viscosity.

Palatability of Oral Intake with Increased Viscosity

Several studies report disadvantages related to the use of thickeners. In some patients, aversion for thickened liquids affected their ability to maintain adequate fluid intake, increasing the risk of dehydration. Daily fluid requirements change according to a person's age and weight, varying between 40 mL/kg for an individual aged between 16 and 30 years, and 25 mL/kg for someone aged over 75 years [79]. Conditions such as diarrhoea and vomiting or general fever need to be taken into account when calculating this, and intravenous fluids may be required in hospitalised patients. Accurate data on the prevalence of patient dehydration when using thickened fluids are not readily available, and some conflicting reports exist. Murray et al. [80] reported that dehydration is high and the amount of fluids taken orally should be increased by "pushing" patients to drink more thickened fluids. However, Hill et al. [81] proposed that more evidence was needed to show that water bioavailability was not affected by adding a thickening agent (xanthan gum) to fluids. Further research is therefore required to determine whether increasing viscosity of fluids increases the risk of dehydration and whether it depends on the type of thickening agent.

Nevertheless, reduced amounts of fluids taken orally will lead to dehydration. If patients have a strong dislike of thickened fluids, their intake may decrease and their fluid levels deplete, leading to dehydration [82]. Speech pathologists reported that, of their patients who required increased viscosity secondary to OD, nectar viscosity was reported to be the best tolerated, i.e. neither liked or disliked [39]. In the same study, the authors go on to state that approximately half the respondents stated that their patients expressed strong dislike of honey-thick and spoon-thick viscosities. The strong dislike was reported as not changing or in fact worsening over time [39].

The type of thickened fluid given to patients has also been researched (either pre-thickened drinks or fluids thickened with a commercially available powder thickener). Whelan [83] showed that patients in an acute

stroke ward had increased fluid intake with commercially available pre-thickened drinks compared with patients whose drinks were thickened with a powder thickening agent. In addition, an audit on the ward showed that 50 % of fluids were thickened to the incorrect recommended viscosity when using a powder thickener, if they were thickened at all. Although it is obvious that thin liquids pose a threat to the airway in those patients requiring thickened liquids, overly thickened liquids may result in reduced acceptance, and potentially result in dehydration. Overall, no patient in either group was reported to reach their minimum daily fluid requirement orally although pre-thickened drinks were better accepted and did not need nursing staff to thicken the drinks,. However, Patch et al. [84] completed a similar study where powder-thickened fluids were reported to have a greater fluid intake (41 % of the recommended daily intake) than those taking commercially available pre-thickened drinks (37 % of the recommended daily intake), but the difference is not seen to be significant, and again, neither group was reported to be taking 100 % of the recommended daily fluid intake. These results should be contrasted with measurement of fluid intake of older people without OD.

When comparing the type of thickening agent used (starch-based versus gum-based) with patients with dysphagia of varying origins, Bridget [85] showed that 68 % of the population in her study preferred drinks with the gum-based thickener compared with 8 % preferring the starch-based thickener (24 % had no preference). The reasons given for the preference of a gum-based thickener were the texture, taste, and appearance of the drinks (clearer). In addition to this, 84 % of the patients in the study reported changes in viscosity over time with liquids thickened with MS, some of the specific comments being "continues to thicken", "thins over time" and "separates". This was corroborated by comments from Cichero and Lam [86] based on research from Stuart et al. [87] who stated that MS based thickeners caused liquids to thicken over time secondary to swelling of the starch molecules whereas gum-based thickeners remained more stable. This was reportedly with the exception of human breast milk where the presence of amylase causes the breakdown of starch and MS thickened liquids actually become thinner over time [88]. This is therefore an important factor for consideration when feeding thickened human breast milk to an infant with dysphagia.

A review by Cichero [89] detected several factors negatively affecting the consumption of thickened liquid such as flavour suppression and a 'coating feeling' in the mouth. Moreover, the failure of thickened fluids to reduce the physiological sensation of thirst has been associated with reduced motivation to drink thickened liquids. Although

Table 1 Physiological changes in the swallowing mechanism when bolus viscosity is altered, listed in the phases of oropharyngeal swallowing

Physiological changes	
Lingual pressure	
Increased bolus viscosity increases the pressure patterns of the anterior tongue (AT) and posterior tongue (PT) muscles	Taniguchi et al. [44]
Bolus viscosity has the potential to influence tongue movement amplitudes, durations and variability during normal, sequential swallowing in healthy subjects	Steele and Van Lieshout [93]
Higher amplitudes of tongue-palate pressure in healthy individuals noted when swallowing nectar- (190 mPa s) and honey-thick (380 mPa s) XG-thickened drinks compared with pressures when swallowing water	Steele et al. [76]
Oral and pharyngeal transit time (PTT)	
Increased oral and pharyngeal transit time in healthy volunteers when bolus viscosity increases from liquid (200cP) to paste (60,000cP) independently of bolus volume	Dantas et al. [58]
Bolus velocity	
Speed of bolus transition of a thicker viscosity is slower than that of a thinner viscosity in healthy volunteers	Inamoto et al. [63]
Mean speed of bolus transition measured in seconds increased with viscosity in patients with head and neck cancer of various origins	Stachler et al. [77]
Bolus velocity was not affected by increasing bolus viscosity with MS thickeners, but patients with OD showed reduced bolus velocity when swallowing thin and thickened boluses compared with healthy volunteers	Clavé et al. [19]
Velocity of thick liquid compared with that of thin liquid is decreased in healthy volunteers	Matsuo et al. [78]
Increased bolus viscosity led to decreased speed of flow into the pharynx in OD subjects	Bisch et al. [17]
The mean bolus velocity of thin liquid bolus was not changed by increasing bolus viscosity to nectar but was significantly slowed at spoon-thick viscosity using XG (vs. thin liquid) in patients with dysphagia associated with ageing and/or neurological disease	Rofes et al. [67]
Hyoid displacement	
Hyoid excursion decreased with increased bolus viscosity measured by VFS in patients with dysphagia of unspecified origin	Choi et al. [49]
Anterior and superior displacement of the hyoid was greater for paste than for liquid bolus during VFS of post-treatment head and neck cancer patients with OD	Zu et al. [57]
Epiglottic contact	
Latency of epiglottic contact was significantly prolonged for thick bolus viscosity compared with thin bolus viscosity	Lee et al. [47]
Laryngeal vestibule closure (LVC) time	
LVC time was not affected when bolus viscosity increased from thin liquid to nectar or spoon thick in patients with OD	Rofes et al. [67]
Patients displaying penetration or aspiration presented delayed LV closure time compared with those with a safe swallow in all the viscosities tested (thin liquid, nectar and spoon thick)	Rofes et al. [67]
Increasing bolus viscosity improved the safety of LVC by reducing penetration and aspiration secondary to reduced delay	Clavé et al. [19]
Pharyngeal delay time (PDT)	
Healthy persons displayed significantly <i>shorter</i> PDT when bolus viscosity was increased from liquid to pudding, but patients with severe neurologic impairments exhibited significantly <i>longer</i> PDT when compared with healthy controls swallowing both viscosities	Bisch et al. [17]
Duration of upper oesophageal sphincter (UOS) opening	
Mean flow rate through the UOS for liquid viscosity was significantly faster than paste viscosity in VFS-manometric study of healthy volunteers	Dantas et al. [58]
The duration of UOS opening increased significantly with increased viscosity in OD patients studied via VFS	Bisch et al. [17]
UOS opening increased at spoon-thick viscosity compared with thin liquid in VFS of OD patients	Rofes et al. [67]
The duration of UOS opening did not vary when comparing thin liquid and thick liquid viscosities using a 320-row area detector CT in healthy volunteers	Inamoto et al. [63]
Duration of UOS opening was not affected by bolus viscosity in VFS results of OD patients	Lee et al. [47]
Swallowing a thick liquid viscosity resulted in a <i>shorter</i> duration of UOS opening when compared with thin liquid in VFS studies of OD patients	Choi et al. [49]

Table 1 continued

Physiological changes

Penetration and Aspiration

Less aspiration was noted in VFS in patients with dysphagia of widely varying origin when viscosity of bolus was increased using both xanthan gum and modified starch	Leonard et al. [70]
Prevalence of penetration/aspiration was not affected with thin versus thick honey viscosity x-ray contrast (1,500cP vs. 3000 cP) during VFS in patients with dysphagia secondary to head and neck cancer/trauma, stroke, neurologic disease or other medical conditions	Hind et al. [46]
Prevalence of airway invasion reduced as viscosity increased when assessed by VFS in patients with dysphagia arising from ageing, stroke and neurodegenerative diseases	Rofes et al. [69]

the absorption and bioavailability of water mixed with thickeners agents has mixed reports, Rolls et al. [90] state that the satiate effect and aeration of drinks during preparation predisposed the subject to feel full after consuming aerated fluids compared with non-aerated fluids. Using this research as a basis, Cichero [89] goes on to state that the aeration of fluids is an important factor for consideration in geriatric care units where large scale mixers are often used in the preparation of the residents' thickened drinks. Regarding individuals' perception and willingness to take modified viscosity, Hind et al. [46] described that low viscosity levels were preferred and less difficult to swallow than higher viscosity levels in the research population of patients with dysphagia arising from head and neck cancer/trauma, stroke, other neurological disease, and other general medical condition such as renal failure.

In a systematic review on the impact of bolus modification on health-related quality of life in individuals with OD, Swan et al. [91] concluded that increased modification of food and fluids correlating with reduced quality of life, although severity of dysphagia may have been a confounding factor.

Discussion and Conclusion

In the current white paper, a bibliographic search was performed to extract salient published data on the effects of bolus modification on swallowing physiology, efficacy and safety in both adults with oropharyngeal dysphagia and healthy persons. Initially, a large number of potential abstracts were found but the selection process led finally to 33 articles. In general, the studies included small sample populations with multiple OD aetiologies (older, neurodegenerative diseases, neurological diseases and structural causes such as head and neck cancer) and presented heterogeneous study designs or methodologies. Even so, articles were properly reviewed considering their

methodological quality and levels of evidence. Data from those articles that met the inclusion criteria and achieved the desired quality were extracted and classified under subheadings in the white paper.

The reviewing process detected a lack of standardised definitions of the levels of viscosity, and multiple subjective terms were used to describe the same range of viscosity levels, and the conditions and equipment used to measure viscosity were not detailed in some papers. In addition, although 60 % of the included articles used either VFS or FEES to examine the effect of bolus modification on the swallowing function, many other instrumental techniques were used. Several types of thickener agents were used to obtain the different levels of bolus viscosities for the study of the effects of bolus modification and only one study directly compared the effects between them (MS/XG) [70]. Finally, the potentially deleterious effects of salivary alpha amylase on bolus rheology of starch-based thickeners should be fully studied and assessed in "in vivo" physiological conditions.

A heterogeneous variety of X-ray contrast media were used in the swallowing function assessment. The development of standardised X-ray contrasts, viscosities and protocols for VFS assessment are needed as well as studies matching the rheology of material swallowed during assessment (clinical and VFS) and subsequent nutritional recommendations. In summary, terminology, shear rate ranges and experimental conditions must be standardised to allow proper comparison between viscosity levels and thickener agents. Moreover, further research is required with larger samples and a wide range of phenotypes of patients with dysphagia, to obtain robust results and to provide safe and consistent recommendations for clinical management of all phenotypes of patients with dysphagia. In general, it appears from the data studied that increasing viscosity of oral intake results in increased safety of swallowing in OD arising from various conditions [17, 19, 78]. A significantly high

reduction in the prevalence of laryngeal penetration and aspiration in OD patients was detected as bolus viscosity increased indicating a strong therapeutic effect [18, 19, 49, 54, 60, 65, 66, 69–71]. In contrast, various studies reported that greater viscosity resulted in increased amounts of oral and/or pharyngeal residue [18, 19] counteracting the positive results noted regarding safety of swallow, with a risk of post-swallow aspiration. In their study of the effects of bolus rheology on aspiration, Leonard et al. [70] noted a marginal difference between liquid thickened with XG versus liquid thickened with MS in the reduction of aspiration. However, although they stated that the difference between XG and MS did not reach statistically significant, it should be noted that they reported that increased viscosity from both thickening agents reduced the prevalence of aspiration compared with unthickened liquid in patients with dysphagia. Some studies highlighted that increasing volume of intake may have a detrimental effect upon the safety of swallowing by increasing risk of aspiration [19]. Other research outcomes indicated that increased bolus volume led to increased pharyngeal residue [19], suggesting a risk of aspiration secondary to residual overspill [68].

Variability of the outcome measurements within the research was high, with measurements including duration of UOS opening; duration of pharyngeal stage transition; laryngeal penetration; amount of residue and bolus size. Due to the mixed results reported regarding the safety of swallowing, levels of viscosity and duration of UOS opening, it can also be concluded that this cannot be taken as a true measurement of the efficacy of swallowing. Other variables need to be considered including the age of the patient with dysphagia (as raised by [49]) in addition to the nature and severity of their swallowing deficit.

One additional point highlighting the need for further research is mixed feeding. None of the research studied the impact that modified viscosity has on subjects with OD who have an enteral feeding tube in place, i.e. nasogastric (NG) tube or nasojejunal (NJ) tube. Leder and Suiter [92] completed a large study of nasogastric feeding tubes' impact on swallowing, regarding aspiration versus no aspiration. Their research included many patient groups but no controls and only included two viscosities: liquid and puree. It is important to describe some limitations, mainly concerning the terms used in the bibliographic search. Little data related to rheological and mechanical properties and their measurements were collected other than for

viscosity. Further studies should include these terms in order to broaden knowledge on rheological characteristics of thickened fluids. Another difficulty considering the main results obtained from this review was how to translate the experimental results from the clinical swallowing assessment into standardised nutritional recommendations for OD subjects.

To summarise, the studies showed that increasing viscosity from liquid to nectar and pudding reduces the prevalence of penetrations and aspirations, but some studies showed that pudding viscosity increased the prevalence of post-swallow pharyngeal residue with MS thickeners. This in itself is a risk and will vary depending on the nature and severity of an individual's disorder, but the research included within the ESSD white paper suggests that patients with OD indeed benefit from taking fluids with increased viscosity to reduce the risk of laryngeal penetration and/or aspiration. Further research on other rheological characteristics of boluses and their effect on OD is needed as well as standardised protocols, definitions and measurements in order for bolus modification to be an evidenced-based treatment for the various phenotypes of patients with OD.

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Compliance with Ethical Standards

Conflict of interest None of the authors have any conflict of interest.

Appendix 1: QualSyst critical appraisal tool by Kmet et al. [29]

A total of 26 studies were published between 1994 and 2014. Of these selected studies, the overall methodological quality of the studies based on the QualSyst ratings as described by Kmet et al. [29] ranged from poor to good with one study ranked as poor (and therefore excluded from the white paper), 2 studies as adequate, 6 studies as strong and 17 studies as good.

Based on the NHMRC Evidence Hierarchy (NHMRC, 1995), 5 were classified as level II evidence and 21 as level III evidence (See Table 2).

Table 2 Assessment of study quality by QualSyst ratings [29] and NHMRC Evidence Hierarchy [30]

Reference	Kmet score (%)	Methodological quality ^a	NHMRC level of evidence
Bhattacharyya et al. [18]	18/22 (82 %)	Good	III
Bisch et al. [17]	20/24 (83 %)	Good	III
Bogaardt et al. [41]	16/22 (73 %)	Strong	III
Chen et al. [71]	13/24 (54 %)	Adequate	III
Choi et al. [49]	21/22 (95 %)	Good	III
Clavé et al. [19]	21/22 (95 %)	Good	III
Clavé et al. [54]	21/24 (88 %)	Good	III
Dantas et al. [58]	19/22 (86 %)	Good	III
Diniz et al. [60]	24/26 (92 %)	Good	II
Goulding et al. [82]	22/26 (85 %)	Good	II
Groher et al. [26]	10/24 (42 %)	Poor	III
Hind et al. [46]	13/24 (54 %)	Adequate	III
Inamoto et al. [63]	20/26 (77 %)	Strong	II
Kelly et al. [94]	16/22 (73 %)	Strong	III
Kuhlemeier et al. [66]	15/22 (68 %)	Strong	III
Leder et al. [48]	23/26 (88 %)	Good	II
Lee et al. [47]	21/22 (95 %)	Good	III
Leonard et al. [71]	21/24 (88 %)	Good	II
Matsuo et al. [78]	19/24 (79 %)	Strong	III
Rofes et al. [67]	21/24 (88 %)	Good	III
Rofes et al. [69]	21/24 (88 %)	Good	III
Stachler et al. [77]	18/22 (82 %)	Good	III
Steele and Van Lieshout [95]	17/22 (77 %)	Strong	III
Steele et al. [76]	22/24 (91 %)	Good	III
Taniguchi et al. [44]	19/22 (86 %)	Good	III
Zu et al. [57]	20/22 (91 %)	Good	III

^a Methodological quality: good >80 %; strong 60–79 %; adequate 50–59 %; poor <50 %

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