DIPLOMARBEIT

Oral stereognosis in patients of different age groups with full dentures in the upper jaw

Orale Stereognose von Patienten mit Totalprothesen im Oberkiefer in unterschiedlichen Altersklassen

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I dedicate this thesis to my parents Ida and Edib Zimonjic.
Danksagung

Es ist mir ein persönliches Anliegen, folgenden Personen meinen Dank auszusprechen:

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Alle personenbezogenen Bezeichnungen sind als geschlechtsneutral anzusehen!
1. ZUSAMMENFASSUNG

Orale Stereognose (OS) oder Mundraumwahrnehmung bezeichnet die Fähigkeit des Menschenohne Zuhilfenahme der Augen mit seinem Mundorgan Objekte zu tasten, zu testen, zu identifizieren und zu diskriminieren [1].


Viele bisherige wissenschaftliche Studien haben nachgewiesen, dass Altern einen negativen Einfluss auf die OS hat [2-12]. Die OS nimmt mit den Jahren ab und dieser Umstand erschwert die Akzeptanz von neuen Teil- oder Totalprothesen, was zu Kau-, Schluck- und Sprechproblemen (myofunktionellen Störungen) führen kann [13].
Jüngere Patienten, die Totalprothesen tragen, haben eine höhere orale Stereognose als Ältere [7].
Laut Jacobs et al. 1998 hat das Geschlecht keinen Einfluss auf die OS [8].
Die vorliegende Arbeit ist eine klinische Studie an 27 Patienten (16 weiblich und 11 männlich), ab einem Alter von 30 Jahren, die Totalprothesen im Oberkiefer tragen. Zur Beurteilung der OS der Patienten, wurde folgender Test durchgeführt: anhand von neun verschieden geformten Testplättchen aus Acrylat (ca. 2mm dick und 12mm im Durchmesser) wurde überprüft, ob die Patienten deren Form erkennen konnten. Die Untersuchung fand an der prothetischen Abteilung der Universitätszahnklinik Wien statt.


Als Hypothese dieser Studie wurde angenommen, dass jüngere Patienten, die Totalprothesen im Oberkiefer tragen, eine höhere orale Stereognose als Ältere haben.

Mit dem Rangkorrelationstest nach Spearman wurde überprüft, ob zwischen dem Alter der Patienten und der OS ein Zusammenhang besteht und diese Hypothese wurde durch die Ergebnisse der vorliegenden Studie bestätigt. Mit dem U-Test wurde überprüft, ob zwischen zwei Altersklassen und der OS ein Zusammenhang besteht, sowie zwischen dem Geschlecht und der OS. Der U-Test zeigte eine signifikante Korrelation zwischen den Altersklassen und der OS, aber keine signifikante Korrelation zwischen dem Geschlecht und OS.
2. ABSTRACT

Oral Stereognosis (OS) is the ability of a person to recognize the shape and surface of an object by manipulating it within the mouth, without looking at it [1].

Oral functions such as chewing, swallowing, sucking and articulation are based on the OS and these functions are sensory regulated. The tactile sense of the mucous membrane receptors transfers the sensations of touch, pain and temperature to the central nervous system (superficial sensibility). The oral sensibility delivers to the central nervous system an accurate picture of the current conditions of the oral cavity and its structures, as well as the type of changes of the normal conditions if they occur. For the shape recognition of an object in the oral cavity the crucial role belongs to the tip of the tongue and the anterior palate. A deficiency of the oral sensory ability may result in the tongue losing its sense for the correct position in the mouth. Sensory deficits are compensated through uncoordinated, forced or exaggerated movements of the tongue. Hence, this maladaptive mechanism (contact tongue-teeth or lip-teeth) becomes responsible for development of myofunctional disorders and inappropriate muscle function during chewing, swallowing and speaking [1].

Previous studies on this topic showed that aging has a negative influence on OS [2-12]. Younger patients with full dentures have a higher oral stereognostic ability than the older ones [7]. OS decreases with the age and this condition in patients with complete dentures make the adaptation process difficult, resulting in chewing, swallowing and speech problems (myofunctional disorders) [13].

Jacobs et al. 1998 proved that the gender has no influence on the oral stereognostic ability [8].

This clinical study included 27 patients (16 females and 11 males) with full dentures in the upper jaw. They had a minimum age of 30 years. In order to evaluate OS of participants, an oral stereognostic ability test (OSAT) was conducted. The OS was tested by the aid of 9
Acrylic test objects of various shapes (circ. 2mm thick and 12mm diameter) specially designed for this purpose. This examination was conducted at the Prosthodontic Department of the Dental University Clinic, Vienna.

The purpose of this study was to examine if younger people with full dentures in the upper jaw have a higher oral stereognostic ability than older patients, as well as to describe the correlation between OS and the two different age groups of the participants (Group 1: 30-60 years, Group 2: from the age of 61 years).

As a hypothesis it was assumed that younger full denture wearers have higher oral stereognostic ability than the older individuals.

Using Spearman's Rank Correlation Test the correlation between the age of the participants and their OS was examined and results showed that the hypothesis was correct. The U-test was applied to examine the correlation between the two age groups and OSA. Statistical results showed a significant difference in OS within the two different age groups. In addition, U-Test was used to examine the correlation between genders and OS. Results showed that the sex of the patients has no influence on OS.
3. INTRODUCTION

3.1 Definition

Stereognosis (also known as haptic perception or tactile gnosis) has been defined as the appreciation of the form of objects by palpation. This definition refers to manual exploration of objects. It is also possible to extend the tactile perception of objects intra orally and this is referred to as oral stereognosis. This term was first introduced by Berry and Mahood in 1966 [15]. The Oral Stereognosis refers to the oral facility to test, identify and discriminate the shape and surface of an object, without looking at them [1]. The information gathered after manipulating the object within the mouth involves a certain amount of motorical activity. It is associated with oral sensory memories obtained from visual and tactile experiences [4].

3.2 Scientific Background

Oral sensory ability was investigated by numerous authors and many different techniques were utilized. Previous studies showed quite inconsistent results [6].

The results provided by a study of Smith and McCord (2002) showed that significant differences in oral sensory ability can be noted between patients with natural dentition and edentulous individuals. Individuals with natural dentition correctly identified more test objects in shorter period of time [16].

The focus of the study of Ikebe et al. 2007 was to determine age-related effects on oral sensory functions of dentate people and edentulous persons who were already well habituated to their complete dentures. Age- related significant differences in oral perception were proven in this study. However, oral sensory function was not significantly different between elderly fully dentate and edentulous participants with full dentures [7]
Grasso and Catalanatto 1979 examined the effects of age and full palatal coverage on the oral sensibility. This study included dentulous and edentulous subjects. In each group oral stereognostic ability was tested twice: in the dentulous group once without palates covered and once with acrylic resin forms fixed to the palate and in the edentulous group once with dentures in place and once without the dentures. They determined there is no difference between patients with and without palatal coverage, but the age of patients showed an impact on OSA. Younger patients had more success in identifying test forms and they also needed less time to do so. There were no significant differences in OS ability in older subjects with or without palatal coverage [6].

Kawagishi et al. 2009 assessed the stereognostic ability of the tongue due to its important role during various stages of eating, swallowing and mastication. Covering the palate showed to have no influence on OSA and there was no significant difference in the number of correct answers between males and females. They found that oral sensory ability can be improved through training. Significant difference regarding the number of correct responses to OS ability test before and after the training was noted. Thus, training might be considered as a new rehabilitation method targeting recovery of OSA in patients with full dentures [9].

The study of Litvak et al. 1971 investigated the relationship of OS to diagnostic and therapeutic prosthetic procedures. They compared levels of OSA to age, to the presence or absence of teeth, speech and mastication and to patient evaluation of their prostheses. The study suggested that there was a decrease in the level of oral perception as age increases and that in older patients aging has as much effect on OSA as the presence or absence of teeth. They emphasized the possibility that there can be improvements in oral sensory function if the edentulous patient has been properly restored with complete dentures. They propose that training might contribute to a better acceptance of denture and learning skills in denture wearing, as well as to improve sensory ability in patients with complete palatal coverage [14].

The purpose of the study of Van Aken et al, 1990 was to investigate the differences in oral perception between satisfaction and non satisfaction of patients with their dentures, with the assumption that if OS has an important influence on patients denture satisfaction, satisfied patients must have a lower perception score than dissatisfied. For that purpose they applied OS ability test. However, the results of their study showed that OS ability test cannot be used
as a predictor of patients adaptation to and the acceptance of full dentures. Although the dissatisfied patients who showed up with better OSA Scores, the differences were not significant. Thus, positive relationship between OSA and patients' satisfaction was not confirmed in this study [12].

Garrett et al. 1993 examined the relationship between OSA and masticatory performance in patients with full dentures and patients with natural dentition. Denture wearers were tested with and without prosthesis in situ. In this study no significant differences between these two parameters were noted. Interestingly, OSAT in this study showed the average number of correct identification was the same for the dentulous and the edentulous group. This indicates that receptors in structures other than those in periodontal ligament are primarily responsible for OSA. Moreover, they noted that dentures removal resulted in slight, but not significant decrease in OSA of denture wearers. The results showed that receptors in periodontal ligament have a minimal impact on oral recognition of shape and size of test objects [5].

Some of the studies analyzed the correlation between oral sensory ability and the degree of denture acceptance. However, they failed to find any significant connection between these two parameters [10] [12] [14] [17].

Litvak et al. 1971 showed that edentulous subjects who reported the greatest post insertion problems and who expressed the lowest level of satisfaction showed higher level of oral perception than those who reported few or no problems [14].

The changes in OSA that occur after insertion of a new denture in experienced and non-experienced full denture wearers was investigated by Amarasena et al. 2010. The results suggest that there was a significant improvement in the OSA of both experienced and non-experienced denture wearers after wearing new dentures for 1 month, irrespective of the previous experience of wearing dentures [2].

Mantecchini et al. 1998 analyzed the relationship between OSA and subject's age, duration of edentulism and degree of satisfaction and acceptability of the dentures. The study showed following results: OSA decreases with age, it is not correlated with duration of edentulism,
covering the palate with the denture does not reduce the OSA, the presence of a correct prosthesis has crucial role in improving OSA [10].

The study of Meenakshi et al. 2014 suggested the OST as a reliable tool for measuring patients' oral stereognostic perception and might be used as one of the clinical aids in appreciating the functional limitations imposed by the prostheses. In this study OST was also used to estimate and understand patients' relative satisfaction with complete dentures. It was suggested that stereognosis testing is not designed to assess specific group of receptors but as an indicator of overall sensory ability of patients [15].

All investigators in this field agreed that OSA Test is a reliable tool for estimation of oral sensory ability of patients. Stereognostic testing is designed to assess overall sensory ability and oral motor ability, but not specific groups of sensory receptors [7] [15]. It involves receptors in oral cavity (periodontal ligament, oral mucosa and periosteum), but also receptors in the surrounding structures such as the muscles, tendons and temporomandibular joints. The oral stereognostic ability test is easy to carry out, does not require any complicated equipment and can be helpful for practitioner in predicting the treatment outcome [18].
4. FUNDAMENTALS

4.1 Anatomy

The oral cavity is lined by a mucous membrane or oral mucosa. Although its major functions are lining and protecting, it is also modified to serve as the organ of taste as well as a sensory organ [19]. It provides a vast amount of information regarding events inside the oral cavity by means of taste buds and receptors that respond to pain, temperature and touch [20].

Because the mouth is the gateway to the alimentary and respiratory tract, the oral mucosa is densely innervated, so that it can monitor all substances entering. A rich innervation also serves to initiate and maintain a wide variety of voluntary and reflexive activities involved in mastication, salivation, swallowing, gagging, and speaking [21].

The nerves arise mainly from the second and third divisions of the trigeminal nerve (V). Afferent fibers of the Facial (VII), Glossopharyngeal (IX), and Vagus (X) nerves are also involved [19]. Sensory nerves that supply mechanoreceptors in the mucosal lining of the oral cavity provide the substrate for a variety of sensations. They are essential for the complex sensory experiences including oral kinesthesia and oral stereognosis [21].

The sensory nerves form a network in reticular layer of the lamina propria. Organized nerve endings are usually found in the papillary region. They consist of groups of coiled fibers surrounded by a connective tissue capsule forming specialized endings such as Meissner's or Ruffini's corpuscles, Krause's bulbous and mucocutaneous end organs. Three different groups of receptors are associated with (vibro) tactile and thermal sensation in oral cavity: mechanoreceptors, thermoreceptors and nociceptors. Sensory receptors are distributed throughout the oral cavity, pharynx and larynx and they show specific regional distribution as
well as the functional role [15]. Each of them responds to a particular stimulus. In the oral cavity the somatic and taste sensory systems predominate [8].

Meissner’s corpuscles (Fig. 1) are a special type of mechanoreceptors. They present nerve endings in the skin and mucous membrane that are concentrated in areas especially responsible for perception of light touch. Meissner’s corpuscles are also special pressure sensitive sensory end organs with a connective tissue capsule and tiny stacked plates in the dermis of the skin of lips and the mucous membrane of the tongue. A single nerve fiber penetrates in each oval capsule, spirals through the interior and ends as a globular mass [22].

![Fig. 1 Meissner's corpuscle](image)

Ruffini’s corpuscle (bulbous corpuscle) (Fig. 2) is an enlarged dendritic nerve ending with elongated capsula. They are slowly adapting mechano- and thermoreceptors located in the deeper layers of the skin and mucous membrane. These receptors are responsible for a kinesthetic sense and control of the position and movements [23].
Krause’s corpuscles (bulboid corpuscles) are sensory organs in the mucous membrane of the lips and the tongue. They are thermoreceptors sensing cold temperature, as well as a pressure sensor that respond to continuous pressure. They appear as cylindrical or oval bodies with a capsule formed of a connective tissue sheath of a medullated fiber. They contain a soft semifluid core in which the axon terminates either in a bulbous extremity or in a coiled mass [23].

Fig. 2 Ruffini corpuscle (Bulbous corpuscle) [23]
Meissner’s corpuscles and Pacinian corpuscles are rapidly adapting receptors that only respond during the dynamic phase of stimulus application, while Ruffini endings and Merkel cells belong to slowly adapting receptors to the stimuli [18].

Distribution of the sensory nerves of the mucosa shows regional differences. However, whole mucosa possesses a superficial plexus of the intraepithelial nerves and a deeper plexus in the lamina propria. The density of sensory receptors is greater in the anterior part of the mouth than in the posterior region and touch sensation is most acute in the anterior part of the tongue and hard palate [19]. Areas of greatest tactile sensitivity and two-point discrimination are found in the tip of the tongue followed by the lips and the hard palate [24].

The stereognostic ability, with tactile sensation and texture recognition and proprioception in humans is regulated by the posterior column-medial lemniscus pathway of the central nervous system. This sensory pathway is responsible for transfer of information from body surface to the cerebral cortex. This information represents sensations such as fine touch, vibration and conscious proprioceptive information, recognition of the texture and tactile pressure [24].
Fig. 4 Posterior column medial lemniscus pathway [19]
Posterior column medial lemniscus pathway conducts nerve impulses for touch, pressure, vibration and proprioception from the limbs, truck, neck and head to the cerebral cortex. This pathway has three orders of neurons [19].

First order neurons extend into the spinal cord and ascend to the medulla oblongata on the same side of the body. In the spinal cord two parts of axons exist: gracile fasciculus and cuneate fasciculus. Nerve impulses for touch, pressure, vibration and conscious proprioception from the upper part of the body propagate along axons in the cuneate fasciculus and impulses from lower part of the body propagate along the axons in the gracile fasciculus [19].

The second order neurons cross to the opposite side of the medulla oblongata and enter the medial meniscus, which represents a link to the posterior nucleus of thalamus. In the thalamus second order neurons create a synapse with third order neurons which project their axons to the primary somatosensory area of the cerebral cortex [19].

Nerve impulses for pain, temperature, itch and tickle rise to the cerebral cortex along the anterolateral pathway. The anterolateral pathway consists of three neuron sets as well as posterior column pathway. The cell bodies of the first order neurons are in the posterior root ganglion, while the second order neurons are located in the posterior gray core of the spinal cord and cross to the opposite side [19].

The axons of the third order neurons are located in primary somatosensory areas on the same side of the cerebral cortex as the thalamus [19].
4.2 Trigeminothalamic pathways to the cortex

Nerve impulses for the somatic sensation from the face, nasal cavity, oral cavity and the teeth rise along the trigeminothalamic pathway to the cerebral cortex. As well as the other somatosensory pathways, the trigeminothalamic pathway consists of three neuron sets [26].

First order neurons spread from somatic sensory receptors in the face, nasal cavity, oral cavity and teeth through the trigeminal nerve into the pons. Part of the first order neurons make synapses in the pons with parts of the second order neurons. The other part raises into the medulla with second order neurons, which crosses to the opposite side of pons and medulla and ascends as the trigeminothalamic tract to the ventro-posterior nucleus of the thalamus [26].

Third order neurons project their axons to the primary somatosensory area on the same side of the cerebral cortex as the thalamus [26].
Fig. 5 The trigeminothalamic pathway [19]
4.3 The Trigeminal Nerve (V)

The trigeminal nerve is the largest of the cranial nerves and emerges from the anterolateral surface of the pons [19].

The larger sensory root has a protuberance called “trigeminal ganglion” and contains cell bodies of the primary sensory neurons and carries nerve impulses for touch, pain and thermal sensations [19].

The smaller motor root contains a nucleus that stems in the pons and is responsible for carrying nerve impulses into masticatory muscles. The main purpose is to control chewing. Trigeminal nerve has three branches: ophthalmic, maxillary and mandibulary. The maxillary nerve contains sensory axons from part of the pharynx, the nasal mucosa, palate, upper teeth and upper lip. The mandibular nerve is responsible for innervation of anterior two thirds of the tongue, mucosa of the cheeks, lower teeth, mouth floor mucosa and skin of mandibular [17].

Fig. 6 Illustration of the branches of the trigeminal nerve [25]
The tactile sensibility of the mucosa receptors conducts sensations for touch, pain and temperature to the cerebral cortex. This pathway represents surface sensibility. Oral mucosa, tongue and teeth are tactile organs of the oral cavity. The receptors of orofacial muscles, tendons, bone and temporomandibular joints are responsible for deep orofacial sensibility (pressure, pain, motion, force) [1].

Oral sensibility conducts information on the condition of the oral cavity structures as well as its changes to the central nervous system [1].
4.4 Trigeminal nerve sensory pathway

The sensory inputs of the oral region are carried by the trigeminal nerve through the trigeminal (Gasserian) ganglion to the brainstem. The afferent signals are transmitted either to the main sensory nucleus of the trigeminal nerve (responsive to discriminate tactile senses, light touch and pressure) or to the descending spinal tract nuclei, including: (i) the nucleus oralis (responsive to cutaneous sensation of oral mucosa); (ii) the nucleus interpolaris (responsive to tooth pulp pain); (iii) the nucleus caudalis (responsive to pain, temperature and crude touch) [18].

![Fig. 7](image)Schematic representation of the trigeminal nerve sensory pathway [22]

From there, signals are transferred across the midline and sent to the thalamus and finally through the thalamocortical projections to the respective cortical areas concerned with orofacial sensation where they can result in conscious perception [18].
4.5 Histology and Embryology of oral sensibility

Oral sensibility is the key element in orofacial motorical development. After the 8th embryonic week, the receptors for taste and touch already exist in the area of tongue and lips. The first swallowing movement happens during the 12th week and first rhythmical sucking movement can be noted in the 29th embryonic week [1].

The palate develops between 7th and 9th week from medial and lateral palatine process. Oral mucosa is built up of keratinized epithelium which covers the hard palate and alveolar ridges and non-keratinized which covers cheeks, lips, soft palate and floor of the mouth. There are three types of non-keratinized cells: Langerhans' cells, Merkel cells and Melanocytes. From the point of oral sensation an important role belongs to Merkel cells. They are associated with terminal axon and is to be believed that they have a function as touch receptors [26].

Fig. 8 Merkel Cell-Neurite Complex [26]
Masticatory mucosa is consisted of layers that contain blood vessels, nerve endings and mixed salivary glands. A third type is specialized mucosa of the tongue that contains papillaes [26]. The anterior part of the tongue is covered with filiform papillaes. They form an abrasive surface that takes part in masticatory process (breaking and compressing food parts to the hard palate). Due to a complex innervation of these papillaes they represent mechano receptors. Therefore papillaes filiformes are specialized touch transmitters [21].

Important role in oral sensation belongs to nerve receptors for touch, heath, cold and pain. They are located in the lips as well as in the whole oral cavity [26]. Sensory nerve network is more developed in anterior regions of the mouth than in posterior. Therefore the touch sensation is more developed in anterior part of the tongue and the palate. In this respect the discrimination ability of the fingertips is between those of the tongue and the palate. Touch receptors in the soft palate are responsible for actions of swallowing, gagging and retching [26].

With aging oral mucosa becomes less hydrated due to a decreased activity of salivary glands and also it becomes thinner. Thus, older people may develop symptoms such as a burning sensations, dryness of the mouth and abnormal taste, i.e. burning mouth syndrom [19].
4.6 Deficit in Oral Stereognostic ability

Due to a poor OS performance the tongue loses its orientation within the mouth. The tongue expresses sensory deficits through uncoordinated and obstructed movements. This compensatory pathological touch mechanism (contact tongue-teeth, lower lip-teeth) is responsible for development of hindered orofacial movements during swallowing and speaking [1].

4.7 Oral Stereognostic Ability (OSA) in patients with full dentures

The oral cavity is a highly developed and specialized sensory system. Palatal receptors have a very important role in OSA [11]. The tongue is a very mobile organ and fulfills complete oral cavity. It is intensively innervated with motoric and sensitive neurons [21].

One of the major concerns of denture wearers is adaptation to new or replacement dentures, regardless of their experience of wearing dentures. The findings of Amarasena et al. 2010 suggest that there was a significant improvement in the OSA of both experienced and non-experienced denture wearers after wearing new dentures for 1 month, irrespective of the previous experience of denture wearing [2].

High oral perception is thought to contribute to poor adaptation to new dentures [27]. This may well be said for all gnathological changes, i.e. new bridgework or even fillings.

Singh and Mattoo 2014 showed that for edentulous patients, dental prosthesis are perceived by the oral sensory apparatus as a foreign body once it is placed on edentulous residual alveolar ridges. Moreover, the prosthesis itself acts as a barrier between the tongue and mucosa that further hampers the stereognostic ability. The ability of individuals to adapt to complete denture prosthesis depends largely on the sensory functions of the structures that surround and support the prosthesis. One of the significant patient-related factors is the ability of the specialized sensory mucosal detectors to warn the mucosa of harmful stimuli. This inherent ability also allows the same mucosa to identify the defect if any present in base of the prosthesis [11].
5. STUDY OBJECTIVES

5.1 Study purpose

The aim of this study was to determine the oral stereognostic level in different age groups of people with full dentures in upper jaw (complete palatal coverage), as well as to examine if younger people with full dentures have higher oral stereognostic ability than older ones. The difference in oral stereognostic perception was tested by identification of small acrylic objects placed in the mouth.

To better understand patients’ relative satisfaction with complete dentures, differences in oral stereognostic sensibility, based on the identification of special test objects placed into the mouth, were compared between the two different age groups of patients.

5.2 Hypothesis

As a hypothesis it was assumed that younger patients with complete dentures in the upper jaw have a higher oral stereognosis than the older ones.

The Null Hypothesis of the study was that there is no difference in oral sensory ability between younger and older complete denture wearers.
6. STUDY DESIGN

This clinical study was approved by the Ethic Committee under number 1759/2015.

Recruitment of study participants was conducted in two ways:

1. From the University Clinic database patient data that fulfilled inclusion criteria was selected. To the selected patients were sent invitation letters explaining study purpose and protocol and they were asked to participate in the study. The individuals not responding within one month were contacted also by phone.

2. Some of the patients were examined during their routine visit at the University Clinic.

All subjects signed a consent form prior the study examination. They all were already previously treated at the University Dental Clinic.

The Study protocol used in this study was suggested from the Otorhinolaryngology Department, Vienna General Hospital (AKH).

In this study participated overall 27 patients, divided into two subgroups depending on their age:

Group 1 - Patients between 30 and 60 years of age

Group 2 - patients older than 60 years.

All the patients were examined at the University Dental Clinic Vienna at the Prosthetic Department, according to the protocol approved by the Ethic Committee.
7. MATERIAL AND METHOD

7.1 Study Population

Overall 27 subjects aged between 31 and 80 years participated in this study. There were 16 females and 11 males volunteers. They all had full dentures in upper jaw and they all were wearing denture for longer than one year prior to this investigation. All of the participants received their full dentures Prosthetic Department at the University Dental Clinic, Vienna.

<table>
<thead>
<tr>
<th>Number of participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female 16</td>
</tr>
<tr>
<td>Male 11</td>
</tr>
</tbody>
</table>

Table 1 General characteristics of sample

7.2 Inclusion and Exclusion Criteria

Inclusion criteria:

- the minimum age of 30 years,
- wearing full denture in upper jaw
- sufficient knowledge of German or English language
- patients who visited University Dental Clinic in the last five years

Exclusion Criteria:

- neuro-psychiatric patients
- uncooperative patients
- patients with oral lesions, pathologies and TMJ disorders
7.3 Examination Technique

This study included 27 patients with full dentures in upper jaw with minimum 31 years of age.

In order to examine the oral stereognostic ability of patients, the oral stereognostic test was conducted. The special test objects, specially designed for this purpose were used. There were nine test pieces, 2 mm thick and the diameters varying from 2-12mm. They were made of pink acrylic, with a smooth surface and secured by thin nylon band, so the participants could not possibly swallow them. The forms used in this investigation were developed for and used in the previous interdisciplinary studies at the Otorhinolaryngology Department, Vienna General Hospital (AKH) and the Prosthetic Department at the University Dental Clinic, Vienna.

A variety of rectangular, circular, oval and polygonal shapes were included. Some items shared similar characteristics to increase the difficulty of discrimination. A sheet of paper depicting all nine test pieces was used during the test, so that participants could assign the forms identified within the mouth respectively.

At the beginning of the test the nature and purpose of the study were explained to each participant. All the participants got a consent form to sign.

Each patient assigned 60 seconds to get acquainted with the basic shape and surface characteristics of the test objects by careful visual and finger touch inspection. After the person got familiarized with the test pieces, all were pulled out of sight. The picture of all test objects was placed in front of the patient. At this point the patient was asked to close his eyes and then, one by one, the test objects were placed on the tongue. The task was to recognize the shape of the object by moving it around the mouth and to point it out on the picture in front of him. Subjects were told that they could use their tongue, cheeks, lips and teeth to identify the shape, but they were instructed to respond as quickly as possible. No practice trials were held. All the participants were tested with the denture being in mouth.
The person was allowed to move the test object around the mouth without any time limitations in order to recognize the exact shape of it. All the patients were tested in one serial with nine test specimens. Participants received feedback on their responses during testing.

On the observation chart it was noted if the person could identify the test object correctly and the amount of time it took to respond. Misidentified items were counted as an incorrect response. Thus all the test forms were tested and answers were noted. The number of correct/incorrect responses to OST formed a Test Score, which was considered as a measure of oral perception.

All participants were tested under the same circumstances, in the same order, to all of them were given the same number of test pieces as well as the time exposure. The examination protocols as well as the test objects were recommended from previous interdisciplinary studies of the Otorhinolaryngology department of General Hospital Vienna and the Prosthetic Department of Dental University Clinic, Vienna.
7.4 Statistical Analysis

The data was collected electronically and analyzed in an Excel program. The study was focused on age-related differences in OSA of volunteers with full dentures in upper jaw.

In order to evaluate the relationship between age of patients and their oral stereognostic ability Spearman's Rank Correlation Test was applied. The same test was used in order to examine relationship between patients’ age and the amount of time needed to recognize the shape of the test piece.

Further, the participants were divided into two groups (Group 1 - patients between 30 and 60 years of age and Group 2 - patients from 61 years of age) and their relationship to oral stereognosis was separately analyzed. Due to the lack of normal distribution, for that purpose U-Test was applied.

In addition, the correlation between the gender and oral stereognostic ability was examined applying the U-Test.
8. RESULTS

8.1 Correlation between patients age and number of correct responses on oral stereognostic ability test (OSAT)

<table>
<thead>
<tr>
<th>Participants</th>
<th>Age</th>
<th>Number of correct responses to OSAT</th>
</tr>
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<tbody>
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<td>1</td>
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<td>6</td>
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<tr>
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</tr>
</tbody>
</table>

Table 2 The patients’ age and the number correct responses to OSAT
**Diagram 1** Correlation between the age of participants and overall number of correct responses to OST

It was assumed that the number of correct matches on OSAT decreases with the increase of patients' age. This theory was tested with the aid of Spearman's Rank Correlation Test. The results showed significant negative correlation between these two parameters ($\alpha = 0.05$; power 0.8; correlation coefficient 0.50) and Null hypothesis was rejected.
8.2 Correlation between the age of patient and OSA Score (related to the amount of time needed for the test object recognition)

<table>
<thead>
<tr>
<th>Participants</th>
<th>Age</th>
<th>OSA Score</th>
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</thead>
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<td>27</td>
<td>80.7</td>
<td>20</td>
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</tbody>
</table>

Table 3 The patients’ age and OSA Score
The time patient needed to identify each object was noted on an examination chart. Correctness of the responses of each object was scored using the OSA Score. The collected data were graded in the following way:

<table>
<thead>
<tr>
<th>Examination responses</th>
<th>Grades</th>
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<tbody>
<tr>
<td>Correct within 10 seconds</td>
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<tr>
<td>Correct within 10-20 seconds</td>
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<tr>
<td>Correct after 20 seconds</td>
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</tr>
<tr>
<td>Incorrect response</td>
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</table>

**Table 4 Oral Stereognostic Ability Score**

**Diagram 2** Correlation between the patients’ age and OSA Score
The sum of Oral stereognostic ability examination grades of each patient forms the OSA Score.

It was hypothesized that younger patients have lower OSA Score. The significance of correlation between the patient’s age and OSA Score was examined by Spearman's Rank Correlation Test. By $\alpha = 0.05$ the test showed significant positive correlation between these two parameters and the hypothesis was proven right.

8.3 Correlation between the two different age groups and the number of correct responses

The group of 27 participants was divided into two age-groups: Group 1 - patients from 30 to 60 years of age and Group 2 - patients older than 61 years. It was supposed there is a correlation between two different age groups and oral sensory ability. To check out this assumption U-Test was applied. The U-Test showed that the group 1 (younger patient group) had more correct responses to OST, with significant correlation by $\alpha = 0.05$, so that the Null hypothesis was rejected.
<table>
<thead>
<tr>
<th>Age group</th>
<th>Number of correct responses to OSAT</th>
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<td>2</td>
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**Table 5** The two age groups of participants and number of correct responses on oral stereognostic ability test
Diagram 3 Correlation between two age groups and the number of correct responses to OSAT
8.4 Correlation between the two different age groups of patients and overall OSA Score

It was supposed that the group with younger patients (from 30 to 60 years of age) has lower OSA Score than the group of patients between the age of 61 and 80.

The U-Test showed significant correlation between the two different age groups to overall OSA Score and Null hypothesis was declined.

<table>
<thead>
<tr>
<th>Age group 1 OSA Score</th>
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</table>

Table 6 The two age groups of participants and OSA Score
Diagram 4 Correlation between the two age groups of patients and OSA Scores

8.5 Correlation between gender and number of correct answers to OST

The number of correct responses showed no significant difference between males and females, even though females came out with more correct responses than males. U-Test was conducted in order to examine this correlation and Null hypothesis was proven.
**Diagram 5** Correlation between the gender and number of correct matches on OSAT
8.6 Correlation between the gender and OSA Scores

After applying U-Test the correlation between gender and overall OSA Scores was proven to not being significant. Thus, Zero hypothesis was proven right.

Diagram 6 Correlation between the gender and overall OSA Scores

Males Females
<table>
<thead>
<tr>
<th>Gender</th>
<th>Number of correct responses on OST</th>
<th>OSA Score</th>
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</thead>
<tbody>
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<td>m</td>
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<td>12</td>
</tr>
<tr>
<td>f</td>
<td>3</td>
<td>12</td>
</tr>
<tr>
<td>m</td>
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<tr>
<td>f</td>
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</tbody>
</table>

**Table 7** Gender, number of correct responses to OST and OSA Scores of all participants
8.7 Remarks

1. Participants age, number of correct responses to OST and OSA Score could not be adopted as normal distribution of data. Due to this fact Spearman's Rank Correlation Test was applied instead of Pearson's Test;
   For the same reason the U-Test was applied instead of t-test [28]

2. OSA Score: the sum of examination grades (addition of items) and the time required for identifying each object were scored i.e. graded. Though it is mathematically not correct, here is accepted as ordinal data [28]
9. DISCUSSION

In general, deterioration of most sensory abilities in the human nerve system occurs almost inevitably, to a different extent with age. Oral sensory ability also declines with the age and the rate of its decline shows a wide individual variation [7]. Both clinical experience and research data have found great variations among denture wearers in their ability to function well with the dentures [5]. With the growing number of seniors in our society, who may be full or partial denture wearers, the prevalence of a decreased function of mastication, eating and swallowing is increasing. These impaired functions significantly affect patients’ quality of life and prosthetic rehabilitation focused on its restoration is of major importance [9].

Problems with complete dentures use are quite common. The technical quality of the denture, condition of the oral structures, psychological and social factors can contribute to a poor denture acceptance and denture dissatisfaction [12][29]. The moveable nature of the prosthesis, mucosal support, and loss of natural teeth with their sensory receptors establish an unnatural situation when full dentures are placed in the mouth. Therefore the treatment of edentulous patients is associated with an unpredictable outcome regarding patient satisfaction and the quality of rehabilitation [4]. The oral perception and proprioception of the oral structures play a major role in adaptation of the patient to prosthesis, especially complete dentures. Both these abilities are affected by the process of aging [11][30].

Numerous studies have investigated the oral sensory ability of people with full dentures. Oral sensory function has been examined by different methods including two-point discrimination, oral stereognosis, vibro-tactile detection, somatic sensitivity, proprioception and thermal sensitivity [4][6]. Many different techniques were used, such as a distinction of thickness, hardness, texture, size and oral manipulative ability [11]. In this study the oral stereognostic ability of patients with complete dentures in the upper jaw was examined.
Many investigators on this topic agreed that OST is the most suitable method in evaluation of OSA. It is easy to perform and does not require any complicated equipment [4][6][14][18]. In this study OST was used in order to evaluate OSA of participants. The same protocol was used in previous interdisciplinary studies at the Otorhinolaryngology Department, Vienna General Hospital (AKH) and the Prosthetic Department of the University Dental Clinic, Vienna.

Results of this study support the findings of Ikebe et al, 2007. Their study showed that the aging has a negative impact on OSA of patients with full dentures, as well as that the older full denture wearers needed significantly longer time to recognize test pieces than the younger ones. They expected older dentate subjects to have better OSA than complete denture wearers, just because their palate was uncovered. However, significant differences were not noted. These findings provide confirmation that sensibility of the palate is not as important as the tongue for the OSA. It seems that tongue compensates the loss of the role of the palate in patients with complete dentures and the role of tongue receptors is far more important than the input of palatal receptors in regard of OS [7].

The study results of Grasso etCatalanatto 1979, Ikebe et al. 2007, Jacobs et al. 2002, Mantechini et al. 1998, Litvak et al. 1971 showed that OSA is age related. They proved negative correlation between the age of patients with complete dentures and their OSA, which was supported with the results of the presented study [6][7][8][10][14].

Jacobs et al. 2002, provided results of literature review which showed that the sex has no influence on OSA [18]. In our study correlation between gender and OSA was not significant, although females had slightly more correct answers on the OS test.

The purpose of this study was determining the levels of oral perception in full denture patients and to relate it to clinical implications in the treatment of the prosthetic patient. This investigation compared levels of oral discriminatory skills of patients to their age. Results of the study showed significant negative correlation between the age of patient and the number of correct responses to OST. Further, test results showed a significant positive correlation between the age of patients and the time they need for test object recognition (OSA Score). Older patients needed significantly longer time to recognize the shape of test objects. Moreover, some of them failed to recognize them at all.
The results support the data gathered in previous studies regarding the correlation of age to OSA: oral perception of full denture wearers decreases as the age increases, therefore inverse relationship of these two parameters was proven.

Evaluating oral stereognostic level may help in relating age of patient to the success of rehabilitation with the dentures. The practitioner could use this information to be more aware of what he can expect in term of patient response during and after treatment.
10. CONCLUSION

The results of this study show that there is a significant correlation between the age of patients with full dentures in the upper jaw and their oral stereognostic ability. Patients between 31 and 60 years of age recognized significantly more test forms in a significantly shorter period of time than the older patients. Older patients with complete dentures in the upper jaw have lower levels of OSA. This study showed no significant difference between male and female in their OSA, therefore influence of gender on OS shows to be irrelevant.

Oral stereognostic test is reliable for measuring patients’ oral stereognostic perception. However, one standardized method for this purpose still has not been developed. Further standardization is a key issue for this kind of testing [8].

It is also important to be aware of the limitations of this study. The study included a relatively small number of participants, although it was sufficient for testing the statistical significance related to the study parameters.

There are many factors that should be further investigated, such as the role of periodontal receptors in oral perception, temporomandibular dysfunction due to loss of teeth and its relation to OSA, as well as the potential influence of smoking and alcohol consumption on OSA.
11. REFERENCES


12. SUPPLEMENT

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Fig. 1 - Meissner's corpuscle

Fig. 2 - Ruffini Corpuscle

Fig. 3 - Krause’s corpuscle

Fig. 4 - Posterior column medial lemniscus pathway

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Fig. 6 - Illustration of the branches of the trigeminal nerve

Fig. 7 - Schematic representation of the trigeminal nerve sensory pathway

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Fig. 9 - Test Objects for Oral Stereognostic Ability Test

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Table 6- Two age groups and OSA Score

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12.3 List of Diagrams

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Diagram 2- Correlation between the age of patients' and OSA Score
Diagram 3- Correlation between two age groups and the number of correct responses to OST
Diagram 4 - Correlation between the two age groups and OSA Score
Diagram 5 - 5 Correlation between the genders and number of correct matches on OSAT
Diagram 6 - Correlation between the genders and overall OSA Scores

12.4 List of abbreviations

OS – Oral Stereognosis

OSA – Oral Stereognostic Ability

OSAT – Oral Stereognostic Ability Test

OSAS – Oral Sterognostic Ability Score
Sehr geehrte Damen und Herren!

im Rahmen einer klinischen Studie zur Untersuchung der Mundraumwahrnehmung bei PatientInnen mit Totalprothesen im Oberkiefer bitten wir Sie um Ihre Teilnahme.

Diese klinische Studie wird an der Bernhard-Gottlieb-Universität Zahnklinik in Wien, Abteilung für Prothetik, durchgeführt.


Als Aufwandsentschädigung bieten wir Ihnen eine kostenlose Prothesenreinigung von Ablagerungen und Zahnstein in einem speziellen Reinigungsbad.

Um Ihre Zeit so wenig wie möglich in Anspruch zu nehmen, bitten wir Sie, einen Termin unter der Telefonnummer +43 664 375 56 13 zu vereinbaren.

Wir bedanken uns schon im Voraus für Ihre Hilfe

Mit freundlichen Grüßen,

Ihr Univ. Prof. DDr. Eva Piehslinger Team
12.6 Informed Consent Form

**PatientInneninformation und Einwilligungserklärung zur Teilnahme an der klinischen Studie**

**Orale Stereognose von Patienten mit Totalprothesen im Oberkiefer in unterschiedlichen Altersklassen**

Sehr geehrte Teilnehmerin, sehr geehrter Teilnehmer!

Wir laden Sie ein, an der oben genannten klinischen Studie teilzunehmen. Die Aufklärung darüber erfolgt in einem ausführlichen ärztlichen Gespräch.

**Ihre Teilnahme an dieser klinischen Studie erfolgt freiwillig. Sie können jederzeit ohne Angabe von Gründen aus der Studie ausscheiden. Die Ablehnung der Teilnahme oder ein vorzeitiges Ausscheiden aus dieser Studie hat keine nachteiligen Folgen für Ihre medizinische Betreuung.**

Klinische Studien sind notwendig, um verlässliche neue medizinische Forschungsergebnisse zu gewinnen. Unverzichtbare Voraussetzung für die Durchführung einer klinischen Studie ist jedoch, dass Sie Ihr Einverständnis zur Teilnahme an dieser klinischen Studie schriftlich erklären. Bitte lesen Sie den folgenden Text als Ergänzung zum Informationsgespräch mit Ihrem Arzt sorgfältig durch und zögern Sie nicht, Fragen zu stellen.

Bitte unterschreiben Sie die Einwilligungserklärung nur

- wenn Sie Art und Ablauf der klinischen Studie vollständig verstanden haben,
- wenn Sie bereit sind, der Teilnahme zuzustimmen und
- wenn Sie sich über Ihre Rechte als Teilnehmer an dieser klinischen Studie im Klaren sind.
Zu dieser klinischen Studie, sowie zur Patienteninformation und Einwilligungserklärung wurde von der zuständigen Ethikkommission eine befürwortende Stellungnahme abgegeben.

1. **Was ist der Zweck der klinischen Studie?**
   Der Zweck dieser klinischen Studie ist es festzustellen, ob jüngere Patienten mit Totalprothesen im Oberkiefer eine höhere Mundraumwahrnehmung als ältere Patienten haben.

2. **Wie läuft die klinische Studie ab?**
   Diese klinische Studie wird an der Bernhard-Gottlieb-Universität Zahnklinik in Wien, Abteilung für Prothetik durchgeführt und es werden insgesamt ca. 100 Personen daran teilnehmen.

   Ihre Teilnahme an dieser klinischen Studie wird voraussichtlich ca. 20 Minuten dauern.

   **Folgende Maßnahmen werden ausschließlich aus Studiengründen durchgeführt:**

   der sogenannte Orale Stereognose Test. In einer ca. halbstündigen Sitzung werden Ihnen eine Reihe kleiner Plastikfigurenkörper (ca. 0-1cm) gezeigt und Sie können diese mit den Händen ertasten. Danach schließen Sie die Augen, die Testkörper werden auf Ihre Zunge platziert und Sie sollten deren Form erkennen (Kreis, Dreieck, Viereck, Stern...). Die Abbildung der Prüfkörper wird vor Ihren Augen liegen. Haben Sie deren Form erkannt, können Sie sie auf einer Abbildung zeigen. Die Untersuchung ist abgeschlossen, wenn wir bei Ihnen alle Prüfkörper getestet haben.

3. **Worin liegt der Nutzen einer Teilnahme an der Klinischen Studie?**
   Es ist nicht zu erwarten, dass Sie aus Ihrer Teilnahme an dieser klinischen Studie gesundheitlichen Nutzen ziehen werden.

4. **Gibt es Risiken, Beschwerden und Begleiterscheinungen?**
   Die im Rahmen dieser klinischen Studie durchgeführte Maßnahme kann zu keinen Beschwerden führen und ist mit keinen Risiken behaftet.
5. **Wann wird die klinische Studie vorzeitig beendet?**

Sie können jederzeit auch ohne Angabe von Gründen, Ihre Teilnahmebereitschaft widerrufen und aus der klinischen Studie ausscheiden ohne dass Ihnen dadurch irgendwelche Nachteile für Ihre weitere medizinische Betreuung entstehen.

Ihr Studienarzt wird Sie über alle neuen Erkenntnisse, die in Bezug auf diese klinische Studie bekannt werden und für Sie wesentlich werden könnten, umgehend informieren. Auf dieser Basis können Sie dann Ihre Entscheidung zur weiteren Teilnahme an dieser klinischen Studie neu überdenken.

Es ist aber auch möglich, dass Ihr Studienarzt entscheidet, Ihre Teilnahme an der klinischen Studie vorzeitig zu beenden, ohne vorher Ihr Einverständnis einzuholen. Die Gründe hierfür können sein:

- Sie können den Erfordernissen der Klinischen Studie nicht entsprechen;
- Ihr Studienarzt hat den Eindruck, dass eine weitere Teilnahme an der klinischen Studie nicht in Ihrem Interesse ist;

6. **In welcher Weise werden die im Rahmen dieser klinischen Studie gesammelten Daten verwendet?**

Sofern gesetzlich nicht etwas anderes vorgesehen ist, haben nur die Studienärzte und deren Mitarbeiter Zugang zu den vertraulichen Daten, in denen Sie namentlich genannt werden. Diese Personen unterliegen der Schweigepflicht.

Die Weitergabe der Daten erfolgt ausschließlich zu statistischen Zwecken und Sie werden ausnahmslos nicht namentlich genannt. Auch in etwaigen Veröffentlichungen der Daten dieser klinischen Studie werden Sie nicht namentlich genannt.

7. **Entstehen für die Teilnehmer Kosten? Gibt es einen Kostenersatz oder eine Vergütung?**

Durch Ihre Teilnahme an dieser klinischen Studie entstehen für Sie keine zusätzlichen Kosten.

Als Aufwandsentschädigung bieten wir Ihnen eine kostenlose Prothesenreinigung von Ablagerungen und Zahnstein in einem speziellen Reinigungsbad.
8. **Möglichkeit zur Diskussion weiterer Fragen**

Für weitere Fragen im Zusammenhang mit dieser klinischen Studie stehen Ihnen Ihr Studienarzt und seine Mitarbeiter gern zur Verfügung. Auch Fragen, die Ihre Rechte als Patient und Teilnehmer an dieser klinischen Studie betreffen, werden Ihnen gerne beantwortet.

Name der Kontaktperson: Univ.-Prof.DDr Eva Piehslinger
Erreichbar unter: 01/400-070-4910

Name der Kontaktperson: Univ.-Prof.Dr Barbara Gsellmann
Erreichbar unter: 01/400-070-4920

9. **Sollten andere behandelnde Ärzte von der Teilnahme an der klinischen Studie informiert werden?**

10. **Einwilligungserklärung**

Name des Patienten in Druckbuchstaben:


Ich erkläre mich bereit, an der klinischen Studie *Orale Stereognose von Patienten mit Totalenprothesen im Oberkiefer* teilzunehmen.

Ich werde den ärztlichen Anordnungen, die für die Durchführung der klinischen Studie erforderlich sind, Folge leisten, behalte mir jedoch das Recht vor, meine freiwillige Mitwirkung jederzeit zu beenden, ohne dass mir daraus Nachteile für meine weitere medizinische Betreuung entstehen.

Ich bin zugleich damit einverstanden, dass meine im Rahmen dieser klinischen Studie ermittelten Daten aufgezeichnet werden. Um die Richtigkeit der Datenaufzeichnung zu überprüfen, dürfen Beauftragte des Auftraggebers und der zuständigen Behörden beim Studienarzt Einblick in meine personenbezogenen Krankheitsdaten nehmen.

Die Bestimmungen des Datenschutzgesetzes in der geltenden Fassung werden eingehalten.


..........................................................................................................................................................

(Datum und Unterschrift des Patienten)
12.7 Examination Chart

Orale Stereognosetest - Bewertungsbogen

<table>
<thead>
<tr>
<th>Ergebnis</th>
<th>0 - 10 Sec.</th>
<th>10 - 20 Sec.</th>
<th>&gt; 20 Sec.</th>
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12.8 Ethics Committee Vote

Votum:

EK Nr: 1759/2014

Projekttitel: Orale Stereognose von Patienten mit Totalprothesen im Oberkiefer in unterschiedlichen Altersklassen

Antragsteller/in: Frau Jasmina Zimonjic

Institution: BGZMK, MUW

Sponsor: Bernhard Gottlieb Universitätssahnklinik, Abteilung für Prothetik

Teilnehmende Prüfzentren:

<table>
<thead>
<tr>
<th>Ethik-Kommission</th>
<th>Prüfzentrum</th>
<th>Prüfärztin/arzt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ethikkommission der Medizinischen Universität Wien</td>
<td>Bernhard Gottlieb Universitätssahnklinik, Abteilung für Prothetik</td>
<td>Frau Univ.-Prof. DDr Eva Pielslinger</td>
</tr>
</tbody>
</table>

Die Stellungnahme der Ethik-Kommission erfolgt aufgrund folgender eingerechter Unterlagen:

<table>
<thead>
<tr>
<th>Dokument</th>
<th>Name</th>
<th>Version</th>
<th>Datum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lebenslauf (CV)</td>
<td>Lebenslauf Dr Jasmina Zimonjic</td>
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<td>24.09.2014</td>
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<td>Patienteninformation</td>
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<tr>
<td>Studienprotokoll (Prüfplan)</td>
<td>Studienprotokoll 6.0</td>
<td>6.0</td>
<td>06.03.2015</td>
</tr>
</tbody>
</table>

Die Kommission fasst folgenden Beschluss (mit X markiert):

□ Es besteht kein Einwand gegen die Durchführung der Studie.

Ergänzende Kommentare der Sitzung am 04.11.2014:

 Zu Prüfplan und Antrag:

Das 4 seitige Studienprotokoll entspricht in der vorliegenden Form nicht den Richtlinien der „Guten wissenschaftlichen Praxis“ der MedUniv Wien:

Der Titel sollte besser "Orale Stereognose von Patienten mit Totalprothesen im Oberkiefer in unterschiedlichen Altersklassen" heissen. Dies wäre in Protokoll, Antrag und Patienteninformation zu korrigieren.

Prinzipiell wäre auch zu erwägen, ob die Aussage der Studie nicht durch die Einführung einer altersgemachten Kontrollgruppe ohne Totalprothese gestärkt werden sollte.

Im Studienprotokoll ist angeführt, dass "diese Studie zur Verbesserung des Adaptation Prozesses von Patienten mit Totalprothesen beitragen soll ", aber es fehlen Angaben darüber, wie das gemacht werden soll.
Es fehlen nähere Angaben zu den Prüfkörpern (Größe und Material; kommerziell erwerblich; vielleicht als Foto verfügbar).
Es fehlt eine Fallzahlberechnung und die Gruppengrößen sind nicht angegeben (wahrscheinlich 50:50).
Warum erfolgt die Reihenfolge der Prüfpräparate nicht randomisiert?
Die Pseudonymisierung anhand der Initialen und des Geburtsjahres ist als Datenschutz unzureichend, eine andere Form der Anonymisierung wird empfohlen.
Eine Nutzen-Risiko-Evaluierung ist anzugeben.
Die Literaturangaben sollten an den entsprechenden Stellen des Textes auch angeführt werden.
Das Rationale der Studie bzw. wie die Gruppe der "jüngeren" und wie die Gruppe der "älteren" Patienten definiert wird ist aus dem Antrag nicht erkennbar.

Die Ethik-Kommission ersucht um Vorlage eines überarbeiteten Studienprotokolls und eines verbesserten Antrags.

Zur Patienteninformation:
Punkt 1: Der Begriff "orale Stereognose" ist laienverständlich zu erklären.
Punkt 4: Es muss heißen "durchgeführte Maßnahme" (nicht "durchgeführtet Massnahme").
Nicht zutreffende Punkte (5, 6, 7, 8) sind zu streichen.
Punkt 12: Die Telefonnummern des AKH Wien sind zu aktualisieren (an die Klappennummer ist eine Null anzuhängen). Ist unter den angeführten Telefonnummern tatsächlich ständige Erreichbarkeit gegeben? Wenn dies nicht der Fall ist, ist das Wort "ständig" zu streichen.
Punkt 14: Die Diplomandin kann die Teilnehmer über die Studie aufklären. Die Ethik-Kommission weist allerdings darauf hin, dass dies in Anwesenheit eines verantwortlichen Arztes erfolgen muss, der auch die Einwilligungserklärung unterschreibt.

Zur Versicherung: nicht erforderlich

Die Ethik-Kommission ersucht die Antragsteller, bei der Wiedervorlage von geänderten Unterlagen ein Exemplar mit hervorgehobenen Änderungen beizulegen.

Ergänzende Kommentare:
Nachtrag vom 9. März 2015:
Die Antragsteller legen am 06.03.2015 überarbeitete Unterlagen vor, die von der Ethik-Kommission akzeptiert werden.

Die aktuelle Mitgliederliste der Ethik-Kommission ist unter der Adresse http://ethikkommission.meduniwien.ac.at/ethikkommission/mitglieder/ abrufbar, Mitglieder der Ethik-Kommission, die für diesen Tagesordnungspunkt als befangen anzusehen waren und daher laut Geschäftsordnung an der Entscheidungsfindung/Abstimmung nicht teilgenommen haben: Frau Eva Pfeilsinger


Dieses Votum ist für berechtigte Benutzer/innen in digitaler Form unter der Adresse https://ekmeduniwien.at/vote/5777/download/ abrufbar.
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<td>Dr. Jürgen Zeulho</td>
</tr>
<tr>
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