The effects of two lubricating products in elderly individuals - A pilot study

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Abstract

Objective: To evaluate two products to treat symptoms of oral dryness in frail, elderly individuals.

Material & Methods: 15 participants were recruited for this pilot study from Karolinska Institutet, Department of Dental Medicine section for Gerodontics and Public Medical Dental Care clinic at Stockholms Sjukhem. The participants used Proxident oral spray with sunflower oil for 4 weeks and then Proxident gel-based flavorless oral moisturizer for 4 weeks. Registration of current medications, general health, dental status, status of the mucosa, plaque index, gingival index, saliva secretion was measured and microbial samples taken at baseline and after four and eight weeks.

Results: Gingival index and MPS (mucosal-plaque score) mean values were improved during the study. Plaque index was relatively constant and no statistically significant changes were found in salivary flow. Lactobacilli increased, Streptococcus mutans were constant and Candida albicans were decreased during the study period but this was not statistically significant.

Conclusion: Proxident oral spray with sunflower oil and non-flavored moisture gel may help patients suffering from dry mouth to improve their oral mucous conditions but it requires further studies to confirm these results. The products can be recommended as comfort products.

Keywords: Dry mouth, hyposalivation, moisturizing products, oral micro flora, salivary flow
Effekten i munhålan av två muntorrhetsprodukter hos äldre individer - En Pilotstudie

Sammanfattning

Syfte: Att utvärdera två produkter mot muntorrhet hos äldre personer.

Material & Metod: 22 deltagare, varav 15 fullföljde, rekryterades till denna pilotstudie från Karolinska Institutet, Odontologiska Institutionen, Gerodontiavdelningen och Folk tandvården, Medicinsk tandvård Stockholms sjukhem. Under fyra veckor fick deltagarna använda Proxident munspray med solrosolja och sedan Proxident munkurtgel utan smak under ytterligare fyra veckor. Registrering av allmän hälsa, aktuella mediciner, tand och slemhinnestatus, plack och gingivalindex, salivmätning och bakterieprovtagning gjordes vid baseline och efter fyra respektive åtta veckor.

Resultat: Gingivalindex och MPS (mucosal–plaque score) förbättrades och plackindex var relativt konstant under studiens gång. En lätt förbättring av den ostimulerade salivsekretionen kunde noteras men ingen statistisk signifikans kunde påvisas. Vad gäller mikroorganismer ökade lactobacillerna, Streptococcus mutans var konstant och Candida albicans minskade men ingen statistisk signifikans noterades.

Konklusion: I denna pilotstudie tycktes Proxident munspray med solrosolja och munkurtgel utan smak, hjälpa människor med muntorrhet att förbättra munslemhinnans kondition men det krävs ytterligare och längre studier. Produkterna kan rekommenderas som komfortpreparat.

Nyckelord: Hyposalivation, muntorrhet, oral mikroflora, saliversättande produkter, salivflöde
Introduction

Saliva

A healthy person produces daily saliva amounts of 0.5-1.5 l. Saliva consists of more than 99% water and less than 1% solid materials such as proteins and salt (Klinge 2010). Oral dryness is a term for both xerostomia which means subjective, perceived dry mouth (Navazesh et al. 2008), and hyposalivation which means an objective reduction of saliva with limit values for stimulated salivation < 0.7ml/min (Nährí 2001) and resting salivation <0.1ml/min (Flink et al. 2005).

Saliva production is important for oral health as it protects the teeth and mucosa. Hyposalivation increases the risk of caries and other diseases (Guggenheimer and Moore 2003). Saliva also plays an important role in facilitating speech and the process of swallowing.

There are different schools on the relationship between a person´s age and their production of saliva. The present consensus seems to be that age does not affect the function of saliva production in healthy, non-medicating adults. Dry mouth can have many different sources, among those the habits of using tobacco and alcohol. It is common as a side-effect of medication, especially in the use of anti-depressives, anti-psychotics, beta-blockers and antihistamines. Today we have an increasing number of elderly who still have their teeth. They often use several different medications and are therefore in the high risk group for hyposalivation (Klinge 2010). According to the
people at the mean age of 80 use on average 5.8 different medicines per person, and the majority of these products have an anti-cholinergic effect which has dry mouth as one of many side-effects (Porter et al. 2004). This often leads to an increase in oral conditions such as increased caries activity and other problems, among those mucosal infections (Läkemedelsboken 2007/2008).

The oral health of dependent and vulnerable elderly in need of special care plays a vital role for each individual. For example, dry mouth can be socially isolating (Navazesh and Kumar 2008; Fox 1996; Närhi 1994) because of the difficulties in talking, chewing, swallowing and bad breath. Another factor of concern for the elderly patient can be the loss of taste which can lead to loss of appetite. Hyposalivation can also cause tender and sore mouth, and sub-standard retention of prosthetic constructions, impacting nutrition and wellness (Närhi 1994).

There are many saliva stimulation products in the form of pastilles and chewing gum, some of them containing fluoride to protect from caries, but treatment methods need to be progressed and suited (Mathews et al. 2008). In an earlier study, Xerodent saliva stimulating tablets were tested in a group of elderly, dentate, patients with drug-induced oral dryness (Wårdh 2009). A tendency to some positive effects were found due to an increase in saliva, and reduced amount of oral bacteria for those who had moderate oral dryness. For individuals with severe oral dryness, the tablets did not help. Also, they were not appreciated by individuals with stomach problems (Wårdh 2009). In cases with severe oral dryness we need to use saliva substitute products. They are not supposed to stimulate, only moisture the oral cavity. This study focus on such lubricating products.
Oral microbial flora

Oral dryness also causes a change in an individual’s oral microbial state. In a study with participants suffering from Sjogren’s syndrome, it was found that these individuals had larger quantities of *Streptococcus mutans*, lactobacillus and *Candida albicans* in the supragingival plaque, the mucosa and tongue root. Twice the amount of *Candida albicans* was found in supragingival plaque compared to the control group (Almståhl et al. 2001). The presence of Pseudomonas and *Candida albicans* in elderly people with more than 10 teeth and requiring nursing care are indicators of a high risk of pneumonia and heart disease (Senpuku et al. 2003). They also need help with oral hygiene (Senpuku et al. 2003). It is generally agreed that the prevalence of specific bacteria in dental plaque is associated with development of periodontal diseases and caries and that good oral hygiene reduces this risk. Oral soft tissue disorders are often infectious diseases, for example, oral candidiasis. An altered oral microbial flora was found in elderly people living in institutions when compared to elderly people living alone (Kaklamanos et al. 2005). A positive correlation has been found between oral infections and cardiovascular disease (Holmlund et al. 2006) and individuals with poor oral hygiene have been found to have an increased rate of upper respiratory tract infections, such as pneumonia (Scannapieco et al. 2003).

Pneumonia can occur through several mechanisms: inhalation of aerosols, local dissemination within the lung and spreading hematogenously from other parts of the body. Aspirational causes are the most common infection route for co-morbidity in elderly (Sumi et al. 2007; Takeshita et al. 2010). Aspiration pneumonia is also the second most common infection in elderly in nursing homes, which also requires hospital
treatment and has the highest mortality (Pace and McCallough 2010; Langmore et al. 1998; Quagliarello et al. 2005). Aspiration pneumonia occurs when pathogens in the mucus from the nose and throat are pulled down into the trachea and lungs and cause infiltrates (Azarpazhooh and Leake 2006; El-Solh et al. 2004). Healthy patients aspirate in their sleep and this does not lead to infection because they have good cough capabilities and proper functioning of the immune system (Azarpazhooh and Leake 2006; Pace and McCullough 2010).

One of the risk factors for aspiration pneumonia to occur is impaired oral health caused by dental disease and poor oral care, as well as the composition of the micro-flora which affects the risk of illness and death in pneumonia (Langmore et al. 2002; Scannapieco 2006). In a study of the risk factors, it was found that a lack of oral hygiene and swallowing difficulties had a significant relationship with pneumonia incidence (Quagliarello et al. 2005).

Depending on dental status oral bacterial flora looks different. In a healthy mouth gram-positive bacteria dominate and in gingivitis there is an equal distribution of gram-positive and gram-negative bacteria. In periodontitis gram-negative bacteria dominate (Pace and McCullough 2010). If a person has a prosthesis it also affects the micro-organisms present (Pace and McCulloch 2010; Sharma and Shamsuddin 2011). Elderly patients who are dependent on help with dental hygiene have a high incidence of respiratory pathogens that usually are not part of the common oral flora (Sumi et al. 2007). Colonization of dental plaque seems to precede the colonization of the oropharynx, which indicates that the teeth serve as reservoirs for pathogens (El-Solh et al. 2004). According to some studies it has been shown that a higher count of oral
Candida is associated with an increased risk of death from aspiration pneumonia (Pace and McCullough 2010; Awano et al. 2008). Frail, elderly people with impaired immune systems may aspirate usually harmless oral micro-flora and this results in opportunistic infections (Pace and McCullough 2010).

**Clinical relevance**

In the last years lubricating products have been popular as a treatment against oral dryness. The market offers different products but few of these products have been evaluated. In the pharmacy they recommend some products in case of drug-induced oral dryness and nursing staff must inform the residents about products and help them to handle the products (Ota et al. 2012). They are not supposed to stimulate the saliva but to a certain extent replace missing mucus saliva and give comfort. Do they also have the potential to increase oral health by reducing oral bacteria? We are rather unaware of what type of effects the products really give. The scientific literature tells us of negatively changed saliva composition in frail elderly patients (Pajukoski et al. 1997), and it would be of great value to know what effects these commonly available products really give us.

**Aim**

The purpose of this study is to evaluate two products against the symptoms of oral dryness in frail, elderly individuals and evaluate salivary secretion and micro-flora before and after using the products.
Research Questions

Will the lubricating products have any objective impact on oral health in regards to plaque, mucosal status, salivary secretion and oral micro-flora?
Materials and Methods

Ethical approval

An application for ethical approval was obtained by the Regional ethics committee in Stockholm. The study was seen as a product test, and the committee did not perform an ethical evaluation nor provide any guidance. Diarienr. 2012/597-31/4.

Participants

22 dependent elderly people were recruited from two places, the Department of Dental medicine at the unit for Gerodontics at Karolinska institutet, and from Public Dental Care at the unit for Medical dentistry at Stockholms sjukhem. Seven did not followed the whole study, while the final group consisted of 15 participants, six participants living in a nursing home and 9 on their own. There were 12 women and three men, born 1924-49. They had 3-30 teeth and they brushed their teeth twice a day and used interproximal cleansing at least once a week. Four of the participants had prosthesis. They suffered from dry mouth daytime and/or night-time. The study products were used on average four times every twenty-four-hours. No participants used the products less than three times every twenty-four–hours.

The inclusion criteria were participants over 65 years, with dry mouth symptoms and understanding Swedish.

The exclusion criteria were cognitive disorders or other limitations that were obstacles for performing the study activities.
Written consent

The participants signed an informed consent about the study. If they wanted they could discontinue their participation without giving any reason. Appendix 1.

Products

The participants started to use one of the two test products for four weeks and after that the other product for four weeks, a modified cross-over design. After each study measurements were carried out and added to the study protocol, ending up in three measurement sessions for each individual. The products were Proxident oral spray with sunflower oil, and Proxident gel-based flavorless oral moisturizer. The products are made in Sweden by Proxident AB. All examinations were carried out by the same two persons together.

Before the start of the study the participants or the care staff got instructions on how to use the products and receive new bottles and how they could assist the elderly. A protocol with instructions for how to use the product as often they needed to and always before bedtime was posted in the patients’ bathroom together with a use list to see how often the product in fact was used.

Study protocol

The study started with baseline data, medications, general health, dental status, mucosal status, plaque index, subjective (VAS -scale) and objective measures of salivation and also supragingival plaque samples for microbial analyses. See study protocol, appendix 2.
**Gingival index**

The condition of gingiva was registered by Gi (Löe and Silness 1963) from 0 – 3.
0 healthy gingiva, 1 slight inflammation, 2 moderate inflammation, 3 heavy inflammation.

**Plaque index**

Plaque was registered with Pi (Silness and Löe 1964) from 0 – 3, 0 no visible plaque, 1 slight plaque registered with a probe, 2 visible but thin plaque on some or all tooth surfaces, 3 visible thick plaque on almost all or all surfaces.

**Mucosal plaque score**

Mucosal plaque score, MPS, is used for both persons with and without natural teeth and prostheses. The index was designed to evaluate oral health and oral hygiene in groups of individuals at institutions and in hospitals. It is composed by two measurements, MS for mucosal disorders, criteria (1) Normal gingiva and mucosa (2) Mild inflammation (3) Moderate inflammation (4) Severe inflammation and PS plaque score (1) No easily visible plaque (2) Small amounts of plaque (3) Moderate amounts of plaque (4) Abundant amounts of confluent plaque. They are added to a single index, measuring a persons’ oral hygiene, not in order to make a diagnosis (Henriksen BM et al.1999).

**Saliva collection**

The participants rested 15 minutes after arrival, the time was registered and they had not eaten, smoked or brushed their teeth for one hour before collecting saliva for a 15
minute period. The participants bend forward and drool in a cup and then the amount of saliva was measured. After that they chewed a piece of paraffin for 30 seconds and then collected stimulated saliva for 5 minutes which was measured (Flink et al. 2005). The saliva collections were mainly performed in the morning time.

**Plaque collection**

Supra-gingival plaque was collected with sterile pellets, from four interproximal supragingival sites. The sampling sites were between the upper right first and second molars, the lower left first and second molars, the upper right second incisor and the canine and the lower left second incisor and the canine. If one or more of these sites were not available, the closest available site was selected.

The samples were transferred to transport medium VMGA III and processed within 24 hours. The analysis of the samples has previously been described (Dahlén et al. 1982). The bottles with VMGA III were shaken on a whirly mixer for 10 seconds and thereafter 0.1 ml was placed in a standardized fashion on each agar plate, using unselective enriched blood agar plates and selective agar plates. The total number of microorganisms growing under anaerobic conditions, colony-forming units (CFU) and the proportion of *Candida albicans*, *Staphylococcus aureus*, enterococci, *Streptococcus mutans*, lactobacilli and pseudomonas were calculated.

Semiquantitative estimations were made according to the following scale:

- **Very sparse growth**: 1-10 CFU
- **Sparse growth**: 11-100 CFU
- **Moderate growth**: 101-1,000 CFU
Heavy growth 1.001-10.000 CFU

Very heavy growth > 10.000 CFU (Dahlén et al. 2003).

The agar plates were made at the laboratory with material from Oxid Ltd (Basingstoke, Hampshire, UK) and Difco Laboratories, Becton, Dickinson and Company (Sparks, MD, USA). According to a microbiologics expert (prof. Maud Wikström, Sahlgrenska academy) we created four groups to take account of the bacteria in this fashion:

1. No growth
2. Very sparse growth and sparse growth = Rarely
3. Moderate growth and heavy growth = Moderate
4. Very heavy growth = Abundant

**Data register**

All collected data which was used for analysis in the study was anonymised, though findings registered in the patient’s dental records.

**Statistical analysis**

Due to the small amount of participants and a study design that was meant to sort suitable variables for following studies, we consider the present study as a pilot. All collected data was registered in an Excel file and the Statistical Sciences of Social Package 16.0 (SPSS) was used. Descriptive and analytic statistics were used. Paired \( t \) test was used for analysis of possible differences between the groups. McNemar test and Bowker’s test for symmetry and Friedman ANOVA was used to compare measurement in the same person. \( P \)-values \( \leq 0.05 \) were considered statistically significant.
Ethical aspects

The participants got training in using the products as well as starting a habit as well as oral examination. If it was necessary, they got help to visit a dentist for treatment. For some individuals the project may be experienced as tiring, but then they could interrupt their participation at any time.
Results

In this study we had a baseline of 22 participants and then 15 at the end. Six of them quit after baseline, and one did the second examination. Two persons felt they did not need the products, one had private reasons and one was in hospital, three others did not give any reason.

Those drop-outs are not included in the study. See Figure 1.

Figure 1. Flow chart. Baseline – drop-outs (n=6) Oral spray 4 weeks – drop-outs (n=1) Dry mouth lubricator 4 weeks (8 weeks from baseline).

Table 1.

| Participants | Females | Males | Total |        |
|--------------|---------|-------|-------|--------|
| Years        | Median 82,5 | Median 83 | Median 83 |        |
|              | Mean 79,7 | Mean 79 | Mean 79,5 |        |
| Number of teeth | Median 21,5 | Median 21 | Median 21,5 |        |
|              | Mean 18,4 | Mean 19,3 | Mean 18,6 |        |
| Number of drugs | Median 5 | Median 8 | Median 6 |        |
|              | Mean 6,6 | Mean 8,3 | Mean 6,9 |        |
Table 1 show the median and mean values for the participants in year of ages, teeth and drugs.

**State of health**

None of the participants had been diagnosed with diabetes but 33.3 % (n = 5) suffered from cardiovascular diseases and 13.3% (n = 2) have had pneumonia under the last year. See Figure 2.

![Health Status](image)

**Figure 2.** Health status 33.3% of the participants suffered from cardiovascular diseases and 13.3% have had pneumonia last year, nobody had diabetes.
**Medicines**

The study group had a total of 89 different drugs. Every person who took medicines had more than four drugs, three participants had no drug at all. The mean value for the group was 6.9. Most common was Alvedon 53.3% (n=8) used daily, Lasix 33.3% (n=5) and Oxascand 26.7% (n=4). Then came Symbicort, Levaxin, Furix, Metroprolol, Trombyl, Waran and Mitrazapine whit 20% (n=3) each. Figure 3 shows if there were two or more participants who took a drug. The medicine intake did not change during the study.

![Commonly Used Drugs](image)

**Figure 3.** Drugs used by two or more participants.

**Oral health**

During the study the gingival index (Gi) and MPS became lower. The mean value of MPS decreased from 3.9 to 3.6 after using the oral spray. After using gel-based oral moisturizer there was a further decrease of the mean value to 3.2 (p=0.04).
The gingival index decreased from 1.1 to 0.7 (p=0.01) after using oral spray and after gel-based oral moisturizer the mean value increased to 0.8 which was still an improvement compared to baseline (p=0.05).

Plaque index was nearly unchanged, we observed a weak decrease in the last four weeks of the study but not significant. See Figure 4

![Figure 4](image)

**Figure 4.** Mean value of MPS (mucosal plaque score), Gingival index and Plaque index.

**Saliva**

Measurement of the stimulated saliva showed a decrease after four weeks from 0.87 ml/min to 0.56 ml/min, then an increase to 0.77 ml/min. The mean value for unstimulated saliva was unchanged from baseline to four weeks and then a small increase occurred from 0.04 ml/min to 0.06 ml/min, without significance, see Figure 5.
Microbial results

Our analysis was divided into four groups starting with 1: no growth, 2: rarely, 3: moderate, 4: abundant. At baseline most participants had lactobacillus (n=14), Candida albicans (n=10) and Streptococcus mutans (n=8), two have Staphylococcus aureus and one pseudomonas. After 4 weeks using Proxident oral spray with sunflower oil, 13 participants had lactobacillus, 11 had candida albicans and 7 had Streptococcus mutans, 2 had Staphylococcus aureus and 2 pseudomonas. When the participants used Proxident gel-based flavorless oral moisturizer for 4 weeks 15 persons had lactobacillus, 11 had Candida albicans, 8 had Streptococcus mutans, one Staphylococcus aureus, one enterococcus and 2 pseudomonas. No statistical significance was found when comparing spray with gel, see Figure 5.
Figure 5. Number of persons and bacteria 0=baseline, 4 weeks and 8 weeks.

*Candida albicans* decreased during the study period, some of the participants migrated from moderate to the rarely group, but the change was not statistically significant.

Figure 6.
Figure 6. *Candida albicans* 1= no growth, 2= rarely, 3= moderate

Both after using spray and gel *Candida albicans* decreased, p > 0.9536 from baseline – 4 weeks (spray) and p > 0.8013 from baseline-8 weeks(gel).
Discussion

Method discussion

The design of the study makes it hard to clarify whether any product was better than the other but the results indicate statistically significant improvement of GI and MPS after 8 weeks. To investigate the difference between sunflower oil and mouth moisture gel, two separate study periods and a larger population would have been required. In this pilot study we were restricted to a small study group in rather frail health condition. It was problematic both to encourage the participants to follow the whole study period and to come to the scheduled dental clinic visits (Muszalik et al.2015). Six of the participants did not continued after baseline and one did not performed the second examination. They suffered from different health problems. In the written consent they were told that they could stop without giving any reason. If a larger study with this focus is planned, it is probably better to recruit participants from, for example, a general practitioner clinic.

We also treated the population as one group, even if there were some changes in their age, medical conditions and drug use. It was not suitable to divide the group into small subgroups. We included study participants based on the inclusion criteria dry mouth and more than 65 years old. None of the participants was smoking, yet smoking is associated with dry mouth (Dyasanoor and Saddu 2014). Saliva samples were all taken during the morning session but not at the exact time which is a weakness.

Further on, bacteria such as *Streptococcus mutans*, lactobacilli and *Candida albicans* may require prolonged use of products for possible changes. The bacteria samples could also have been analyzed in a different way, with a more specific measurement of numbers and frequencies of bacteria. The product Oral spray with sunflower oil is commonly used at hospitals and in nursing homes in many years and the other product
A gel-based flavorless oral moisturizer was a newly introduced product we wanted to evaluate.

Results for VAS and OHIP-14 are shown in another part of the study, (Magister Thesis Caroline Croonquist Girestam KI 2015).

**Saliva flow**

Plaque index was constant during the study time, a weak decrease could be seen after 8 weeks but was not statistically significant. However, the improved values for gingival index GI and MPS suggest that the oral mucosal conditions improved. Unstimulated saliva increased after 8 weeks but no statistical significance could be shown here. Concerning stimulated saliva a decrease was observed after 4 weeks and then an increase again after 8 weeks. The amount of saliva produced is influenced by several factors; the "biological clock", the time of day, stress, chewing power and number of teeth (Dawes 1972; Flink et al. 2005). Several participants in the study said they were troubled by dry mouth mostly at night. We intended to perform the saliva measurements at the same time of day but had to make some alterations in the time schedule that can have influenced the result. Possibly sympathetic innervation also must be taken into account. It may have influenced the results when participants were nervous of the first test and then become more comfortable (Clark et al.2014). Salivary glands are affected both by sympathetic and parasympathetic innervation, therefore resting saliva and stimulated saliva varies (Nederfors 2000). It is mostly the mucus-resting saliva which influence if you experience dry mouth. The attendees were elderly people over 65 years
old with an average of 6.9 different medications on a daily basis. More than four drugs daily contribute to a risk of suffering from dry mouth (Pajukoski et al. 1997; Wårdh 2009). Some drugs with anticholinergic effect inhibits parasympathetic nervous system and leads to reduced saliva quantity (Saleh et al. 2015). Diuretics such as Lasix, Retard and Furix and psychotropic drugs e.g. Oxascand and Mitrazapin, which were commonly used medications of the participants, reduce the amount of saliva. Other medications that can cause dry mouth and which participants used, were Imovane, Madopark, Metroprolol, Mollipect, Morphine and Omeprazole. 33% of the participants had cardiovascular disease. Drugs with anticholinergic effect are used in heart rhythm disorders and for high blood pressure. Metroprolol e.g. is used for high blood pressure and decreases saliva quantity (Saleh et al. 2015). It is difficult to increase saliva flow depending on what the participant’s basic condition is. Many seniors take several medicines with oral dryness as a co-effect (Nederfors 2000).

**Oral Health**

Participants had maintained their oral hygiene habits and the slight rise of saliva was not big enough to affect the amount of plaque. The plaque index was relatively constant during the study time. Dry mouth increases the plaque of the oral cavity which leads to gingivitis (Gerdin et al. 2005; Osterberg et al. 1984). An improvement of gingival index could be seen after 4 weeks when oral spray with sunflower oil was used. The index went up slightly after the use of mouth moisture gel but the value was lower than at the baseline indicating that the products have a positive impact on gingiva. The MPS is a unified index for amount of plaque and oral mucosal condition, both for dentate and denture wearers (Henriksen et al. 1999). MPS showed an average decrease during the
study time. Decreased mucus saliva makes the oral mucosa brittle and causes great discomfort for the patient (Cassolato and Turnbull 2003). The unstimulated saliva is harder to substitute and saliva replacement products can be recommended frequently to dry mouth patients to good effect. Stimulated saliva can be impacted by the individual by the numbers and consumption of food and drink. (Nederfors et al.1993).

**Micro-flora**

Laboratory analysis of the samples were done for *Streptococcus mutans* and lactobacilli associated with dental caries and *Candida albicans, Staphylococcus aureus,* pseudomonas and enterococci associated with mucosal infection (Dahlén 2006). *Streptococcus mutans* was constant but lactobacilli increased slightly. Many of the participants had sweets and other sugar products to hand and it is known that at low salivary secretion rates, the pH of saliva and buffer capacity decreases (Almståhl et al. 2001). The evaluated products did not seem to have the capacity to change these circumstances during the study period.

In *Candida albicans* the participants move from a higher group to a lower one. *Candida albicans* was a frequent finding in our study group but it decreased over time depending on increased oral hygiene or possible effect from the products. However, this finding should be regarded as a trend, since statistical significance was not reached.

*Staphylococcus aureus* were rarely detected in this study as well as pseudomonas and enterococci. Enterococci are resistant to many antimicrobials and associated with hospital infections (Emoni and Gaynes 1993) and were detected in only one participant.
A high proportion of one or more of these opportunistic microorganisms in oral samples has been shown to correlate to shortening of life expectancy (Wårdh and Wikström 2013).

In summary, there are several different saliva substitute products commercially available that alleviate dry mouth. Very few studies have been done in the area perhaps because those products are not prescribed medications. In a revive article (Furness et al. 2011) the conclusion was that it is no strong evidence that any topical treatment is effective for relieving the sensation of dry mouth. A Japanese study (Ota et al. 20012) tested a moisturizing micro-gel spray in patient with cancer treatment suffering from symptoms of dry mouth, there was significant improvement of the symptoms at night and on awakening. The conclusion was that the moisturizing micro-gel spray was particularly effect for relieving symptoms of dry mouth in patients with cancer. In this pilot study MPS and gingival index became lower and the condition of oral mucous improved. Several studies often done investigation about quality of life and patient satisfaction for the treatments not with objective data. Saliva substitutes applied to the oral mucosa of sprays, gels, oils or viscous liquids and all articles obtain for further trials and the review (Hahnel et al.2009) concluded that “while saliva substitutes appear to relieve symptoms, data are limited and sometime ambiguous”. Further research is required to develop guidelines on how dry mouth patients can be helped in the best way. Today, there are no clear directives about what products should be recommended (Ship et al. 2007). It needs a developed cooperation between elderly and dental care concerning the elderly patient´s oral health and to better involve the nursing staff.
Conclusion
Proxident oral spray with sunflower oil and moisture gel without taste may help patients suffering from dry mouth to improve their oral mucous conditions, but it requires further studies to confirm these results. The products can be recommended as comfort products.

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Appendix 1

INFORMATION TO TEST SUBJECTS
In regard to the study “Treatment of dry mouth syndrome”
You are being asked if you want to take part in a study. Please read this information carefully.
Many older people suffer from dry mouth symptoms and risk getting problems with their teeth and mouth.
You will be able to test non-prescription medicines to treat dry mouth. In connection with this we will examine your mouth and ask you some questions. All of this is free of cost.
Taking part in the study is voluntary. At any time you are free to stop your participation in the study without reason and without this impacting you negatively. All details gathered during the study in regard to you will be handled confidentially, in other words it will not be possible to see that you have taken part in the study. In accordance with the Personal Information Act (PUL) you have the right to request the information gathered on you in the study once a year and have any errors corrected. The responsible entity for this purpose is Karolinska Institutet and in case you have a request of this nature please contact Inger Wårdh, tel. 08-524 882 26.

Please ask questions about the study or if there is something in this information that you do not understand.

…………………………………………………………………………………………

Hereby approve of taking part in the study according to the conditions described above, Location and date

…………………………………………………………………………………………

Name

…………………………………………………………………………………………
Study protocol

Appendix 2

Name ________________________________
Personal identification number __________________________
Date ________________________________
Female • Male •
Examiner ________________________________ Dept __________________________

Have you, or have you had, during the past year: Heart/cardiovascular disease (BT, stroke)
Diabetes
Pneumonia
Medicines (APO-dose where relevant): ………………………………………………………
…………………………………………………………………
………………………………………………………………………………………………
………………………………………………………………………………………………

Pureed food
How often do you brush your teeth/dentures? ………………………………………………………
How often do you clean between your teeth? ………………………………………………………
Do you get assistance?

Number of rooted teeth Upper jaw ________ Lower jaw ________
Of which functioning roots Upper jaw ________ Lower jaw ________
Number of implants (fixtures) ________ regio____________________________

Removable prosthetics:
Entire upper jaw prosthetics ☐ Entire lower jaw prosthetics ☐
Partial prosthetic in upper jaw, on tooth ☐ Implant ☐
Partial prosthetic in lower jaw, on tooth ☐ Implant ☐

MPS
Plaque index ___________ Gums index ___________
Salivation Stim; ml/min ________ Unstim; ml/min ________
Löe/Silness
Gingival index Level 0 _____ Level 1 _____ Level 2 _____ Level 3 _____
Silness/Löe
Plaque index Level 0 _____ Level 1 _____ Level 2 _____ Level 3 _____
Other findings: ________________________________________________
Comment on the products: _______________________________________

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