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EXPLORING CAUSES, PREVENTION AND CONSERVATIVE UP-TO-DATE SOLUTIONS FOR ROOT CARIOUS LESIONS IN COMMUNITY-DWELLING OLDER ADULTS

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Porto Alegre

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Tese apresentada ao Programa de PósGraduação em Odontologia, Nível Doutorado, da Universidade Federal do Rio Grande do Sul, como pré-requisito final para a obtenção do título de Doutora em Odontologia.

Área de Concentração: Saúde Bucal Coletiva.

Orientadores:
Prof. Dr. Fernando Neves Hugo.
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ABSTRACT

León Araya, Soraya. **Exploring Causes, Prevention and Conservative Up-to-date Solutions for Root Carious Lesions in Community-Dwelling Older Adults.** 2019. 121 pages. Doctoral thesis (PhD in Dentistry, Dental Public Health) – Faculty of Dentistry, Federal University of Rio Grande do Sul, Porto Alegre, Brazil.

The research presented in this doctoral thesis is the result of the collaboration project between the Gerodontology and Cariology Unit of the School of Dentistry of the University of Talca in Chile and Department of Preventive and Social Dentistry of the Faculty of Dentistry of the Federal University of Rio Grande do Sul in Porto Alegre, Rio Grande do Sul, Brazil. The information presented in this doctoral thesis is divided into 6 chapters. Chapter 1 is focused on contextualizing the topic of interest from the demographic and clinical perspective. Chapter 2 shows the main results of a randomized controlled clinical trial (RCT) focused on non-invasive therapies for root caries lesions (RCLs), based on fluoridated dentifrices. Chapter 3 describes a study based on a sub-sample of the RCT, that sought to show the adherence to non-invasive treatments for RCLs in older adults. Chapter 4 addresses the impact of non-invasive therapies for RCLs on the quality of life associated with oral health (OHRQoL) in older adults. Chapter 5 explores the role of saliva in the presence and activity of RCLs in an older population. Finally, Chapter 6 delivers a series of conclusions and recommendations derived from the results obtained during the course of this doctoral thesis.

Key words: Root caries lesions, caries activity, randomized clinical trial, fluoride toothpaste, aging, OHRQoL, salivary flow.

LISTA DE ABREVIATURAS E SIGLAS

RCLs	Root Caries Lesions
RDFS	Root Decayed and Filled Surfaces
DFS	Coronal decayed and filled surfaces
FDP	Fixed Prosthetic Denture
BMI	Body Mass Index
RCI	Root Caries Index
WHO	World Health Organization
ICDAS	International Caries Detection and Assessment System
CEJ	Cement-enamel Junction
PPM	Part per million
RCT	Randomize Control Clinical Trial
F	Fluoride
EFAM	Functional Evaluation of Older Adults
MMSE-SF	Short Mini-Mental State Examination
AUDIT-C Test	Alcohol Use Disorders Identification Test
CONSORT	Consolidated Statement of Reporting Trials
SES	Socio-economic Status
RR	Relative Risk
SD	Standard Error
NNT	Number Needed to Treat
CI	Confidence Interval
NaF	Sodium Fluoride
NaMFP	Sodium Monofluorophosphate
CaF_2	Calcium Fluoride
Ca	Calcium
WI	Wear Index
OHRQoL	Oral Health-Related Quality of Life
OHIP-14Sp	Oral Health Impact Profile-14 Spanish
ARC	Active Root Caries

FSNE	Flujo Salival No Estimulado
FSE	Flujo Salival Estimulado
SOGCh	Geriatric Oral Society of Chile

LIST OF CONTENTS

CHAPTER 1

Introduction: Root caries; a highly prevalent disease in older adults, rationale and aims of the Doctoral Thesis

1.1. Introduction

The world population continues to grow older rapidly as a consequence of changes in fertility and mortality rates, and the process is particularly advanced in industrialized nations where the people tend to live longer (He et al. 2016). These demographic changes had their most dramatic moment in the latter part of the 20th century and the first part of the 21st century and are predicted to continue in the future (Oeppen and Vaupel 2002). Yet the pace of aging has not been uniform. A distinct feature of global population aging is its uneven speed across world regions and development levels. Most of the more developed countries in Europe have been aging for decades, some for over a century. In 2015, only one sixth of the world lived in a developed country, but more than one third of those aged 65 and older and over half of those aged 85 and older lived in these countries. Older populations in developed countries are projected to continue to grow, but at a much slower pace than those in less developed countries, particularly in Asia and Latin America. By 2050, less than one-fifth of the world's older population will reside in more developed countries (He et al. 2016).

This phenomenon of aging has also occurred due to medical advances and an improved living environment that ultimately extend the average life span. However, the increase in life expectancy at birth of the world population was not associated with an increase in healthy life years, but rather with an increase in years lived with disability (Collaborators 2016), resulting in a complex situation in which the number of people needing nursing care has increased. While increased life-expectancy is to be welcomed, it poses numerous challenges to public health. In this context, health policymakers are progressively shifting from the concept of prolonging the life span in calendar years towards favouring quality years, meaning years of life in good health. This implies the compression of morbidity at the end of life (Fries 2005). This novel concept also involves oral health, requiring treatment concepts that assure oral health, masticatory function and oral health-related quality of life until the end of life, or at least for as long as possible. Namely, to delay surgical or operative interventions, maximizing the preservation of biological capital (Giacaman 2017).

In some industrialized countries and regarding the independent older population, more teeth are retained, a lower prevalence of severe periodontitis is observed, and caries experience is reduced compared with previous surveys (Dye et al. 2015). However, another epidemiological literature on oral health in the older population is not very encouraging, and it indicates profound imbalances among countries and regions and as a function of institutionalization (Murray Thomson 2014; Petersen et al. 2010). This disparity is mainly attributable to differences in socioeconomic conditions and in the availability of and access to oral health services (Gil-Montoya et al. 2015) as is the case of our own Latin American region in which, of the few studies still available in most of these countries, it is possible to observe poor oral health as a common feature of older adults in the region (León et al. 2018b).

Dental public health in Latin American region has historically focused on schoolchildren, depriving the older population from attention and coverage (León et al. 2018a). But this situation must change due to the most recent projections of the United Nations, the proportion of the population aged ≥60 y is projected to increase from about 10% in 2010 to 25% by 2050. In considering future trends consequently, the older population in Latin American region at risk of developing the most prevalent oral diseases (caries and periodontal diseases) is increasing dramatically. Across age groups, caries and periodontal diseases are among the most prevalent diseases in mankind and, if untreated, lead to tooth loss, edentulism, loss of masticatory function, poor nutrition status, as well as loss of self-esteem, social difficulties and diminished quality of life (Kassebaum et al. 2014a; 2014b; 2015; Tonetti et al. 2017).

1.2. Root Caries: a highly prevalent disease in older adults

With the increase in life expectancy and the increase in natural teeth retained among older adults in the most of industrialized countries, root caries has been predicted to become a significant public health problem (Bansal et al. 2011). It is known that one-third of the older adult population bears most of the root caries burden (Anusavice 1995; Griffin et al. 2004).

Root caries reported around the world is varied with root caries prevalence among population samples varying from 9.8% (Locker and Leake 1993) to 71% (Kim et al. 2012), while the incidence and increment of root caries vary from 12.4% (Fure 2004) to 77% (Powell et al. 1998) and 0.3 (Locker 1996) to 4.4 (Powell et al. 1998) on root surfaces respectively. A recent longitudinal study conducted in Latin America showed an incidence of 47,3% (Bidinotto et al. 2018). In a recent systematic review showed that the root caries increased over time even among the healthier older adults. Length of follow-up influenced root caries estimates due to a bias towards relatively healthier older adults retained in the study. Even so, the increase in root caries even among the healthier older adults, should be considered by both clinicians and healthcare planners/policy makers in their provision of services (Hariyani et al. 2018).

The root surface may be more vulnerable to mechanical destruction than the crown because there are differences in topography, morphology, composition, and structure of cementum and dentine when compared to the anatomic crown (Carrilho 2017). In a population who is frequently exposed to scaling by dental health professionals and cervical abrasion for inadequate tooth brushing, the cementum layer is frequently abraded away, exposing the dentine. Root cementum and dentine are structurally different from enamel and react differently to cariogenic challenges. In particular, the critical pH of dentine and cementum is approximately 6.4 (Melberg 1986) while that of enamel is 5.5 (Stephan and Miller 1943). More recently, it has been confirmed that the solubility of the mineral of root tissues is higher than that of hydroxyapatite (Shellis 2010), but indicated that such solubility is probably lower than suggested previously, ranging from 5.66 to 5.08. Critical pH represents the equilibrium between tooth mineral and dental plaque fluid. It means that the mineral of the root is more soluble than that of the enamel; therefore, it is much easier to demineralize the root surface in comparison to enamel. The dental root tissues, cement/dentin, apart from having a lower mineral content exhibit a remarkable number of organic components, such as collagen fibers and fibrils. In addition, the calcified matrix of dentin is permeated by tubules that host the cytoplasmic processes of odontoblasts. Thus, a very important characteristic of odontoblasts is the capacity to continuously form dentin as secondary (when tooth becomes functional as a daily deposit) and tertiary dentin (as a reaction to an external aggression) (Abou Neel et al. 2016).

a) Etiology of Root Caries Lesions (RCLs)

The etiology of the initiation and progression of RCLs is the combination of cariogenic bacteria and fermentable carbohydrate on the root surface (Clarkson 1995). *Lactobacillus, Streptococcus mutans,* and *Actinomyces* have been implicated in the development of RCLs (Beighton and Lynch 1995; Brailsford et al. 1998).

Once the root is exposed, a new ecological niche will be formed on the root surface. This surface, which used to be an anaerobic microenvironment underneath the gingival tissue, becomes an aerobic microenvironment with variable nutrient availability. The gingival crevicular fluid, a serum-like exudate, for example, is in contact with the root tissue and it can be exploited as a source of nutrient for microorganisms established in that niche. The microbiota composition also would change in the biofilm due to the microenvironment change.

After root exposition, regions where Sharpey's fiber systems were implanted are gradually exposed and converted into canals through which the microbial penetration may occur to gain the proximity to the tissue. Furthermore, improper toothbrushing, or periodontal treatment of root surfaces often damages or completely removes the cementum, thus exposing the dentin. It has been shown that the cementum and the dentin tubules are obliterated by mineral changes from oral fluids due to the de-remineralization process at the interface tooth and saliva/crevicular fluid (Schüpbach et al. 1989).

In the presence of a cariogenic root biofilm, the fermentable carbohydrate from diet is converted into organic acids, and the RCLs is initiated in the exposed root site. Currently, the RCLs is defined as a process of 2 stages (Takahashi and Nyvad 2016). The first stage is characterized by mineral dissolution and the second one by the degradation of the organic matrix of the root surface. First, the microbial niche presents less oxygen and carbohydrate availability than the one above the enamel. Consequently, bacteria do not survive in an acidic environment (non-mutans species). After gingival recession, this microenvironment changes and the microbiota may have to adapt to the new conditions above the cementum/dentin. In the presence of high amount of sugar, the mineral exchanges between oral fluids and tooth surface eventually lead to the demineralization of root hard tissues (inorganic phase of RCLs). The progression of lesion depends on the collagen degradation by endogenous or exogenous collagenases (organic phase of RCLs). It was suggested that collagen matrix degradation could only be possible after demineralization and the reason is that the substrate is not approachable for collagenases in the mineralized tissue. The demineralized collagen serves as a scaffold for colonizing bacteria (Takahashi and Nyvad 2016). Besides demineralization, bacteria could be also involved in matrix degradation (Nyvad and Fejerskov 1990).

b) Risk Factors associated with RCLs

Root caries is a complex, multifactorial disease and it is not clear whether the risk factors for this disease are the same across diverse populations.

A systematic review of RCLs risk factors with data from cohorts published between 1970 and June 2009 (Ritter et al. 2010) revealed that the overall quality of the studies was moderate, with the most commonly tested variable (not exactly as a risk factor) being root decayed and filled surfaces (RDFS) at baseline, which had been tested in 12 of the 13 studies. This was found to be significant in 7 out of the 12 studies. The second most frequently examined variable was age, which was included in 10 studies and was significant in 2. **Table 1** presents a summary of the variables examined in more than one study. It is difficult to come to any conclusion about the role of variables which have been examined even across many studies as each study may define the variable in their own way.

Table 1 Summary of variables tested as potential risk indicators for RCLs. Adapted from Ritter et al. (Ritter et al. 2010).

Variable	Times tested	Times significant
Baseline RDFS	12	7
Age	10	2
Smoking	9	1
Medication use	9	2
Gender	8	2
Lactobacilli counts	8	3
Streptococcus mutans counts	8	1
Saliva Flow rate	8	1
Diet	6	0
Dental visit pattern	5	1
Plaque index	4	3
Baseline coronal DFS	4	0
Education	4	0
Oral higiene status	3	0
Ethnicity	3	1
Prosthetic crown/FPD	3	1
Use of interdental cleaning aid	3	1
Attachment loss	3	1
Use of removable partial denture	2	2
Candida	2	1
BMI	2	0
Marital status	2	0
Alcohol use	2	0
Income	2	0

RCLs: Root Caries Lesions
RDFS: Root decayed and filled surfaces
DFS: Coronal decayed and filled surfaces
FDP: Fixed Prosthetic Denture
BMI: Body Mass Index

A literature search beyond the date of this systematic review identified 2 longitudinal studies reporting risk models. In the first of these studies (Sánchez-García et al. 2011), the final prediction model included 6 risk factors for root caries: limitations in basic daily living activities, smoking, not using dental mouthwash, high *Streptococcus mutans* count, ≥ 6 healthy root surfaces at baseline, and a baseline root caries index of 8% or higher. In the other longitudinal study it was found that the risk of RCLs increased with: age, the presence of any gingival recession, having at least one filled or decayed root surface at baseline, and having at least 5 filled or decayed coronal tooth surfaces at baseline (Sugihara et al. 2014).

Root caries risk factors are usually measured among the general aetiological factors of dental caries, such as susceptible surfaces, biofilm and availability of fermentable carbohydrate (Närhi et al. 1999; Powell et al. 1998). Conversely it has been suggested that, in fact, a combination of behavioral, contextual and societal factors influence the way caries develops in individuals and in populations (Holst et al. 2001). The most recent longitudinal study in older adult populations from middle-income countries showed that the associated factors with the incidence of RCLs were geographic location of residence, age, frequency of tooth brushing, stimulated saliva flow rate and presence of removable partial denture (Bidinotto et al. 2018).

While many studies have published prediction models for RCLs, there is a need for external validation of any future models which show promise in RCLs prediction. Future models should also aim to include variables other than past root caries experience. Inclusion of past root caries experience compromises the use of these models as true preventive tools as they preclude the opportunity to identify a high risk individual before they become exposed to the disease (Carrilho 2017).

c) Indexes and scoring for RCLs:

The epidemiological studies of root caries report their findings in a variety of ways using different indices. During 1970s and 1980s, there was great interest in the epidemiology of root caries. Many of these studies simply counted the number of carious and restored root surfaces and presented it as root decayed and filled surfaces (RDFS). Sumney et al. in 1973, reported the percentage of the population with one or more root surface caries lesions and also presented the average number of lesions per person per tooth surfaces available (Sumney et al. 1973). Then, Banting et al. reported the percentage of the population with at least one filled or decayed root surface and also the mean number of decayed root lesions per patient alongside the mean number of restored root surfaces per patient (Banting et al. 1980). In 1980, Katz proposed a new measure which he named the Root Caries Index (RCI) (Katz 1980) for scoring and reporting root surface caries. From the mid-1980s onwards, the RCI became one of the 2 standard measures used for reporting RCLs prevalence (the other being RDFS), with most studies reporting both in conjunction to give as rounded a picture as possible.

Thus, the traditional measurement of caries in the cavitation stage, excluding stages of cavities prior to cavitation (WHO 2013), may no longer be sufficient to reflect the changes in the incidence of caries in the present populations that today exhibit a global rate slow progression (Glass et al. 1983). In addition, it has been shown that caries detection at the cavitation level results in a significant underestimation of the real caries experience in populations (Ismail et al. 1992; Pitts and Fyffe 1988). For many years, the recording of non-cavitated caries lesions was deliberately avoided due to the belief that it is not possible to reliably detect the pre-cavitation stage in the stages of caries (WHO 1997). However, several studies contradict this statement and it has been shown that inter- and intra-examiner reliability is not necessarily reduced when non-cavitated caries lesions are included in the registration system, provided that the examiners are trained and calibrated before the study (Pitts and Fyffe 1988).

There is additional complexity when researchers add in descriptors, such as quiescent, active, inactive, or recurrent. It can then be difficult to decipher whether they have included “inactive” lesions in their calculations of RDFS or RCI.

The assessment of the activity of RCLs has been classically done according to their visual appearance (color) and tactile sensation. Based on color, RCLs with a yellowish to brown appearance were generally classified as active, whereas lesions with a brownish to black appearance were typically classified as inactive. However, Lynch and Beighton (Lynch and Beighton 1994) associated the tactile sensation of RCLs with respect to their color and distance from the gingival margin. Remarkably, the authors found that color is not a useful diagnosis criterion for activity, but rather distance from the gingival margin is a useful criterion. The authors observed that active (soft) lesions developed closest to the gingival margin, whereas inactive (hard) lesions were found farthest away from the gingiva. Proximity to the gingival margin is the result of attachment loss and exposure of dentin leading to an increased caries risk.

The formalization of visual and tactile criteria into caries classification systems such as ICDAS has been slow, with proposed criteria but little validation. The following are the ICDAS codes for the detection and classification of carious lesions on the root surfaces (ICDAS 2005). One score will be assigned per root surface. The facial, mesial, distal and lingual root surfaces of each tooth should be classified as follows:

Code E: If the root surface cannot be visualized directly as a result of gingival recession or by gentle air-drying, then it is excluded. Surfaces covered entirely by calculus can be excluded or, preferably, the calculus can be removed prior to determining the status of the surface. Removal of calculus is recommended for clinical trials and longitudinal studies.

Code 0: The root surface does not exhibit any unusual discoloration that distinguishes it from the surrounding or adjacent root area nor does it exhibit a surface defect either at the cemento-enamel junction or wholly on the root surface. The root surface has a natural anatomical contour, OR the root surface may exhibit a definite loss of surface continuity or anatomical contour that is not consistent with the dental caries process. This loss of surface integrity usually is associated with dietary influences or habits such as abrasion or erosion. These conditions usually occur on the facial surface. These areas typically are smooth, shiny and hard. Abrasion is characterized by a clearly defined outline with a sharp border, whereas erosion has a more diffuse border. Neither condition shows discoloration.

Code 1: There is a clearly demarcated area on the root surface or at the cemento-enamel junction (cej) that is discoloured (light/dark brown, black) but there is no cavitation (loss of anatomical contour < 0.5 mm) present.

Code 2: There is a clearly demarcated area on the root surface or at the cemento-enamel junction (cej) that is discoloured (light/dark brown, black) and there is cavitation (loss of anatomical contour ≥ 0.5 mm) present.

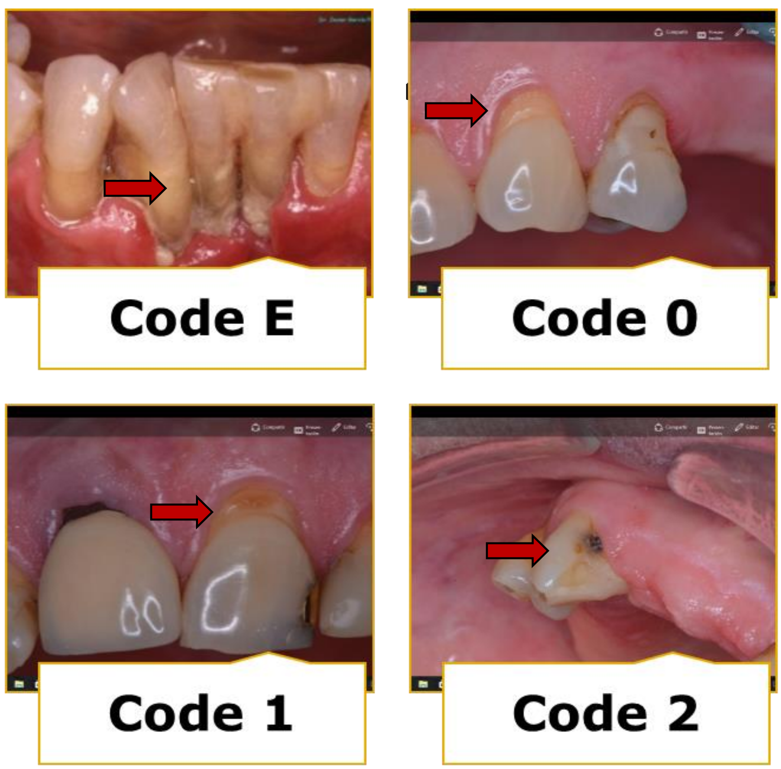
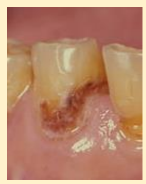


Figure 1. Clinical images of ICDAS codes for the detection and classification of carious lesions on the root surfaces (ICDAS 2005).

On the other hand, in the late nineties, Nyvad et al. propose diagnostic criteria (**Table 2**), based mainly on tactile sensation and visual appearance and considering the activity criteria.

Table 2 Clinical criteria for differentiating active and inactive RCLs (Carrilho 2017; Fejerskov 2015; Nyvad et al. 1999).

	Nyvad's Criteria	
	Active Lesion 	**Inactive Lesion** 
Visual Appearance	Typically, yellowish or light-brown and brownish discoloration. Dull/matte Typically covered by biofilm Usually close to the gingival margin	Typically, brownish or black. Shiny smooth Often no covered by biofilm Distant from the gingival margin
Tactile Features	Feels soft, sticky/leathery on gently probing. Whit/without localized/manifest cavitation Margins of cavity are sharply demarcated	Feels hard on gentle probing Cavity formation may be rough/uneven Margins of cavity are smooth

Active lesions are those that are progressing at the time of examination and hence need immediate professional treatment: non-operative or operative. Active lesions are yellowish or light brownish in color and are typically covered by a microbial deposit that may vary considerably in thickness. The carious tissue feels soft or leathery on gentle probing. There may be localized cavitation of the surface, but soft areas of an active lesion may be extensive without obvious loss of tooth substance. When cavitation occurs, the margins of the cavity are sharp and irregular. Lesions tend to spread laterally and often coalesce with minor neighboring lesions. The lesions may eventually encircle the tooth, in particular when they are located along the cemento-enamel junction. It is of interest that the lesions rarely seem to extend in an apical direction as the gingival margin recedes. Rather new lesions develop at the recessed level of the gingival margin. This may occur irrespective of an inactive lesion being located more coronally **(Table 2)**.

Inactive (arrested) lesion are typically dark brown, often almost black. The surface of the lesion is usually shiny and smooth, and hard on gentle probing. This also applies when the lesion exhibits a frank cavity with distinct loss of tissue. However, if cavitation has occurred the margins most often appear smooth although the surface of the cavity is rough/uneven. In case of long-standing inactive lesions, the root surface may appear glossy and only discoloration suggests previous caries activity. Inactive lesions are considered to be arrested or slowly progressing, and further lesion progression may be controlled by daily toothbrushing with fluoride toothpaste, only. The term “inactive” covers lesions in which no further progression is expected to take place, provided there are no changes in caries risk factors, such as oral hygiene, diet, salivary flow, and medication. Nevertheless, minute areas within the surface of an inactive lesion may be covered by biofilm and demineralization may predominate at that particular spot. The classification, therefore, covers the lesion as a whole **(Table 2)**.

Histologically, the main characteristic of inactive lesions is the presence of a distinctly mineralized, hard surface layer. Also, the lesion is separated from the underlying sound dentin by a distinct layer of sclerotic dentin (Schüpbach et al.

1992). This sclerotic layer is an advanced guard between the demineralization front and the dental pulp, and it is a fundamental condition for successful lesion inactivation (Schüpbach et al. 1990). Another typical aspect of inactivated lesions is that the dentin tubules present intratubular mineralization with an irregular precipitation pattern (Schüpbach et al. 1990), and ghost cells of microorganisms are present between these crystals. Concomitantly, the intertubular dentin also presents itself fully remineralized up to the surface of the lesion (Schüpbach et al. 1992). Furthermore, as previously mentioned, a zone of dentin sclerosis is clearly identified in the interface between the inactive lesion and the underlying sound dentin (Schüpbach et al. 1992).

This distinction between inactive and active stages of root surface caries is of clinical importance, as it shows that root surfaces react to the dynamic physicochemical processes taking place at the biofilm-root surface interface due to intermittent pH changes. If these processes are interfered by regular biofilm removal, active lesions may become arrested and converted to inactive lesions (Nyvad and Fejerskov 1986). While assessing lesion activity, it is important to bear in mind that, within the same lesion, it is possible to find active and inactive areas, as well as areas undergoing remineralization. Therefore, during an examination of a clinically sound root surface, it may be possible to observe areas of unaltered tissue interspersed with areas of demineralization (Nyvad and Fejerskov 1982).

Although several dental indexes have been used to describe oral health, information on the prevalence of root caries is typically not described in most of the studies (León et al. 2018b). Given the increasing tooth retention in older adults, screening for root caries should be incorporated in future surveys, as increased prevalence is expected (Griffin et al. 2004). At this point, incorporating RCLs activity indicators, even in epidemiological surveys could contribute to this minimal intervention dentistry approach.

d) A non-invasive alternative for treatment of RCLs.

Current approaches for the management of the most prevalent oral pathologies, dental caries and periodontal diseases usually involve removing healthy dental tissues. The conventional restoration of cavitated caries lesions has led to a cycle of restorations that ends with tooth extractions at an early age and with the need of complex and expensive oral rehabilitation (Deligeorgi et al. 2001). The burden of disease is so high that the available human and financial resources are not sufficient to resolve the demands for dental care, considering that the governments have targeted resources in restorative therapies, leaving aside preventive measures (Petersen et al. 2010). In this sense, prevention has been systematically excluded in this age group in most of countries, not being identified as an important and constituent part of the solution to oral problems that afflict people of this age (León et al. 2018b). Even so, many times we have to question, who are the people who make the decisions of public policies. Are technically trained people? or are they only politically appointed and untrained people for decision making?

Oral health policies and clinical procedures must consider the life-course approach to achieve good oral health and function. Restorations must not be the first treatment to implement. Evidence has shown that non-invasive or minimally invasive techniques to treat carious lesions are effective and must be preferred over surgical approaches, to avoid complex and expensive restorative therapies, increasing tooth function for longer years (Dannan 2011; Frencken et al. 2012; Murdoch-Kinch and McLean 2003; Slayton et al. 2018; Wierichs and Meyer-Lueckel 2015).

Restorative management for RCLs has also become challenging due to poor visibility and access to the lesions, moisture control, proximity to the pulp and to the gingival margin, and to the high organic content that impairs the optimal adhesion of conventional restorative materials. Successful treatment of RCLs in older adults can be challenging, especially for those with limited mobility, inadequate financial resources or lack of dental health insurance (Kandelman et al. 2012). Scientific evidence-based selection of suitable restorative materials for RCLs is rather unsubstantiated, as studies have reported failure rates up to 68% within 12 months (Hayes et al. 2014). Thus, prevention or lesion arrest appears to be a more reasonable approach, if clinical conditions are appropriate.

Clinical studies have shown that the initiation of RCLs might be significantly delayed by the implementation of preventive dental programs or by chemical agents professionally applied by the dentist or by the patients themselves. Some of these interventions have been shown to prevent the onset of new RCLs, shifting active to inactive lesions. Fluoridated products are the dental therapy with the most robust body of evidence available, and in the case of RCLs, they have been successfully used as a non-invasive therapy for active lesions (Slayton et al. 2018; Wierichs and Meyer-Lueckel 2015).

Delivered in several formats, fluoride has proven to be highly effective in preventing RCLs in older adults (Holmgren et al. 2014), and it is widely used in the clinic. The anticaries effect of fluoride is related to its ability to alter ionic mineral saturation of the tooth, aiding remineralization and preventing demineralization. Also, at high concentrations it may interfere with bacterial metabolism and acid production. The better preventive and therapeutic effect observed with high-fluoride toothpastes (14 ppm) could be the result of higher fluoride concentrations in saliva and in the biofilm. Since root tissues are more prone to demineralization at a higher pH (6.5) than enamel (5.5), preventive and non-invasive measures to control RCLs appear as the most suitable strategies to approach this problem (Vale et al. 2011).

Fluoride-containing toothpastes are considered the most rational topical fluoride delivery vehicle as they are the major source of fluoride in communities where water fluoridation is not available. In fact, regular toothbrushing with fluoridated toothpaste (F-toothpaste) acts at two levels; mechanically disrupting the dental biofilm, and on the other hand, delivering fluoride to inactivate RCLs (Nyvad and Fejerskov 1986). Studies have suggested that only half of the treatment effect of brushing with fluoride toothpaste could be ascribed to fluoride, and the other half to the cleaning effect. Thus, quality of oral hygiene might play a significant role on the outcome of interventions with fluoride (Marinho et al. 2003). Based on many studies, it is possible to state that only active RCLs that cannot be accessed by toothbrushing should be surgically removed and then restored using minimally invasive techniques (operative treatment) (Heasman et al. 2017). A recent systematic review showed that daily use of toothpaste containing 5,000ppm F- seems to be more efficacious in reducing active RCLs when compared to dentifrices containing 1,100 to 1,450ppm. This is even more important in older adults with exposed root surfaces. Indeed, high-dose fluoride toothpastes have been shown to inactivate 51% more RCLs compared with standard fluoride toothpastes (Wierichs and Meyer-Lueckel 2015).

The advantages of a non-invasive approach using 5,000 ppm F-toothpastes seems an attractive alternative to traditional restorative treatment for older adults, allowing expanded access to care, at a much lower cost and suitable for non-clinical settings. One of the most remarkable features of this therapy is its self-application nature. The most expensive component in dental care provision is the dentist. Hence, therapies that can be delivered without the permanent presence of the dentist may substantially expand coverage at a very low cost (León and Giacaman 2018).

The advancement of knowledge on the aetiology and pathogenesis of oral diseases that has resulted in innovative, effective and conservative therapies (Schwendicke et al. 2016) has not been effectively transferred to the academic community that forms the new generations of professionals, or to the professional staff that work in public or private health services. An interdisciplinary approach needs to be considered. Simple interventions may be delivered by non-dental professional or technical personnel, so the curriculum of non-dental health professions should incorporate general concepts of oral health in older adults. Furthermore, it is important to actively involve the dentist in geriatric teams (Kaufman et al. 2016). To fulfil these objectives, it is necessary to develop professional competences on new dentists for the care of the geriatric patient and train specialists with abilities to evaluate and treat more complex oral health problems, focused mainly on fragile and dependent populations (Ettinger 2012; León 2016) and with a focus on minimal intervention treatment. There is a need for innovative oral health intervention programmes and community initiatives for oral health promotion or alternative therapies for older people. This is an area where there is a need of extensive research. Policymakers and healthcare providers often give low priority to care for this population group and are not sufficiently aware of the advances in prevention and treatment of prevalent oral conditions, which prevents their transfer to the general population (Petersen et al. 2010).

The increasing prevalence of RCLs can be significantly controlled by simple and efficient treatment approaches with high-fluoride toothpastes. Yet, the cause of the problem is sugars available to the biofilm, so preventive or therapeutic protocols must include sugars consumption control measures in order to optimize the caries-preventive effect. Public policy and community clinical protocols should include this non-invasive approach during routine clinical practice. This alternative may allow including older adults among the countries' strategic oral health programs (León and Giacaman 2018). Non-invasive approaches to treat prevalent dental problems would expand coverage, optimising resources and improving access to dental care. Good oral health is essential to healthy aging. Because effective interventions to prevent and control oral disease exist, good oral health can be achieved by older adults. The public health system and specifically who makes decisions, can play a vital role in ensuring that this occurs.

1.3. Rationale of the Doctoral Thesis

Oral disease is common to all countries and populations, regardless of socioeconomic status, and older people are at a particularly high risk. The consequences of poor oral health are considerable. In fact, it is well recognized that good oral health is a key factor in healthy ageing and is associated with general health, morbidity and mortality in elders (Holm-Pedersen et al. 2008). Untreated oral disease can result in pain and difficulty chewing, swallowing and eating, which in turn leads to food avoidance, dietary modification and even nutritional shortcomings that subsequently give rise to a range of other conditions. Even in cases where the disease element has been dealt with, including replacing missing teeth, difficulties in eating and chewing may remain. Individuals may avoid fruits and vegetables, even cereals. These changes can lead to malnutrition, and for those wearing dentures, alterations in the oral tissues creating ill-fitting dentures that in turn give rise to pain and discomfort (Batchelor 2015).

The evidence suggests that ageing per se has no or very limited effect on the outcomes of prevention or treatment of dental caries or periodontal diseases (Axelsson et al. 1991; Griffin et al. 2007; Heasman et al. 2017; Lindhe et al. 1985; Trombelli et al. 2010). However, it is important to avoid complacency in preventive care and treatment as changes may occur in disease vulnerability in elders due to a variety of factors including illness and frailty, use of medications, reduced salivary secretion, widespread prevalence of (poor) fixed and removable dental prostheses and changes in vision, tactile sensitivity, cognitive and motor function, including the ability to perform effective oral hygiene. An individualized oral healthcare plan is therefore especially important in vulnerable elders.

The global burden of oral diseases remains a critical and often underestimated problem (Collaborators 2015). The Global Burden of Diseases 2010 Study determined untreated caries in permanent teeth to be the most prevalent chronic disease worldwide, affecting 35% of the global population (Kassebaum et al. 2015).

This age-standardized prevalence hasn't changed between 1990–2010 and varies greatly between countries. Prevalence peaks occur at the age of 25 years, perhaps due to the wash-out of school-based prevention efforts, and at 70 years, as root caries emerge (Hyde et al. 2017). Dental caries and is a chronic condition, highly prevalent, largely irreversible, and cumulative in nature (Kassebaum et al. 2015). Caries remains a major oral health problem among older persons for various reasons: the increase in treatment and maintenance of teeth rather than their extraction; age-related salivary changes; a poor diet; exposure of the root surface by gingival recession; and a greater likelihood of drug treatment with xerostomia as a side-effect (Thomson 2004; Wyatt et al. 2014). For the same reasons, treatment of caries may become technically more challenging in elders. There are indications, for example, that restorations in older persons have a shorter survival time than in younger individuals (Stewardson et al. 2011).

As mentioned earlier, in most industrialized countries an increasing number of the population are retaining teeth for longer, albeit in some cases only a few. The proportion of the population with some teeth will increase with each age cohort. However, the legacy of past oral disease remains. The tooth retention is also associated with an increased risk of developing caries lesions and specifically root caries lesions (RCLs) even among the healthier older adults (Hariyani et al. 2018). While the current rate of disease progression may have been reduced through the widespread adoption of fluoride-containing toothpastes in the early 1970s, the oral tissues remain at risk of disease throughout life (Batchelor 2015).

Delivered in several formats, fluoride has proven to be highly effective in preventing RCLs in older adults (Holmgren et al. 2014; Walls and Meurman 2012), and it is widely used in the clinic. A systematic review showed that in three randomize control clinical trial (RCT) using F-toothpaste containing 5,000 ppm was effective in inactivating RCLs, when compared to dentifrices containing 1,100 to 1,450 ppm (Wierichs and Meyer-Lueckel 2015). Besides, a recent report by an expert panel suggests that clinicians should prioritize the use of 5,000 ppm fluoride toothpaste to arrest non cavitated an cavitated RCLs (Slayton et al. 2018). However, the authors identified a low number of clinical trials, with a high risk of bias, which provides only limited evidence. Additionally, clinical studies on RCLs have focused on older adults living in long-term care (Ekstrand et al. 2008; Ekstrand et al. 2013; Tan et al. 2010). Few studies, however, have been conducted with community-dwelling elders (Srinivasan et al. 2014; Wyatt et al. 2014), who represent the vast majority of the older population in the world (Ettinger and Beck 1984; Fiske 2000). Independently-living older adults may have a vast number of differences in comparison with institutionalized people (Chatterji et al. 2015), so studying this population in terms of non-invasive therapies for RCLs is needed, as well.

The use non-invasive approaches to caries has been advocated and should be given high priority, before considering invasive treatments (Schwendicke et al. 2015). Appears as a universal approach to traditional restorative treatment for older adults, allowing expanded access to care, at a much lower cost and suitable for non-clinical settings.

1.4. Aims of the Doctoral Thesis

Based on the abovementioned, the aim of this Thesis was to investigate the impact and the effectiveness of a non-invasive and self-administered approach for the management of RCLs in community-dwelling elder Chileans.

To address this aim, this thesis specifically will:

1. Compare the activity and incidence of RCLs after 2 years of treatment with 1,450 or 5,000 ppm fluoride dentifrices.

2. Assess adherence to a non-invasive treatment for RCLs through the use of an oral hygiene regimen, in community-dwelling elders.

3. Evaluate the impact of a non-invasive treatment of RCLs with fluoridated dentifrices on oral health-related quality of life, in independently-living elders

4. Determine whether salivary flow is related with the prevalence and activity of RCLs in community-dwelling-older adults.

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CHAPTER 2

Self-administered Non-invasive Treatment with High-fluoride Toothpastes for root caries lesions; a randomized controlled clinical trial.

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Soraya León, Katherine González, Fernando N. Hugo, Karla Gambetta, Rodrigo A. Giacaman. **High Fluoride Toothpaste for Preventing and Arresting Root Caries in Community-Dwelling Older Adults: A Randomized Controlled Clinical Trial**

Abstract

Objective: Self-administered non-invasive therapy with high-fluoride dentifrices is an attractive alternative to traditional restorative treatment of root carious lesions (RCLs), but the available evidence is still scarce, particularly in community-dwelling older adults. The aim of this randomized controlled trial (RCT) was to compare the effectiveness of toothbrushing with 5,000 ppm versus 1,450 ppm fluoridated toothpaste (F-toothpaste) on preventing and arresting RCLs, in community-dwelling elders. **Methods:** A two years double-blinded RCT was carried out with 345 independently-living older adults, with at least one RCL at baseline. Participants were instructed to brush twice per day with a randomly assigned high-fluoride (5,000 ppm F) or a conventional F-toothpaste control (1,450 ppm F) toothpaste. Incidence of new and arrest of existing RCLs was recorded at two years and compared with the baseline data. Lesions were detected and diagnosed by ICDAS criteria for presence, and Nyvad's criteria for lesion activity. Baseline and follow-up clinical examinations were performed by one calibrated examiner for both criteria (Kappa=0.81 prior to the baseline, 0.83 at one year). Linear mixed regression model with repeated measures (i.e., baseline and at two years) tested the differences between groups. Results were considered significant if $p<0.05$. **Results:** The percentage of activity varied significantly at two years. The control group significantly increased the mean percentage of RCLs activity from baseline to two years (24.32% vs 40.52%; $t=-6.70$; $p=0.001$). Conversely, the intervention group showed lower RCLs activity (29.74% vs 3.72%; $t=14.40$; $p=0.001$). Root caries incidence was 93.5% and 35.2% in the 1,450 ppm and 5,000 ppm in the F-toothpaste groups, respectively, with a relative risk (RR) of 0.10 [CI: 0.05 – 0.19]. **Conclusion:** Non-invasive treatment with 5,000 ppm F toothpaste resulted more effective than 1,450 ppm F toothpaste in preventing and arresting RCLs after two years, in community dwelling elders. The results are supportive of the recommendation of high fluoride tooth-paste for preventing and arresting root caries in independent-living older adults. ClinicalTrials.gov NCT02647203.

Clinical Significance: RCLs can be effectively prevented and arrested with the use of 5,000 ppm F toothpaste. Oral health programs directed to community-dwelling older adults might benefit from the inclusion of high fluoride toothpaste in their portfolio.

Keywords: Root caries lesions, caries activity, randomized clinical trial, fluoride toothpaste, aging.

2.1 Introduction

Higher economic development along with more widespread access to fluoride are leading to increased tooth retention (Leon et al. 2018). Although tooth retention may mean increased quality of life (Zhao et al. 2011), it may originate niches for biofilm stagnation and the possibility of root caries lesions (RCLs). Epidemiological studies have shown a trend for a higher incidence of RCLs, in an age-dependent manner (Griffin et al. 2004), including systemically healthy older adults (Hariyani et al. 2018).

Restorative management of RCLs is typically challenging, considering the difficulties in visibility, moisture control, access to the lesion, proximity to the pulp and to the gingival margin, and the high organic content of dentine (Amer and Kolker 2013). Evidence for the choice of restorative materials for RCLs is neither abundant nor convincing, as studies have reported failure rates of up to 68% after 12 months (De Moor et al. 2011; Hayes et al. 2014; McComb et al. 2002). When dentine is the only adherent substrate, as it is the case in many RCLs, retention of the restorative material can be compromised in the long term (Cardoso et al. 2011). Hence, appropriate management of the lesions, either restoratively or non-operatively is highly desirable for patients and clinicians alike, especially in older adults.

Fluoridated products are the most extensively used agents for caries prevention and one of the main preventive measures for root caries in older adults (Walls and Meurman 2012). Undisputed evidence has revealed that fluoride (F) is effective, not only in the prevention, but also in the arresting of RCLs (Holmgren et al. 2014). The anti-caries effect of F is related to its ability to alter ionic saturation with respect to tooth mineral, thus, aiding remineralization and preventing demineralization. Likewise, at high concentrations it may interfere with bacterial metabolism and acid production (Murray et al. 1991b). Based on structural differences and arguably lower critical pH, dentin would be more susceptible to caries than enamel (Hoppenbrouwers et al. 1987). The differential risk between both tissues, along with the increasing rate of RCLs reported, has stimulated research, focused on the effects of F on root dentine and on RCLs (ten Cate et al. 1998; Vale et al. 2011). Since fluoridated toothpastes are the major source of F in many communities, where water fluoridation is not available (ten Cate 2013), regular toothbrushing using fluoridated toothpastes has been described as the most rational way to administer topical F (Nyvad and Fejerskov 1986). The rationale for this statement derives from the fact that it puts in place two protective mechanisms; dental biofilm disruption and sustained F delivery. In the absence of the risk of fluorosis, there are potential benefits of high F toothpastes in older populations. A recent systematic review showed that the daily use of dentifrices containing 5,000 ppm F is more efficient in reducing active RCLs than dentifrices containing between 1,100 and 1,450 ppm F (Wierichs and Meyer-Lueckel 2015). Although these promising findings, the authors concluded that there was a low number of clinical trials, with high risk of bias, meaning that the evidence to support a recommendation is limited. Furthermore, most clinical studies on RCLs with high F dentifrices have focused on older adults living in long-term care facilities (Ekstrand et al. 2008; Ekstrand et al. 2013; Tan et al. 2010), with few studies conducted on community-dwelling elders (Srinivasan et al. 2014; Wyatt et al. 2014). Independently-living people represent most of the older adult population worldwide. Large longitudinal studies following populations into ageing have shown that an increasing number of older adults are independently living, mobile and active in their communities (Ettinger and Beck 1984; Fiske 2000; Sonnega et al. 2014). Hence, new studies should be prioritized on this population. Thus, the hypothesis of this study was that self-administered 5,000 ppm F toothpaste is more effective in preventing and arresting root caries that conventional toothpaste in independent-living older adults.

2.2 Material and Methods

Study design. A double-blinded RCT with two parallel arms was conducted with subjects recruited from community clubs of older adults from Talca, Chile. To be eligible, participants had to be 60-year-old or more, community-dwelling, living in areas with fluoridated water (0.7 ppm F) and independently-living according to the Functional Evaluation of Older Adults (EFAM for its abbreviation in Spanish) criteria (Silva 2005), formally enrolled in community centers. The EFAM criteria comprise several psychological, biological and social items, that allow a comprehensive view on the functionality of the older adult. Intraorally, participants had to have at least five remaining teeth and one active RCL (Fejerskov 2015; Nyvad et al. 1999). Subjects with cognitive impairment or alcoholism were excluded from the study, using the Short Mini-Mental State Examination (MMSE-SF) (Quiroga et al. 2004) and the Alcohol Use Disorders Identification Test (AUDIT-C Test), respectively (Babor et al. 2001).

The study and the informed consent form were approved by the Ethics Committee of the University of Talca (number:2013-047). The study coordinator explained the nature of the study and invited the subjects to voluntarily take part of the RCT. All participants signed an informed consent form. If the lesions progressed during follow-up, they received professional treatment by the research team. This RCT complies with the CONSORT (Consolidated Statement Of Reporting Trials) statement (Moher et al. 2012).

Sample size was calculated with the software GRANMO (Institut Municipal d'Investigació Médica, Barcelona, Spain), for the comparison of two means (arrested RCLs) in independent populations considering a previous study (Ekstrand et al. 2013). Thus, accepting an alpha error of 0.05 and beta error of 0.2 in a two-sided test, the common standard deviation was assumed to be 1.11 with an estimated drop-out rate of 20 percent, a total of 304 participants was necessary (n=152 per group) to recognize as statistically significant a difference greater than or equal to 0.4 units. Following simple randomization procedures through a computer-generated list of random numbers prepared by an investigator with no clinical involvement in the trial, subjects were randomly assigned to one of the two treatment groups: Control group: 1,450 ppm F-toothpaste as NaF (Colgate Total®); and Intervention group: 5,000 ppm F-toothpaste as NaF (Colgate Duraphat® 5,000 Plus). Both toothpastes were available in the Chilean market, by the time of the investigation, and were covered with color-coded opaque tape and saved in numbered containers until allocation.

Intervention. Oral and written instructions were given to participants to toothbrush twice per day, after breakfast and before bedtime. To increase F concentration and retention, participants were also instructed not to rinse with water after brushing and to only eliminate the excess of the dentifrice by spitting out. The amount of toothpaste to be used had to be about the size of a pea. Toothbrushing duration was standardized, recommending a sweeping technique for two minutes, without formal training. By tape-covering the tubes, neither the patients nor the study principal investigator knew the type of toothpaste the participants were using. Additional toothbrushes and toothpastes were provided to the volunteers every three months and adherence to treatment was checked by returning the used dentifrices and toothbrushes to the investigators.

Clinical examinations at baseline and follow-up. Primary outcomes, regarding effectiveness of fluoridated toothpastes on RCLs, was the incidence of RCLs per root surface after two years, detected by ICDAS (ICDAS 2005) and lesion inactivation or arrest, using Nyvad's criteria for lesion activity per root surface, also after two years (Fejerskov 2015; Nyvad et al. 1999). Baseline and follow-up clinical examinations were performed by a single calibrated examiner. Intra-examiner kappa obtained prior to the beginning of the study was 0.81 and 0.83 at one year. Dental mirrors and graduated (in mm) periodontal probes were used during the examinations in a conventional dental clinical setting. At baseline, professional prophylaxis was carried out in each participant and then every six months, followed by the RCLs assessment. Root surfaces were scored during the baseline and the follow-up examination as sound, inactive (arrested) or active. Root surfaces that showed new RCLs or that were restored or lost throughout the follow-up period were also registered in a root odontogram, that included RCLs detection and activity assessment. Other variables included were age, sex and socio-economic status (SES). SES was classified as lower when the respondent declares that family income is not enough to afford the most basic items in a month and upper when family income is enough.

Statistical analysis. Sociodemographic information of patients was described by groups at baseline and compared using Chi squared test (χ^2). Descriptive analyses included the calculation of the lesion type frequency distribution and the number of teeth with RCLs, both active and arrested, per patient. The percentage of caries activity per patient was calculated by the following formula (number of teeth with active lesions/number of total teeth) x 100. The difference (Δ) in the percentage of activity was calculated between baseline and the two-year assessment. Mean and standard deviation were compared by groups using t-test accompanied by bootstrapping techniques, as normality assumption was not met. Any patient that developed new active RCLs during the study period was identified to calculate the incidence and the Relative Risk (RR), using z test. Linear mixed model with repeated measures (i.e., baseline and two-year assessment) were performed to evaluate the main effect of age, sex, SES and treatment upon percentage of RCLs activity. Statistical analyses were performed using the statistical SPSS v25 (IBM, NY, USA).

2.3 Results

A total of 355 participants were initially invited to be part of the study and assessed for eligibility. While all accepted the invitation, 10 were excluded because they did not meet all the inclusion criteria. Thus, a final sample of 345 subjects, 258 (74%) females and 87 (26%) males, were randomized to the control or the intervention groups. Recruitment and clinical examinations took place at the School of Dentistry of the University of Talca, Chile, from July 2014 to November 2016. Age of the respondents ranged between 61 and 88 years (mean 69.63±6.25).

After two years, 65 individuals were lost to follow-up; 34 from the control and 31 from the intervention group (**Figure 1**).

Final data correspond to the 280 subjects who completed the two years follow-up period. At baseline, there were no significant differences between groups regarding sex, age, SES and educational level (**Table 1**).

Table 1. Socio-demographic and clinical characteristics of the study population at baseline and comparisons between treatment group, Talca, Chile, 2014.

			1,450 ppm F^-		**5,000 ppm** F^-		
	Variable	Category	n	%	N	%	p value (χ^2)
Socio-demographic	Sex	Men	45	(26.2)	42	(24.3)	p = 0.68
		Women	127	(73.8)	131	(75.7)	
	Age	60 a 69	92	(53.5)	88	(50.9)	p = 0.62
		70 or +	80	(46.5)	85	(49.1)	
	Socio-economic status	Upper	112	(65.1)	109	(62.6)	p = 0.68
		Lower	60	(34.9)	64	(37.4)	
	Educational level (years)	≤ 8	51	(29.7)	42	(24.3)	p = 0.32
		9-12	57	(33.1)	70	(40.5)	
		>12	64	(37.2)	61	(35.2)	
Clinical	Teeth	Sound	1.250	(56.9)	1.342	(53.6)	p = 0.0016*
		Lesions	948	(43.1)	1.163	(46.4)	
	Activity	Active	585	(61.7)	804	(69.1)	p = 0.0004*
		Inactive	363	(38.3)	359	(30.9)	

*= $p<0.05$

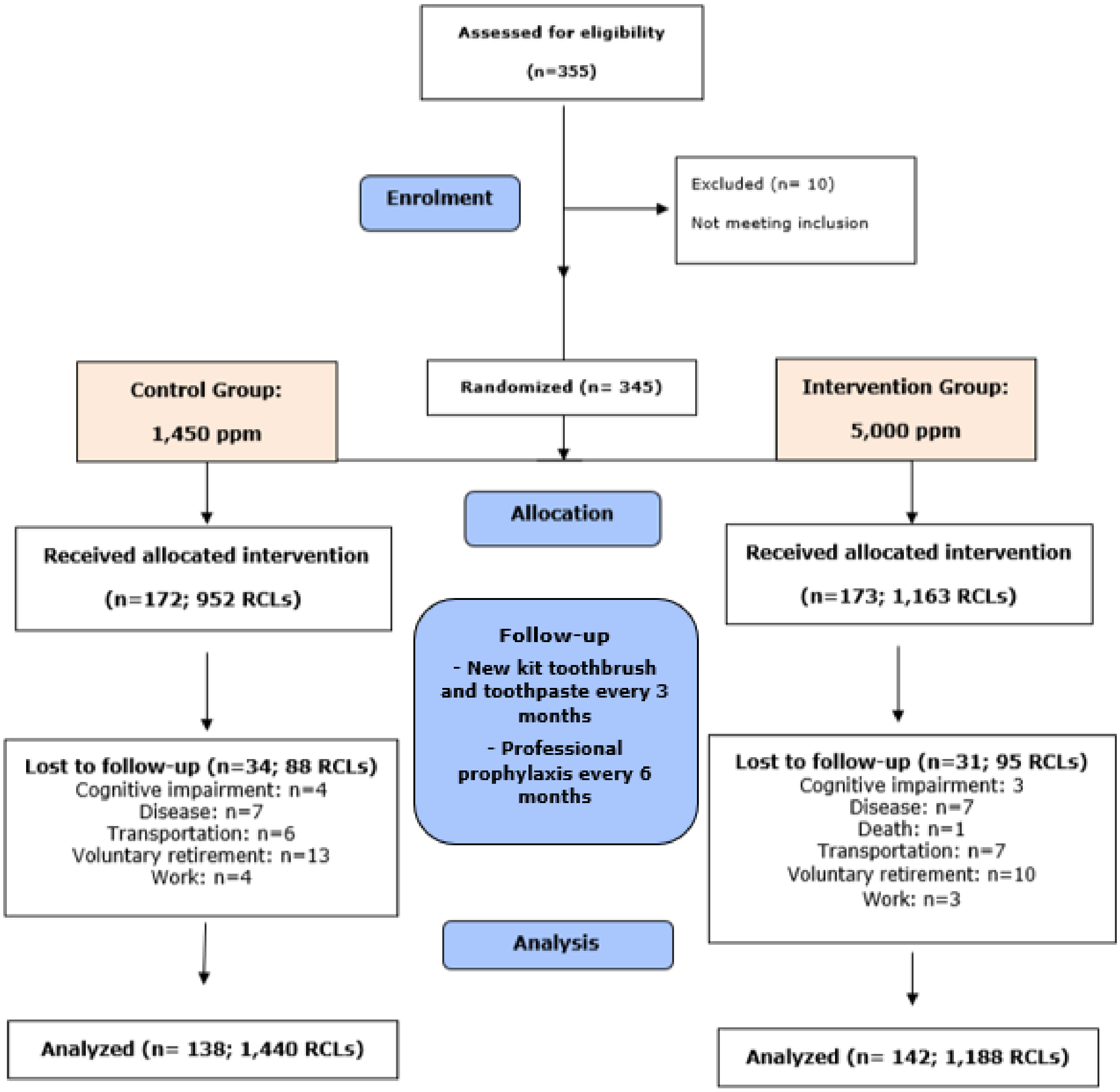

Figure 1. Flow diagram

However, a higher number of lesions (RCLs= 1,163; p = 0.0016) and higher activity (RCLs= 804; p = 0.0004) was found in the 5,000 ppm F-toothpaste group compared with the control at baseline (**Table 2**). For those patients who completed the study, 2,111 RCLs were identified in 345 subjects at the baseline examination (**Table 2**). The mean number of RCLs at two years was 6.12 (2,111/345), the mean number of active RCLs was 4.04 (1,393/345) and the mean number of inactive RCLs was 2.09 (722/345). Table 2 also shows the fate of the baseline lesions in terms of whether they changed to inactive (arrested) or to active, remained active or remained inactive. Likewise, sound root surfaces at baseline were examined to verify the onset of new lesions or whether they remained sound. Very few of the teeth with RCLs were extracted or restored during the follow-up at two years. Data showed that a higher number of active RCLs at baseline became inactive in the intervention group (5,000 ppm) (699/804=87%) than in the control group (1,450 ppm) (234/589=40%). Regarding inactive lesions at baseline, while 54% (196/363) became active in the control group at two years, only 3% (12/359) transformed from inactive to active in the intervention group. At the final examination, a total number of 2,625 RCLs were identified in 280 subjects. The mean number of RCLs at two years was 9.37 (2,625/280); the mean number of active RCLs was 3.75 (1,050/280) and the mean number of inactive RCLs was 5.62 (1,575/280).

Table 2. Data at baseline and outcomes after the two-year follow-up, by lesion, Talca, Chile, 2014-2016.

	Baseline					Follow-up at 2 years							
				Fate of baseline RCLs		New RCLs			Lost		Total number of RCLs		
Group	Total number of RCLs	Number of active RCLs	Number of inactive RCLs	Fate of active baseline RCLs	Fate of inactive baseline RCLs	New active RCLs	New inactive RCLs	Total new RCLs	Filled	Extracted	Total active RCLs	Total inactive RCLs	Total RCLs
1,450 ppm n=172	952	589	363	290 active 234 inactive 32 filled 30 extracted	196 active 147 inactive 17 filled 9 extracted	429	144	573	49	39	915	525	1,440
5.000 ppm n= 173	1,163	804	359	45 active 699 inactive 33 filled 27 extracted	12 active 314 inactive 14 filled 21 extracted	37	81	120	47	48	94	1,094	1,188
Total n= 345	2,115	1,393	722			466	225	693	96	87	1050	1,575	2,625

When comparing both assessments, the average number of teeth with RCLs, both active or arrested, varied between the study groups **(Table 3).** There was a higher mean number of teeth with RCLs in the intervention group than in the control group at baseline (8.19 vs 6.98; t=-2.63; p=0.01). At the two years assessment this difference was reversed, with higher mean number of RCLs in the control group compared with the intervention arm (10.43 vs 8.36; t=3.89; p=0.002). The number of teeth with active RCLs was also statistically different for both treatments. At baseline, lesions treated with the 5,000 ppm toothpaste had higher mean number of active RCLs than the control group (5.66 vs 4.27; t=- 3.39; p=0.002). At the end of the follow-up, these values were significantly reversed (t=14.73; p=0.002), with 0.66 (±

2.36) teeth with active RCLs in the intervention group compared with 6.63 (± 4.20) in the group treated with 1,450 ppm F toothpastes.

Table 3. Average number of teeth with RCLs and percentage of activity per treatment group, analyzed by patient at baseline and two-year follow-up, Talca, Chile, 2014-2016.

	Baseline		2 years	
	1450 ppm	**5000 ppm**	**1450 ppm**	**5000 ppm**
Number of teeth with RCLs (mean ± SD)**	6.98 ± 4.04	8.19 ± 4.19	10.43 ± 4.69	8.36 ± 4.21
Number of teeth with inactive RCLs (mean ± SD)*	2.63 ± 2.59	2.53 ± 2.50	3.80 ± 3.58	7.70 ± 4.02
Number of teeth with active RCLs (mean ± SD)**	4.27 ± 3.35	5.66 ± 3.52	6.63 ± 4.20	0.66 ± 2.36
% of activity (mean ± SD)**	24.32 ± 16.66ˆ	29.74 ± 18.44 ˆˆ	40.52 ± 23.30 ˆ	3.72 ± 12.32 ˆˆ

**Independent t-test p value < 0.05 for both groups at baseline and 2 years of follow-up

*Independent t-test p value < 0.05 for both groups at 2 years of follow-up only

ˆPaired sample t-test for 1450 ppm group p value < 0.05

ˆˆPaired sample t-test for 5000 ppm group p value < 0.05

The percentage of activity also varied significantly at two years. The mean value for the control group was statistically higher than the intervention group (40.52% vs 3.72%; t=16.59; p=0.001). The control group significantly increased the mean percentage of activity from baseline to the two-year assessment (24.32% vs 40.52%; t=-6.70; p=0.001). Conversely, the intervention group showed the opposite behaviour, with a significant reduction of activity (29.74% vs 3.72%; t=14.40; p=0.001).

The incidence of patients developing new RCLs was statistically different between both treatments **(Table 4).** In the control group 93.5% of patients developed new RCLs compared only with the 35.2% of patients in the high-F toothpaste group. The RR for the intervention group was 0.10 [95% CI: 0.05 – 0.19] (p<0.001). Thus, subjects exposed to the intervention group have 90% less likelihood of having new RCLs than those in the control group. Namely, subjects exposed to the control group have 3 times more risk of presenting new RCLs than those who are in the intervention group. The number needed to treat (NNT) was 1.71, that is, it would be necessary to treat 2 patients with high-F toothpastes, to avoid a new RCL with respect to those that would occur in the 1,450 ppm F group.

Table 4. Patients with new RCLs, Talca, Chile, 2016.

Groups	New RCLs presence n (%)	New RCLs absence n (%)	Total n (%)
1450 ppm	129 (93.5)	9 (6.5)	138 (100)
5000 ppm	50 (35.2)	92 (64.8)	142 (100)
RR = 0.10; 95% CI = 0.05 – 0.19; z test = 6.99; p value <0.001; NNT = 1.71			

The linear mixed model confirmed that the type of treatment had a statistically significant effect upon the percentage of activity. Treating RCLs with 1,450 ppm toothpastes increased the mean percentage of RCLs activity (p<0.001). There was also an increase in the percentage of activity with age (p<0.001). Sex and SES failed to show a significant effect on the percentage of activity **(Table 5).**

Table 5. Linear mixed regression model for % of activity, Talca, Chile, 2016.

Variables		Estimates	SE	p value	95% CI
Group	*1450 ppm*	14.22	1.50	<0.001*	11.26 – 17.18
Sex	*Female*	-1.63	1.78	0.36	-5.13 – 1.87
SES	*Low SES*	0.85	1.63	0.60	-2.30 – 4.05
Age	*In years*	0.51	0.12	<0.001*	0.27 – 0.75

SE standard error; CI confidence interval; SES socio-economic status; ppm parts per million

*= $p<0.05$

2.4 Discussion

Only few RCTs have been conducted on RCLs prevention using high-fluoride toothpastes. Despite promising results, evidence is still blurry to be conclusive that 5,000 ppm F-toothpastes are effective on preventing and/or arresting existent RCLs in older adults (Slayton et al. 2018), including frail and vulnerable people (Ekstrand et al. 2008; Ekstrand et al. 2013). To the best of our knowledge, no study of this type has been conducted with community-dwelling elders. Unlike institutionalized older adults, in this group, self-care has a special connotation and importance, as in most cases, personal oral care is not assisted and the results from these self-administered interventions might vary from a more controlled administration. Since effectiveness of high-F doses in lesion arresting may be the result of the combined effects of abrasion and mineral re-deposition on the surface layer of root dentin, appropriate oral hygiene is key to achieve clinical success, verified as reversal of active lesions. Studies have shown that under favorable conditions and when the root surface is readily available to toothbrushing, even those lesions with a distinct cavity extending deep into dentin can be controlled and inactivated (Nyvad and Fejerskov 1997).

Our results clearly demonstrated that it is possible to prevent and arrest RCLs using self-administrated and non-invasive therapies with 5,000 ppm F-toothpaste in independent-living, community dwelling older adults. It was interesting to observe that despite a higher mean number of teeth with RCLs in the intervention group than in the control group at baseline, the results showed dramatically lower caries activity for the experimental intervention after two years. These results may be explained by F enrichment of the oral environment, i.e., saliva and the dental biofilm after using a 5,000 ppm F toothpaste, twice per day. The bioavailability of F allows the formation of CaF_2 on the tissues, all of which may hamper biofilm formation and reduce the levels of putative cariogenic bacteria, such as *S. mutans* and *Lactobacillus* (Ekstrand 2016). The toothpaste used in this study contains sodium fluoride (NaF), which along with sodium monofluorophosphate (NaMFP) are the most commonly used fluoridated agents in toothpastes (Holloway and Worthington 1993; Mellberg 1991). Regardless of the salt used, F contained in dentifrices are attributed to act through precipitation of a low acid-resistant calcium fluoride (CaF_2)-like layer on the tooth surface, forming a “mechanical barrier”, by the formation of bioavailable reservoirs within the dental biofilm. Alternatively, a microbiological effect has been reported, whereby there would be a formation of intercellular or intracellular Ca “bridge” with fluoride at fixed bacterial sites (Vogel et al. 2010). CaF_2 formation and the effect of F on the dental biofilm and on its remineralizing capacity has been reported to be dose-dependent, which may be why the toothpaste of the experimental group performed substantially better than the conventional F concentration counterpart (Tenuta and Cury 2013). High-F varnishes also act by forming CaF_2 reservoirs in the dental biofilm (Gonzalez-Cabezas and Fernandez 2018), and the repeated application or longer retention time warrants better remineralizing potential (Giacaman et al. 2017). Some studies suggest that by using high-F toothpastes (5,000 ppm F, for example), concentrations of about 800 ppm F are reached in saliva within 2 min of toothbrushing, which is about 7 times higher than the 100 ppm required to create CaF_2 (Ekstrand 2016). Others have also reported this dose-dependency for the effect of F-toothpastes on RCLs. An experimental study showed that 5,000 ppm F-toothpaste was more effective for controlling RCLs formation and progression than a fluoride concentration of 1,300 or 1,500 ppm (Garcia-Godoy et al. 2014). Dentifrices containing higher F concentrations (5,000 ppm F and 2,800 ppm F) seem to enhance acid resistance of bovine root dentine (Diamanti et al. 2010) and to increase F concentration in saliva (Ekstrand et al. 2015; Mannaa et al. 2014b; Nordström and Birkhed 2009; 2013). Likewise, a RCT showed that 5,000 ppm F-toothpaste controlled RCLs progression more efficiently among elders than regular toothpastes of 1,000 ppm to 1,450 ppm fluoride (Ekstrand et al. 2013). Large variations in the effect of a 5,000 ppm F dentifrice was described among participants of a multi-center clinical trial (Srinivasan et al. 2014). Despite the existent clinical evidence for the efficacy of the 5,000 ppm F-toothpastes, a pilot *in situ* study indicated that a concentration of 1,100 ppm F-toothpaste was enough to reduce root dentine demineralization in a highly cariogenic environment, albeit with a relatively small sample size (Botelho et al. 2014). Other studies have shown that the combined use of acidulated phosphate F (APF) gel (12,300 ppm F) and 1,100 ppm F dentifrices or 22,600 ppm F varnish with 1,450 ppm F dentifrice were not as effective as a 5,000 ppm F-toothpaste, in inhibiting and arresting dentin caries lesions (Ekstrand et al. 2008; Fernández et al. 2017). On the other hand, it has been argued that the effect of fluoridated products on RCLs could not be attributed only to the effect of F, but also to the application mode (Heasman et al. 2017). Indeed, alternative causal explanations for the positive results obtained with 5,000 ppm F, over the control toothpaste is the synergistic effect of the brushing and the periodical application of F on the tissues and its penetration within the dental biofilm forming CaF_2, as above mentioned (Nyvad and Fejerskov 1986).

In the present study, it was decided to instruct patients not to rinse after brushing and perform oral hygiene with toothbrushing in the morning and at night. This recommendation supposes an interesting discussion, as this is a controversial topic, for which there is no agreement either among clinicians or researchers. The rationale behind this recommendation is two-fold; on the one hand, there is some evidence showing variations in the concentration of F in saliva, relative to the circadian rhythm. Thus, with higher F values are detected early in the morning and then at night than those found during the day (Ekstrand et al. 2015). Circadian cycles could induce lower flow rates of saliva, concentrating F in the morning and at night (Dawes 1972). On the other hand, refraining from rinsing after brushing, supposes higher F retention for longer times in contact with the hard-dental tissues and the ubiquitous dental biofilm. In fact, a study showed a two-fold increase in salivary F when young people using toothpastes of 5,000 ppm F were instructed to refrain from rinsing after brushing (Nordström and Birkhed 2009). Moreover, it has been stated that if the F concentration in the dental plaque reaches higher level than 10 ppm, F can interfere with bacterial metabolism (Murray et al. 1991a). While brushing with conventional 1,450 ppm F-toothpastes reaches levels around 10 ppm F in the dental biofilm, a 5,000 ppm F toothpaste increases salivary F up to approximately 14 ppm (Nordström and Birkhed 2009; 2013). Interestingly and potentially an explanation for our results, it was reported that pH drop in response to a 10% sucrose rinse was lees pronounced when subjects had brushed with 5,000 ppm than when they had used 1,450 ppm F toothpaste (Mannaa et al. 2014a; Mannaa et al. 2014b). High F concentrations may alter the biofilm cariogenic potential, decreasing the levels of acid-producing microorganisms (Mannaa et al. 2014b).

The effectiveness of F dentifrices is not only determined by F concentration, but also by the frequency of use. F should be constantly available in the oral fluids to maximize its effect. An *in situ* study demonstrated a positive correlation between the frequency of use and the reduction of root dentine demineralization, although no significant association was found between the frequency and the remineralization of existing carious lesions (Nóbrega et al. 2016). A recent systematic review (Wierichs and Meyer-Lueckel 2015) showed that RCLs can be controlled by daily brushing with fluoridated toothpastes. In addition to high-F dentifrices, active carious lesions can be inactivated using other forms of professionally applied F, including varnishes or gels. Based on our findings and other similar studies, it would be possible to recommend that only active RCLs that cannot be accessed by toothbrushing should be surgically removed and then restored using minimally invasive techniques (Slayton et al. 2018). Otherwise, professionally applied non-invasive or, as in this case, self-applied therapies should be preferred, unless other considerations are in place, like aesthetics.

The relative risk (RR) for the onset of new RCLs in the intervention group was 0.10 (95% CI: 0.05–0.19), which would provide 90% reduction, as compared with older adults using a regular toothpaste. Similar studies for the treatment of RCLs using non-invasive approaches have reported similar, but lower RR for this type of intervention. Indeed, Ekstrand et al. (Ekstrand et al. 2008), reported a 0.65 RR, Lynch et al. (Lynch et al. 2000) a 0.72 RR, Baysan et al. (Baysan et al. 2001) found a 0.85 RR (95% Cl, 0.52–0.80) and Ekstrand et al. (Ekstrand et al. 2013), a 0.41 RR (95% CI, 0.33–0.50). A systematic review including the studies of Baysan and Ekstrand (2013), pooled 315 RCLs for the experimental and 321 for the control group, obtaining a 0.49 RR (95% Cl, 0.42–0.57) (Wierichs and Meyer-Lueckel 2015). There is another RCT reported (Srinivasan et al. 2014), but the RR cannot not be calculated. In general, most of the studies on non-invasive management of RCLs with F toothpastes report RR of around 0.5, which implies that the risk is reduced to half when using toothpastes with higher F concentration. In our study, RR was much higher, reaching a 90% reduction in the intervention group, probably because it was a 2-year follow-up, unlike the other studies, where follow-up is much shorter, reducing the opportunity to reach all the beneficial effect. Additionally, during the first period after the beginning of the intervention, both groups may be motivated with the study, maximizing toothbrushing. This enhanced mechanical effect may blur the differences between groups, derived from the F- dose. Thus, a short-term assessment may find results as those reported in the literature. Conversely, the two-year follow up in this study might exclude the motivational initial effect, minimizing the mechanical and preserving mostly the chemical activity of F-.

Consistent with other studies (Hayes et al. 2016), the linear mixed model confirmed that the type of treatment and older age had a statistically significant effect upon the percentage of RCLs activity. Lesions created by the carious process and their consequence (fillings and extractions) are mostly irreversible, in terms of caries experience, so it is expected that age was associated with RCLs. There seems to be a higher caries risk with age, due to many putative factors acting together at that age, as it has been reported (López et al. 2017; Ritter et al. 2010; Tonetti et al. 2017). Less investigated, immune senescence may be an interesting contributor to root caries and lesion progression (López et al. 2017; Preshaw et al. 2017). Importantly, age impacts on physical and cognitive impairment, as well as on a reduced access to care (Tonetti et al. 2017). These other factors may also become part of the complex mix of protective/risk factors acting during aging. Neither sex nor SES had an effect on the results of the non-invasive therapy. Given that this RCT provided with toothpaste and toothbrush, independent of the SES, results were not affected by this variable. In a real-life setting, it is possible that SES plays an important role in the outcomes of an intervention like this. Although it could be of interest, education level was not included as a variable to avoid variability and uncontrolled factors beyond the treatment itself, but also because in Latin American countries like Chile, education is used as a proxy for SES.

We acknowledge some limitations of the study design. No brushing assessment before the beginning of the study was done. Individuals with better motor skills could have entered the study with dissimilar initial conditions. We believe these limitations could have been ameliorated due to the large sample and to an even distribution of the subjects between both study arms, nonetheless. Another source of bias could have been the lack of dietary control. Both limitations may have converted this RCT into a rather pragmatic randomized clinical trial (Williams et al. 2015), that is, a study conducted under real-world circumstances. This makes our study closer to the reality of community-dwelling elders, who are autonomous and do not require assistance to perform daily oral care.

2.5 Conclusion

Taken together, self-administered non-invasive therapy with high-F dentifrices appears to be highly effective in arresting active and in preventing RCLs in community-dwelling elders. Treatment with a 5,000 ppm F-toothpaste appears to be an attractive alternative to traditional restorative treatment for older adults, allowing expanded access to care, at a much lower cost and suitable for non-clinical settings. The increasing prevalence of RCLs can be significantly controlled by simple and efficient treatment approaches like this. Public and private practices should consider including this type of treatment in their routine clinical protocols.

Acknowledgments

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Appendix

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	34
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	35-36
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	37-38
	2b	Specific objectives or hypotheses	38
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	39-40
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	-
Participants	4a	Eligibility criteria for participants	39
	4b	Settings and locations where the data were collected	39
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	40-41
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	40-41
	6b	Any changes to trial outcomes after the trial commenced, with reasons	-
Sample size	7a	How sample size was determined	40
	7b	When applicable, explanation of any interim analyses and stopping guidelines	-
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	40
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	40
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	40
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	40
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	40-41
	11b	If relevant, description of the similarity of interventions	-
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	41-42
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	-
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	44
	13b	For each group, losses and exclusions after randomisation, together with reasons	44
Recruitment	14a	Dates defining the periods of recruitment and follow-up	42
	14b	Why the trial ended or was stopped	-
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	43 and 46
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	-
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	45-49
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	49
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	-
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	-
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	56
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	56
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	53-54
Other information			
Registration	23	Registration number and name of trial registry	57
Protocol	24	Where the full trial protocol can be accessed, if available	-
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	57

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

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CHAPTER 3

Role of treatment compliance in the reversal of active root caries lesions using a non-invasive strategy for the management of root caries lesions in older adults.

This chapter will be submitted to Operative Dentistry for publication as:

Soraya León, Matías Pérez, Fernando N. Hugo, Daniel Bravo-Cavicchioli, Karla Gambetta, Rodrigo A. Giacaman. **Evaluation of adherence to a non-invasive therapy for RCLs, based on fluoridated dentifrices in community-dwelling elders.**

Abstract

Introduction: Toothbrushing can be a method to monitor a non-invasive therapy with consistent evidence showing its effectiveness in reducing and controlling dental caries, when associated with fluoridated toothpastes. To verify an effect after clinical indication, it is key to have objective methods to monitor treatment adherence, especially in older adults under self-applied therapies. **Objective:** To assess adherence to a non-invasive treatment with toothbrushing and toothpastes in community-dwelling older adults, over a period of two years. **Materials and methods:** Fifty Chilean community-dwelling older adults took part in a trial, which was a subsample of a randomized controlled clinical trial of self-administered non-invasive therapies with high-fluoride dentifrices on preventing and arresting RCLs. To evaluate adherence to the indicated toothbrush and fluoridated dentifrice, participants were examined annually for 2 years. At each examination, the use of the toothbrush and the dentifrice were evaluated using the wear index (WI) and the percentage of pasted used, respectively. Data were descriptively analyzed and through comparisons between groups. **Results:** Mean WI of the entire sample of people was 31.4 (±24.1) and 36.1(±27.3) at 1 and 2 years, respectively. Considering that a non-worn toothbrush WI is 34 or lower, this result can be considered as low. Conversely, the mean value of the % of paste used during the 3-month period was 84.1(±16.9) at 1 year and 82(±17.1) at 2 years. When sex, age, socioeconomic status and treatment type were compared, only subjects treated with 1,450 ppm F used slightly more paste than those treated with 5,000 ppm F, but this difference disappeared at 2 years. **Conclusion:** Independently-living older adults enrolled in an RCT are adherent to a toothpaste and a toothbrush regimen. Further research seems needed to standardize methods to assess adherence to treatment.

Keywords: Adherence to treatment, toothbrush wear index, fluoride toothpaste, aging, non-invasive treatment.

3.1 Introduction

A shift in the biofilm equilibrium through regular toothbrushing and the use of high fluoride toothpastes, can delay or even inactivate RCLs (Kidd and Fejerskov 2004). Whilst there is some evidence on the effectiveness of controlling dental caries, solely by biofilm disruption with toothbrushing, there is a more robust evidence on the adjunctive effect of fluoride on root caries control (Carrilho 2017). Toothbrushing is the method of choice for cleaning and removing the biofilm from free dental surfaces, with consistent evidence showing the effectiveness of toothbrushing in reducing the levels of dental biofilm (Van der Weijden and Slot 2015) and in controlling dental caries when associated with fluoridated toothpaste (Marinho et al. 2003).

An important factor related to brushing efficiency is bristle wear during use. Whether worn bristles reduce the ability to remove dental plaque compared with new brushes remains controversial because some studies indicated a higher level of plaque control in patients using new toothbrushes (Conforti et al. 2003; Rosema et al. 2013), while others have found opposite trends (Hogan et al. 2007; Tan and Daly 2002; van Palenstein Helderman et al. 2006). Nevertheless, bristle wear can serve as a parameter for brush replacement as the bristle condition appears to be a more appropriate measure of brush replacement than the commonly used toothbrush age (Rosema et al. 2013). The cleaning capacity of a toothbrush decreases as it is used (Glaze and Wade 1986) and wears out, due to bristle thinning and tip wearing, becoming easily bent and curved (Muller-Bolla et al. 2007). Therefore, assessing the degree of toothbrush wearing may be a way to evaluate the degree of adhesion to toothbrushing. There are different methods of analysis, being the most reliable and with less variability the one used by Rawls and Mkwayi-Tulloch, who developed a "wear index" to quantitatively measure the bristles and classifying the brushes as a function of its general state of deterioration (Rawls et al. 1989). The “wear index (WI)” is the most used measure to evaluate bristle wear in a toothbrush, offering quantitative means of comparing brushes of different dimensions at various stages of splaying. It appears to be suitable not only for research, but also for quality control, the setting of standards, and for substantiation of advertising claims (Rawls et al. 1989; Glaze and Wade 1986; Muller-Bolla et al. 2007)

On the other hand, adherence to the use of toothpaste can be measured in relation to its use. The use of toothpaste is an intervention at the patient-level that requires adequate patient adherence to be successful. The use of 5,000 ppm fluoride toothpaste, as well as any other type of fluoridated toothpaste, requires filling prescriptions and patient adherence, which implies daily use at home. Because adherence to self-administrated therapies requires commitment and independence to be successful, this intervention may not be feasible for populations in nursing homes and for those with special needs. Furthermore, this treatment may not be covered universally by insurance (Slayton et al. 2018). The economic factor may be an important barrier in countries where the income of the older population is low, therefore the adherence to this type of treatment can be affected. Initiatives at the public health system level become important. In relation to attitudes and behavioral factors relating to toothbrushing, there are not studies in older populations. In fact, most studies have been carried out in adolescents and children. In these studies, 'fresh breath' was as a reason for toothbrushing (Nordström and Birkhed 2017). Perhaps in an older population this might not be the main reason to achieve adherence.

Estimates in different populations of the average amount of toothpaste dispensed for toothbrushing have ranged widely, from 0.25 g to 1.38 g (Levy 1993). It should also be noted that some of these dispensing studies may not reflect current practice, many are now several decades old, and recent influences that may have changed behavior include the introduction of modern toothbrushes (which may have smaller heads) and updated professional advice for the control of toothpaste dosage, professional recommendations that play a very important role. On the other hand, visual information in commercial advertisements may be of importance. Typical images of a long line of toothpaste on the toothbrush, as seen on TV and magazine pictures, are strongly suggestive of being the most appropriate way to dispense toothpaste. Regarding the frequency of use, there is strong evidence to support the recommendation to brush twice daily with fluoride toothpaste since it increase the caries-preventive effect by 14% compared to brushing once a day (Marinho et al. 2003). Brushing teeth twice per day (before going to bed and once after a meal, preferably in the morning) seems to be sufficient for most individuals (Ellwood et al. 2008) .

There is no evidence about adherence to treatment in older adults. Thus, it is very important to determine if the older population uses the toothbrush and toothpaste properly, to reach the expected results (Leavell and Clark 1965). It has been demonstrated, though, that low adherence to prescribed medical regimens is ubiquitous. Typical adherence rates are at about 50% for medications and are much lower for lifestyle prescriptions and other more behaviorally demanding regimens, and specifically for long-term interventions (Haynes et al. 2002). For this reason, it is relevant to explore adherence in long-term treatments, such as non-invasive therapies based on fluoridated dentifrices. Therefore, the purpose of this study was to determine long-term adherence to a non-invasive treatment for RCLs, through the use of oral hygiene elements; toothbrush wear and toothpaste use, at 1 and 2 years in community-dwelling elders.

3.2 Material and Methods

Subjects. This study was conducted among Chilean community-dwelling older adults who participated in a randomized controlled clinical trial (RCT) of self-administered non-invasive therapies with high-fluoride dentifrices for the prevention and arrest of RCLs (Chapter 2). Sixty-year old or older persons with at least 5 remaining teeth in the mouth and one RCL were recruited from community clubs in Talca, Chile. Participants came from areas with fluoridated water (0.7 ppm F) and were community-dwelling (detailed criteria can be found above). Although all the participants of the RCT were instructed to return the toothbrushes and the tubes, a convenience sample of 50 subjects was selected from those who returned all the elements after 2 years. This sample size was consistent with a previous study aimed to assess the toothbrush wear index (Muller-Bolla et al. 2012).

Clinical procedures. Patients were provided with an oral hygiene kit for personal use, consisting of a toothbrush and toothpaste for personal use, depending on the allocated arm of the RCT. Participants were instructed to brush twice a day, after breakfast and just before bedtime (Nordström and Birkhed 2010), without post-brushing water rinsing (Nordström and Birkhed 2009), and only spitting out the excess toothpaste. A pea-sized amount of toothpaste had to be used at each brushing (about 0.25 g) (Levy 1993). A demonstration of the toothpaste dosing was carried out to each participant. The toothpaste tubes were blinded with tape and both the patients and the study's principal investigator were blinded for the type of treatment each participant was receiving during the entire duration of the study. Subjects were instructed to replace the toothbrushes (soft bristles) provided every 3 months with a new toothbrush (Super 7 Soft, PHB®, Dentaid®, Cerdanyola, Spain), also provided by the researchers. The two non-invasive treatment with toothpastes were: Control group: 1,450 ppm F-toothpaste as NaF (Colgate Total®) and Intervention group: 5,000 ppm F-toothpaste as NaF (Colgate Duraphat® 5,000 Plus). At each toothbrush and toothpaste change, the protocol was reinforced to the participants to maximize compliance. Patients received the same kit every 3 months (toothbrushes and fluoridated dentifrices) and had to return the tube and the toothbrush, used during the previous period to the study coordinator, annually, during the next clinical appointments. For example, for the one-year assessment, the kit provided at 9 months had to be kept and returned. Only toothpaste tubes and toothbrushes from the end of the first and the second year were retrieved and considered in the study.

The study took place at the School of Dentistry of the University of Talca, from July 2014 to November 2016. Socio-demographic data of the participants were registered at the beginning along with clinical data from oral examinations. All the participants received one session of supragingival prophylaxis every six months.

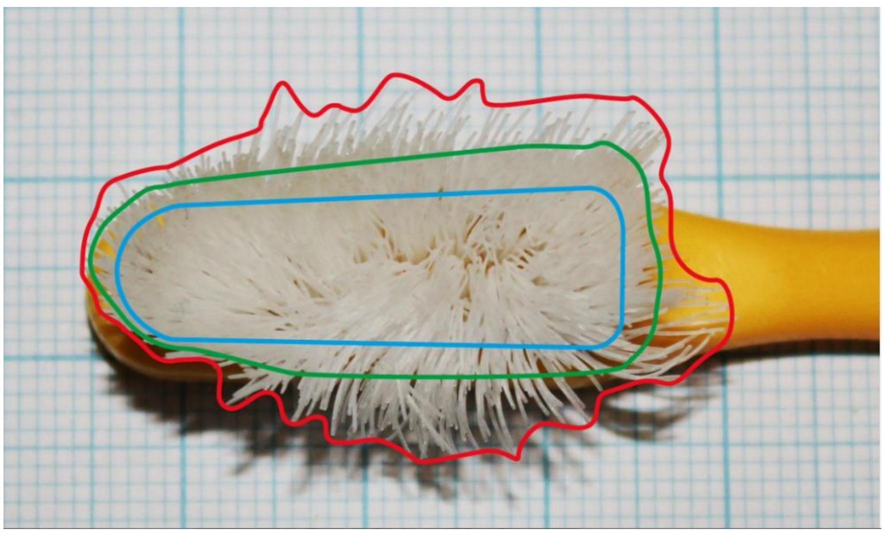
Evaluation of oral hygiene elements. A yearly follow-up was carried out to evaluate the toothbrush wear index and the amount of toothpaste used, as surrogate indicators of adherence to treatment.

<u>Toothbrushes</u>: A digital camera (Canon, EOS REBEL T3, Lens EFS 18-55 mm.) with a tripod (ROKINON, T60) and graph paper for background, were used to calculate the wear index. A standardized photograph was obtained, placing the camera on a tripod at 22 cm of the focal point (toothbrush). The camera was maintained at a fixed height above the toothbrush for all photographs. A front photograph of the bristles was taken (**Figure 1**) and the area of the worn bristles was calculated comparing the area occupied by the bristles of a new (A_0) (a blue line represents this WI) with those of a worn brush (A_f) (a red line represents this WI), using a graph paper. The Wear Index (WI) (Rawls et al. 1989) was calculated as follows:

$$WI= [(A_f - A_0) \times 100 / A_0]$$

Photographic images of the total brushing area were captured for a new toothbrush and for the 50 worn brushes, 25 of each group. Toothbrush and toothpastes were analyzed after 3 months of use. The outer brushing areas of the used toothbrushes were digitally traced and processed using Adobe Photoshop CS

6, v13.0.1.1 software (Adobe Corporation, California, USA). The drawings of each of the 50 bristle surfaces of the toothbrushes were overlapped on the graph paper. A blue outline corresponded to the outline of a new toothbrush, which correspond to a WI of 34%, in this particular toothbrush. Other toothbrushes may lead to different WI, when not used, dues to their original shape. A red outline of the bristle areas was drawn around the worn bristles. Both areas were then calculated and compared. It has been reported that a WI of 68% indicates that a toothbrush should be replaced (Glaze and Wade 1986). In Figure 1, a green line represents this WI. To assess reproducibility of the tracing procedures, the operator measured the bristle area 10 times, in five randomly selected toothbrushes.



New toothbrush
Toothbrush at wear index threshold of 68%
Most worn toothbrush

Figure 1 Outlines of brushing areas in the toothbrush correspond to those in the 50 toothbrushes tested.

A cut-off point ≥ 34% was considered as “Adherent” and <34% as “Non-adherent” to the use of toothbrush.

Fluoridated dentifrices**:** To estimate the average use of an individual that strictly followed the study instructions, a previous assay was conducted by the investigators. Five new toothpaste tubes (A) were used to estimate the amount of toothpaste contained in the tubes of each type of dentifrice. Total content of the toothpaste tubes was weighed by emptying it into a precipitated glass and weighed on a precision scale. The 1,450-toothpaste weighed 62 grams and the 5,000 ppm weighed 49.2 grams (B). Once measured the content of the toothpaste, empty tubes were also weighed. Single doses for each toothpaste were defined as a pea-size (0.25 grams). When scaling it to a 3-month period of use, total amount ideally should have been 45 grams (G).

Thus, the percentage of paste used was calculated as follows:

% paste used= F x 100/G, where:

A= Weight of the new container (tube + content), 75 grams for 1,450 ppm and 51 grams for 5,000 ppm.

B= Weight of the total content; for 1,450 ppm was 62 grams. and for 5,000 ppm was 49 grams.

C= Weight of the used container (tube + content) delivered by the subject.

D= Weight only of the tube (D= A-B)

E= Weight of the real content remaining (E= C-D)

F= Weight of the real content used (F= B-E)

G= Ideal dose to use: 45 grams

Thus, values ≥ 100% were classified as “Adherent” and below 100% as “Non-adherent” to paste used.

Ethical considerations. The study and the informed consent form were approved by the Bioethics Committee of the University of Talca (number: 2013-047). All participants signed an informed consent form and received oral explanations about the nature of the study. Performed procedures on human subjects followed the ethical standards of the institutional and national research committee and the Helsinki Declaration of 1964 and its later amendments.

Data analysis. The normality tests were performed with the Shapiro-Wilk and Kolmogorov-Smirnov tests depending on each case for each of the variables to be studied, considering a level of significance of 5%. Mann Whitney U-test was used to test the distribution of sociodemographic variables and treatment in relation to the adherence variables (WI and % of paste used) at different times. The paired sample-test was used to compare WI and % of paste used at different times in the total sample. p-values < 0.05 were considered significant. Statistical analyses were performed using the statistical SPSS v25 (IBM, NY, USA).

3.3 Results

Hygiene elements from 50 subjects (25 per group) were included, of which 60% were female and 40% were male. Forty six percent were between 60 to 69 years old and 54% were 70 years old or older, with a mean of 69.63 ± 6.25 years. Seventy six percent of the participants came from a high SES, and 24% to from a low SES.

Mean WI of the entire sample of people was 31.4(±24.1) and 36.1(±27.3) at 1 and 2 years, respectively **(Table 1)**. Considering that when new, the WI of the toothbrush used here is 34 or lower, this result can be considered as low. Conversely, the mean value of the % of paste used during the 3-month period was 84.1(±16.9) at 1 year and 82(±17.1) at 2 years **(Table 1)**.

Table 1. Paired sample -test for %WI and % Paste used at 1 and 2 years for the total sample of patients.

	WI		**% of paste used**	
	1 year	2 years	1 year	2 years
Mean (SD)	31.4 (24.1)	36.1 (27.3)	84.1 (16.9)	82 (17.1)
	p = 0.34		p = 0.34	

When analyzing adherence to the non-invasive treatment in relation to the different sociodemographic variables; sex, age and SES, no significant differences were found either in the WI or in the % paste used **(Table 2)**.

When adherence was evaluated by treatment type, only subjects treated with 1,450 ppm F used more paste (90%) than those treated with 5,000 ppm F (78.7%) (p=0.002), but this difference disappeared at 2 years **(Table 2)**.

Table 2. Descriptive analyses of socio-demographic variables and mean values of % WI and % paste used in different time points.

	Variables n (%)	1 year		2 years	
		% WI mean (SD)	% Paste used mean (SD)	% WI mean (SD)	% Paste used mean (SD)
Sex	Female = 30 (60)	33.2 (28.2)	86.5 (8.6)	36.5 (29.8)	82.9 (16.6)
	Male = 20 (40)	28.7 (16.6)	80.7 (24.6)	35.6 (23.8)	80.6 (18.2)
Age group	60-69 y = 23 (46)	34.4 (31.9)	84.7 (18.9)	37.7 (30.1)	85.8 (15.3)
	70 or + y = 27 (54)	28.8 (14.8)	83.7 (15.5)	34.9 (25.1)	78.8 (18.2)
SES	Low = 12 (24)	39.3 (30.2)	89.9 (6.2)	36.7 (15.6)	87.5 (10.3)
	Upper = 38 (76)	28.9 (21.8)	82.3 (18.8)	36.0 (30.2)	80.3 (18.5)
Treatment	1,450 ppm = 25 (50)	28.6 (16.4)	90.0 (12.6)*	36.0 (23.4)	85.5 (14.7)
	5,000 ppm = 25 (50)	34.1 (30.1)	78.7 (19.1)*	31.1 (36.1)	78.5 (18.9)

*Mann Whitney U test = 150.000; p value = 0.002
WI= Wear index

3.4 Discussion:

This study explored an innovative way to assess compliance in a non-invasive approach for the management of RCLs, using toothbrushes and toothpastes, in community dwelling older adults. On the best of our knowledge, no similar studies have been conducted before. The follow-up of this study was up to 2 years, which can be considered as a long-term study, especially in older adults and the results suggest adherence to the toothpaste and toothbrush regimen.

In general, there was not adequate adherence to treatment, when the WI was considered, result that could be influenced by the number of teeth present in the sample. It is important to mention that the WI used here was obtained from studies with dentate subjects. When using WI in older adults with fewer teeth, therefore, results may be biased. Thus, lower WI of 34% may underestimate compliance. Further studies should define specific thresholds for older adults particularly edentate, adjusting for the number of teeth present. If the % of paste used is taken into account, a much higher adherence was observed, reaching the optimal level (Table 1). Whether worn bristles reduce the ability to remove dental plaque compared with new brushes remains controversial because some studies indicated a higher level of plaque control in patients using new toothbrushes, consequently with a low WI (Rosema et al. 2013). Reasons for the low WI observed may have come from the periodical change of the toothbrushes. There is not a consensus among professionals on when to replace a toothbrush. Most national dental associations recommend replacing a toothbrush after about 3 months, based on expert's opinion, not based on evidence (Muller-Bolla et al. 2012). Moreover, the bristle quality may explain why a compliant use of the toothbrush may result in little splaying over time, keeping adequate results in terms of plaque removal. When using the WI, it has been suggested that after three months of use, a value of 68% was obtained and used a guideline for replacement (Glaze and Wade 1986). Finally, the toothbrush used in this study comes with a case to cover the head and protect the bristles. This simple device keeps the bristles orderly and may have influenced the low WI found in this study.

Although not significant, there was a slight trend towards lower toothbrush wear and use of toothpaste in females, subjects older than 70 years and those from an upper SES, at both time points. The lack of gender differences in adherence in not surprise, as studies have reported that non-adherent behavior varies in men and women, but it is not possible to attribute a more clear non-adherent behavior to either group (Thunander Sundbom and Bingefors 2012). The fact that older people appears slightly less compliant may be attributed to a general decrease in motor skills, visual ability, fragility or depression observed with age. Yet, in our cohort differences no evident differences in motor skills could be detectable and therefore, the adherence variable did not significantly change. In general, sociodemographic variables have been considered as a poor indicator of adherence (Vermeire et al. 2001).

As expected, WI resulted similar between the conventional and the high fluoride toothpaste groups. The only significant difference in adherence to the non-invasive treatment was observed in the % of paste used between both type of toothpastes. Subjects under a high fluoride toothpaste seemed to use lower amounts. Certain physical characteristics of the tube may have played a role in these differences observed. Conventional toothpastes come in a softer tube, which may facilitate the release of higher amounts of paste because participants may have found it easier to squeeze. Furthermore, if participants had lower muscle strength and decreased grasp, the tube of the 5,000 ppm F paste may have resulted more difficult to squeeze. Likewise, the diameter of the orifice to dispense the product is narrower in the 5,000 (6 mm) as compared to the 1,450 ppm F paste (8 mm). The wider orifice may make impossible to dispense exactly the same amount of toothpaste in both products.

Low adherence to prescribed medical regimens is a ubiquitous problem. Typical adherence rates are about 50% for medications and are much lower for lifestyle prescriptions and other more behaviorally demanding regimens (Haynes et al. 2002). Ways to cope with no adherence is to implement simple measures, such as directly asking for the use, monitoring the use requesting the retrieval of the drug container oi, in our case, the empty tube (Haynes et al. 2002). Successful interventions for long-term regimens are all labor-intensive but ultimately can be cost-effective. In our case, constant monitoring and surveillance was carried out every 3 months, which could explain the high adherence in terms of the use of toothpaste. An additional issue is that the kits with the toothbrush and the toothpaste were given only if the patient returned to their appointment. The latter allowed better control and protocol reinforcement. Yet, many participants of the RCT failed to retrieve the hygiene products.

We acknowledge limitation in this study. Not all the participants returned the element and if they did, in many cases, they did it at 1 year and not at the second year, or vice versa. The latter limited the sample size. It would have been ideal to monitor WI and the % of paste used every 3 months, however, for practical reasons, this assessment was restricted only to 1 and 2 years. Using only one type of toothbrush limits the extent of the conclusion, as the results of low WI may have been caused by technical properties of this, but not other, type of toothbrush. On the other hand, although not specifically indicated and unlikely in our opinion, participants could have shared the toothbrush or the toothpaste with other family members, which could have influenced the results.

Measuring study compliance as presented here is promising, as the methodology used is simple and low-priced. Scaling up the approach to the clinical setting should not be difficult and is highly recommended considering all the limitations discussed and rethinking a new methodological design.

3.5 Conclusion:

In general terms, elderly participants of an RCT based on toothbrushing with a fluoridated toothpaste appear to adhere to the indicated treatment, using bristle wear and the amount of toothpaste used as proxy measures. Adherence to the non-invasive therapy for RCLs in community-dwelling older adults, however, appears to be low when using a standard index to quantify bristle splaying, but is high when using the amount of toothpaste used.

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CHAPTER 4

Impact of a non-invasive approach with high-fluoride toothpastes for the treatment of root caries lesions on the quality of life of community-dwelling elders.

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Abstract

Purpose: Non-invasive treatment of root caries lesions (RCLs) may impact Oral Health-Related Quality of Life (OHRQoL), but no evidence is available. The purpose of the study was to assess changes in OHRQoL among patients exposed to non-invasive treatment of RCLs with conventional or high-fluoride dentifrices. **Methods:** To be eligible, subjects had to be 60 years old or older, independently-living, with at least five teeth and one RCL. The OHIP-14Sp, oral examination and socio-demographic data were documented at the beginning of the study (T0). The presence and activity of RCLs were detected and diagnosed. Subjects were randomly assigned to either the control (1,450 ppm F) or to the experimental treatment group (5,000 ppm F). A new set of measurements was obtained at 12-months (T1). Mean comparisons were carried out using Student's T-test for total OHIP-14Sp scores. To determine whether T1 OHRQoL scores were different regarding gender, age and socioeconomic status, mean OHIP-14Sp scores were obtained and compared with those variables at 12-months. **Results:** An overall improvement in OHRQoL after the non-invasive treatment of RCLs was verified when T1 was compared to T0 ($p<0.0001$). Regarding treatment type, no significant differences were detected between both groups ($p=0,114$). Subjects with higher income and more years of formal education had better OHRQoL than those with a lower salary ($p<0.0001$) and with less years of education ($p=0.0006$). **Conclusions:** Non-invasive treatment for RCLs in community-dwelling elders appears to positively impact OHRQoL. Better OHRQoL was associated with higher socioeconomic and educational level. No significant differences were detected regarding the fluoride concentration in the dentifrices.

Keywords: Quality of Life; Oral Health-Related Quality of Life; Oral Health; OHIP; Root caries lesions; Dental caries; Fluoridated toothpaste; High-fluoride dentifrices; Non-invasive treatment; elderly.

4.1 Introduction

The world is facing an unprecedented demographic transition. In addition to living longer, people are retaining more teeth (Batchelor 2015; Kinsella and He 2009). Having more teeth retained into older ages has resulted in increased prevalence of the most frequent oral diseases: periodontal diseases and dental caries. Regarding dental caries, older adults are usually affected by root caries lesions (RCLs), with a worldwide prevalence of approximately 30%-60% (Griffin et al. 2004). RCLs usually affect older adults with predisposing risk factors, including high root caries experience, advanced age, smoking, medication use with resulting xerostomia, among many others that have been tested (Ritter et al. 2010). In this scenario, understanding the disease and its consequences appears as a relevant matter. Restoration of RCLs is challenging, as restorative procedures imply difficulties in moisture control, the nature of the tissues for adhesion and the lack of retention in deeper root cavities. Furthermore, a growing number of patients with RCLs experience limited mobility, which means restrictions to traditional and appropriate restorative treatment (Lo et al. 2006). On the other hand, dental anxiety or dental fear is reported for about 36% of the population, including 12% describing extreme dental fear (Hill et al. 2013). Dental anxiety can have serious implications in subject's oral health, acting as a barrier for dental care (Freeman 1999). High dental anxiety has been associated with low oral health-related quality of life (OHRQoL) (McGrath and Bedi 2003; 2004). Conversely, when people attend routine dental visits a protective effect on OHRQoL (Almoznino et al. 2015) has been linked.

Considering the drawbacks of the conventional therapy for RCLs, non-invasive treatment of these lesions is highly desirable for patients and clinicians and may impact OHRQoL. Several approaches to prevent initiation or inactivate RCLs have been proposed. A recent systematic review of the literature identified different types of applications and agents to reduce the initiation or to inactivate RCLs (Wierichs and Meyer-Lueckel 2015). A daily use of dentifrice containing 5,000 ppm F- showed greater efficacy in reducing active RCLs than dentifrices containing 1,100 to 1,450 ppm F-. We carried out a comprehensive search for the potential association between non-invasive therapies for RCLs and OHRQoL in older people, but no evidence seems to be available. The purpose of the present study, therefore, was to assess changes in self-reported OHRQoL among older patients exposed to non-invasive treatment of RCLs using high-fluoride toothpastes over a period of one year. This study is part of a randomized controlled clinical trial designed to evaluate RCLs arrest using non-invasive therapies with fluoridated dentifrices.

4.2 Methods

Subjects. This longitudinal study was conducted among Chilean community-dwelling older adults who participated in a randomized controlled clinical trial of self-administered non-invasive therapies with high-fluoride dentifrices on preventing and arresting RCLs. The study protocol for the RCT was registered at ClinicalTrials.gov NCT02647203. Data were collected from July 2014 to December 2015 in the School of Dentistry of the University of Talca. To be enrolled in the primary study, participants had to meet the following inclusion criteria: to be 60 years of age or older, independently-living according to the Functional Evaluation of Older Adults (EFAM for its abbreviation in Spanish) criteria (Silva 2005), have at least five teeth and at least one RCL and be able to answer the OHIP-14Sp questionnaire (León et al. 2014). Participants were excluded from the study if they showed signs of cognitive impairment or alcoholism, which were corroborated by the principal investigator. If there was no clarity about the exclusion criteria, the Short Mini-Mental State Examination (MMSE-SF) (Quiroga et al. 2004) and the Alcohol Use Disorders Identification Test (AUDIT-C Test) (Babor et al. 2001) were applied.

Sample size was calculated with the software GRANMO, for the comparison of two means (presence of carious lesions) in independent populations, considering a previous study (León et al. 2016). Accepting an alpha risk of 0.05 and beta risk of 0.2 in a two-sided test, a total of three hundred and forty-two participants were required (n=171 per group). A difference greater than or equal to 4 units was needed to consider the differences as statistically significant. The common standard deviation was assumed to be 11.79. During study design, an anticipated drop-out rate of 20% was established to calculate the sample size. Hence, a sample of two hundred seventy-four older adults was necessary. The study and the informed consent form were approved by the Bioethics Committee of the University of Talca (number: 2013-047). All participants signed an informed consent form and received oral explanations about the nature of the study.

Questionnaire. The instrument for the present investigation (OHIP-14Sp) was the Chilean validation (León et al. 2014) of the OHIP-14 questionnaire developed by Slade and Spencer (Slade 1997). Items were grouped into seven domains and respondents were invited to answer the OHIP-14Sp questions by frequency of the problems using a 5-point Likert scale (0, never; 1, hardly ever; 2, occasionally; 3, fairly often; and 4, very often), using the original tool proposed by Slade and Spencer, based on the assumptions made by Locker et al. (Likert 1932; Locker 1988; 1995). Questions were read out loud, one by one, by two trained dentists, making sure that the subjects clearly understood each question. A printed chart with the Likert-type scale with clear and big characters was used to graphically show each oral question, so people would have a permanent visual reference to facilitate the answers. This ordinal scale is considered as a valid response scale for this type of survey (Sierwald et al. 2011). Once all the questions were answered, the researchers filled the questionnaire. This strategy was devised due to the high prevalence of elderly Chileans with low educational levels and high rate of visual problems. Scores were calculated using the additive method, considering values ranging between 0 and 56, which has demonstrated a high discriminatory ability (Larsson et al. 2004; Rener-Sitar et al. 2008; Robinson et al. 2003). The final score was calculated by the sum of fairly often/very often responses, and occasionally/fairly often/very often. Thus, total score ranged from 0 to 14. Higher scores indicate poorer OHRQoL (Khalifa et al. 2013; León et al. 2014).

Data collection. The OHIP-14Sp questionnaires were applied before the beginning of the self-administered non-invasive therapy with fluoridated dentifrices at the baseline (T0). Subsequently, all the participants received one session of supragingival prophylaxis every six months. Oral examination and socio-demographic data of the participants were documented at the beginning of the study. RCLs were detected and diagnosed by ICDAS II criteria for presence (ICDAS 2005), and Nyvad's criteria for caries activity (Fejerskov 2015; Nyvad et al. 1999). Baseline and follow-up clinical examinations were performed by one calibrated examiner (Kappa intra- examiner 0.81). Subjects were interviewed to fill out a socio-demographic survey that included sex, age, socio-economic status and educational level. Once the evaluations were completed, each patient was provided with an oral hygiene kit, consisting of a toothbrush and toothpaste, either of high or low fluoride concentration, depending on the study arm randomly assigned for the clinical trial. The same protocol was applied again at the 12-month control (T1). The protocol for the clinical trial of self-administered non-invasive therapies with fluoridated dentifrices included instructions for brushing twice a day, after breakfast and just before bedtime (Nordström and Birkhed 2010), with the 5,000 ppm F as NaF (Duraphat® 5,000 Plus, Colgate-Palmolive, Therwil, Switzerland) or 1,450 ppm F as NaF (Colgate Total®, Colgate-Palmolive, San José Iturbide, Mexico), without post-brushing water rinsing (Nordström and Birkhed 2009), and only spitting out the excess toothpaste. A pea-sized amount of toothpaste had to be used at each brushing (about 0.25 g). A demonstration of the toothpaste dosing was carried out to each participant. The toothpaste tubes were blinded with tape and both the patients and the study's principal investigator were blinded for the type of treatment each participant was receiving during the entire duration of the study. Subjects were instructed to replace the toothbrushes (soft bristles) provided every 3 months with a new toothbrush (Super 7 Soft, PHB®, Dentaid®, Cerdanyola, Spain), also provided by the researchers. At each toothbrush change, the protocol was reinforced to the participants to maximize compliance. Patients received the same material every 3 months (toothbrushes and fluoridated dentifrices).

Ethical considerations. The study was approved by the Bioethics Committee of the University of Talca (number: 2013-047). Performed procedures on human subjects followed the ethical standards of the institutional and national research committee and the Helsinki Declaration of 1964 and its later amendments. Informed consent was signed by all the participants in the study.

Data analysis. Mean comparisons were calculated using Student's T-test for total OHIP-14Sp scores at T0 and T1. To determine whether T1 OHRQoL scores of subjects undergoing non-invasive therapies for RCLs were different regarding gender, age and socioeconomic status, mean OHIP-14Sp scores obtained at the 12-month time-point were analyzed for each of those socio-demographic variables. Student's T-test and ANOVA test for educational level were used to estimate the differences, with a significance level of 0.05. Statistical analyses were performed using the statistical R v3.2.2 software (The R Foundation for Statistical Computing, Vienna, Austria).

4.3 Results

The OHIP-14Sp test was applied to 345 older adults before the start of the self-administered non-invasive therapy with fluoridated dentifrices at baseline (T0 - baseline). The second questionnaire (T1 – 12 months) was completed by 306 subjects. Of the 306 patients, 75% were female and 25% were male. The mean±SD age of the respondents was 69.63±6.25 years. After 1 year, 39 individuals were lost to follow-up for different reasons (**Fig. 1**).

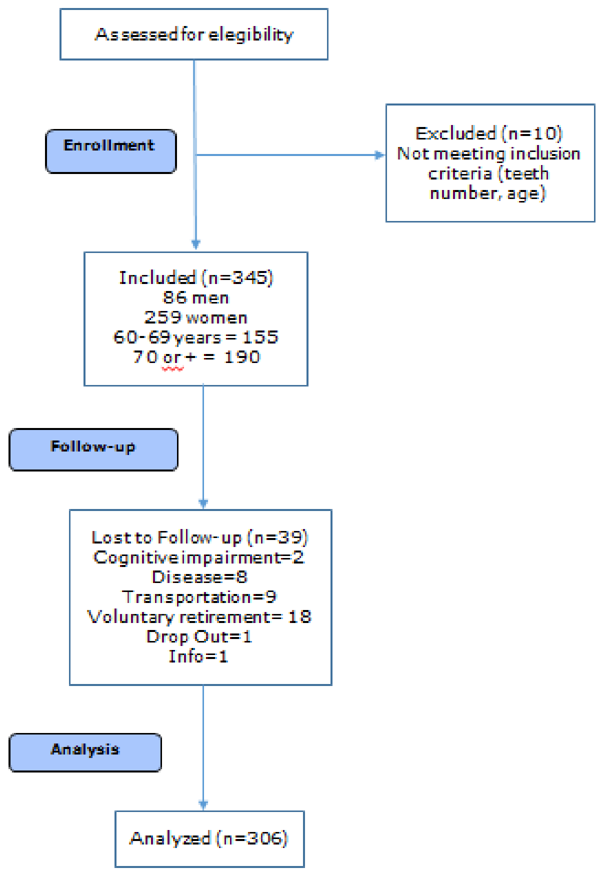

Figure 1 Flow diagram

Socio-demographic variables are presented in **Table 1.**

Table 1. Socio-demographic characteristics of the study population of older adults.

Variable		n	(%)
Sex	Women	231	75.5
	Men	75	24.5
Age	60-69	162	52.9
	70 or +	144	47.1
Educational Level (years)	>12	118	38.6
	9-12	109	35.6
	≤8	79	25.8
Socio-economic status	Upper	201	65.7
	Middle or Lower	105	34.3

OHRQoL assessed at T0-baseline showed that 51% of the subjects had a score lower than 14, considered as good OHRQoL. At 12 months (T1) there was an overall increase to 65.7%. On the other hand, a reduction from 49% to 34.3% of the subjects who self-reported poor OHRQoL at T0-baseline was observed at 12 months **(Fig. 2).**

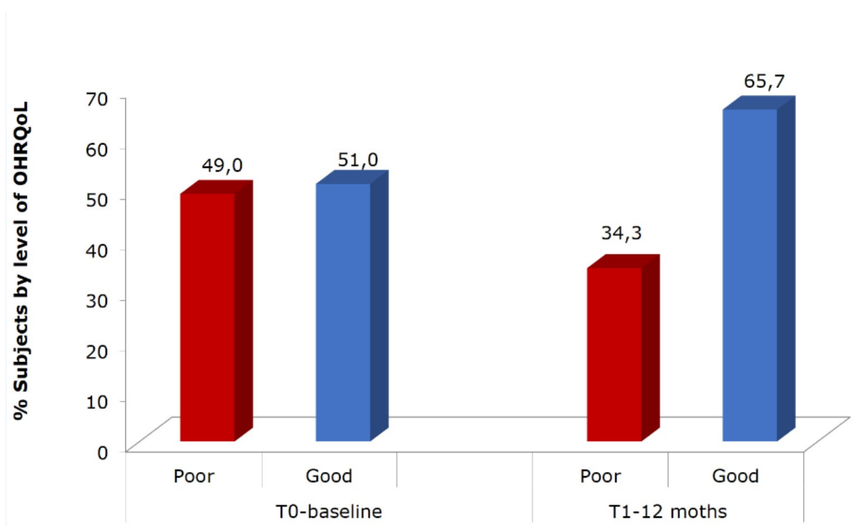

Figure. 2. Changes in OHRQoL after 12 months follow-up. Bars represent percentage of participants with poor (red) or good (blue) OHRQoL, according to a predetermined cut-off point.

Mean comparison between OHIP-14Sp scores obtained at T0 and at T1, regardless of the type of intervention received, showed significant differences between both scores (Student's T-test, p-value<0.0001), with an overall improvement on OHRQoL after the non-invasive treatment for RCLs **(Table 2).** When we analyzed the variation in OHRQoL according to the type of fluoridated dentifrice used at 12 months, no significant differences were detected (Student's T-test, p-value= 0.114).

Table 2. Means comparison for the total OHIP-14Sp score at T0 and T1 of the study population of older adults.

OHRQoL (OHIP-14Sp)	Mean	SD	p
T0-Baseline	15.85	9.9	
T1-12 months	12.22	9.3	< 0.0001 (T)

(T) Student's T-Test; (*) p < 0.05

When exploring the influence of socio-demographic variables on OHRQoL at T1, significant differences between subjects with higher and lower socioeconomic status were found (Student's T-Test, p-value<0.0001). Subjects with higher income had lower OHIP-14Sp scores, indicating better OHRQoL than those with lower income. Significant differences between OHIP-14Sp scores were detected for educational level (ANOVA, p-value=0.0006). Participants with a lower educational level, represented as having less than 8 years of formal education, had higher OHIP-14Sp scores, which means poor OHRQoL. No significant differences were observed for sex or age **(Table 3)**.

Table 3. Means comparison for the total OHIP-14Sp score for socio-demographic variables at T1 of the non-invasive treatment for RCLs.

Socio-demographic variables	Median	SD	p
Sex			
Woman (n=231)	12.77	9.76	0.068 (T)
Man (n=75)	10.51	7.66	
Age			
60 – 69 (n=162)	12.66	9.65	0.378 (T)
70 o + (n=164)	11.72	9.83	
Socioeconomic Status			
Upper (n=201)	10.44	8.28	<0.0001 (T)(*)
Middle or Lower (n=105)	15.61	10.29	
Educational Level (years)			
> 12 (n=118)	10.20	8.0001	0.0006 (A)(*)
9-12 (n=109)	12.12	8.89	
≤ 8 (n=79)	15.35	10.92	

(T) Student's T-Test; (A) Anova/ Tukey; (*) $p < 0.05$

4.4 Discussion

Despite the improvement in OHRQoL after one year of non-invasive therapy for RCLs with fluoridated dentifrices, the results might be explained by multiple factors involved in the same intervention besides the use of the dentifrice. Indeed, no differences were detected between the experimental arms of the randomized controlled trial for RCLs. The original hypothesis was that higher concentrations of fluoride would decrease dentin hypersensitivity and the progression of RCLs, resulting in better OHRQoL. Results, however, failed to show differences between both treatments, but did show an overall improvement on OHRQoL, regardless of the type of treatment. Hence, the search for an explanation of the results in OHRQoL must focus on other intervening factors. The prophylaxis performed to all the participants every six months could result in lower self-perceived halitosis, as these procedures have shown to reduce volatile sulfur compounds in patients with periodontitis (Guentsch et al. 2014). Periodontal diseases may compromise OHRQoL. In fact, most studies have shown a negative impact of periodontitis on OHRQoL (Al-Harthi et al. 2013). Furthermore, halitosis is part of one of the OHIP-14Sp dimensions, so its reduction may impact the overall questionnaire score and be interpreted as good OHRQoL. Similarly, supragingival prophylaxis every six months could have improved the periodontal condition, affecting oral health perception. Although several clinical studies have been conducted to assess the impact of periodontitis on OHRQoL, comparing and synthesizing those findings is difficult due to the lack of clarity on an operational definition of the periodontal status and OHRQoL (Araújo et al. 2010; Aslund et al. 2008; Cunha-Cruz et al. 2007; Jowett et al. 2009; León et al. 2014; Needleman et al. 2004; Reisine et al. 1989) and the high heterogeneity of methods and reporting in the studies. It is important, therefore, to adjust for confounding factors, particularly any of the multiple clinical conditions that may impact people's lives, consequently avoiding data misinterpretation or spurious associations (Al-Harthi et al. 2013). Thus, preventive dental care received periodically during the intervention may lead to better OHRQoL. As a matter of fact, it has been shown that positive health-related behavior and regular dental check-ups have a protective effect on OHRQoL and are associated with better dental status (Almoznino et al. 2015; Montero et al. 2014). Furthermore, older adults who reported brushing once a day or less and that had fewer natural teeth also reported deteriorated OHRQoL (dos Santos et al. 2013) compared to those who brushed at least twice per day.

On the other hand, the Hawthorne effect could be another explanation for our results. This effect is recognized as a reaction of subjects to the realization that they are in a study under observation (Adair 1984). The Hawthorne effect corresponds to any unexplained result in an experiment carried out on human subjects, on the assumption that the results occurred due to the mere presence of the subjects in the experiment. Thus, volunteers in a study have experiences or signs that otherwise would not have appeared if they had not participated in the research (Parsons 1992). The Hawthorne effect has been described to alter subject behaviors, which may account for the improvement in some of the outcome variables (Claydon et al. 1996; Feil et al. 2002; Gilbert et al. 1998; Owens et al. 1997). The Hawthorne effect, however, could be experienced by a limited amount of time, usually not exceeding six months (Feil et al. 2002). Thus, based on the latter, we believe that this artifact can be ruled out in our study and the impact of the non-invasive therapy could be explained by a direct effect of the treatment, including a positive dental experience, as discussed below. Additionally, the non-invasive intervention applied here could have impacted dentin hypersensitivity, which is also one of the dimensions of the OHIP-14Sp. Fluoridated toothpastes containing 5,000 ppm F may help to reduce, to some degree, the symptoms of dentin hypersensitivity associated with non-carious lesions and active RCLs (Petersson 2013).

Another variable associated with a self-administered treatment is dental fear, which is likely to induce treatment delays, leading to more severe dental issues and/or symptomatic dental attendances. People with dental fear are usually afraid of visiting the dentist, and it has been reported that they have more missing teeth than people with lower or no fear (Armfield et al. 2007). A study from our group showed that older adults who self-reported dental fear were less likely to have visited the dentist than those who did not (Mariño and Giacaman 2017). Since participants in our study faced a relaxing clinical environment, without the use of high speed or any other invasive procedure, results in the terms of the perceived OHRQoL could have been influenced by the absence of dental fear and a high compliance, as well.

The effect of the interpersonal relationship between dentist and patient on OHRQoL is an underexplored research area. Although few OHRQoL studies have looked into patient–provider dynamics (Muirhead et al. 2014), studies from other fields have reported positive experiences in terms of patient communication, trust, empathy and respect, influencing health outcomes and therefore, quality of life (Beck et al. 2002). Unmet physical health needs negatively affect quality of life (Slade et al. 2005). This is likely to be similar in dental health. In our study, participants were periodically examined and listened to, so their positive OHRQoL may have derived from a better rapport. Trust in dental service providers could have also been particularly important for elders, typically less prone to engage in shared decisions with the professional, unlike younger adults. It has been shown that older people's increased trust in physicians leads to a more compliant and deferential role (Trachtenberg et al. 2005). Trust and confidence in dental professionals, therefore, may ease stress and hesitation during dental treatment. If the lack of trust in the dentist is added to the unsatisfied dental needs, dental anxiety may be greatly increased, which is a known factor associated with poor OHRQoL (Mehrstedt et al. 2007).

When analyzing socio-demographic variables, we found significant differences between subjects with a higher income, who had a better OHRQoL than those with low income. In our study, we intentionally chose to work with participants from clubs. People of higher socioeconomic status tend to participate more in clubs, as they do not have to work after retirement. On the other hand, working with organized groups, allows compliance and follow-up (Silva et al. 2013). Furthermore, people from higher socioeconomic status usually retain more teeth. The same situation was observed regarding educational level. Subjects with an educational level of less than 8 years had higher OHIP-14Sp scores, denoting worse OHRQoL.

Demographic and socio-economic characteristics added to oral health status may impact OHRQoL in older adults (Fuentes-García et al. 2013; Tsakos et al. 2009). It has been reported that there is a gradient between social position and OHRQoL in elderly adults (Erić et al. 2012; Fuentes-García et al. 2013; Tsakos et al. 2009). Moreover, socio-demographic variables, including race, transport constraints, education and income, have been associated with OHRQoL (Gilbert 2005; Makhija et al. 2006). It has been shown that poverty directly predicts poorer dental health, which leads to worse OHRQoL. Socio-economic inequalities, therefore, are an important determinant of OHRQoL (Rebelo et al. 2016). More oral accumulated damage in people from lower socio-economic status over a lifetime may explain results in OHRQoL. Our results agree with previous studies showing the relationship between socio-economic indicators and poor oral health in older people (Erić et al. 2012; Kressin et al. 1997; Locker and Jokovic 1997; Tsakos et al. 2009). For sex and age, there were no statistically significant differences in the perceived OHRQoL. The study had a greater proportion of women, like many other international studies (Gao et al. 2015; Nummela et al. 2011). Subjects were recruited from community clubs of older adults, which have a predominantly female participation, like other social organizations in Chile (SENAMA 2008). Yet, no statistically significant differences were found in OHRQoL between male and female older adults.

Subjectivity of the OHRQoL construct encourages the deepening of these findings through a qualitative approach. As discussed above, many variables may have intervened in explaining changes in OHRQoL. Thus, a deeper analysis of each one of them is suggested. Although we decided to conduct the randomized controlled trial with both arms using non-invasive therapies for RCLs, it would be of interest to compare the impact of treatment on OHRQoL comparing a non-invasive with a conventional treatment. Given the results of this study, non-invasive therapies for RCLs in community-dwelling older people seem an attractive option for many reasons that go beyond the realm of the oral aspects, including OHRQoL.

4.5 Conclusions

Non-invasive treatment for RCLs in community-dwelling elders appears to impact positively on OHRQoL. Better oral health perception was associated with higher socio-economic status and educational level. No significant differences were detected regarding the fluoride concentration in the dentifrices. A deeper understanding of the reasons why this type of therapeutic approach may affect the quality of life is strongly suggested and deserves more research.

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CHAPTER 5

Role of saliva in root caries; association between salivary flow and root caries lesions prevalence and activity in older adults.

This chapter is based on the publication cited below:

León S, Castro E, Arriagada K, Giacaman RA. **“RELACIÓN ENTRE FLUJO SALIVAL Y CARIES RADICULAR EN ADULTOS MAYORES AUTOVALENTES”.** Revista Clínica de Periodoncia, Implantología y Rehabilitación Oral (PIRO) Volume 9, Issue 3, December 2016, Pages 253-258. (Published in Spanish).

Abstract

Introduction: Although the role of saliva in the protection against root caries has been widely controversial, few studies have examined the association with salivary flow. **Objective:** To determine if a decreased salivary flow is related to increased prevalence and activity of root caries in the elderly living in the community. **Materials and methods:** A cross-sectional study was conducted on 332 elderly participants. Subjects were interviewed, completed a sociodemographic questionnaire, were orally examined, and donated a sample from unstimulated and stimulated salivary flow. Clinical examinations were carried out to assess prevalence and activity of root caries using ICDAS criteria. The 'Root Caries Index' (RCI) and percentage of Active Root Caries (ARC) were calculated. Data were analysed using the Student t test, ANOVA and Kruskal Wallis, with a significance level of .05. **Results:** Salivary flow was significantly lower in women and in subjects with high drug consumption and systemic diseases ($P<0.05$). Although neither RCI nor the percentage of ARC differed in relation to unstimulated salivary flow, they were slightly higher in people with normal stimulated salivary flow ($P<0.05$). **Conclusion:** Salivary flow does not appear to be numerically associated with the prevalence or the activity of root caries in independent older adults.

KEYWORDS: Salivary flow; Root caries; Caries activity; Aging

5.1 Introducción

La población mundial está envejeciendo a un ritmo alarmante (OMS 2015). Éste fenómeno es considerado uno de los cambios epidemiológicos más grandes del último siglo. Este proceso demográfico único en la historia trae consigo aparejados desafíos políticos, económicos, socioculturales y biomédicos. Chile es actualmente el tercer país más envejecido de Latinoamérica experimentando un envejecimiento avanzado y se espera que para el 2025 ocupe el primer lugar en Latinoamérica y el Caribe (OMS 2015). Chile además, se encuentra en medio de una transición epidemiológica en relación a salud bucal debido a la creciente disminución en las tasas de edentulismo, acompañándose en general de una mejor salud bucal de la población (Mariño et al. 2015). A pesar de ello, aún existe una gran variedad de problemas de salud bucal, como la pérdida de dientes causadas principalmente por caries y enfermedad periodontal. Los estudios han demostrado que con el aumento de la expectativa de vida, las personas mayores conservan más dientes lo que a su vez se asocia con un mayor riesgo de caries, específicamente caries radicular (Nicolau et al. 2000). Además de los múltiples factores que intervienen en la aparición de caries, en la caries radicular emergen algunos elementos particulares como la recesión gingival que expone las superficies radiculares, la hiposalivación por enfermedades sistémicas y polifarmacia y el uso de prótesis parciales removibles, todos ellos más frecuentes en personas mayores (Gregory and Hyde 2015).

Las lesiones radiculares no son de difícil detección y se han propuesto varios sistemas para lograr diagnosticarlas, como el Root Caries Index (RCI) (Katz 1986), o la profundidad de las lesiones con respecto a la pulpa (Billings et al. 1988) y actualmente los criterios ICDAS (International Caries Detection and Assessment System) que clasifican la lesión como parte de un proceso continuo que comienza con signos tempranos previos a la cavitación (Ismail et al. 2007). Sin embargo, estas clasificaciones no determinan el grado de actividad de la lesión, lo que es mucho más complejo de establecer. Se han propuesto algunos métodos para determinar actividad de las lesiones que básicamente consideran la textura, color, contorno de la superficie y distancia de la lesión al margen gingival para establecer actividad (Ekstrand et al. 2008; Nyvad and Fejerskov 1986).

Por su parte, la acción anticaries y remineralizadora de la saliva ha sido bien caracterizada desde hace muchos años y por lo tanto parece razonable pensar que una disminución del flujo llevaría a la generación de un mayor número de lesiones. Sin embargo, esta relación entre flujo disminuido o alterado y la aparición de lesiones de caries no ha sido del todo bien esclarecida. La mayoría de los estudios han mostrado que un flujo salival disminuido está relacionado con un mayor número de caries radicular (Lacoste-Ferré et al. 2013). Muchos de estos estudios incluyeron a población institucionalizada, pero la situación a este respecto en población autovalente, que representa la mayor cantidad de población, no ha sido descrita. Contrariamente, otros estudios no han encontrado una asociación entre un flujo salival disminuido y mayor cantidad de caries radiculares en adultos mayores (Ekstrand et al. 2008). Dada la falta de evidencia con respecto a la relación entre el flujo salival y caries radicular en adultos mayores autovalentes, el objetivo de esta investigación fue determinar si existe relación entre un flujo salival disminuido y un aumento en la presencia y actividad de caries radicular.

5.2 Materiales y Métodos

Se realizó un estudio de corte transversal en 332 personas mayores autovalentes provenientes de clubes de adultos mayores de la ciudad de Talca, Chile. La muestra de pacientes participa en un ensayo clínico randomizado que busca probar la efectividad de terapias no invasivas en base a dentífricos fluorados para el tratamiento de la caries radicular en personas mayores autovalentes. Los datos del presente estudio corresponden al examen inicial. Por ello, los criterios de inclusión fueron tener 60 años o más, ser autovalente de acuerdo al Examen de Funcionalidad en el Adulto Mayor (EFAM) que predice funcionalidad (Silva 2005), pertenecer a una comunidad con agua potable fluorada (aprox. 0,7 ppm), tener al menos cinco dientes con exposición de superficie radicular y presentar 1 o más lesiones de caries radicular. Los criterios de exclusión fueron alcoholismo y deterioro cognitivo. Los participantes fueron examinados en el Centro de Clínicas Odontológicas (CCO) de la Universidad de Talca. Se les aplicó una encuesta sociodemográfica, en donde además se recopiló información sobre enfermedades sistémicas y consumo de fármacos. Se les evaluó clínicamente la presencia (Ismail et al. 2007) y actividad de caries radiculares (Ekstrand et al. 2008) el flujo salival estimulado y no estimulado (Ericsson 1959), variables que se detallan a continuación:

Medición del Flujo Salival. Se realizó el examen de flujo salival en condiciones estandarizadas, entre las 8:30 a 11:00 hrs. para minimizar las variaciones asociadas al ciclo circadiano. Los participantes no debían consumir alimentos por lo menos una hora antes del examen, ni haber realizado cepillado de dientes al menos 12 horas antes (Heintze et al. 1983). Se recolectó saliva no estimulada por 15 minutos y se permitió un descanso de al menos 5 minutos para realizar el examen de flujo salival estimulado por 5 minutos, utilizando una pastilla de parafina. Tanto el flujo salival no estimulado (FSNE) como estimulado (FSE) se clasificaron dicotómicamente en normal y bajo, basándose en los criterios de Ericsson (Ericsson 1959).

Evaluación de caries radicular. Para la detección y clasificación de caries radicular se utilizaron los criterios ICDAS (Ismail et al. 2007)**.** Se calculó el RCI (Root Caries Index) (Katz 1986) para expresar la prevalencia de caries por paciente. Para determinar el estado de actividad o inactividad de las lesiones se utilizaron los criterios de Ekstrand (Ekstrand et al. 2008) mediante un examen visual y táctil que incluía cuatro variables clínicas: textura relacionada a la dureza, contorno suaves o irregulares, ubicación con respecto al margen gingival y color de la lesión (amarillento a negruzco). Los participantes fueron categorizados dicotómicamente en sujetos con caries radiculares activas (CRA) o inactivas (CRI). Si había 1 o más lesiones activas, el paciente era clasificado en el grupo de lesiones activas y por el contrario la ausencia de lesiones inactivas lo clasificaba en el grupo de lesiones inactivas. Adicionalmente, se calculó el porcentaje de lesiones activas por paciente (número de CRA / dientes con superficies expuestas). Los exámenes fueron realizados por dos investigadores experimentados, entrenados y calibrados en los criterios ICDAS de detección de caries radicular, en los que se obtuvieron valores del test Kappa inter-examinador de 0,75 e intra-examinador de 0,81. Los participantes fueron sometidos a un destartraje supragingival con el fin de tener mejor acceso a las superficies radiculares y mejorar la certeza diagnóstica.

Consideraciones éticas. El protocolo del estudio fue aprobado por el Comité de Ética institucional de la Universidad de Talca y antes de adscribirse al estudio, los pacientes debieron firmar un consentimiento informado. A cada paciente se le explicó su condición bucal y recibió una sesión de educación en higiene oral, además de un set de elementos de higiene.

Análisis estadístico. Los datos obtenidos fueron analizados con el software SPSS v15.0 para Windows (IBM Corporation, Somers, Chicago, EE.UU.) y sometidos a supuestos de normalidad utilizando Kolmogorov Smirnoy. Se aplicó Test T de Student, Anova y Kruskal Wallis para pruebas no paramétricas. Se consideró un nivel de significancia de 0,05.

5.3 Resultados

Del total de los 332 participantes, un 74,01% eran mujeres y 25,9% hombres. En cuanto a la edad, el 53,1% tenían entre 60 a 69 años y el 46,8% 70 o más años. Un importante número de los sujetos consumía entre 3 a 5 fármacos (45,9%), entre los cuales la mayoría pertenecía al grupo de beta bloqueadores, diuréticos tiazidas y estatinas y presentaba 1 a 2 enfermedades sistémicas (50,1%), siendo la hipertensión arterial y la dislipidemia las enfermedades más prevalentes (48,78% y 39,02% respectivamente). El promedio de dientes conservados en los sujetos de estudio fue de 18,7 dientes no existiendo diferencias entre hombres y mujeres. Solo el 53,4% y el 44,1% de los adultos mayores incluidos en el estudio mostraron un flujo salival normal, tanto no estimulado, como estimulado, respectivamente, según la clasificación de Ericsson (Ericsson 1959) **(Tabla 1).**

Tabla 1. Variables sociodemográficas, sistémicas y de flujo salival de la población en estudio.

Variables independientes	n	%
Sexo		
Mujeres	245	74,0
Hombres	86	25,9
Edad		
60 a 69	176	53,1
≥70	155	46,8
N.º fármacos		
0	51	15,4
1 a 2	90	27,1
3 a 5	152	45,9
≥6	38	11,4
N.º enfermedades sistémicas		
0	26	7,8
1 a 2	166	50,1
≥3	139	41,9
Flujo salival no estimulado		
Normal	177	53,4
Bajo	154	46,4
Flujo salival estimulado		
Normal	146	44,1
Bajo	185	55,8

Tanto los valores de FSNE ($p<0,001$), como los del FSE ($p=0,002$) fueron menores en mujeres que en hombres. Ni el FSNE ($p=0,77$) ni el FSE ($p=0,75$) mostraron diferencias estadísticamente significativas en ambos grupos de edad**.** Se apreció un menor FSNE ($p=0,03$) y FSE ($p=0,01$) con el aumento en el número de fármacos. De la misma manera, hubo menor FSNE ($p=0,009$) y FSE ($p=0,03$) cuando aumentó el número de enfermedades sistémicas **(Tabla 2).**

Tabla 2. Flujo salival no estimulado (FSNE) y estimulado (FSE) en ml/min, según las variables de sexo, edad, número de fármacos y de enfermedades sistémicas.

			FSNE		FSE	
Variables	Categorías	n	Media (DE)	p	Media (DE)	p
Sexo	Hombres	86	0,4 (0,30)	< 0,01 (T)*	1,5 (0,80)	0,002 (T)*
	Mujeres	246	0,3 (0,20)		1,2 (0,60)	
Edad	60 a 69	176	0,3 (0,20)	0,77 (T)	1,2 (0,60)	0,75 (T)
	≥ 70	156	0,3 (0,20)		1,2 (0,70)	
Número de fármacos	0	51	0,4 (0,03)	0,03 (A)*	1,3 (0,10)	0,01 (A)*
	1 a 2	91	0,3 (0,02)		1,4 (0,08)	
	3 a 5	152	0,3 (0,02)		1,2 (0,06)	
	≥ 6	38	0,2 (0,04)		1,0 (0,10)	
Número de enfermedades sistémicas	0	26	0,4 (0,04)	0,009 (A)*	1,5 (0,10)	0,03 (A)
	1 a 2	167	0,3 (0,02)		1,3 (0,05)	
	≥ 3	139	0,3 (0,02)		1,1 (0,06)	

A: Anova; DE: desviación estándar; T: test t de Student.
* $p \leq 0,05$.

El RCI de la población fue 51,42% con un promedio de CRA de 31,29% (resultados no mostrados). Al contrastar el RCI con el FSNE no se detectaron diferencias estadísticamente significativas entre flujos normales y alterados (p=0,09). Tampoco fue posible visualizar diferencias con relación al %CRA (p=0,2). Por el contrario, se observaron diferencias estadísticamente significativas en el caso del FSE, tanto a nivel del RCI (p=0,04), como a nivel del %CRA (p=0,02) **(Tabla 3).**

Tabla 3. Índice de caries radicular (RCI) y porcentaje de caries radiculares activas (%CRA) según flujo salival no estimulado (FSNE) y estimulado (FSE)

	n	RCI Media (DE)	% CRA Media (DE)	Personas con CRA n (%)
FSNE				
Normal	178	0,53 (0,01)	33 (1,8)	161 (90,4)
Bajo	154	0,49 (0,02)	30 (2,1)	137 (89,0)
Valor *p*		0,09 (A)	0,2 (A)	
FSE				
Normal	147	0,54 (0,02)	34 (2,06)	135 (91,8)
Bajo	185	0,49 (0,01)	29 (1,81)	163 (88,1)
Valor *p*		0,04* (A)	0,02* (A)	

A: Anova; DE: desviación estándar.
% CRA: número de CRA/número de dientes con superficie expuesta.
RCI: C + O/C + O + S *100, donde C: cariadas correspondientes a códigos 1 y 2 del ICDAS radicular; O: obturaciones cervicales —excluyendo prótesis fija unitaria (PFU) o plural (PFP)—; S: superficie radicular sana, correspondiente a código 0 del ICDAS radicular.
* $p \leq 0,05$.

5.4 Discusión

Los valores de flujo salival tanto no estimulado como estimulado fueron predominantemente normales, lo que es similar al estudio de Heintze, utilizando la misma metodología de recolección de flujo salival (Heintze et al. 1983). Las mujeres mostraron un menor flujo salival que los hombres. En este punto la literatura es contradictoria, pues mientras algunos estudios coinciden con nuestros resultados (Heintze et al. 1983; Smidt et al. 2010), otros postulan que no hay diferencias en el flujo salival según sexo (Elishoov et al. 2005). Aun así, se han postulado dos posibles factores que pueden explicar esta diferencia. Primero, que las mujeres presentan menor cantidad de glándulas salivales menores en comparación a los hombres (de Almeida et al. 2008) y a que son de menor tamaño. También se asocia a la menopausia como factor causal de disminución de flujo salival (Smidt et al. 2010) y a la mayor frecuencia de “sequedad bucal” en mujeres. Por otro lado, existen estudios que concluyen que la menopausia no está relacionada con disfunción salival de la parótida (de Almeida et al. 2008).

Contrariamente a lo esperado, no se detectaron diferencias entre los grupos de edad considerados. Estudios similares han señalado que el flujo salival se mantiene relativamente constante con la edad en personas sanas y específicamente dentro del grupo de adultos mayores con 60 años o más (Smith et al. 2013), lo que coincide con nuestros resultados. Sin embargo, Lima et al. mostró que en personas mayores se presenta una menor producción de saliva al día en comparación con adultos de mediana edad, pero que esta situación parece estar más relacionada con enfermedades sistémicas y el uso continuo de medicamentos, que con el envejecimiento como tal (Lima 2004). Se ha considerado que el consumo de fármacos es el principal factor causante de la hiposalivación en adultos mayores (Smidt et al. 2010). Se han descrito más de 400 medicamentos que generan efectos sobre el flujo salival, pero no todos tienen una base experimental para comprobar esta condición. De manera similar, se han reportado variadas enfermedades sistémicas que disminuyen el flujo salival, específicamente la enfermedad cardiovascular que produciría una microangiopatía y macroangiopatía que alteraría la irrigación glandular o podría deberse al efecto específico de los fármacos que la tratan (Smidt et al. 2010). A pesar de todo lo anterior, una reciente revisión sistemática mostró que existe una disminución de ambos tipos de flujo salival cuando se comparan adultos y adultos mayores, lo que no pueden explicarse sobre la base del uso de fármacos (Affoo et al. 2015). Otro estudio mostró que el flujo salival estimulado y no estimulado se mantiene constante con la edad en la glándula parótida, mientras que sí existieron diferencias en relación a edad en las glándulas submaxilares y sublinguales para ambos flujos (Diaz de Guillory et al. 2014). En nuestro estudio, la población participante fue dividida aleatoriamente en sujetos de 60 a 69 años y mayores de 70. Es muy posible que esta división no sea lo suficientemente precisa ni oportuna para detectar las variaciones de flujo con la edad. La división del presente estudio tuvo relación con una necesidad de contar con poblaciones de tamaño comparables.

Dada la falta de metodologías de diagnóstico estandarizadas y de aceptación universal, es difícil hacer comparaciones entre estudios. Para los análisis de este estudio se consideró el RCI, índice de amplia utilización. El RCI promedio resultante de este estudio fue de 51,4% lo que se considera bastante alto en comparación al único estudio nacional que evaluó RCI obteniendo un 8,23% (Mariño et al. 2015). Es importante destacar que este dato de RCI, no puede ser considerado como representativo de la población autovalente de nuestra región, ya que este estudio es parte de un estudio principal que pretende evaluar terapias no invasivas para caries radicular en el cual como parte de los criterios de inclusión está el presentar al menos una caries radicular. El porcentaje total de caries radiculares activas fue de 32,6%, siendo mayor en hombres versus las mujeres, 37,3% y 31,1% respectivamente. No hay estudios aún que evalúen la actividad de caries radiculares en población autovalente, sólo existen unos pocos estudios en población dependiente acerca de intervenciones con fluoruros, que no son atingentes a esta discusión (Ekstrand et al. 2008), por lo que estos datos pueden ser considerados los primeros en mostrar la prevalencia de caries activas en lesiones de caries radiculares. En este estudio no se evidenciaron diferencias en el RCI entre un flujo salival no estimulado normal y alterado e incluso se detectó la existencia de un menor RCI cuando el flujo salival estimulado está alterado. No existe un consenso en cuanto a si hay una relación directa entre una disminución del flujo salival y la prevalencia de caries radicular. Si bien muchos autores coinciden en que hay un aumento de la presencia de caries radicular con un flujo salival disminuido, considerándolo como factor de riesgo (Gregory and Hyde 2015), otros estudios evidencian que el flujo salival por sí sólo es un pobre predictor de caries radicular, ya que no genera cambios estadísticamente significativos en la prevalencia de caries radicular (Guivante-Nabet et al. 1998). Pese a que es vastamente aceptado que la saliva juega un rol crítico en el mantenimiento de la salud bucal en general, la caries radicular es una enfermedad de etiología multifactorial. Por lo tanto, desde una perspectiva epidemiológica, la tasa de flujo salival por sí sola se considera un pobre predictor para el número de lesiones cariosas (Billings 1993). Según una reciente revisión sistemática, los predictores de caries radicular más determinantes son el número de dientes y el índice de placa (Ritter et al. 2010). Por ello, no necesariamente un flujo salival disminuido por si solo podría aumentar el riego de presentar caries radicular, pero puede causar cambios en las condiciones ambientales orales aumentando el riesgo presentar las lesiones (Närhi et al. 1998).

Es de central importancia explicar la falta de asociación entre caries radicular y actividad de las mismas y los valores del flujo salival. La caries en su concepción actual es una enfermedad ecológica biofilm y azúcar dependiente (Fejerskov 2004). En ese contexto, el parámetro del volumen de saliva que considera el flujo salival puede ser cuestionable e insuficiente, ya que no considera la ecología alterada que pueden provocar los factores de riesgo principales como el azúcar y el biofilm y los factores protectores, tanto su presencia como su ausencia. En esa misma línea de pensamiento, se debe considerar la composición de la saliva, la cual tendría un efecto en la desmineralización, más allá de su cantidad. Por ejemplo, la composición de la saliva no estimulada es más determinante en la desmineralización de la superficie radicular, tomando un rol importante los compuestos inorgánicos presentes en ella, los que actúan como buffer disminuyendo el pH crítico de la dentina y remineralizando la superficie dentaria. Por otra parte, nuestro grupo de investigación ha mostrado que sujetos libres de caries expresan mayores cantidades de proteínas y en particular la IgA (Castro et al. 2016). Todo lo anterior sugiere que la calidad de la saliva podría ser más relevante en su asociación con caries radicular que la cantidad, enfatizando la necesidad de analizar factores clave de su composición que puedan condicionar una mayor actividad de caries, o bien proteger contra su desarrollo.

En relación a la actividad de caries radicular, es difícil comparar estudios debido a la gran variedad de criterios diagnósticos de actividad. A pesar de ello, se han encontrado correlaciones entre flujo salival no estimulado y actividad de caries radicular (Guivante-Nabet et al. 1998) con parámetros de color, textura, contorno y localización muy semejantes al de nuestro estudio. Aunque no hay mayores estudios que busquen la relación específica entre el flujo salival y la actividad de caries radicular, el nuestro mostró una diferencia estadísticamente significativa al comparar el porcentaje de caries radicular activas según el flujo salival estimulado. Sin embargo, contrario a lo que se esperaría, el porcentaje de caries radicular activas fue mayor en un flujo salival estimulado normal. Conforme a lo ya señalado, la caries es una enfermedad multifactorial y por lo tanto, pese a esta relación, estos resultados se deben considerar más bien parciales, ya que no hay una relación con la prevalencia de lesiones, sino solo de su actividad y este parámetro puede ser afectado por los otros factores intervinientes en el proceso de caries. La creciente población de personas mayores con alta carga de enfermedades y polifarmacia asociada y mayor conservación dentaria, hacen que la investigación de la asociación entre hipofunción salival y caries radicular cobre mayor relevancia. Nuevos estudios considerando elementos moleculares de análisis, como el análisis de la proteómica saliva son sugeridos.

5.5 Conclusión

Considerando las limitaciones inherentes a un estudio de corte transversal, el flujo salival no parece asociarse numéricamente con una mayor presencia o actividad de caries radicular en adultos mayores autovalentes. Se requiere realizar estudios prospectivos y moleculares que permitan dar una mejor respuesta a estas interrogantes.

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CHAPTER 6

Conclusions and Recommendations

6.1 Conclusions

Based on the findings of this Doctoral Thesis, the following conclusions can be drawn:

1. Self-administered non-invasive therapy with 5,000 ppm F-toothpaste appears to be highly effective in arresting active RCLs and in preventing new lesions, in community-dwelling elders.
2. This doctoral thesis comes to reinforce the limited evidence supporting the efficacy of high doses of fluoride for the prevention and treatment of RCLs.
3. The toothpaste and toothbrush regimen appear as a method simple and inexpensive to evaluate a non-invasive therapy for RCLs in community-dwelling older adults. But it is necessary to define specific thresholds for older adults particularly edentate, adjusting for the number of teeth present.
4. Non-invasive treatment for RCLs based on fluoridated dentifrices in community-dwelling elders appears to impact positively on OHRQoL.
5. Better oral health perception was associated with higher socio-economic status and educational level. No significant differences were detected regarding the fluoride concentration in the dentifrices.
6. Salivary flow does not appear to be numerically associated with a greater presence or activity of RCLs in community-dwelling elders.
7. No association could be demonstrated between RCLs prevalence and activity and a decreased salivary flow. Although saliva is key in caries protection, our studies seem to demonstrate that the decrease in RCLs activity in the subjects under study was mainly based on the self-administered non-invasive therapy with 5,000 ppm F-toothpaste.

8. The dose-dependent preventive and therapeutic effect observed with high-fluoride toothpastes could be the result of higher fluoride bioavailability in the dental biofilm and in saliva, enhancing the beneficial effect of fluoride in inhibiting demineralization and promoting remineralization.

9. It is also important to remark the potential impact that the work contained and implied in this doctoral thesis has had and will have on the advancement of the discipline of Gerodontology in Chile and beyond. This work has allowed to make advocacy for the need to include older persons in plans and programs from the State. The outcomes of this work led the candidate and the adviser in Chile to be invited as experts to participate in the construction of the clinical guidelines, protocols and work tables, all of which are in place today in the country. It is expected, therefore, that these results will be translated into practice at a larger scale, thus favorably impacting on the well-being of the Chilean elderly population. In 2016, the PhD candidate created, along with her team, the first Master's Program in Gerodontology in the Latin American region. This program is intended to train advanced human resources in the dental care of frail and dependent elderly people. Subsequently, the PhD candidate was elected the first President of the Geriatric Oral Society of Chile (SOGCh), which was created on May 4, 2018. Using the platform of the Master's Program of the University of Talca and the recently created SOGCh, the candidate and her team have started the process of the formal recognition of the clinical specialty of Gerodontology in Chile, before the Ministry of Health of Chile. In summary, the thesis work presented here has significantly contributed to the advancement of research in the field of Cariology for older adults, with strong additional implications at the academic, clinical and public policy levels.

6.2 Recommendations

1. The present and future generation of dental practitioners will confront the challenge of providing dental care for a growing number of older adults. Root caries is becoming a rising problem for this segment of the population. There is a higher incidence and prevalence in older people living in the community and residents of nursing homes, particularly those with dementia and neurological conditions. In addition, the number of affected surfaces increases with age, confirming the notion that root caries is cumulative.

2. Root caries will remain a significant oral condition in the future and strategies for successful and cost-effective prevention and management are needed. The increasing incidence and prevalence of RCLs can become a great challenge for public health due to global aging. This oral disease can be significantly controlled by simple and efficient treatment approaches like self-administered non-invasive therapies with high-fluoride dentifrices. Public and private practices should consider including this type of treatment in their routine clinical protocols since there are significant health, quality of life and economic issues associated with root caries.

3. Preventing the onset of caries lesions across the life span should be the primary goal of a caries management plan. However, once the disease is present, clinicians deal with the challenge of determining the appropriate approach to stop the consequences of the cariogenic process, which can be achieved by applying interventions at the patient level and managing the manifestation of the disease at the lesion level. Patient-level interventions aim to reestablish the mineralization balance. This intervention usually requires adequate patient adherence for success and include, but are not limited to, diet counseling in reducing sugar consumption, and oral hygiene instructions and reinforcement, for example toothbrushing with fluoride toothpaste. Lesion-level interventions include non-invasive treatment, for example

toothbrushing with high fluoride toothpaste, which is able to stop the disease process minimizing loss of tooth structure.

4. This non-invasive therapy with high-fluoride dentifrices mandates to actively monitoring non-cavitated and cavitated lesions during the life course, especially in older adults, as age has been associated with more caries risk factors and systemic conditions that may impact negatively on oral health. The life course approach results key to preserve the “biological asset”. The traditional restorative treatment without a defined maintenance program must be replaced by a control regime that needs to be periodically monitored.

5. Non-invasive therapies like the one tested here should be rapidly and readily incorporated into public and private oral care settings. The robust results of this research, along with the conservative, inclusive and inexpensive nature of the approach makes implementation, ethically mandatory.

6. A deeper understanding of the reasons why the non-invasive therapy with high-fluoride dentifrices as a type of therapeutic approach may affect the quality of life is strongly suggested and deserves more clinic research.

7. Due to the controversial results regarding the relationship between salivary flow and RCLs, it is necessary to perform prospective studies that allow a better understanding of the behavior of the salivary flow over time. Furthermore, basic science studies may provide clues on the molecular switch in saliva composition with aging.

ANEXO: Temo de consentimento livre e esclarecido

CONSENTIMIENTO INFORMADO

Título del Proyecto: **"Evaluación de terapias no invasivas para la caries radicular en adultos mayores autovalentes"**

Se le aplicarán encuestas y cuestionarios en relación a salud general y bucal. También se realizarán exámenes de flujo salival y recuento de placa bacteriana. Luego, se le realizará un examen intraoral donde se identificará la presencia de caries radiculares, posteriormente se realizará una higiene bucal. Al término de la sesión se le entregarán implementos de higiene bucal y se le hará una educación sobre su uso. Al ser un estudio prospectivo esto se realizará 5 veces por en un periodo de 24 meses.

He sido informado/a sobre el estudio, los procedimientos que se realicen, no implican un costo. He recibido una explicación satisfactoria sobre el propósito de la actividad, así como de los beneficios sociales que se espera éstos produzcan. La información será absolutamente confidencial y no aparecerán mi nombre ni mis datos personales en libros, revistas y otros medios de publicidad derivadas de la investigación. La decisión de participar es absolutamente voluntaria. Si no deseo participar en ella o, una vez iniciada la investigación, puedo hacerlo sin problemas. Los investigadores responsables Dra. Soraya León (sleon@utalca.cl) y la Dra. Pía Troncoso (piatroncoso@utalca.cl) podrán aclarar cualquier duda que me surja en el teléfono 71- 2201547, en el horario entre las 9:00 y las 13:00 horas en el período comprendido en la investigación. Entiendo las declaraciones contenidas en el documento y la necesidad de hacer constar mi consentimiento, para lo cual lo firmo libre y voluntariamente.

Yo,...CI:............................ .... de nacionalidad.., mayor de edad o autorizado por mi representante legal, con domicilio en ...., consiento en participar en la investigación denominada: **"Evaluación de terapias no invasivas para la caries radicular en adultos mayores autovalentes",** y autorizo a las Dras. Soraya León Araya y Pía Troncoso, investigadores responsables del proyecto y/o a quienes ellas designen como sus colaboradores directos y cuya identidad consta al pie del presente documento, para realizar los procedimientos requeridos por el proyecto de investigación descrito.

Fecha: ..../......./........   Hora: ....

Firma de la persona que consiente: ____

Investigador responsable: __________________________________