Journal of Dentistry 113 (2021) 103794

Contents lists available at ScienceDirect

Journal of Dentistry

journal homepage: www.elsevier.com/locate/jdent

The survival time of restorations is shortened in patients with dry mouth

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ARTICLE INFO

Keywords:
Hyposalivation
Xerostomia
Restoration
Survival
Composite
Crown

ABSTRACT

Objectives: The aim of this retrospective data collection study was to determine the effect size of dry mouth on the survival of restorations and teeth.
Methods: The data were collected from the electronic patient files of City of Oulu Public Dental Services (Finland). Study population consisted of 71 dry mouth patients and 142 control patients. The survival of 3208 restorations were analyzed using Kaplan-Meier survival curves and multivariate Cox regression analysis with shared frailty for patients. Separate analyses were performed for the survival of the teeth.
Results: The hazard ratio of restorations in dry mouth patients was 2.08 (95% CI: 1.65-2.63) compared to the control patients. For the dry mouth patients, the fixed prosthetic crowns outlasted composite fillings of all sizes, but the difference increased concomitantly with the filling size. The dry mouth patients had hazard ratio of 1.98 (95% CI: 1.02-3.82) for tooth extractions compared to the control patients. The teeth with fixed prosthetic crowns outlasted the teeth with direct restorative materials.
Conclusions: The survival time of restorations and teeth are severely shortened in patients with dry mouth. Especially the survival time of the large composites is short in dry mouth patients whereas fixed prosthetic crowns have acceptable survival time also in dry mouth patients.
Clinical significance: When informing a dry mouth patient on the expected survival of a restoration or tooth, one should take into account that dry mouth patients´ restorations and teeth have severely shortened survival time.

1. Introduction

Dry mouth is a common health issue found in 22% of adults [1]. Dry mouth includes both xerostomia (sensation of oral dryness) and hyposalivation (pathologically lowered salivary flow rate). International diagnostic criterion states that 0.1 ml/min of unstimulated saliva is the cut-off point for hyposalivation [2]. Caries and xerostomia are common among patients with hyposalivation, although xerostomia and hyposalivation occur also independently [3,4]. Moreover, already patients with unstimulated salivary flow rate below 0.2 ml/min have elevated prevalence of caries and xerostomia [3,5,6]. The most evident causes for dry mouth are Sjögren's syndrome and radiotherapy to neck or head region but a more common cause are medications especially polypharmacy and sedatives [7-10]. Age above 50 years and female sex are also associated with dry mouth [8,9].

The restorations of dry mouth patients have high failure rate [11-14]. However, these studies do not possess a control group of patients with normal salivary flow rate and therefore the effect size of dry mouth on restoration survival has not been determined. The survival of restorations is affected by several characteristics e.g., tooth type, restoration materials and size plus age, sex and oral hygiene of the patient [15-19]. Of these characteristics the restoration material is of great interest because if correctly chosen it may compensate for the other disadvantageous characteristics. The studies on restoration survival in dry mouth patients are solely on direct restorations which precludes comparisons of direct and indirect materials [11-14].

As world population, life expectancy, number of teeth in the seniors and the proportion of seniors with polypharmacy continue to increase, it is safe to assume a concomitant increase in dry mouth patients with need for restorative treatment [20-23]. In order to provide personalized

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https://doi.org/10.1016/j.jdent.2021.103794
Received 19 March 2021; Received in revised form 21 August 2021; Accepted 25 August 2021
Available online 3 September 2021

dental care for dry mouth patients it is necessary to determine the survival of different restoration materials in patients with dry mouth. Therefore, the aims of this practice-based retrospective data collection study were to i) determine the effect size of dry mouth on restoration and tooth survival and ii) compare the survival of different restoration materials in dry mouth patients.

2. Materials and methods

2.1. Study design and participants

This is a retrospective practice-based data collection study. The data was collected from the electronic practice management system Effica® (Tieto, Helsinki, Finland) of the Public Dental Services in the City of Oulu, Finland. Data collection covered the time period from January 1st, 2003 to December 15th, 2015. Only patients with restorative treatment during this time period were included in the study. Inclusion criterion for the dry mouth patients were registered diagnosis of either hyposalivation or xerostomia. The patients who had been diagnosed with dry mouth were identified using a search function in the electronic practice management system Effica®. To have close to similar numbers of restorations in dry mouth patients and their control patients, two control patients with same sex and date of birth were selected for each dry mouth patient. We collected patients' date of birth, sex, dry mouth diagnosis (hyposalivation or xerostomia) and two etiological factors of dry mouth (Sjögrenś syndrome and history of radiotherapy to neck or head region). For each operation we collected the operation type (restoration or extraction), date, treated tooth and its surfaces, restoration material and the indication for the operation. The restoration materials were categorized to direct resin-based composite (hereafter composite), glass ionomer cement, amalgam or fixed prosthetic crowns made of gold, ceramics, or their combination.

2.2. Statistics

To describe the data, we used frequencies and distributions. Kaplan-Meier survival curves were drawn to compare survival of restorations in control and dry mouth patients. The patients with dry mouth were further divided into two subgroups of patients (Sjögrenś syndrome/history of neck or head radiotherapy and hyposalivation/xerostomia of unspecified etiology) after preliminary analysis revealed similar survival curves for the restorations of these patient subgroups. Survival curves were also drawn to compare the survival for composites of different sizes and fixed prosthetic crowns in dry mouth patients. The composites were grouped to three size categories after preliminary analysis revealed similar survival curves for restorations in two or three surfaces and four or five surfaces. Third set of survival curves were drawn to compare survival of fixed prosthetic crowns and composites covering four or five surfaces stratified by patient group (dry mouth or control). Fourth set of survival curves were drawn to compare survival of class V fillings made of either composite or glass ionomer cement. The differences in survivals were statistically tested using log-rank test. Right-censoring was used for analyzing the survival of the restorations. We considered a restoration right-censored when there was no record that the restoration had been repaired or replaced or that the tooth had been extracted. In the teeth survival analysis the teeth that had not been registered extracted were considered right-censored.

The mean annual failure rate at 12 years (AFR) of the restorations was calculated using the formula: AFR = 1 - $\sqrt[12]{x}$, where x is cumulative proportion surviving at 12 years. In addition, we calculated hazard ratios for the restorations and teeth using multivariate Cox regression models with shared frailty. The models consider observations within the same patient correlated. We used MedCalc (version 19.5.2., MedCalc Software Ltd, Ostend, Belgium) to draw Kaplan-Meier survival curves and SAS/STAT® for Cox regression analyses (version 9.4, Cary, NC, USA) but SPSS software in all other analyses (Statistical Package for the Social Sciences, version 26, IBM, Armonk, New York, USA).

2.3. Ethics

The study was performed according to the Declaration of Helsinki and the study protocol was approved by the City of Oulu Department of Healthcare.

3. Results

3.1. Demographics

We identified in total 71 patients that fulfilled our inclusion criteria of dry mouth patients. Of them, 23.9% were male and 76.1% were female which is in accord with the proportions in several previous studies [8-10]. Sjögrenś syndrome and radiotherapy to neck or head region were registered as etiological factors of dry mouth in 22.5% and 9.9% of cases (respectively) whereas xerostomia and hyposalivation with unspecified etiology were registered for 36.6% and 31.0% of cases (respectively). The mean age at dry mouth diagnose was 52.2 (SD = 16.7) years. At the end of the data collection period the mean age of patients with dry mouth was 60.6 (SD = 17.0) years.

3.2. Distribution of restorations

During the observation period the 71 dry mouth patients had received 2042 restorations whereas the 142 control patients had received only 1166 restorations. The distribution of restorations by characteristics of patients and restorations are in Table 1. The fixed prosthetic crowns comprised 49.6% of the five-surface restorations in the dry mouth patients. Of the glass ionomer fillings 45.4% were in class V cavities. Amalgam was used in only 17 fillings and therefore the amalgam fillings were omitted from further analyses. In addition, the nine restorations in deciduous teeth were omitted from further analyses because of their small number. Only six restorations were excluded from further analyses because of missing data.

3.3. Survival of restorations

The survival of composites was shorter in the dry mouth patients than in the control patients ($p < 0.001$). Further survival analysis

Table 1
Statistical analysis of patient-, restoration- and tooth-related characteristics (n = 3179).

Characteristics	Restorations n (%)	AFR (%)	Hazard ratio (95% CI)
Patient group			
Control	1150 (36.2)	5.3	1.0
Sjögren's syndrome or radiotherapy	993 (31.2)	20.9	2.94 (2.17-3.98)
Xerostomia or hyposalivation	1036 (32.6)	10.6	1.70 (1.32-2.20)
Sex			
Female	2225 (70.0)	10.5	1.0
Male	954 (30.0)	10.1	1.36 (1.06-1.75)
Age (continuous variable)			1.006 (1.00-1.012)
Restoration material			
Fixed prosthetic crowns	220 (6.9)	6.6	1.0
Resin based composite	2633 (82.8)	10.4	5.57 (4.12-7.52)
Glass ionomer cement	326 (10.3)	11.8	8.35 (5.98-11.66)
Number of surfaces in the restoration			
1	1173 (36.9)	9.0	1.0
2 or 3	1328 (41.8)	10.7	1.66 (1.47-1.89)
4 or 5	678 (21.3)	12.2	2.17 (1.85-2.55)
Tooth type			
Premolar	816 (25.7)	9.8	1.0
Molar	951 (29.9)	9.9	1.31 (1.13-1.51)
Anterior	1412 (44.4)	11.0	1.15 (1.01-1.32)

showed distinct survival curves for composites in patients with xerostomia or hyposalivation of unspecified etiology compared to patients with Sjögrenś syndrome or history of radiotherapy to head and neck region (Fig. 1, $p < 0.001$). The survival of composites in dry mouth patients was associated with the size of the composite but the fixed prosthetic crowns outlasted all sizes of composites (Fig. 2, $p < 0.001$). The survival of fixed prosthetic crowns was longer than large composites in both dry mouth and control patients (Fig. 3, $p < 0.001$). In the class V fillings of the dry mouth patients, the composites survived longer than the glass ionomer cement fillings (Fig. 4, $p = 0.02$, $n = 374$). Whereas in the class V fillings of the control patients, the survival of composite and glass ionomer cement fillings were similar (Fig. 4, $p = 0.38$, $n = 172$).

3.4. Hazard ratios and annual failure rates for restorations

The first multivariate Cox regression analysis revealed that the dry mouth patients´ restorations had 2.08-fold hazard ratio (95% CI: 1.65-2.63) compared to the restorations in control patients. The analysis was adjusted for tooth type, restoration size and restoration material plus patient sex and age. The second multivariate Cox regression analysis revealed that the hazard ratio for restorations was even higher in patients with Sjögrenś syndrome or history of radiotherapy to head or neck region (Table 1). Restoration material and size showed high hazard ratios whereas the hazard ratios according to tooth type and patient sex were smaller (Table 1). The third multivariate Cox regression analysis was performed to determine the effect of omitting patient characteristics sex and age on the hazard ratios associated with dry mouth, restoration material, number of surfaces and tooth type. On average the effect of omitting age and sex on the hazard ratios for the other characteristics was only 0.05 units. The fourth multivariate Cox regression analysis revealed that the hazard ratios for the composite restorations covering one, two or three and four or five surfaces were respectively 2.71 (95% CI: 2.02-3.64), 4.44 (95% CI: 3.31-5.95) and 5.91 (95% CI: 4.34-8.04) compared to the fixed prosthetic crowns. The analysis was adjusted for dry mouth etiology, tooth type plus patient sex and age. Additional adjustments of any of the multivariate analyses for mandibular/maxillary or right/left side of the jaw did not change the hazard ratios essentially.

The mean annual failure rates across 12-year observation period (AFR) are shown in Table 1. The AFR for the dry mouth patients was 15.6%. The AFR were in accordance with the results on hazard ratios except for the type of the tooth and sex of the patient.

3.5. Indications for operative treatment

In patients with dry mouth, caries adjacent to restoration was the predominant indication for operative treatment (40.0%) followed by chipping (20.5%) and various other indications (13.2%) whereas the remaining 26.3% of indications had not been registered. The indications for operative treatment had not been registered for 61.4% of the operations on control patients and therefore further analyses were not performed for them.

3.6. Tooth extractions

Tooth extractions per patient were twice as common in the dry mouth patients than in the control patient (1.66 and 0.86 respectively). Of the extracted teeth that had been restored during the observation period only six (4.5%) had been restored with a fixed prosthetic crown whereas 127 had been restored using only direct filling materials (composite, glass ionomer or their combination). Cox regression analysis revealed that the patients with dry mouth had hazard ratio of 1.98 (95% CI: 1.02-3.82) for tooth extractions compared to the control patients. The analysis was adjusted for restoration material, number of surfaces in the restoration, tooth type plus patient sex and age. A separate Cox regression analysis was performed for tooth survival in dry mouth

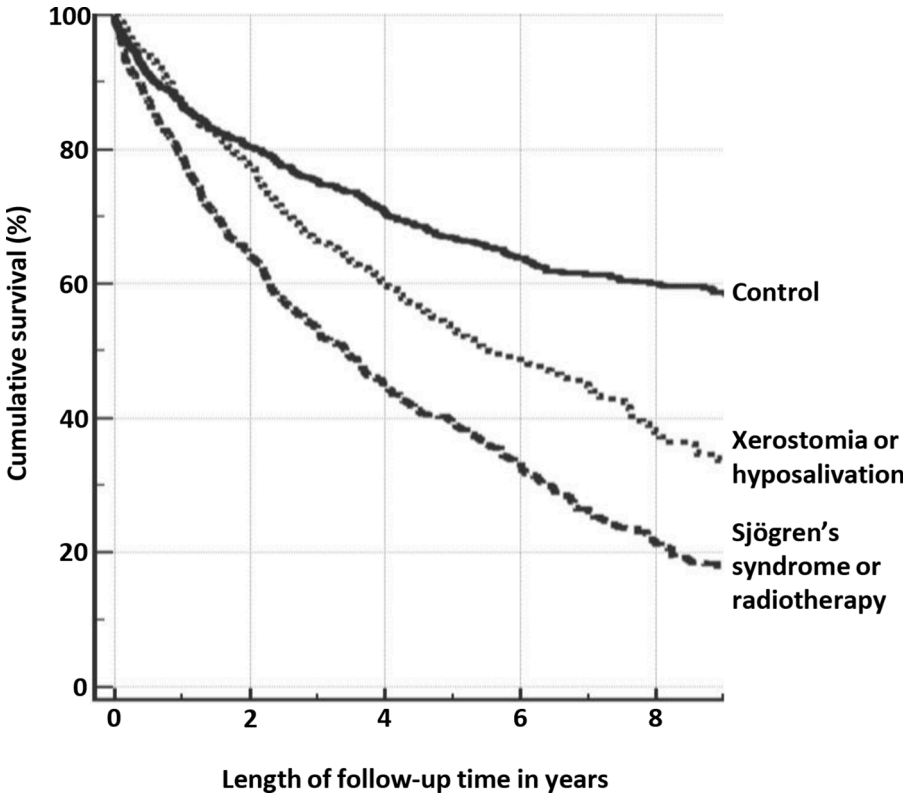

Fig. 1. The survival curves for composites (n = 2633) stratified by dry mouth etiology (Sjögrenś syndrome or radiotherapy to head and neck region, or xerostomia or hyposalivation of unspecified etiology). The follow-up time was cut to nine years because of the low number of cases beyond this point.

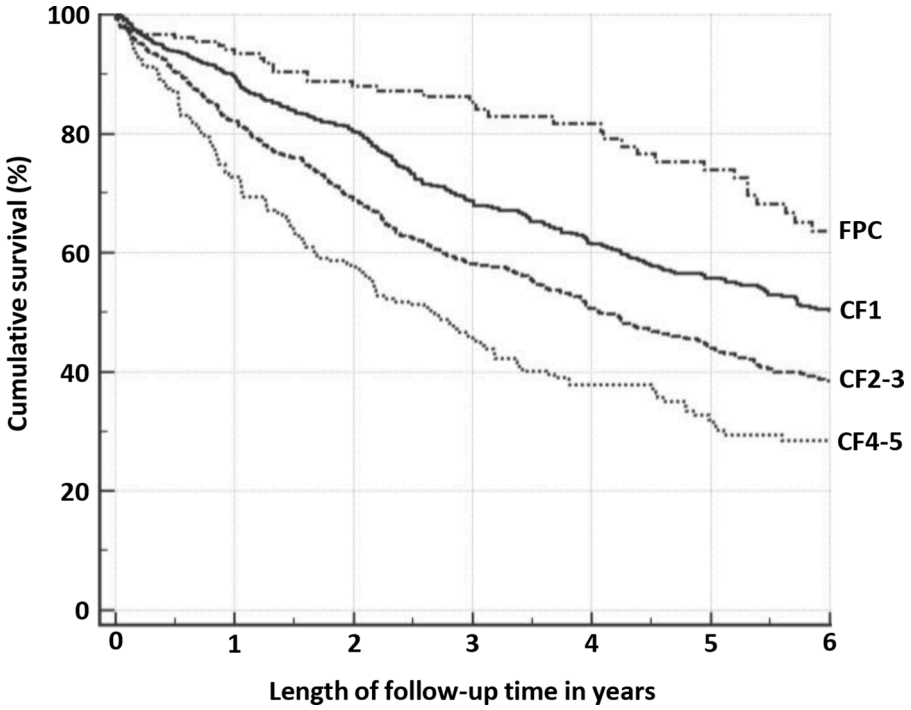

Fig. 2. The survival curves for dry mouth patients´ fixed prosthetic crowns and composites stratified by size (n = 1789). FPC: fixed prosthetic crowns, CF1: composite fillings covering one surface, CF2-3: composite fillings covering two or three surfaces, CF4-5: composite fillings covering four or five surfaces. The follow-up time was cut to six years because of low number of fixed prosthetic crowns beyond this point.

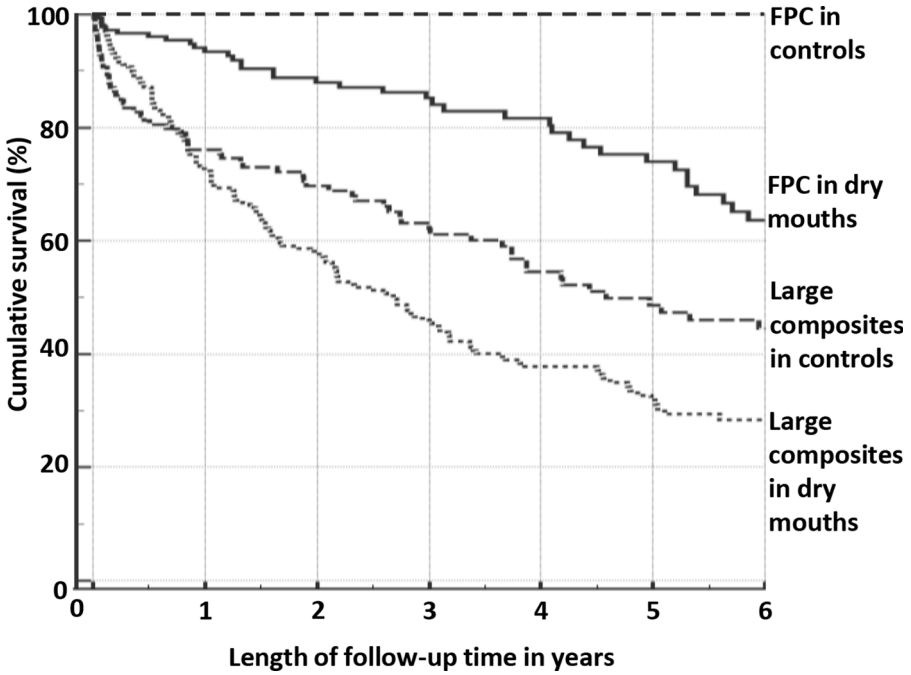

Fig. 3. The survival curves for fixed prosthetic crowns (n = 220) and large composites (covering four or five surfaces, n = 410) stratified by patient group (dry mouth or control patients). FPC: fixed prosthetic crowns. The follow-up time was cut to six years because of low number of fixed prosthetic crowns beyond this point.

patients stratified by the material of the preceding restoration. Compared to teeth with fixed prosthetic crowns the teeth with composites had hazard ratio of 4.97 (95% CI: 1.56-15.78) and the teeth with glass ionomer cement had hazard ratio of 15.16 (95% CI: 4.59-49.96) for extraction. The analysis was adjusted for number of surfaces in the restoration, tooth type plus patient sex and age.

4. Discussion

Despite the high prevalence of dry mouth and the high caries incidence associated with the dry mouth, this is the first time the effect size of dry mouth on restoration survival has been determined [1]. We found that the hazard ratio of the restorations in dry mouth patients was as high as 2.1-fold compared to the restorations in control patients.

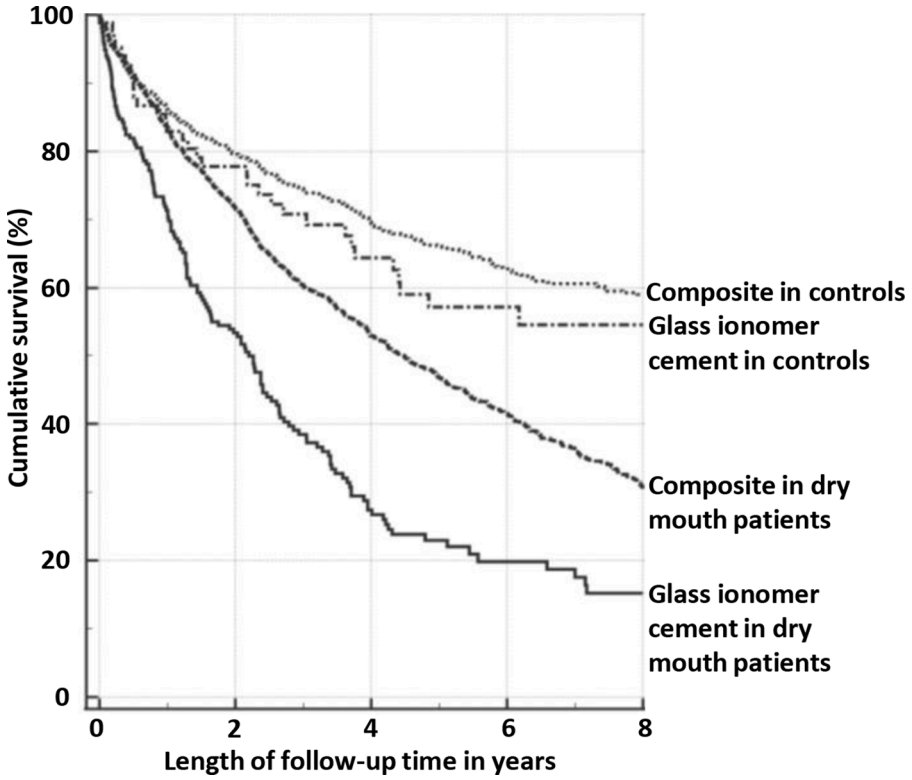

Fig. 4. The survival curves for class V fillings (n = 546) stratified by patient group (dry mouth or control patients) and filling material (composite or glass ionomer cement). The follow-up time was cut to eight years because the number of glass ionomer cement cases was low beyond this point.

Furthermore, the AFR for the dry mouth patients was three-fold compared to the control patients. Already now the majority of restorations are replacements [24]. But the presumable increase in the number of patients suffering from dry mouth would increase the proportion of replacements even further [20,22,23]. The newer cohorts of dry mouth patients are not only greater in number, but they also have more teeth than the cohorts we have been treating until now [21]. This will lead to an increasing number of teeth in dry mouths that need twice as frequent restoration replacements compared to the teeth in normal population.

The survival of restorations in Sjögren's syndrome or radiotherapy-induced hyposalivation patients was shorter compared to the patients with hyposalivation or xerostomia of unspecified etiology. The short survival of restorations in Sjögrenś syndrome and radiotherapy patients may result from saliva quality and/or secretion rate being even lower in these patients compared to the patients suffering from hyposalivation or xerostomia of unspecified etiology [25]. Although, other symptoms related to radiotherapy and Sjögrenś syndrome such as trismus or sensitive mucosa may hinder efficient oral hygiene and thus contribute to the short survival of restorations [26,27].

The survival of the composite fillings was longer than the glass ionomer cement fillings but shorter than fixed prosthetic crowns. In the patients suffering from dry mouth, the survival of composites of all sizes was shorter than the survival of fixed prosthetic crowns. But since the composite survival shortened as a function of size, the large composites had especially short survival in dry mouth patients. This short survival of large composites in dry mouth patients is information of great interest to the dry mouth patient for his/her decision-making of restorative material. However, in the data of this study the laborious and expensive fixed prosthetic crowns may have been placed in teeth with good prognosis (some coronal tooth substance left) whereas teeth with poor prognosis (very little coronal tooth substance left) may have been predominantly restored using the cheap and simple composite. Another source for bias is the lack of assessment criteria of the restorations. The difference in the survival of fixed prosthetic crowns and fillings may have resulted in part from clinicians´ lower threshold to replace the fillings than the far more expensive fixed prosthetic crowns. In general, there is insufficient data to support one restorative treatment or material over another [28,29]. However, the dry mouth patients presented a subgroup of patients whose fixed prosthetic crowns outlasted large composite fillings. This association should be however studied further in randomized controlled trial before any causal relations can be stated.

Of the studied restoration materials glass ionomer cement fillings had the shortest survival. Although, glass ionomer cement may have been used as temporary filling material or chosen for cases with very poor prognosis. Our results on class V restorations in dry mouth patients are in accordance with the previously published randomized controlled trials: composite has better survival than glass ionomer cement fillings [12,14]. The poor survival of glass ionomer cement fillings in class V fillings of dry mouth patients may result from the material drying out and losing some of its mechanical properties [30]. In control patients there was no difference between the survival of composite and glass ionomer cement fillings which is in accordance with the systematic review on class V restorations [31].

Our findings are in accordance with the previous findings that sex and tooth type are associated with the hazard ratio of restorations [15-19]. Although, the hazard ratio for dry mouth, restoration material and cavity size were far greater than the hazard ratio for sex and tooth type. One should take into consideration that the additive effect of several of these variables may result in drastic reduction of restoration survival. Many patient-related characteristics that are associated with restoration survival (e.g., oral hygiene and diet) were not accountable because they are not routinely registered in Public Dental Services records in Finland [32]. However, the patient-related characteristics we were able to account for (age and sex) had only a minor impact on our results on hazard ratios for dry mouth and restoration type.

Since caries adjacent to a restoration was the most common indication for restoration replacement for the dry mouth patients, the frequent replacement of the restorations increases the risk of "tooth death spiral"

i.e., continually enlarging replacement restorations leading eventually to the extraction of the tooth [33]. This death spiral hypothesis is supported by our finding that dry mouth patients had 2.0-fold hazard ratio for tooth extractions. Furthermore, the teeth with fixed crown prosthetics had the lowest hazard ratio of being extracted followed by composite and glass ionomer cement fillings. The small number of extractions in the data is a limitation of the study. In addition, the direct restorative materials may have been used in teeth with poor prognosis to start with. If that has been the case, the low hazard ratio for extraction found in teeth with fixed crown prosthetics may be explained mainly on the remaining tooth structure rather than on the restorative material. However, regardless of the invasive tooth preparation necessary for the fixed prosthetic crowns, few of them had been extracted. The middle-aged Sjögrens syndrome patients are missing three times more teeth than the normal population [34]. Our finding on high hazard ratio for tooth extractions in dry mouth patients is especially interesting as the number of teeth mediates the effect of xerostomia to lowered quality of life [35].

The most common dry mouth diagnosis was xerostomia followed closely by hyposalivation. However, many of the xerostomia patients may have had hyposalivation but the diagnosis had not been confirmed with saliva secretion rate test. There is no special subsidization of dental treatment for hyposalivation patients in Finland and therefore the differential diagnostics between xerostomia and hyposalivation has minor additional value for the patient. Patients with Sjögren's syndrome and hyposalivation resulting from radiotherapy to neck or head region are entitled to heavily subsidized dental care and salivary flow rate measurement is necessary to confirm the diagnosis. Sjögrens syndrome patients comprised almost a quarter of the dry mouth patients and radiotherapy-induced dry mouth patients a tenth of the dry mouth patients. The proportions of different dry mouth etiologies are however not representative. The small number of dry mouth patients in a city as big as Oulu may result from diagnostic lag or the dry mouth patients seeking dental care from private dental clinics [1,7]. The etiology for dry mouth was not registered for two thirds of our patients. The common etiological factors (age, female sex and polypharmacy) are probably etiological factors for many of these dry mouth patients [7-10]. It is unlikely that the number of medications would decrease significantly over time among polypharmacy patients [36]. But the salivary gland atrophy progresses over time [37]. As a result, there is only a small risk that some of our patients would have recovered from dry mouth during the observation time. Which justifies the use of onetime dry mouth diagnosis when assigning a patient into the dry mouth group.

A strength in a retrospective data collection study such as ours is that all fillings made by all dentists working for City of Oulu Public Dental Services have been included in the analyses, which reduces the selection bias of participants. The record-keeping of patient files is meticulous, and the coding is unified. As a result, only six of the observed 3208 restorations were omitted from analyses because of missing data. All Finnish citizens are allowed to receive dental care in the heavily subsidized public dental services, but it is still possible that some of our patients have chosen to attend private dentists at some point of the observation time. If this were to have happened, the data on those operations has not been available for us to collect in the public dental services database. An obvious limitation to our study is the lack of randomization, which may have resulted in selection bias when choosing restoration materials. Furthermore, retrospective data collection study is able to identify associations but not causal relations. To determine whether the fixed prosthetic crowns instead of large composite fillings actually causes longer survival time of a restoration, a randomized controlled trial would be necessary. However, the data collection studies and randomized controlled trials may complement each other.

5. Conclusions

Restoration and tooth survival were severely shortened in the dry mouth patients. Especially their glass ionomer cement fillings and large composite fillings (covering four or five surfaces) had short survival whereas the fixed prosthetic crowns had acceptable survival. When informing a dry mouth patient on the expected survival of a restoration, one should take into account that dry mouth patients' restorations and teeth have severely shortened survival time.

CRediT authorship contribution statement

Leinonen Jukka: Conceptualization, Formal analysis, Data curation, Writing – original draft, Visualization. **Vähänikkilä Hannu:** Formal analysis, Data curation, Writing – review & editing. **Raninen Ellinoora:** Investigation, Writing – original draft. **Järvelin Laura:** Investigation, Writing – original draft. **Näpänkangas Ritva:** Conceptualization, Writing – review & editing. **Anttonen Vuokko:** Conceptualization, Writing – review & editing, Supervision.

Declaration of Competing Interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgements

We would like to thank Päivi Harju for picking out the cases, and Tiia Järvistö and Heli Junell for their invaluable help with the data collection. We gratefully extend our gratitude to City of Oulu Public Dental Services for handing out their data to our disposal. This research did not receive any specific grants from funding agencies in the public, commercial, or not-for-profit sectors.

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