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Prediction of high caries increment in adults – a 5-year longitudinal study from North-East Germany

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1 Introduction

1.1 Objective of the study

The purpose of this study is to determine risk factors and risk indicators predicting high dental caries increment in adults (20 - 79 years) living in North-East Germany in order to develop a prediction model. The study is based on the longitudinal data obtained from the "Study of Health in Pomerania" at baseline (SHIP-0) and at the 5-year follow-up (SHIP-1).

1.2 Motivation for the study

Dental caries prevalence and incidence has decreased in the industrialized countries and even worldwide [Petersen et al. 2005]. Nevertheless, coronal caries in adults is still a major problem considering quality of life as well as treatment costs. Generally, in the industrialized countries a polarized distribution of caries can be observed, which emphasizes the need for an early identification of people at high risk of dental caries incidence in order to apply a time and cost effective preventive therapy [RKI 2009, Bratthall et al. 2005, Bader et al. 2001, Hausen 1997].

Therefore, dental caries as a multi-factorial, localized, infectious oral disease has been a target of studies for decades in order to find the right formula of risk factors and risk indicators predicting caries incidence in groups and individuals [Selwitz et al. 2007, Powell 1998]. Even so, most cross-sectional as well as longitudinal studies concentrated on examining children up to 16 years of age or elderly populations aged over 65 years. Only very few studies examined younger adult populations [Powell 1998]. Therefore, a need for longitudinal coronal and root caries incidence studies especially in adults remains evident [NIH 2001] and Hausen [1997] stated in a review that "… with present knowledge of dental caries no accurate prediction in an individual person or tooth is possible."

The prediction of caries incidence in children has been well investigated, as the main predictors are high baseline dmfs/t and low parental social status/educational status [Twetman and Fontana 2009, Alm et al. 2008, Tagliaferro et al. 2008, Reisine and Psoter 2001]. Contrarily, meaningful results in caries prediction in adults are rare, though it will become even more essential as the population in most parts of Europe is aging [Giannakouris 2008]. In a cohort study with a similar study objective and similar methods performed in elderly Mexicans, a practical prediction model using multiple

factors was developed for a 12-months root caries incidence [Sánchez-García et al. 2011]. Similarly, the aim of this study is to develop a prediction model for high increment of coronal caries in adults aged 20 - 79 years.

1.3 Special strengths of the study and its design

This study is based on the longitudinal data obtained from SHIP-0 (baseline) and SHIP-1 (5-year follow-up). Especially the large sample size as well as the collection of many different factors, which allows analyses of special combinations concerning oral, medical and socio-economic variables validates the outcome of the study. According to the World Health Organization (WHO) the standard representative adult populations are adults aged 35 - 44 years and seniors aged 65 - 74 years [WHO 1997]. Nevertheless, adults belonging to different age groups might have different risks of coronal caries. Therefore, adults aged 20 - 79 years at baseline (SHIP-0) were included in the Study of Health in Pomerania, which, to my knowledge, makes it one of the very few population-based longitudinal studies with dental data and, therefore, poses an excellent basis for statistical analyses [Hensel et al. 2003].

1.4 Clinical value

Building on the knowledge obtained from studies on caries prediction in children and adults in the past decade, the objective of this cohort study is to determine baseline risk factors and risk indicators predicting high dental caries incidence in adults. The identification of the patients at high risk of caries increment plays an essential role for the aim to decrease caries levels in general and for the reduction of the polarized distribution of caries experience as the distribution of caries has been changing due to population-based prevention [Burt 1998]. With an accurate prediction in this study group, which is thought to be representative for the aging population in Germany, preventive and restorative demands can be estimated. Furthermore, these results could be the basis for preventive strategies modifying major risk factors in adult populations [Hellwig and Altenburger 2011]. Moreover, group prevention could be started on the basis of the findings in this study as the adults at high risk of high caries increment could be identified. Consequently, a preventive approach could be established and the foundation can be laid whether the focus of prevention should be put on the high risk group concerning behavioural and socio-economical factors or on the entire population e.g. with the application of chemical substances [Ten Cate 2001].

2 Literature review

2.1 Aetiology and definition of dental caries

Dental caries as a multi-factorial, localized, infectious oral disease is seen as a process of chronic demineralisation of dental hard tissues involving the interaction of multiple biological factors such as the host (teeth and saliva), the agent (biofilm/dental plaque) and substrate (diet) over time and might affect dentate individuals a life long [Pschyrembel 2007]. Furthermore, the process of dental caries is not constant throughout life, occurring in time periods of an unbalanced shift towards the process of demineralisation and non-sufficient remineralisation and/or fluoride use [Fejerskov 1997 review]. Carious lesions can be localized on crown and root surfaces and are often defined depending on the stage of the process and its different therapeutic approach into initial caries, *caries media* and *caries profunda*. Initial caries lesions are non-cavitated, demineralised so-called white spots within the enamel, which can be treated with the application of fluoride. *Caries media* defined as a cavitated lesion reaching at maximum to the mid of the dentine is usually treated via filling therapy, whereas endodontic therapy or extraction might be necessary for *caries profunda*, which is described as a deeply cavitated lesion reaching into the 2nd half of dentinal tissue close to the pulp [Selwitz et al. 2007, NIH 2001].

2.1.1 Definition of the DMFT/S

DMFS is an index for decayed, missing and filled tooth surfaces due to caries, which was introduced already in 1938 [Klein et al. 1938]. It is used in dental epidemiology to characterize the coronal caries experience of a person on a surface level in contrast to the DMFT (decayed, missing and filled teeth), which stands for caries experience on a tooth level. The index is calculated for 28 permanent teeth excluding the wisdom teeth with 4 to 5 surfaces each. This leads to 128 surfaces, which can be affected by caries (experience) at maximum [Oral health database 2011].

2.2 Epidemiology of dental caries

2.2.1 Caries prevalence in the world

Worldwide, dental caries is still considered one of the main epidemic diseases as it affects major parts (60 - 90 %) of children and adult populations in industrialized and

developing countries [Peterson et al. 2005, Hobdell et al. 2003]. This holds true although its prevalence declined significantly in the past decades. The caries decline is displayed by the decrease of the decayed missing filled teeth index (DMFT) [WHO 2003]. Especially the underprivileged groups of all ages in the world suffer intensely under the burden of dental caries exhibited by a polarized distribution of caries prevalence [WHO 2003, Ten Cate 2001, Ettinger 1999].

2.2.2 Caries prevalence in the Western world

Despite the clear decline in dental caries in Western Europe, groups with a lower socio-economic status are more frequently affected by caries, due to the association between poor living conditions and an unhealthy lifestyle [Petersen and Yamamoto 2005], which affects dietary, smoking and drinking habits as well as oral health and hygiene behaviour. Dental caries becomes a burden especially for the aging and elderly population for the reason that the number of remaining teeth in adults increases [RKI 2009, Petersen et al. 2005, Ten Cate 2001].

2.2.3 Caries prevalence in Germany

In Germany, two large-scale representative studies recently collected national data on the prevalence of dental caries in different age groups of the population: The German Oral Health Survey called "Deutsche Mundgesundheitsstudie" (DMS) and the "Study of Health in Pomerania" (SHIP).

2.2.3.1 German Oral Health Survey (DMS)

In the fourth cross-sectional German Oral Health Survey "Deutsche Mundgesundheitsstudie IV" (DMS IV) completed in 2005, the oral health of in total 4,631 subjects was examined. The response was 63.1 % and the sample included 925 adults aged 35 - 44 years and 1,040 seniors aged 65 - 74 years [Micheelis and Schiffner 2006].

As in 1997 the third cross-sectional German Oral Health Survey (DMS III) was completed with 3,065 subjects with a response rate of 63.6 %, comparable data is available to observe caries incidence along with the identification of potential risk factors and risk predictors for dental caries in this eight year period [Micheelis and Schiffner 2006, Micheelis and Reich 1999]. For the first time, a decline in coronal caries prevalence in German adults could be observed. This decline is reflected by the decrease of the missing teeth (MT) component from 3.9 in DMS III to 2.4 in DMS IV

in adults aged 35 - 44 years and from 17.6 to 14.1 in seniors aged 65 - 74 years. These findings reflect that in the post-war generation extraction was a more common therapy, especially in the former GDR [Micheelis and Bauch 1996]. In retrospect, root caries prevalence increased in seniors, but remained on a similar level in middle-aged adults. In 1997, only 20.5 % of dentate seniors had root caries, whereas in 2005 already 34.6 % of this group had root caries, assuming that longer tooth life and periodontal treatment lead to gingival recession and therefore, put more teeth at risk of root caries [RKI 2009, Powell et al. 1998]. In DMS IV, adults aged 35 - 44 with a lower school education showed less satisfying oral hygiene, a low frequency of dental visits and significantly more caries experience, both for DMFS and root decayed filled surfaces (RDFS). The degree of filled surfaces (FS) was similar in all socio-economic classes, whereas the DT and MT component was significantly higher in subjects with a low socio-economic status [Micheelis and Schiffner 2006]. Even in seniors aged 65 - 74, DMFS scores were significantly connected to the level of school education, although school had been completed many decades ago. In contrast to the DMFS values, the root caries index (RCI) was not significantly connected to the degree of school education, but positively correlated to a better oral hygiene and more frequent dental visits, possibly as they were the only group with retained teeth. Seniors with a lower socio-economic status were at 2.9 times higher risk to be toothless than subjects with a high socio-economic status. A general relationship between oral health behaviour and general health behaviour could be identified. Smoking was found to be a significant risk factor for periodontal disease as the risk to develop periodontal disease was 8 times higher for smokers. Smoking also enforces cardiovascular disease and is often connected with alcohol consumption and/or a sweet diet. Thus, the body mass index (BMI) and especially the DMFS as well as the RDFS increased [Al-Habashneh et al. 2009, Micheelis and Schiffner 2006].

In adults and seniors carious lesions developed mainly interdentally and on root surfaces. Subjects with low school education, smokers and females were significantly at higher risk of caries [RKI 2009, Micheelis and Schiffner 2006].

2.2.3.2 Study of Health in Pomerania (SHIP)

In the cross-sectional survey SHIP-0 (20 - 79 years, response 69 %) 4,022 participants were orally examined from 1997 to 2001. After excluding 499 edentulous subjects (12 %) the remaining 3,523 were included in the dental examination collecting parameters for oral health including e.g. coronal caries (DMFT/S) and root caries (RDFS, RCI), periodontal parameters and restoration according to WHO guidelines

[Mack et al. 2004, Hensel et al. 2003, Splieth et al. 2003 and 2004]. In contrast to the polarized distribution of coronal caries, root caries filled surfaces (RDFS) were quite evenly distributed. For each subject, RDFS counts of one or two were common. The mean RDFS increased from 0.4 per individual aged 25 - 34 to 2.3 for each individual aged 55 - 64 and declined for older seniors due to fewer remaining teeth [Splieth et al. 2004]. RDFS were predominantly found on buccal surfaces, especially in lower premolars. 69.5 % of affected root surfaces were filled. In SHIP-0 the values of the RCI and the DMFS increased with age [Splieth et al. 2004]. Furthermore, dentate women had generally higher DMFS scores than men. Treatment needs due to primary or secondary carious lesions (DS) were low, while the caries prevalence was found to be high compared to Sweden or the USA, but on a similar level than nationwide data for Germany [Splieth et al. 2003]. Females of the representative age group for adults (35 - 44 years) had a DMFT of 9.5 ±2.6 (DMFS 34.0 ±14.1; DS 0.6 ±1.9), whereas men of this age group had lower caries experience with a DMFT of 8.2 ±2.9 (DMFS 27.4 ±14.0; DS 0.6 ±1.4). Women of the representative age group for seniors (65 - 74 years) had a clearly higher DMFT of 12.3 ±2.3 (DMFS 53.0 ±13.8; DS 0.2 ±0.8), while males in this age group again had a lower caries experience (DMFT of 11.9 ±2.7; DMFS 52.1 ±14.8; DS 0.3 ±1.1) [Splieth et al. 2003].

2.3   Definition of caries risk factors and risk predictors

Risk is the probability of a harmful event occurring during a certain period [Rodrick 1992]. Risk factors are variables obtained from cross-sectional data, which show a significant association with a certain harmful event (e.g. dental caries). Risk factors may not be necessarily aetiological factors, but they are used to create a risk model. In comparison, risk predictors detected in longitudinal studies are baseline factors with the ability to predict upcoming events and, therefore, are associated with the disease. Nevertheless, risk predictors are not necessarily causal factors; still, they are used in prediction models [Tagliaferro et al. 2008].

Relevant predictors need to predict an event with a high sensitivity, e.g. a true positive rate of 100 % means that all healthy people will be recognized as healthy, and a high specificity, e.g. a true negative rate of 100 % means that all sick people are recognized as being sick. For an accurate prediction, an accumulated specificity and sensitivity of 160 % is targeted [Hausen 1997, Kingman 1990]. The fraction of false negative results, which comprises sick subjects predicted to be healthy, needs to be as

low as possible. In a review, Powell [1998] pointed out that long time periods in incidence studies lead to a less precise sensitivity of a prediction model – possibly due to changes in the course of time.

Dental caries as a multi-factorial disease seems unlikely to be predicted by a single risk predictor [NIH 2001]. Despite high sensitivity and specificity values, the prediction in individual adults is difficult and often inaccurate [Söderholm and Birkhed 1988]. In order to justify the effort of special preventive treatment for identified caries high risk groups, these groups should not exceed one third of the population, otherwise the preventive treatment should be targeted at the entire population [Hausen 1997]. In addition, it is important for the application of a preventive strategy that dominant risk factors in high risk groups are susceptible to change [Sbaraini and Evans 2008].

In the following paragraphs an overview will be given on the risk factors identified in cross-sectional studies and the potential predictors of dental caries.

2.3.1 Oral factors

2.3.1.1 Caries experience

Most caries prediction models use an index for caries experience such as DMFS or DMFT scores as one of their key variables. DMFS/T and RDFS in adults refer to caries experience in the past which correlate with the subject's age and do not describe precisely the current caries activity at the point of investigation, whereas decayed coronal surfaces (DS) and decayed root surfaces (RDS) emphasize on the present situation [Fontana and Zero 2006]. Nevertheless, most studies on caries prediction in adults provide information that previous caries experience on coronal (DMFS) and/or root surfaces (RDFS) are strong predictors as they reveal the capability of the host to deal with the process of the disease [Selwitz et al. 2007, NIH 2001, Gilbert et al. 2000, Scheinin et al. 1994, Joshi et al. 1993].

In a 24-month incidence study on coronal caries in Florida/USA, baseline DS, FS and number of teeth were identified as significant baseline factors predicting dental caries incidence in adults [Gilbert et al. 2001]. One has to be aware that prosthetic restoration like crowns may play a key role for increased DMFS scores. It may not be unlikely that a vast majority of incident crowns were applied on teeth without active coronal caries [Gilbert et al. 2000].

The number of teeth has a highly significant influence on the RDFS index, as every single tooth with gingival recession is predisposed for the development of root

caries [Sugihara et al. 2010]. Loss of teeth reduces the possible amount of surfaces at risk for gingival recession and root caries. Therefore, the number of remaining teeth and their gingival recession are key factors in the development of root caries [Fure 2004, Splieth et al. 2004, Gilbert et al. 2001]. As the RDFS are generally quite low in epidemiologic surveys, the root caries index (RCI) represents the fraction of root caries/filling to the root surfaces at risk, emphasizing the root caries risk [Winn et al. 1996, Katz 1984].

In a 24-month incidence study of root caries in American adults, several variables related to caries experience like the "… presence of root decay, root filling(s), coronal decay, non-carious root defects, number of teeth present, percent of teeth with at least 4 mm of attachment loss" were identified as predictive baseline clinical conditions for root caries incidence [Gilbert et al. 2001]. These results stand in line with the finding that the "… best predictor for root caries in adults is past root caries experience" [Powell 1998]. Furthermore, Powell [1998] states in a review on caries prediction that interestingly "previous disease on root surfaces best predicts disease incidence on coronal surfaces, while previous disease on coronal surfaces is the best predictor of disease incidence on root surfaces."

As an explanation for the low but rising prevalence of root caries researchers emphasize that extractions were a common therapy in the post-war generation, especially in the former GDR and describe the shift to more endodontic treatment as a major reason for an increase in the number of remaining teeth and a higher risk for coronal and root caries [Splieth et al. 2004, Micheelis and Bauch 1996]. Moreover, loss of teeth or else a low number of remaining teeth can be seen as a marker of extensive dental disease and a rather surgical approach to its treatment [Sivaneswaran 2009].

In the Cariogram, which is a computerized risk assessment model using an algorithm of several variables, past caries experience is also one of the major factors used for caries risk assessment [Ruiz Miravet et al. 2007, Bratthall et al. 2005].

Still, the prediction in adult populations based on caries experience as a single factor has not been found to be accurate [Selwitz et al. 2007, Scheinin et al. 1994]. Whereas in children caries experience in the primary dentition is a highly significant predictor for caries incidence in the permanent dentition [Tagliaferro et al. 2008, Vanobbergen et al. 2001].

Fontana and Zero [2006] suggested to use the variable "caries activity" for caries prediction, which poses a different approach than caries experience. Caries

activity depends on the current amount and the severity of active carious lesions as well as plaque accumulation rather than DMFS values, which mostly refers to past caries experience and, therefore, do not necessarily reflect the caries activity at the examination point.

Nevertheless, with present knowledge the conclusion can be drawn that clinical parameters like caries experience on coronal and/or root surfaces as well as the number of remaining teeth are the most accurate predictors of caries incidence in adults [Gilbert et al. 2001, Powell 1998, Worthington et al. 1997].

2.3.1.2 Tooth morphology, tooth surface and position

In adults, root surfaces of anterior teeth along with premolars and interdental surfaces are more likely to develop coronal carious lesions [RKI 2009]. In a 10-year caries incidence study in Chinese adults, molars were most susceptible and lower anterior teeth least prone to coronal caries [Luan et al. 2000]. In a recent study in Chinese adults molars and premolars were most susceptible for root caries [Du et al. 2009], in contrast to earlier studies were upper canines and lower premolars [Hellyer et al.1990] or lower molars [Katz et al. 1982] were found to be most prone to root caries. In SHIP-0 root carious lesions were most common on buccal surfaces and in mandibular premolars [Splieth et al. 2004].

2.3.1.3 Saliva

The pH of dental plaque can fall below the critical value 5.3 after carbohydrate intake and leads to a localized demineralisation of dental hard tissues [Wilding and Solomon 1996, Stephan and Miller 1943]. Wilding and Solomon [1996] assumed on the bases of rare caries findings in lower incisors, as they stand near the outflow of salivary glands, that "If the total outflow of saliva can be increased, there is a greater chance of protection of all the teeth in the arch." As saliva contains calcium and phosphate ions remineralisation can take place. Therefore, the buffer capacity, the secretion rate and the composition of the saliva are thought to be relevant in decelerating the carious process and strengthening the physiological equilibrium of re- and demineralization [Selwitz et al. 2007, Wilding and Solomon 1996, Edgar and Higham 1995]. On the one hand, salivary flow and the composition have been identified as potential risk factors for caries in cross-sectional studies [Selwitz et al. 2007, Leone 2001, Reich et al. 1999] and were successfully used in a caries prediction model [Tamaki et al. 2009]. On the other hand, salivary flow rate and buffer capacity were not found to be significant risk

factors in a recent cross-sectional study in Kuwait in adult patients with severe caries [Akpata et al. 2009].

Subjects with xerostomia or hyposalivation, e.g. after radiation therapy or due to the Sjögren-syndrome, are more likely to develop caries [Craddock 2008, Leone and Oppenheim 2001]. Still, the prediction of caries incidence via salivary factors has not shown conclusive evidence. Nevertheless, with further research on saliva factors using modern proteomic techniques this field of research looks promising [Ligtenberg et al. 2007].

2.3.1.4 Bacteria

Streptococcus mutans and *Lactobacillus spp.* have been identified as the main microorganism involved in the carious process [Selwitz et al. 2007]. Therefore, microbial tests (e.g. Dentocult®) have been commonly used in studies investigating patient's caries risk and caries prediction models. High counts of salivary Mutans Streptococci and/or Lactobacilli were found to be significantly associated with coronal and root caries incidence especially combined with high sugar intake or past caries experience [Tamaki et al. 2009, Akpata et al. 2009, Nishikawara et al. 2006, Fure 2004, NIH 2001, Reich et al. 1999, Scheinin et al. 1994].

In a recent one year cohort study in elderly Japanese, the prediction of the risk group of coronal caries incidence was shown. The combination of a saliva test that recognises specifically secretory IgA against *Streptococcus mutans* and the modified Saliva Check SM was used for the detection of the high risk group [Senpuku et al. 2010].

2.3.1.5 Dental plaque

Dental plaque with its microorganisms is an aetiological factor of dental caries [Selwitz et al. 2007] and periodontal disease [Seneviratne et al. 2011]. Several dental plaque indices have been developed in order to monitor the patient's oral health and to determine the patient's caries risk. In some studies the caries risk increases with a rising plaque index [Al-Habashneh et al. 2009, Reich et al. 1999, Joshi et al. 1993].

In order to evaluate the patient's current caries activity and caries risk the quantity of plaque is relevant [Fontana and Zero 2006]. Furthermore, the amount of plaque is susceptible to change and therefore, is relevant in the control of the carious process [Sbaraini and Evans 2008].

2.3.1.6 Periodontal disease and gingival recession

Gingival recession frequently occurs after periodontal treatment and the arrest of periodontal disease. This leads to root surfaces, which are exposed directly to the oral environment and consequently gingival recession poses especially a potential risk for root caries [Yoshihara et al. 2007, Powell 1998]. Additionally, gingival inflammation has been found to be significantly associated with higher caries experience in young Swedish adults [Julihn et al. 2006]. Furthermore, the mean DMFT in Jordanian adults was significantly higher in patients with chronic gingival and chronic periodontal disease [Al-Habashneh et al. 2009]. The depth of the periodontal pocket was also related to root caries risk [Yoshihara et al. 2007] and an attachment loss of more than 4 mm was found to be predictive of coronal caries incidence [Gilbert et al. 2001]. Nevertheless, in a recent study investigating the risk profiles of root caries and periodontal disease no significant correlation was found between root caries and the severity of periodontal disease [Fadel et al. 2011]. The findings in a review on periodontal disease suggest in accordance to the non-specific plaque theory that insufficient oral hygiene correlates with gingival inflammation and periodontal disease [Manson and Waite 1983 review]. Moreover, considering that the natural progress of periodontal disease is low, the influence on DMFT is probably also low, as periodontal disease can actually only affect the MT component, which occurs late (> 50 years of age) in life [Neely et al. 2005, Löe et al. 1992].

2.3.2 Host factors

2.3.2.1 Age

As the DMFT/S and RDFS stand for accumulated caries experience, these indices increase with age: older age groups have higher caries experience [RKI 2009, Bratthall et al. 2005, Luan et al. 2000, NIH 2001]. Nevertheless, the number of DS, meaning unrestored carious defects, is generally low and has a tendency to remain constant or even decline throughout life [Splieth et al. 2003].

2.3.2.2 Gender

Female gender has been identified as a potential risk factor for higher dental caries experience in the Western World. Women generally show higher DMFS scores than males [Armfield et al. 2009, Selwitz et al. 2007, Micheelis and Schiffner 2006, Splieth et al. 2003], as they attend the dentist regularly and undergo dental treatment at an

earlier point [Astrøm et al. 2011]. One can speculate that these higher DMFT/S values are, therefore, due to a higher oral rehabilitation rate, which means more restorations (e.g. fillings, crowns or bridges) and consequently more affected surfaces due to dental treatment.

2.3.2.3 Genetic factors and immune system

An isolation of genetic factors is principally complicated, but through twin studies the hypothesis of genetic contribution to dental carries risk has been underlined in various studies and was summarised in a review. Shuler [2001] stated that "inherited disorders of tooth development with altered enamel structure increase the incidence of dental caries." This means that inheritance plays a role in the susceptibility and the resistance to dental caries since it contributes to the development of dental hard tissues such as mineral content, enamel porosity, enamel proteins, to altered immune response and sugar metabolism as well as to the function of salivary glands.

2.3.2.4 General medical factors

General health conditions like cardiovascular and cerebrovascular diseases or diabetes, have similar risk factors as oral diseases like caries and periodontitis [Zoellner 2011 review]. Important risk factors are, e.g. specific dietary habits, tobacco and alcohol abuse. A clear differentiation between the disease and the habit as a risk factor or just as a marker seems difficult because the habits affect the disease and the other way around. Hypertension and cancer are common diseases in aging populations, especially in subjects with tobacco and alcohol abuse [Peterson et al. 2005]. Moreover, altered immune response induced by HIV/AIDS or immune suppressive medication poses an increased risk to dental caries incidence [Madigan et al. 1996].

Diabetes

Diabetes has been called the 6th complication of periodontal disease [Löe 1993]. Diabetics are at rising risk of root caries due to deeper periodontal pockets and gingival recession. But after severe stages of periodontal disease they are at lower risk of root caries as the number of teeth decreases [Yoshihara et al. 2007].

In a study on caries risk in children with diabetes type I a "statistically significant positive relationship between caries risk and metabolic control was found, with a sevenfold increased risk of impaired metabolic control after 3 years in those assessed with high caries risk at onset (OR 7.3; $p < 0.01$)" [Twetman et al. 2003].

Hypoalbuminaemia

Serum albumin is used as a practical indicator of general health status in elderly individuals. In a 6-year longitudinal study in 266 randomly selected 70 year-olds in Japan, a decreased level of serum albumin was found to be associated with higher root caries prevalence and concluded that therefore,"...persons with hypoalbuminaemia are at high risk for root caries" [Yoshihara et al. 2007].

Xerogenic medication

The hypothesis that xerogenic medication results in an increased development of carious lesions seems to be a logical approach to the clinical observation that patients with radiation therapy in the area of salivary glands are highly susceptible to caries [Thomson et al. 2002]. Additionally, higher salivary flow seems to be a caries protective factor [Wilding and Solomon 1996]. Nevertheless, only few longitudinal studies have investigated this premise and surprisingly no strong evidence for an association between xerogenic medication and caries has been identified [Thomson et al. 2002].

2.3.3 Behavioural factors

2.3.3.1 Diet

The nutrients and minerals of the diet have direct and indirect effects on the caries risk. The dynamic caries process is influenced by the composition and the pH of the saliva, which itself is influenced by the diet [Touger-Decker and van Loveren 2003].

Subjects with hereditary fructose intolerance have statistically lower caries experience than control groups, which is quite directly connected to a diet with reduced intake of cariogenic sugars [Shuler 2001]. Caries incidence strongly depends on the frequency of sugar/carbohydrate intake and its time of exposure to the dental hard tissues [Burt and Pai 2001, Krasse 2001, Gustaffson 1954], which nowadays is often increased due to regular soft drink consumption [Burt et al. 2006]. An increased body mass index (BMI) associated with an unhealthy and misbalanced diet was also found to be related to a higher DMFS in a representative group of low-income African-American adults [Burt et al. 2006]. Diets containing lots of cheese and other milk products may decrease the caries risk as well as using sugar-free, alcohol-based chewing gums [Touger-Decker and van Loveren 2003]. In a retrospective longitudinal study on the correlation between diet intake and dental caries in Japanese seniors a

positive association between a milk and milky product diet and root caries prevalence was depicted [Yoshihara et al. 2009]. Still, caries prediction using single dietary variables is less reliable than combinations of dietary factors (amount/frequency of sugar, food adhesiveness and dietary fluoride exposure), which is due to the complexity of dietary patterns [Ruxton et al. 2010].

2.3.3.2 Smoking

In a recent cross-sectional study in young Jordanian adults the mean DMFT was significantly higher in smokers of all ages [Al-Habashneh et al. 2009]. In accordance with earlier findings cigarette smoking correlates with a deterioration of periodontal conditions also in a representative population in Japan [Ojima et al. 2006], leading to a higher risk of root caries incidence. In a 10-year longitudinal study in Swedish elderly the number of cigarettes or else the amount of tobacco was identified as one of the predictors of coronal and root caries incidence [Fure 2004]. Smoking poses a severe risk to multiple general health conditions [Department of Health, Education, and Welfare (USA) 1985] and, therefore, could be seen as a confounding factor for low health competence [Peterson et al. 2005].

In the above-mentioned 12-months longitudinal study with a similar study objective and similar methods, the prediction model included amongst others the variable smoking [Sánchez-Garcia et al. 2011].

2.3.3.3 Dental anxiety

Dental care has been detected in several studies to play a role in caries incidence [Beck and Drake 1997, Powell 1998]. In the 24-month longitudinal Florida Dental Care Study the attitude and the approach towards dental care were baseline factors predicting coronal caries incidence. Regular attendees of dental services were found to benefit with fewer dental symptoms and lower coronal caries incidence [Gilbert et al. 2000]. In the National Survey of Adult Oral Health (NSAOH) in Australia a significant relationship between dental fear and higher DT, higher MT and a lower FT could be identified [Armfield et al. 2009]. In an epidemiological survey on German soldiers, who had to attend dental check-ups, anxious individuals had significantly higher numbers of carious lesions (DS). Nevertheless, the results do not conclude specifically whether caries experience causes dental anxiety or, in retrospect, if dental anxiety poses a risk to higher DS [Eitner et al. 2006].

2.3.3.4 Frequency of tooth brushing

A decrease of invasive treatment as well as the shift to more preventive therapy could be observed since the access to regular fluoride use in 1971, e.g. from fluoride containing tooth paste [Mjör et al. 2008]. In Helsinki, a representative study was conducted on 5,028 dentate Finnish adults aged 30 years and older. The subjects with a higher self-reported frequency of tooth brushing showed a lower prevalence of root caries [Vehkalahti and Paunio 1988]. Whereas, in a more recent study in the USA no statistically significant relationship between a self-reported low frequency of tooth brushing and more surfaces with root caries was recognized [Reisine and Psoter 2001].

2.3.4 Socio-economical and financial factors

In children, socio-economic factors like the mother's education or the father's income have been identified as one of the best predictors for dental caries [Tagliaferro et al. 2008]. In adults, lower socio-economic status was identified as a risk factor for dental caries due to reduced access to dental care as well as lower desire for dental care [NIH 2001]. Furthermore, the socio-environmental context plus the state health care system play an important role in aging populations receiving dental care. Especially immobile elderly are in rising need for dental care, but in Western Europe, they are not fully able to obtain dental services [Holm-Pedersen et al. 2005]. Reisine and Psoter [2001] reviewed selected socio-economic variables and concluded that the relationship between low socio-economic status and higher caries prevalence is weaker in adults 18 - 64 years of age than in children. Furthermore, they criticized the inconsistency and the variation in the measurement of the socio-economic status.

As the income and the type of occupation generally highly correlate with the socio-economic status, consequently these easily collected variables were also used in caries prediction studies. In the NSAOH Australian adults with a low income and no dental insurance had higher scores of DT and DMFT [Armfield et al. 2009, Sivaneswaran 2009]. In China low income was also observed as one of the socio-economic risk factors of root caries [Du et al. 2009].

2.3.4.1 Education

In schoolchildren the mother's level of education is a significant predictor of caries incidence [Tagliaferro et al. 2008]. In a life-course model for adolescents, the school grade was also associated to dental caries prevalence [Nicolau et al. 2003]. Moreover, in Istanbul/Turkey subjects with a low or no education belonged more frequently to the

Significant-Caries-Index-group (SiC-group). This means that subjects with lower education levels were at higher risk to belong to the high caries group [Namal et al. 2008]. In a representative African-American low-income adult population, the DMFS rises with higher education which stands in contrast to the findings of many other studies in the Western World [Burt et al. 2006]. A plausible comparison could be drawn to the Third World where rising wealth usually coincides with higher availability and consumption of refined sugars [Yabao et al. 2005]. Amazingly, in a 5-year longitudinal study on caries increment in elderly inhabitants of Helsinki/Finland it was also concluded that "within the limitations of the study the level of education of elderly is not directly associated with the increment in caries" [Siukosaari et al. 2005]. Contrarily, in the NSAOH Australian adults (18 - 65 years) with lower education had higher DT and higher DMFT scores [Sivaneswaran 2009]. This general trend was also confirmed in a recent cross-sectional study where Danish adults with a low education had significantly higher DMFS scores [Krustrup and Petersen 2007]. The German Oral Health Survey DMS IV revealed a similar, statistically significant association for carious defects and low school education [RKI 2009, Micheelis and Schiffner 2006].

2.3.4.2 Ethnicity

In a cross-sectional survey on young Swedish adults, a foreign-born mother was identified as a risk factor for dental caries prevalence [Julihn 2006]. Moreover, in another large-scale cross-sectional study on root caries in Chinese adults, subjects belonging to an ethnic minority were at higher risk for root caries [Du et al. 2009]. In Florida/USA race was even identified as a predictive baseline factor for caries incidence in the 24-month incidence study of coronal caries [Gilbert et al. 2000]. Nonetheless, one has to consider that this factor might rather depict the socio-economic status or health behaviour than genetic influence.

## 2.4 Summary of the main caries risk factors and predictors

In children a conceptual model summarizing many of the presented caries risk factors was developed [Fischer-Owens et al. 2007], which might outline a concept for adults (Figure 1).

2.4.1 Caries risk factors

In most cross-sectional studies low socio-economic status, low education and smoking was significantly related to a higher caries experience. Furthermore, higher age, higher

intake of sugar containing drinks and female gender correlated with more caries experience.

Figure 1: A conceptual model of child, family, and community influences on the oral health outcomes of children [Fischer-Owens et al. 2007].
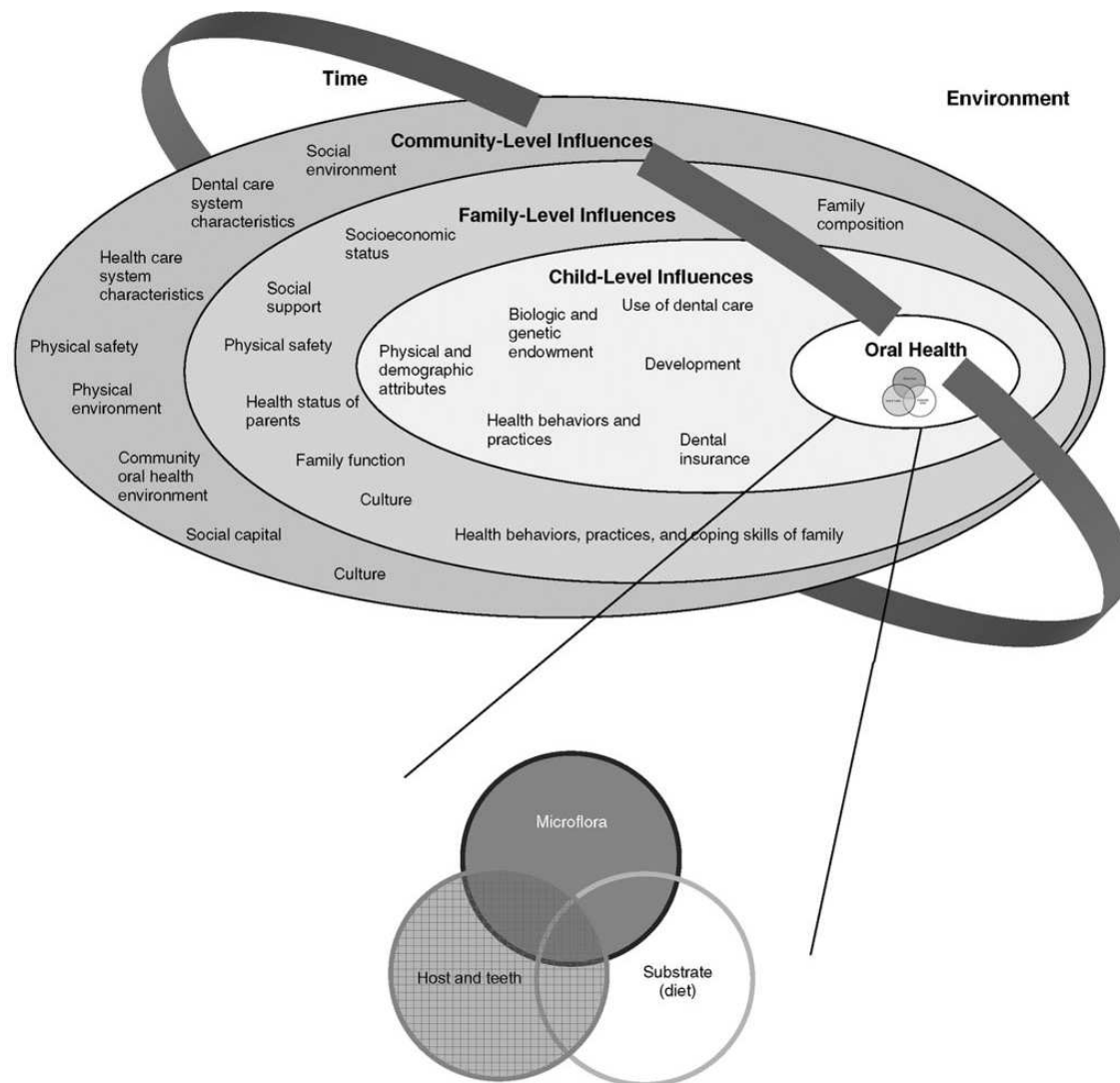
2.4.2 Predictors of caries incidence

The most practical predictors of caries incidence have been past caries experience and the number of remaining teeth, as they are clinically, easily available variables. In several studies high counts of *Streptococcus mutans* and *Lactobacillus spp.* were associated with higher coronal and root caries incidence. In contrast to the findings in cross-sectional studies, the prediction of caries incidence in adults via the factors low socio-economic or financial status has been low. Contrariwise, in children the long-term influence of the socio-economic status on high caries increment has been shown.

3 Material and methods

3.1 General study sample and design

3.1.1 Baseline examination SHIP-0

This population-based epidemiological health survey in the federal state Mecklenburg-Vorpommern (M-V) in North-East Germany "Study of Health in Pomerania" (SHIP) is an ongoing longitudinal study with a time spread of about 5 years. From a total number of 212,157 people living in the study area of Western Pomerania at the last population count in December 1995, an age- and sex-stratified sample was randomly drawn according to a two-stage stratified and cluster sampling scheme. The study region was defined by the 3 cities Stralsund, Greifswald and Anklam and their rural districts excluding the islands of Usedom and Darß (Figure 2).

Figure 2: Map of the geographical location of the study area
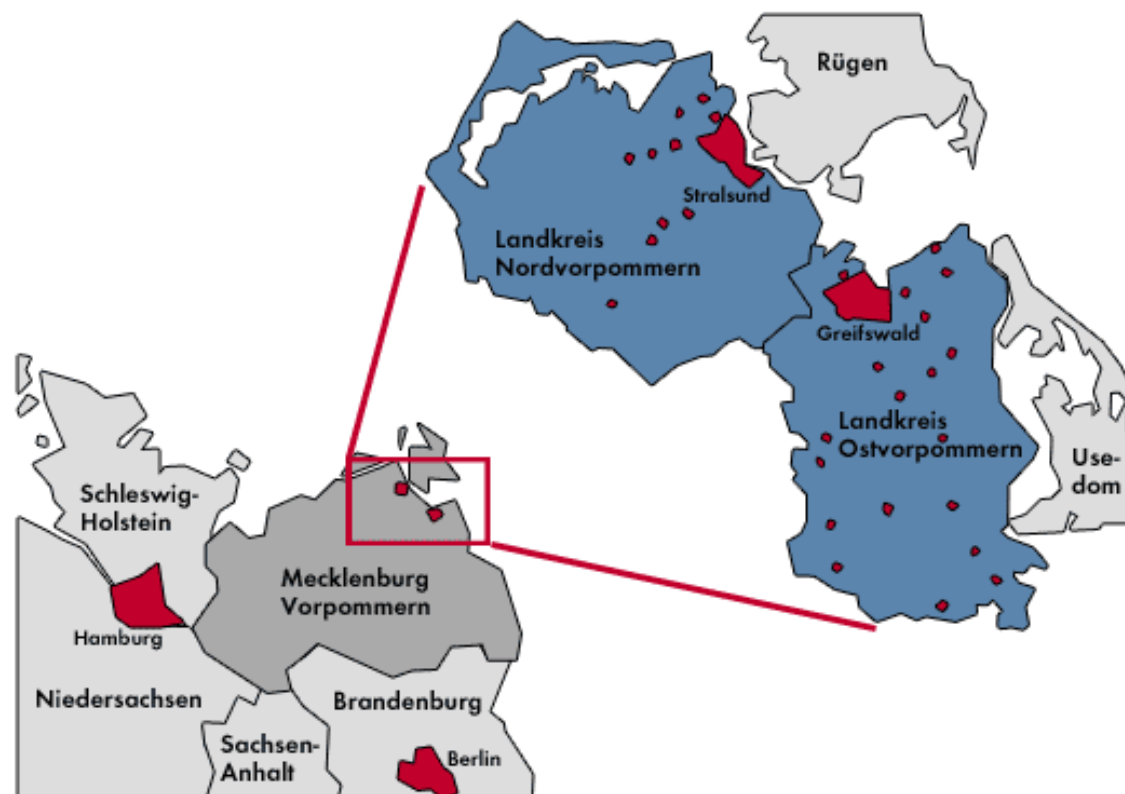
www.medizin.uni-greifswald.de/cm/fv/ship/stud_desc_en.html

At first, communities called primary sampling units (PSUs) were drawn at random within these 3 regions. Every PSU with more than 1,500 inhabitants was included in the

target sample, whereas from the smaller PSUs, only a subset was chosen at random. In the second stage, the population of the selected cities and communities was divided into 24 strata according to gender (male/female) and 5-year age groups. The test persons reflecting the population in the smaller communities and the larger cities were sampled from these strata (Table 1).

Table 1: Response of the net sample in SHIP-0 according to gender and age (5-year age group) [modified Community Medicine Research Net 2012]

Contacted		Drop-outs		Participants	
	N	N	%	N	%
Total	6,267	1,957	31.2	4,310	68.8
Men					
20 - 29	475	164	34.5	311	65.5
30 - 39	501	154	30.7	347	69.3
40 - 49	538	182	33.8	356	66.2
50 - 59	540	162	30.0	378	70.0
60 - 69	544	140	25.7	404	74.3
70 - 79	508	187	36.8	321	63.2
Total	3,106	989	31.8	2,117	68.2
Women					
20 - 29	475	114	24.0	361	76.0
30 - 39	528	129	24.4	399	75.6
40 - 49	543	147	27.1	396	72.9
50 - 59	561	131	23.4	430	76.6
60 - 69	543	189	34.8	354	65.2
70 - 79	511	258	50.5	253	49.5
Total	3,161	968	30.6	2,193	69.4

Due to the low proportion of the population of M-V compared with the population of Germany and the low number of foreigners living in the study area, foreigners were not included in the study design. Baseline data (SHIP-0) were collected in centres stationed

at Greifswald and Stralsund between the 16th of October 1997 and the 19th of May 2001. The net sample without migrated persons or passive non-responders (N = 615) anddeceased persons (N = 126) included 6,267 people aged 20 - 79. 4,310 persons were examined, which resulted in an overall response rate of 68.8 % [Haring et al. 2009]. After quality assurance and data control the number of the study sample was corrected, as 2 participants were examined twice (N = 4,308). The response of the net sample in SHIP-0 is presented in detail in Table 1.

The rate of response was slightly higher in women (69.4 %) compared to men (68.2 %). Looking at the different age groups the response varied in women from 76.6 % in the 50 - 60 year-olds to 49.5 % in the 70 - 80 year-olds, and from 74.3 % (60 - 70 years) to 63.2 % in the 70 - 80 year old men (Table 1) [Community Medicine Research Net 2012].

More detailed information on the response also in comparison to other studies has been published elsewhere [Latza et al. 2004].

Data collection at baseline consisted of four parts: medical examination, oral health examination, computer-aided interview and a self-administrated questionnaire. This information was recorded online into a computerized databank [Community Medicine Research Net 2012].

The methods applied in SHIP have been described in detail in a former publication [John et al. 2001]. Coronal and root caries prevalence in SHIP-0 has been published already [Splieth et al. 2004 and 2003].

3.1.2 5-year follow-up SHIP-1

All participants in SHIP-0 were invited again for the 5-year follow-up (SHIP-1). The subjects were examined between the 23rd of October 2002 and the 1st of September 2006 in Greifswald. The data was collected according to the data collection in SHIP-0 including again a medical examination, an oral health examination, a computer-aided interview and a self-administrated questionnaire. 3,300 of the 4,308 participants in SHIP-0 took part in SHIP-1 (response rate = 76.6 %). Meaning that 1,108 subjects were lost to the follow-up examination, of which 231 subjects died between the two studies and 130 subjects were passive non-responders due to migration. 649 subjects refused to participate and were labelled active non-responders. The follow-up response proportion was then 85.3 % [Community Medicine Research Net 2012, Haring et al. 2009].

The recruitment procedures performed in SHIP and its effects on attrition and bias have been published in detail elsewhere [Haring et al. 2009].

3.2 Study area and its population

As the "Study of Health in Pomerania" is a population-based epidemiological longitudinal health survey a vast description of the study area and its population is essential. A population can be described by several factors: age, gender, birth rate, death rate, the migration of the population and the educational status. Moreover, the life expectancy of the population helps to describe the life-quality and the health of the population (Figure 3, Table 2). Additionally, the time frame (in this case: the decade after the reunification of Germany) has to be taken into consideration [Statistical Institute M-V 2011].

Figure 3: Development of the population in Mecklenburg-Vorpommern from 1990-2010. The figure portrays the number of people who moved-in and moved-out as well as the relation between the number of life-births and the people who died [modified from Statistical Institute M-V 2011].
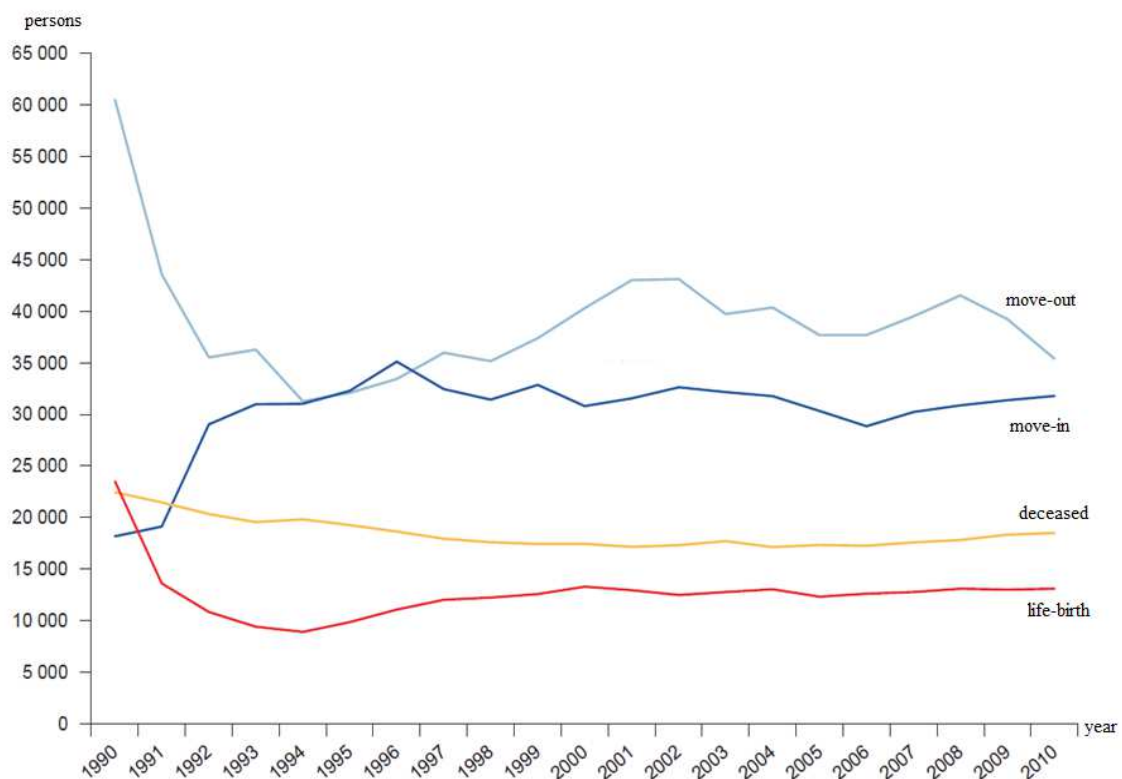
www.statistik-mv.de/cms2/STAM_prod/STAM/_downloads/Bevoelkerung/Bevoelkerung2011.pdf

In 2001, the life expectancy of men in Mecklenburg-Vorpommern was 72.5 years for a new-born, 74 years for a 30 year-old, 76 years for 50 year-old and 81.5 years for a 70 year-old. In contrast to men, women have a considerably higher life-expectancy. The life-expectancy for a female new-born was 80 years, for a 30 year-old almost 81 years,

for a 50 year-old almost 82 years and for a 70 year-old 84.5 years [Statistical Institute M-V 2011]. All further information can be obtained from Table 2.

Table 2: Descriptive data on the population of Mecklenburg-Vorpommern
[modified from Statistical Institute M-V 2011]

Attribute	1991	2000	2005	2010
Population at 31st Dec. of the year	1.891,700	1.775,700	1.707,300	1.642,300
Male	920,700	877,700	846,200	813,300
Female	970,900	898,000	861,000	829,000
Inhabitants per km²	79	77	74	71
Foreign population	9,800	33,600	39,400	39,000
Private households	742,500	820,100	833,600	853,100
One person households	179,800	280,000	302,000	344,300
Multi person households	562,700	540,100	531,600	508,800
Life-births	13,635	13,319	12,357	13,337
Deceased	21,477	17,460	17,384	18,738
Move-in	19,123	30,829	30,340	31,745
Move-out	43,583	40,307	37,692	35,375
Pupils attending school	287,696	227,420	157,409	129,444
Students	13,260	27,171	34,690	39,562

www.statistik-mv.de/cms2/STAM_prod/STAM/de/bhf/index.jsp

www.statistik-mv.de/cms2/STAM_prod/STAM/de/gb/index.jsp

All over the years from 1990 till today the number of migrated persons has always exceeded the number of the people who moved into the county. The total loss of population due to migration each year decreases though from 24,460 in 1991 to 3,630 in 2010 (Table 2). Similarly, the number of deceased people has exceeded the number of life-births in this time frame (Figure 3). This shows that the number of people who died or moved away during the time frame of this study quite precisely reflect the demographic changes of the population in the entire county of Mecklenburg-Vorpommern.

3.3 Oral health examination and quality assurance

The dental examination was performed by eight licensed dentists. Before the data collection started and twice a year during data collection, they received training in assessing these measures and indices by a certified cariologist. All examinations were conducted in a dental chair with professional illumination and without the use of a saliva ejector or an air jet. At baseline, 4,022 participants took part in the comprehensive oral examination [Hensel et al. 2003]. 499 edentulous persons were excluded from further dental examination. In the remaining 3,523 dentate participants of SHIP-0, coronal caries was diagnosed visually using a probe to touch the tooth surface softly, which stands in accordance to the guidelines of the World Health Organization [WHO 1997]. Primary and secondary caries as well as enamel and dentine caries were recorded separately. Coronal caries was examined on a surface level in order to calculate the number of carious defects, missing, filled surfaces (DMFS) [Oral health database 2011] in a half-mouth design after no statistically relevant right-left difference was detected in the pilot phase [Community Medicine Research Net 2012]. This stands in accordance to the findings of Gülzow and Maeglin [1964]. Therefore, the half-mouth method was considered to present a realistic view of the caries prevalence [Hensel et al. 2003].

As premolars, first and second molars have 5 surfaces and anterior teeth 4 surfaces each, at maximum 64 surfaces can be affected by caries in this half-mouth design (Figure 4). For the examination of the periodontal situation the periodontal probe PCP 11 (Hu Friedy, Chicago, IL) was used.

In the final quality control in caries diagnostics Cohen's kappa reliability coefficients [Fleiss 1981] of 0.9 - 1.0 (intra-examiner) and 0.93 - 0.96 (inter-examiner) were attained. Quality assurance and control during the study consisted of semi-annual interim analyses, renewed certifications and specialist seminars. The interim evaluations were used to identify implausible examiner differences, the frequency of entering 'data not collectable', undefined missing entries and mean examination time per examiner as well as other implausibilities [Hensel et al. 2003]. Semi-annually, these results were reported to an external Data Safety and Monitoring Committee.

Figure 4: Excerpt from the original dental examination sheet for the DMFS. The data sheet shows that data collection is performed in the half-mouth-design. All incisors and the canines have 4 surfaces each. The premolars and molars have 5 surfaces each: palatinal (p) or lingual (l), buccal (b), distal (d), mesial (m), occlusal (o). Moreover, a differentiation is made between healthy (= 0), enamel defect (= 1), dentine caries (= 2 and 3), filling (= 4), secondary caries (= 5), extracted (= 6) and others (= 7), not obtainable (= 8). [Community Medicine Research Net 2012]

DMF-S-Index

Teilnehmer-Nr.:

P
B
D
M
O   Oberkiefer

7 6 5 4 3 2 1

Kennzeichnung

0	gesund
1	Schmelzdefekt
2	Dentinkaries <=3mm
3	Dentinkaries > 3mm
4	Füllung
5	Sekundärkaries
6	extrahiert
7	Sonstiges
n	nicht erhebbar

7 6 5 4 3 2 1

O
M
D   Unterkiefer
B
L

www.medizin.uni-greifswald.de/cm/fv/dokumente/SHIP0_Zahnmedizinische_Untersuchungen.pdf

The interview was conducted by two trained professionals. The number of teeth was determined by a full-mouth examination with a maximum of 28 teeth. An excerpt from the dental questionnaire is presented in order to get an idea of the data acquisition (Figure 5). The definitions of the dental variables and the Exposure variables are presented in the following sub-chapter.

Figure 5: Excerpt from the dental questionnaire including the most important variables applied in the model. [Community Medicine Research Net 2012]

ZAHN- UND MUNDGESUNDHEIT

UNT.-Nr.: «USUCHER» UNT.-Zentr.: «ZENTRUM» UNT.Datum: «DATE»
Teiln.-Nr.: «TEILN_NR» UNT.Zeit: «START»

1	Haben Sie noch eigene Zähne?		| «EIGZAHN» |
(239)	1	Ja	**EIGZAHN**
	2	Nein	⇒5
	8	Weiß nicht	
	9	Antwort verweigert	
2	Wie empfinden Sie den Gesundheitszustand Ihrer Zähne?		| «GESZAHN» |
(240)	1	Sehr gut	**GESZAHN**
	2	Gut	
	3	Zufriedenstellend	
	4	Weniger gut	
	5	Schlecht	
	8	Weiß nicht	
	9	Antwort verweigert	
3	**Die Menschen putzen sich unterschiedlich oft die Zähne. Wie oft putzen Sie sich gewöhnlich**		
(241)	**die Zähne?**		| «PUTZ1» |
	1	3mal täglich und öfter	**PUTZ1**
	2	Normalerweise 2mal täglich	
	3	Normalerweise 1mal täglich	
	4	Mehrmals pro Woche	
	5	1mal pro Woche (oder seltener)	
	8	Weiß nicht	
	9	Antwort verweigert	
4	**Ist Ihnen schon einmal von zahnärztlichem Personal gezeigt worden, wie man sich seine**		
(242)	**Zähne putzen soll?**		| «PUTZ2» |
	1	Ja	**PUTZ2**
	2	Nein	
	8	Weiß nicht	
	9	Antwort verweigert	
5	**Wie sind Sie mit dem Aussehen Ihrer Zahnreihen zufrieden?**		| «AUSSEHEN» |
(243)	(Auch von Zahnersatzträgern beantworten lassen!)		**AUSSEHEN**
	1	Sehr zufrieden	
	2	Zufrieden	
	3	Weniger zufrieden	
	4	Unzufrieden	
	7	Entfällt	
	8	Weiß nicht	
	9	Antwort verweigert	
6	**Wann waren Sie das letzte Mal bei Ihrer(m) Zahnärztin/Zahnarzt?**		|«ZAHNARZT»|
(244)	1	Innerhalb der letzten 6 Monate	**ARZTWANN**
	2	Innerhalb der letzten 7-12 Monate	
	3	Vor mehr als 1 Jahr	⇒7
	8	Weiß nicht	
	9	Antwort verweigert	
6a	**Wie oft waren Sie in den letzten 12 Monaten beim Zahnarzt?**		| «ZAHNFREQ» | mal
(244a)			**ZAHNFREQ**
	98	Weiß nicht	
	99	Antwort verweigert	

www.medizin.uni-greifswald.de/cm/fv/dokumente/SHIP0_Zahnmedizinisches_Interview.pdf

3.4 Selection of the study sample for analyses

4,022 of the 4,308 participants in SHIP-0 participated in the oral examination. Oral data on caries, periodontal disease, etc. was collected from 3,523 dentate subjects as 499 were edentulous. In SHIP-1, the 3,300 responding participants were asked to be re-examined orally according to the criteria set in SHIP-0. The loss of 1,108 participants

in the follow-up as previously mentioned was due to migration, death and active non-response during this 5-year period and still resulted in a high response proportion of 83.6 %.

Longitudinal data of the oral examination concerning caries increment was available in 3,184 subjects out of the 3,300 participants in the follow-up as few participants (N = 116) disagreed to undergo the dental examination. 426 of these 3,184 subjects were edentulous at baseline and were excluded from further analyses, leaving 2,758 (1,334 male and 1,424 female) participants in the study group. The exclusion of the edentulous participants founded in the obvious matter that these patients bias the statistical findings. Edentulous participants cannot have any caries incidence. In addition, the outcome of the prediction of caries increment would be weaker as the suspected high risk group (e.g. edentulous) could not present any further caries increment. Furthermore, subjects with a baseline DMFS > 55 were excluded (N = 189) from statistical analyses, as they by definition cannot belong to the high caries increment group ($\geq$ 9 surfaces of caries increment), while belonging to the high caries risk group regarding the DMFS as the marker of caries experience. Similarly to the edentulous, these subjects would bias the findings. At last, few participants (N = 4) with an age > 79 years were excluded as this age group is too small for an adequate analysis and interpretation. A drop-out analysis was performed and presented in a separate chapter below.

The entire process of the selection of the final study sample can be obtained from a consort diagram on the following page (Figure 6).

Up to 20 missing cases ($\approx$ 1 %) have to be noted in the prediction models as these few participants lack data on any of the applied variables.

For an overview, the age of the subjects in the study group is enlisted according to 5-year age groups in Table 3. All age groups consist of at least 140 till at maximum 307 subjects which refers to 5 - 12 % of the sample each. Merely, the number and the percentage of adults in the older age groups (> 70 years) are relatively small and, therefore, the results on caries incidence in these age groups should be looked at with caution (Table 3).

Figure 6: Consort diagram: Flow-chart of the selection of the study group from sampling to the final study sample used for statistical analyses displaying the drop-outs at the different stages.
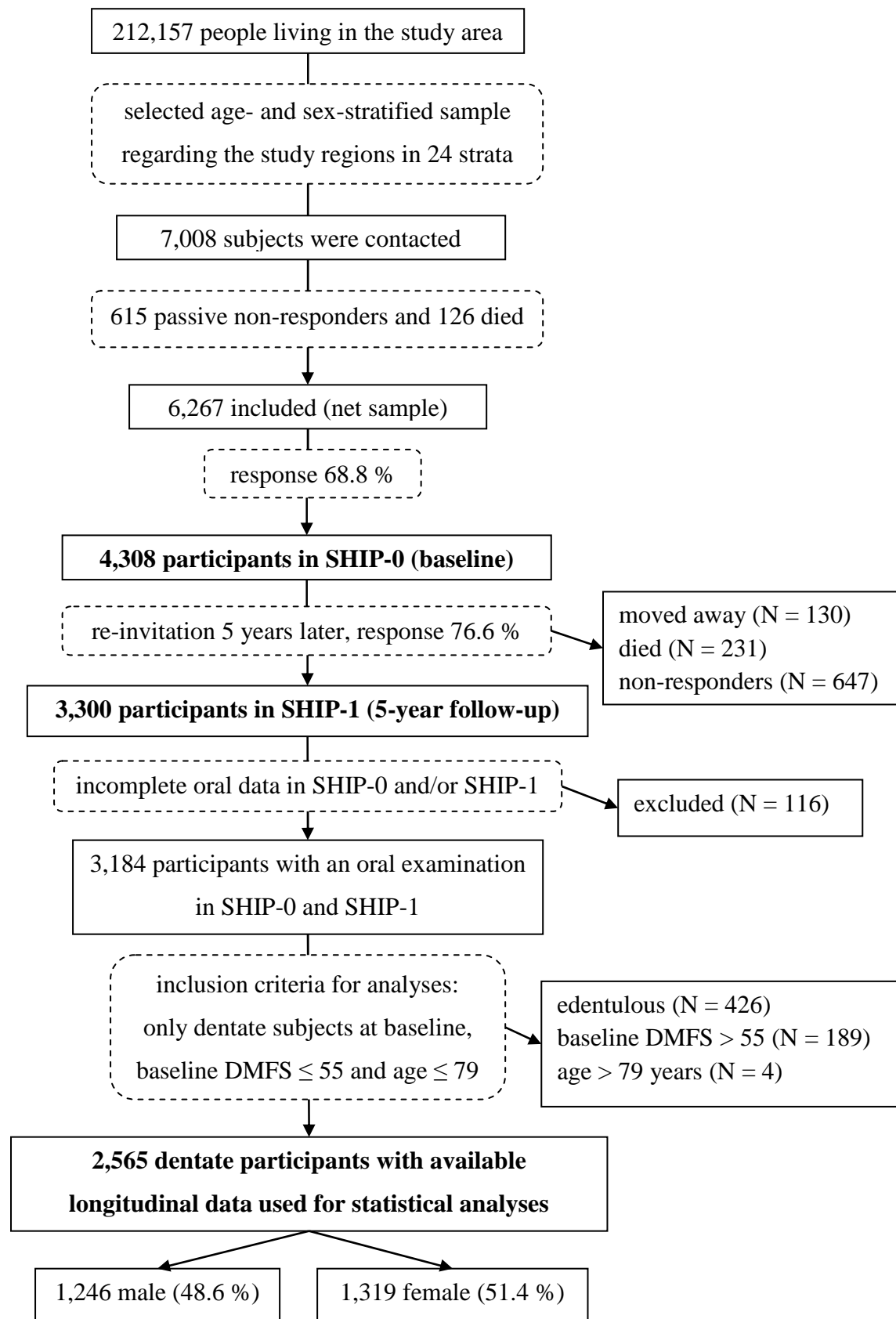
Table 3: Numbers and percentages of participants in the study sample are enlisted according to the baseline age, which is categorized into 5-year age groups.

Age group	N	%
20 - 24	164	6.4
25 - 29	230	9.0
30 - 34	293	11.4
35 - 39	288	11.2
40 - 44	272	10.6
45 - 49	299	11.7
50 - 54	264	10.3
55 - 59	307	12.0
60 - 64	207	8.1
65 - 69	140	5.5
70 - 74	56	2.2
75 - 79	45	1.8
Total	**2,565**	**100**

3.5 Statistical methods

Descriptive and analytic statistics were performed using the programme PASW Statistics 18 with the support of a professional mathematician of the University of Greifswald.

3.5.1 Definitions and categories of variables

3.5.1.1 Primary outcome variable: 5-year caries increment

The main variable is 5-year caries increment. Generally, in longitudinal studies diagnostic transitions can occur. As in large scale epidemiological studies with high caries prevalence reversals due to examiner misclassifications happen, a method for adjustment proposed by Beck et al. [1995] was used. A surface detected as decayed or filled at baseline can be confirmed or unconfirmed in the follow-up. Theoretically, an unconfirmed surface can be classified into four different groups: true increment vs. false increment, or true decrement vs. false decrement. A true decrement of DMFS is not possible as caries experience by definition cannot decrease. Still, due to examiner

misclassifications false increment or false decrement can be found, which adulterates the observation of true caries increment (Figure 7).

Figure 7: Theoretical diagnostic transitions of DMFS in longitudinal coronal caries studies [modified, Beck et al. 1995]
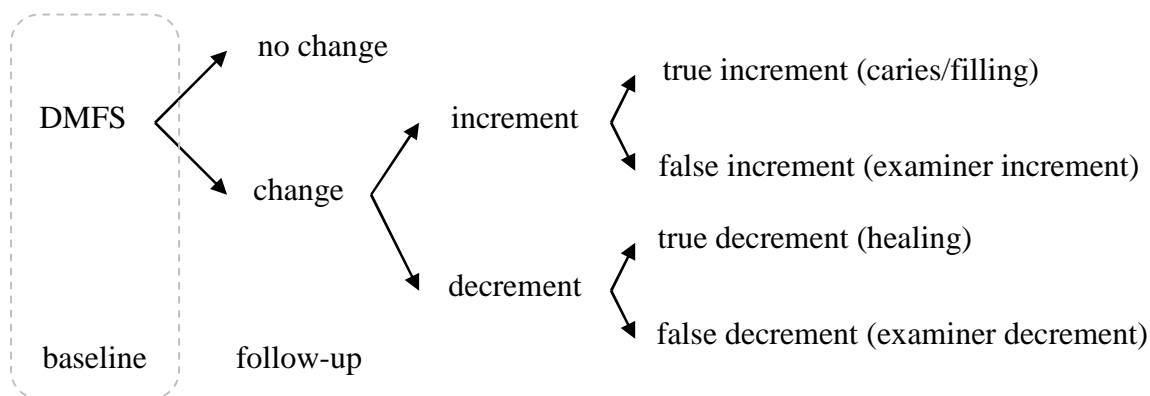
Assuming that examiner reversals are positively related to baseline caries prevalence with the number of examiner reversals being high when caries prevalence is also high, an adjustment is wise. Furthermore, the assumption stands that there is a negative relationship between the frequency of examiner increments and baseline caries increment [Beck et al. 1995]. In a large proportion of participants a negative caries increment was observed, this is especially obvious looking at the distribution of the net caries increment (NCI) in the present study (Figure 8). Knowing that this by definition is not possible, the necessity for adjustment of the caries increment variable becomes evident. Comparing Figure 8 and Figure 10, the influence of adjustment especially on the negative caries increment becomes apparent.

The formulas for the calculation of the adjusted caries increment, the Net Caries Increment (NCI) and the crude caries increment (CCI) are presented in Table 4. The adjusted caries increment presents a compromise between the NCI and the CCI as both fall to extremes. Reversals (y_3) are considered, but they are adjusted according to the baseline caries prevalence (y_4) [Beck et al. 1995]. The formula for adjusted caries increment proposed by Beck et al. [1995] was also used in a recent similarly designed study on root caries incidence [Sánchez-Garcia et al. 2011].

Table 4: Diagnostic transitions of the dental surface in a longitudinal caries study clarifying the model of mathematical adjustment of the variable caries increment. The formulas for adjustments are presented below [modified from Beck et al. 1995]

Observed status (t_0/baseline)	observed status (t_1/follow up)		
	+	**-**	**Total**
+	y_4	y_3	$y_3 + y_4$
-	y_2	y_1	$y_1 + y_3$
Total	$y_2 + y_4$	$y_1 + y_3$	$y_1 + y_2 + y_3 + y_4$

y_1 = surface diagnosed sound at t_0 and t_1

y_2 = surface diagnosed sound at t_0 and carious/filled at t_1 (CCI)

y_3 = surface diagnosed carious/filled at t_0 and sound at t_1

y_4 = surface diagnosed carious/filled at t_0 and t_1

Net Caries Increment (NCI) = $(y_2 + y_4) - (y_3 + y_4) = y_2 - y_3$

Adjusted Caries Increment   = $y_2 \times (1 - (y_3 / y_3 + y_4))$

On the one hand, the mean values ± standard deviation (SD) and especially the distribution of the NCI and the adjusted caries increment differ considerably with 2.73 ±5.20 (NCI) vs. 3.71 ±4.70 (adjusted caries increment). On the other hand the mean values for the crude caries increment compared to the adjusted caries increment are a lot more alike. Still, a slight overestimation might have happened with a mean of 3.85 ±4.78 surfaces of crude care increment (CCI). The adjustment especially leads to a more polarized distribution as the proportion with few surfaces of caries increment rises and the part with rather average caries increment decreases slightly, as especially all values with a negative NCI are adjusted (Figure 8, Figure 9, Figure 10).

Figure 8: Net caries increment (NCI) on a surface level in German adults (N = 2,565) aged 20 - 79 years in a half-mouth design in a time period of 5 years. All subjects with negative increment have either true reversals or reversals due to examiner misclassifications.
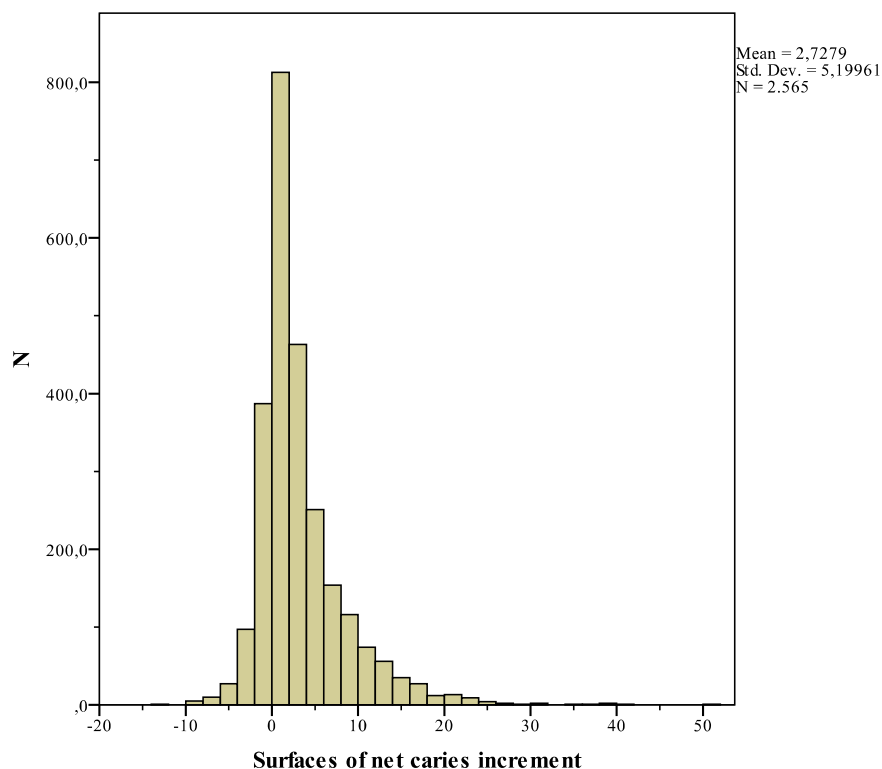
Figure 9: Crude caries increment (CCI) on a surface level in German adults (N = 2,565) aged 20 - 79 years in a half-mouth design in a time period of 5 years.
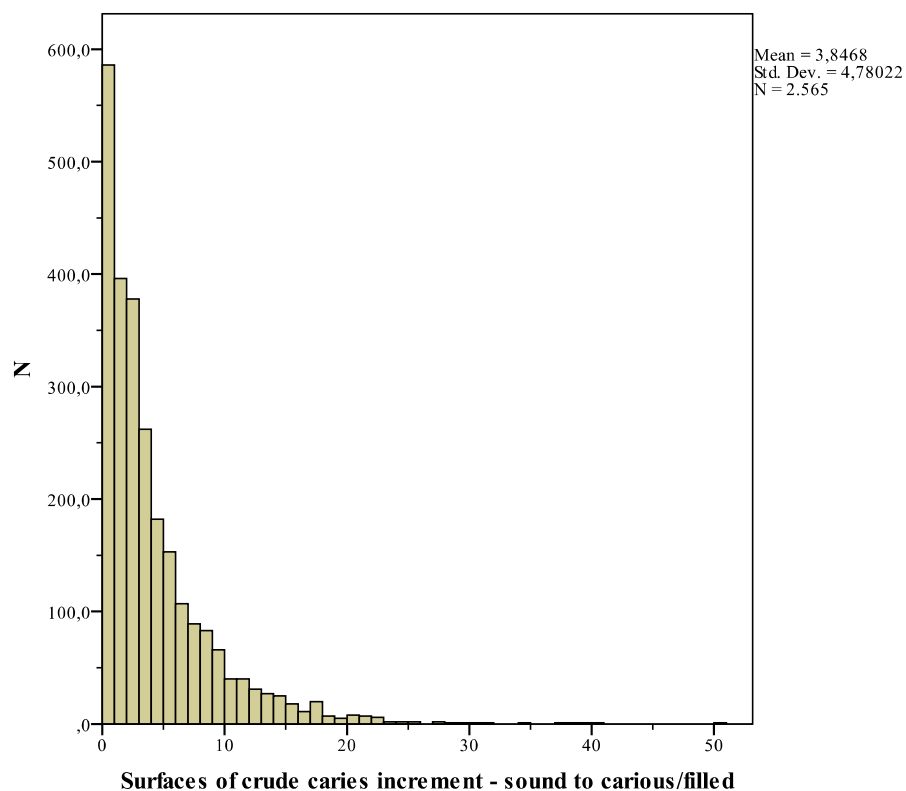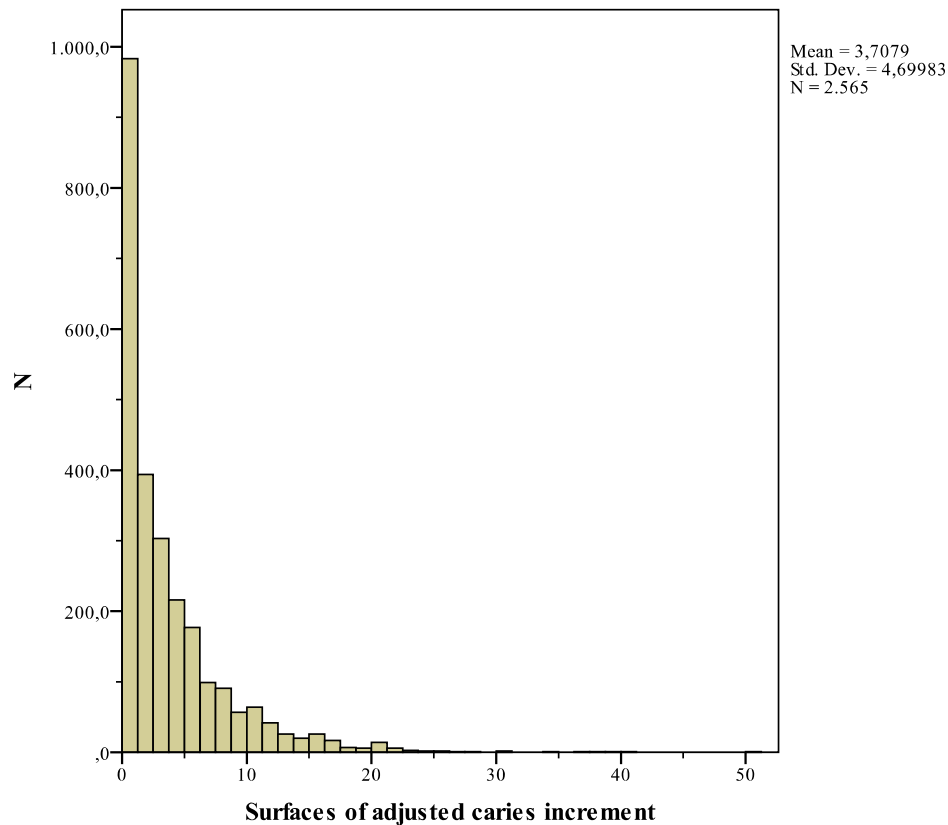
Figure 10: Adjusted caries increment on a surface level in German adults (N = 2,565) aged 20 - 79 years in a half-mouth design in a time period of 5 years.


Furthermore, the adjusted 5-year caries increment was categorized into different sizes of risk groups, in order to select an appropriate threshold for the high caries increment risk group (Table 5).

Table 5: Definition of the caries increment risk group with different thresholds of 5-year caries increment in German adults aged 20 - 79 years in half-mouth design.

Definition of the risk group	Threshold of caries increment	N
Caries increment	Yes	1,979 (77.2 %)
	No	586
25 % caries increment risk group	High ($\geq$ 5 DMFS)	669 (26.1 %)
	Low ($<$ 5 DMFS)	1,896
17 % caries increment risk group	High ($\geq$ 7 DMFS)	454 (17.7 %)
	Low ($<$ 7 DMFS)	2,111
10 % caries increment risk group	**High ($\geq$ 9 DMFS)**	**292 (11.4 %)**
	Low ($<$ 9 DMFS)	**2,273**
5 % caries increment risk group	High ($\geq$ 13 DMFS)	139 (5.4 %)
	Low ($<$ 13 DMFS)	2,426

For the final prediction model the 10 % caries increment risk group was used, as the size of this group is reasonably small, while it presents at the same time a vast amount (> 40 %) of the total caries increment. Moreover, the predictive model showed higher sensitivity and specificity as well as a higher area under the ROC-curve in contrast to e.g. the 25 % risk group which was analysed in preliminary analyses. The threshold for the risk group was, therefore, set at an increment of ≥ 9 DMFS in the half-mouth design, consisting and identifying about the top 10 % of the participants with the highest caries increment. One has to be aware that these risk participants are taken from the total sample of all adults included in the statistical analyses, which is only determined by the threshold of 9 surfaces of caries increment in the half-mouth design. This means that the risk group itself is, therefore, not adjusted to age, which is presented below (Figure 11).

Figure 11: The proportion of the participants in the high caries increment group (11.4 % in the total sample) versus the reference group in the total sample of dentate adults (N = 2,565) according to the 5-year age groups.
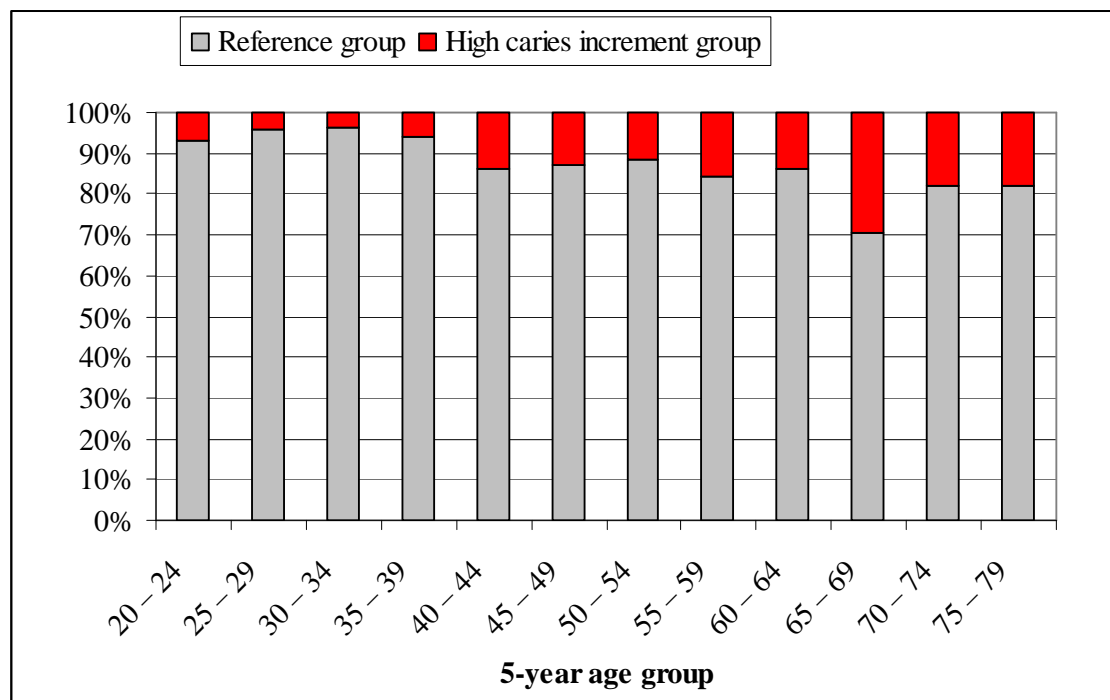
3.5.1.2 Exposure variables

The definitions of the most relevant factors investigated are presented in Table 6. The variable gender was recorded in the questionnaire. The subjects' age at the baseline examination was categorized into 5-year age groups, beginning from 20 - 24 years till 75 - 79 years. The educational level was defined as the self-reported highest level of

school education ($<$ 10 years vs. $\geq$ 10 years) which is based on the German school system. The monthly household income (in German Marks; 1 € = 1.956 German Marks) was divided by the square root of the number of persons living in the household and categorized into tertiles ($>$ 2,150/month; 2,150 - 1,500/month; $<$ 1,500/month) and/or dichotomously with the threshold 1,500/month. Marital status was categorized into living with a partner or being single. Smoking was defined as current smoker (vs. ex- or never-smoker). The self-reported description of the participants' self-perception of teeth and the general health status was categorized into two groups (excellent/good vs. not good/bad). The self-reported reason for the last dental visit being an indicator of dental anxiety was defined as pain-associated vs. not pain-associated dental visit. Similarly the last dental visit was categorized into two groups (within the last 12 months vs. longer ago than 12 months). Moreover, the variable steady/permanent dentist was defined dichotomous (yes vs. no). Baseline DMFS values were used, and as the correlation to the caries increment was identified as quadratic, baseline DMFS was squared and centred for adjustment (DMFS squared and centred).

Different periodontal variables were used. Bleeding on probing (BOP) and dental plaque were defined as percentages of the affected sites. The clinical attachment loss (CAL) was defined as the mean CAL per subject. The intensity of periodontitis was categorized into 5 groups (no PA, mild PA, middle PA, severe PA, no common tooth loss) according to the age based attachment loss $>$ 4 mm.

Diabetes was defined according to the self-report of being diabetic and the level of HbA1c in the blood test into the 4 groups (no diabetes, diabetes as HbA1c $>$ 7 but subject unaware, self-reported diabetes (controlled), and uncontrolled (HbA1c $>$ 7) but known diabetes).

The waist circumference was recorded in centimetres. In addition, the self-reported answers (yes vs. no) to the factor "problems with alcohol", "club member" and "sport on a regular basis" were used. The type of medical insurance was categorized into state vs. private insurance. The variable medication was not taken into consideration after preliminary analyses.

Table 6: Definition of the most frequently used variables

Variable	Reference	Risk
Caries increment risk group (10:90)	Increment < 9 DMFS	Increment ≥ 9 DMFS
Gender	Female	Male
School education	≥ 10 years	< 10 years
Self-perception of teeth	Excellent/good	Not good/bad
Age group (5-year)	20 - 24 (youngest)	
Pain associated dental visit	No	Yes
General health (self-reported)	Excellent/good	Not good/bad
Last dental visit	< 12 months	> 12 months
Registered at one dentist	Yes	No
Smoking	Never/ex-smoker	Current smoker
Monthly income (DM)	≥ 2,150	< 2,150
Problems with alcohol	No	Yes
Sport on a regular basis	Yes	No
Medical insurance	Private	State
Club/group member	Yes	No
Diabetes	HbA1c < 7 and no self-reported diabetes	HbA1c > 7, subject unaware; known, controlled diabetes or uncontrolled diabetes (HbA1c > 7)
Marital status	Living with a partner	Single

3.5.2 Significance testing and model building

3.5.2.1 Descriptive statistics

The study population was screened for significant associations to the different exposure variables in cross tabulations and by comparing the mean value of the caries increment in groups with different exposing factors using the bi-variate analysis. According to these findings the significant variables ($\alpha = 0.15$) were considered for further investigation. Continuous data were expressed as the mean and standard deviation (mean ±SD). In the case that data are not distributed normally, as e.g. in coronal caries prevalence and coronal caries increment, the median is mentioned additionally. Categorical data were expressed as the number and/or percent values. For continuous data, comparisons between groups were made using the Mann–Whitney's-U test, and

for categorical data with the chi square test (χ^2). The t-test and/or the analysis of variance (ANOVA) were performed to test whether or not the means of a metric variable (in this case mainly the adjusted caries increment) differ significantly between groups (nominal variable). The significance level was set at a p-value ≤ 0.05.

3.5.2.2 Analytic statistics

After preliminary analyses the binary logistic regression, generally used for the prediction of the probability of occurrence of an event [Hilbe 2009], was chosen for the prediction of the caries increment risk group (10 % caries increment risk group). The Hosmer-Lemeshow-test was performed in this model to evaluate the goodness of fit, comparing the expected counts with the observed counts according to subgroups [Hosmer and Lemeshow 2000]. Variables that showed a significant association ($\alpha = 0.15$) with the caries increment were taken into consideration in the prediction model. This means that the significant variables were added to the model stepwise looking at the significance of change by a backward likelihood ratio (LR). In case no significant improvement of the model was achieved the variable was not included in the model. Furthermore, the odds ratio (OR) with a 95 % confidence interval (CI) was calculated, as it is frequently used in epidemiological studies. The OR points out the strength of association or non-independence between two binary data values [Viera 2008]. The binary logistic regression does not produce a relative risk ratio (RR), but probabilities needed for the creation of an ROC-curve [Hilbe 2009].

The Receiver Operating Characteristic (ROC), plotting the true positive rate vs. the false positive rate for a binary classifier system, was chosen to evaluate the strength of the prediction. The area under the curve (AUC) summarizes the findings of the ROC by presenting the probability that a classifier will rank a randomly chosen positive instance higher than a randomly chosen negative one. The values lie between 0.5 and 1 (best prediction possible). The AUC should be clearly above 0.5 (meaning probability of choice by flipping a coin), at best or preferably > 0.8 (Figure 12) [Hanley and McNeil 1982, Fawcett 2006].

After receiving the predictive model with the largest area under the ROC, the model was stratified due to gender in order to screen for gender-dependent interactions.

Figure 12: An example of a ROC curve with a high area under the curve, displaying the values of the sensitivity and (1 - the specificity) in the curve compared to the worst case scenario (reference line: AUC = 0.5) presented via the diagonal line.

http://www.medcalc.org/manual/roc-curves.php
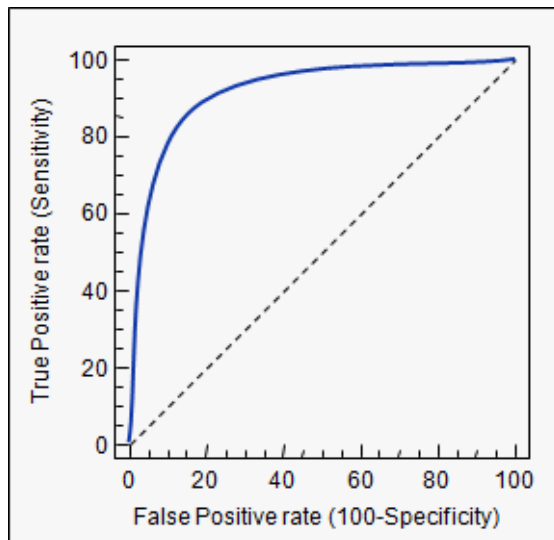
3.6 Ethical aspects

The study was approved by the Ethics Committee of the University of Greifswald, and all participants gave a written informed consent. The study conformed to the principles embodied in the Declaration of Helsinki [Community Medicine Research Net 2012].

3.7 Financing

SHIP-0 and SHIP-1 were financed by the "Bundesministerium für Bildung und Forschung" (Federal Ministry of Education and Research) in the Grant period: 1st of January 1997 - 30th of June 2007 and by the "Kultusministerium des Landes Mecklenburg-Vorpommern" (Ministry of Education, Sciences and Culture). Furthermore, SHIP-0 was supported by the "Sozialministerium des Landes Mecklenburg-Vorpommern" (Ministry of Social Affairs) and the "Klinikum der Hansestadt Stralsund" (Clinics in Stralsund) as well as several industry partners [Community Medicine Research Net 2012].

3.8 Data safety

All data of SHIP are owned by the "Forschungsverbund Community Medicine" (Community Medicine Research Net) of the Medical Faculty of the University of Greifswald. The use of the data is regulated by this research net, which has to agree to the data request. Data safety has a high priority in this study, for that reason the

personal data and the data of the examination are saved in different locations controlled by different personal. All systems are controlled daily to malware. All data sheets of a participant, interviews and other medical examination data are collected in a Case Report Form. Data for researchers is handed out and transferred anonymously coded to a random subjects' number [Community Medicine Research Net 2012].

3.9 Drop-out analysis

In the process of data cleaning (Figure 6) drop-outs had to be noted. For these drop-outs (edentulous, baseline DMFS > 55 surfaces in half-mouth and subjects > 79 years) the main characteristics like mean age ±SD, gender, school education, smoking status and the self-perception of teeth are presented in order to exclude selection bias. The drop-outs were significantly older ($p < 0.001$), had a lower school education, were more frequently current smokers, but had a better self-perception of their teeth (Table 7).

Table 7: Drop-out analysis presenting the main characteristics of the study sample versus the drop-outs (edentulous, baseline DMFS > 55, age > 79 years)

Variable	Study sample	Drop-outs
N	2,565	619
Mean age (years)	45.3 ±13.9	63.7 ±10.4
Gender (%)	1,246 males (48.6 %) 1,319 females (51.4 %)	296 males (47.9 %) 323 females (52.1 %)
School education (< 10 years)	27.7 %	68.6 %
Smoking (current)	31.2 %	71.8 %
Self-perception of teeth (not good/bad)	27.5 %	11.8 %

Already the mean age at baseline of all the participants in SHIP-0 versus the remaining participants used for statistical analyses from SHIP-1 differed significantly ($p < 0.001$). The mean age at the examination date in SHIP-0 (N = 4,308) was 50.8 ±16.6 years for men and 49.8 ±16.4 years for women. Whereas, the age of the study sample used for statistical analyses (N = 2,565) was in average 46.2 ±14.2 years for men and 44.5 ±13.7 years for women, while drop-outs had a highly significantly higher mean age at baseline (63.7 ±10.4 years, $p < 0.001$, Table 8). The mean age differed highly significantly in all groups between men and women.

Table 8: Drop-out analysis presenting the significantly different mean age at baseline for males and females in the different samples.

Variable	N	Gender	Mean ±SD (years)	Sig.
Baseline age (SHIP 0)	4,308	male	50.8 ±16.6	< 0.001
		female	48.8 ±16.1	
Baseline age (study sample)	2,565	male	46.2 ±14.2	0.001
		female	44.5 ±13.7	
Baseline age (drop-outs) *	619	male	65.6 ±9.7	< 0.001
		female	62.06 ±10.8	

* Due to the selection for statistical analyses (Figure 6): edentulous (N = 426), baseline DMFS > 55 (N = 189), age > 79 years (N = 4)

4 Results

4.1 Distribution of caries increment – descriptive statistics

4.1.1 Half-mouth caries increment according to age and gender

The mean 5-year caries increment in the study population (N = 2,565) was 3.71 ±4.70 surfaces, with a median of 2 surfaces in the half-mouth design. Male participants had a mean caries increment of 4.05 ±5.30 surfaces; whereas in women this was significantly lower (3.39 ±4.02 surfaces, p < 0.001, t-test). Moreover, men of all age groups had higher or at least the same caries increment than women (Figure 13), who on the contrary had significantly (p < 0.001) higher levels of caries experience (DMFS/T) at baseline (mean DMFS 27.10 ±14.00, median 26 vs. in females mean DMFS 30.67 ±13.68, median 31). According to the different 5-year age groups the mean caries increment was between 2.65 ±3.00 surfaces and 5.80 ±6.59 surfaces (Figure 13). Adults older than 40 years had highly significantly more caries increment than young adults with 20 - 24 years of age (p ≤ 0.003, t-test, Table 9).

Figure 13: Mean 5-year caries increment in the half-mouth design throughout all 5-year age groups differentiated by gender in a dentate adult population (N = 2,565) in North-East Germany.
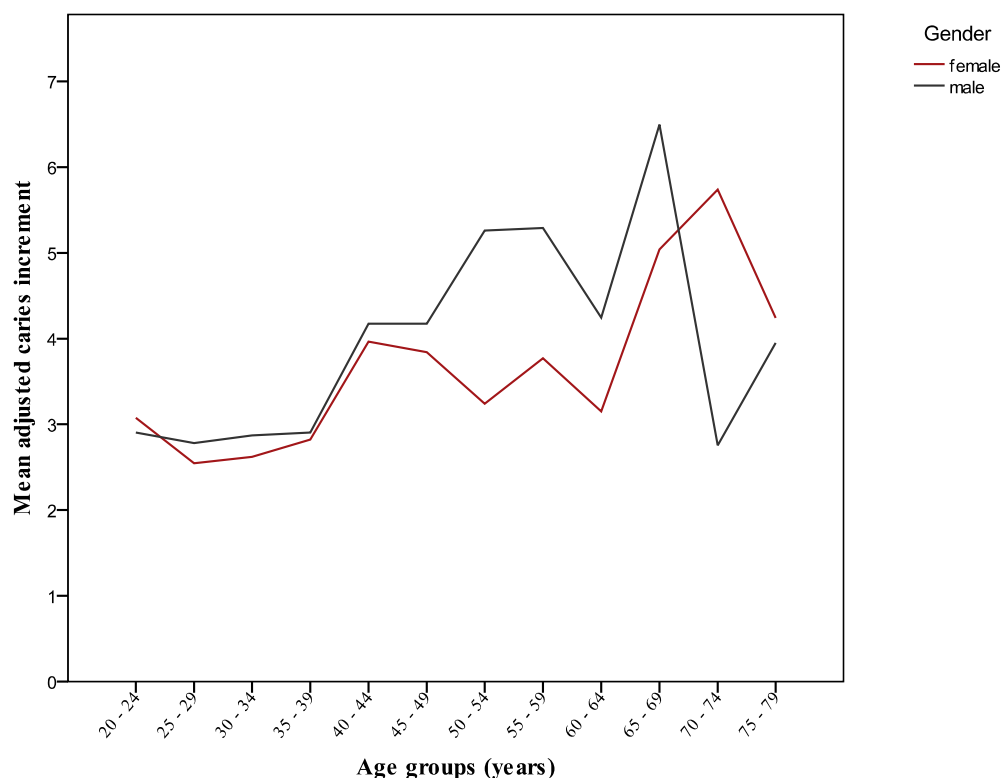
Table 9: Half-mouth 5-year caries increment (mean ±SD) according to the 5-year age groups in a dentate adult population (N = 2,565) in North-East Germany. The significance level was tested via the t-test. The reference age group are the 20 - 24 year-olds.

Age group	Mean caries increment (±SD)		Median *	N	Sig.
20 - 24	3.00	±3.18	2	164	Ref. group
25 - 29	2.65	±3.00	1.88	230	0.478
30 - 34	2.73	±2.96	1.86	293	0.788
35 - 39	2.86	±3.35	1.87	288	0.699
40 - 44	4.07	±5.67	2	272	< 0.001
45 - 49	4.00	±4.71	2	299	< 0.001
50 - 54	4.20	±5.95	2.57	264	< 0.001
55 - 59	4.51	±5.29	2.86	307	< 0.001
60 - 64	3.74	±4.53	1.94	207	< 0.001
65 - 69	5.80	±6.59	3	140	< 0.001
70 - 74	3.93	±4.47	2.91	56	0.003
75 - 79	4.06	±4.32	2	45	0.001

* Due to the adjustment of the caries increment according to Beck et al. [1995] the median is not always a whole number.

4.1.2 Overview on significant factors to the mean caries increment

The mean number of surfaces affected by caries increment differed significantly with several exposing factors. Subjects with a school education less than 10 years had a highly statistically significant higher caries increment than the ones with at least 10 years of school career (4.41 ±5.30 vs. 3.41 ±4.40, $p < 0.001$, t-test, Table 10). This finding was detected in almost all age groups. Only in the 35 - 39 and 65 - 69 year-olds higher school education did not show lower mean caries increment (Figure 14). Furthermore, in the younger (20 - 24) and the middle-aged (45 - 65) parts of the displayed study population the influence of the educational level on caries increment was clearly detectable. In the 20 - 24 year-olds the mean caries increment in the half-mouth design differed by about one surface according to the educational status, and in the 60 - 64 year-olds by more than 1.5 surfaces (Figure 14).

Figure 14: Half-mouth 5-year caries increment (mean ±SD) throughout all 5-year age groups differentiated by the level of school education in a dentate adult population (N = 2,565) in North-East Germany.
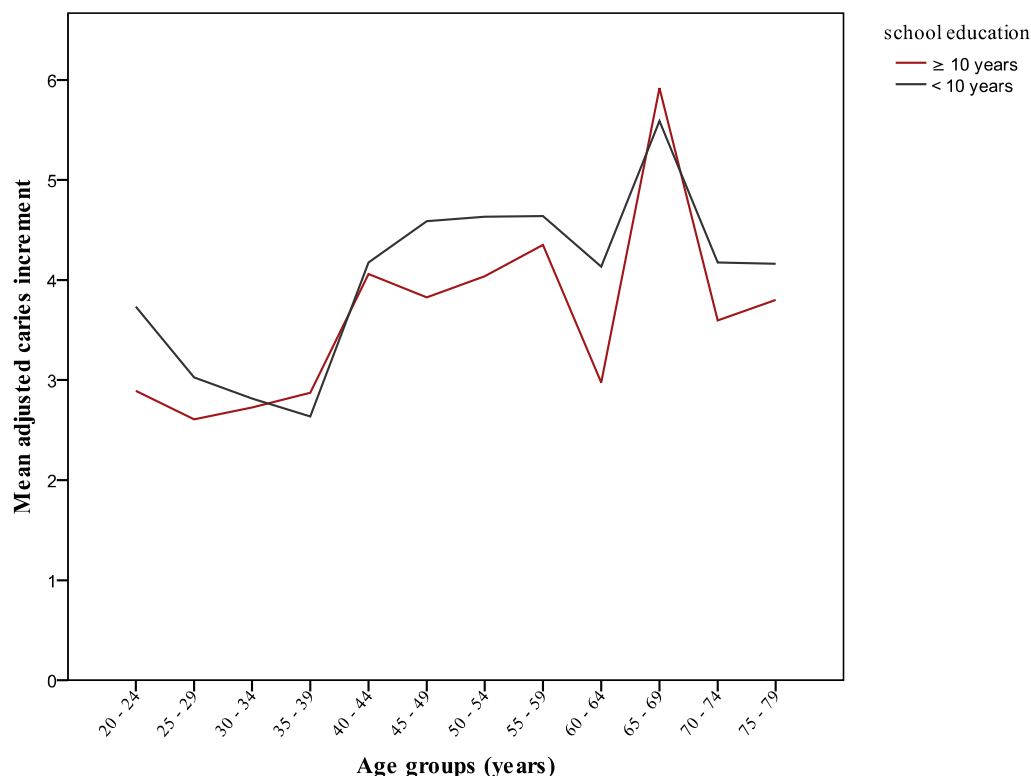
Moreover, the self-reported appearance of teeth, dental anxiety, expressed by the variable pain-associated dental visit, and being registered at a certain dentist had a highly significant impact on the mean caries increment (Table 10). The mean caries increment was also significantly influenced by the self-reported general health and the marital status (Table 10).

4.1.3   Significant exposing factors to the top 10 % caries increment group

Similarly, these mentioned factors (Table 10) were also highly significantly associated with the high caries increment group with the size of about 10 %. Additionally, the smoking status, the time period from the last dental visit and the factor sport on a regular basis had a significant impact (Table 11) and were, therefore, used in the building process of the prediction model.

Table 10: Overview on the 5-year caries increment (mean ±SD) in a half-mouth design in a dentate adult population (20 - 79 years) in Western Pomerania (N = 2,565) enlisted due to different exposing variables with a significant influence on the mean caries increment. Significances were determined via the t-test or ANOVA.

Exposure	Category	Mean	SD	Median *	N	Sig.
All	Total	3.71	±4.70	2	2,565	
Gender	Male	4.05	±5.30	2	1,246	< 0.001
	Female	3.39	±4.02	2	1,319	
School education	< 10 years	4.41	±5.30	2	711	< 0.001
	≥ 10 years	3.41	±4.40	2.73	1,851	
Self-perception of teeth	Not good/bad	4.72	±5.73	2.84	706	< 0.001
	Excellent/good	3.31	±4.13	2	1,855	
Pain-associated dental visit	Yes	4.73	±5.37	3	303	< 0.001
	No	3.65	±4.58	2	2,260	
General health (self-reported)	Not good/bad	4.27	±5.28	2.66	375	0.012
	Excellent/good	3.61	±4.59	2	2,182	
Registered at one dentist	No	4.81	±6.78	2	114	0.01
	Yes	3.65	±4.57	2	2,449	
Household income (tertile)	< 1500	3.90	±4.82	2	771	0.034
	1500 - 2150	3.90	±4.61	2	726	(ANOVA)
	> 2150	3.39	±4.68	2	951	
Marital status	Single	4.01	±4.72	2	590	0.056
	With Partner	3.60	±4.64	2.38	1,963	

* Due to the adjustment of the caries increment according to Beck et al. [1995] the median is not always a whole number.

Table 11: Fraction of participants (N = 2,565) in the high caries increment group (10 %) according to the significantly (α < 0.15) associated exposure variables, which are tested in the prediction model. Significance testing was performed with the Chi square test for all factors but age (ANOVA).

Exposure	Factor	5-year caries increment		N	Sig.
		< 9	≥ 9		
Age in years	Mean ±SD	44.5 ±13.8	51.8 ±13.1	2,565	0.001
Gender	Male	1,077 (86.4 %)	169 (13.6 %)	1,246	0.001
	Female	1,196 (90.7 %)	123 (9.3 %)	1,319	
School education	< 10 years	570 (83.0 %)	121 (17.0 %)	711	< 0.001
	≥ 10 years	1,681 (90.8 %)	170 (9.2 %)	1,851	
Pain-associated dental visit	Yes	248 (81.8 %)	55 (18.2 %)	303	< 0.001
	No	2,024 (89.6 %)	236 (10.4 %)	2,260	
Marital status	Single	507 (85.9 %)	83 (14.1 %)	590	0.016
	With Partner	1,757 (89.5 %)	206 (10.5 %)	1,963	
Smoking	Current smoker	692 (86.6 %)	107 (13.4 %)	799	0.03
	Never/ex-smoker	1,569 (89.6 %)	183 (10.4 %)	1,752	
Self-perception of teeth	Nod good/bad	586 (83.0 %)	120 (17.0 %)	706	< 0.001
	Excellent/good	1,685 (90.8 %)	170 (9.2 %)	1,855	
Registered at a certain dentist	No	2,180 (89.0 %)	269 (11.0 %)	2,449	0.006
	Yes	92 (80.7 %)	22 (19.3 %)	114	
General health (self-reported)	Nod good/bad	315 (84.0 %)	60 (16.0 %)	375	0.002
	Excellent/good	1,951 (89.4 %)	231 (10.6 %)	2,182	
Last dental visit	> 12 months	211 (85.4 %)	36 (14.6 %)	247	0.093
	< 12 months	2061 (89.0 %)	255 (11.0 %)	2316	
Sport (regularly)	Yes	1185 (89.5%)	139 (10.5 %)	1,324	0.145
	No	1,088 (87.7 %)	153 (12.3%)	1,241	

4.1.4 Non-significant exposing factors to the mean caries increment

Neither the variable smoking (current smoker vs. rest), nor diabetes, nor self-reported problems with alcohol had statistically significant influence on the mean caries increment (p > 0.15). Similarly, the type of medical insurance (state or private) and being a club member were not statistically correlated with the mean caries increment (Table 12). Likewise, none of the variables associated with periodontal disease as, e.g.

mean pocket depth, BOP or plaque showed a significant correlation to the mean caries increment (exact definition of these factors see chapter 3.5.1.2). Most of these not significantly correlated variables were, therefore, not considered in the prediction model. An exception posed the factor smoking as it showed a significant (and also gender-dependent) association with the high caries increment group (Table 11).

The number of remaining teeth was not found to be a significant predictor of high caries increment in this adult population and as it is not a dichotomous variable; the findings were not presented in the table.

Table 12: Overview on non-significant variables expected to have a relevant influence on the half-mouth 5-year caries increment (mean ±SD) in a dentate adult (20 - 79 years) population in Western Pomerania (N = 2,565). The significance was tested via the two sided t-test.

Exposure	Category	Mean	SD	Median	N	Sig.
Smoking	Current smoker	3.79	±4.70	2	799	0.510
	Never/ex-smoker	3.66	±4,66	2	1,752	
Problems with alcohol	Yes	4.20	±4.96	2	109	0.262
	No	3.68	±4.69	2	2,448	
Sport on regular basis	No	3.84	±4.86	2	1,241	0.171
	Yes	3.59	±4.32	2	1,324	
Medical insurance	State	3.69	±4.65	2	2,463	0.550
	Private	4.00	±5.42	2	84	
Last dental visit	> 12 months	4.07	±5.69	2	247	0.192
	< 12 months	3.66	±4.58	1.96	2,316	
Club/group member	No	3.79	±4.85	2	1,455	0.302
	Yes	3.60	±4.49	2	1,100	
Diabetes	No	3.72	±4.72	2	2,326	0.347
	Yes	3.42	±4.19	2	228	

* Due to the adjustment of the caries increment according to Beck et al. [1995] the median is not always a whole number.

4.1.5 Caries increment in the different sizes of risk groups

The impact of the different sizes of the caries increment risk groups on the mean caries increment can be seen in Table 13. The median of the 25 % caries increment risk group is 8 surfaces (mean: 9.69 ±5.27), the 10 % caries increment risk group had already a median of 12 and a mean of 14.02 ±5.63 surfaces of caries increment. The mean caries

increment throughout all age groups for the reference group was about 2.5 surfaces whereas the high risk group had more than a 5-fold higher value in this 10 % risk group. Regarding the age, the mean caries increment of the 10 % caries increment risk group showed similar characteristics, when compared e.g. to the 17 % caries increment risk group (Figure 15) and the overall curve (Figure 13). Moreover, these figures showed that the high caries increment group was mainly responsible for the overall variation of the mean caries increment in the different age groups.

Table 13: 5-year caries increment (mean ±SD) in half mouth design in adults (20 - 79 years) population in Pomerania (N = 2,565) enlisted due to different sizes of caries increment risk groups.

Group size	Caries increment	Mean	SD	Median *	N
All	Total	3.70	±4.70	2	2,565
Caries increment group	Yes	4.81	±4.83	3	1,979 (77.2 %)
	No	0	±0.0	0	586
Risk group (25 : 75)	High (≥ 5 DMFS)	9.82	±5.33	8	669 (26.1 %)
	Low (< 5 DMFS)	1.55	±1.42	1	1,896
Risk group (17 : 83)	High (≥ 7 DMFS)	11.78	±4.70	10	454 (17.7%)
	Low (< 7 DMFS)	1.97	±1.84	2	2,111
Risk group (10 : 90)	**High (≥ 9 DMFS)**	**14.04**	**±5.64**	**12**	**292 (11.4 %)**
	Low (< 9 DMFS)	**2.38**	**±2.32**	**1.9**	**2,273**
Risk group (5 : 95)	High (≥ 13 DMFS)	17.93	±6.05	16	139 (5.4 %)
	Low (< 13 DMFS)	2.89	±3.00	2	2,426

* Due to the adjustment of the caries increment according to Beck et al. [1995] the median is not always a whole number.

The mean caries increment in the largest part of the population throughout all age groups was about 2 surfaces (half-mouth), whereas the risk group no matter what size (5 - 25 %) had significantly higher caries increment (Figure 15).

In this study population 1/4 of the sample had about 2/3 of the total caries increment. Moreover, the 10 % of the sample with the highest caries increment account for more than 40 % of the gained surfaces. This proved, that caries increment in this sample of German adults was not normally distributed, as a clear polarisation was depicted (Figure 10, Figure 15, Table 14).

Figure 15a/b: Mean 5-year caries increment in the half-mouth design throughout all 5-year age groups in the 10 % (upper graph) and the 17 % (lower graph) caries increment risk group vs. the rest in a dentate adult population (N = 2,565) in North-East Germany. The 17 % risk group is only shown exemplarily.
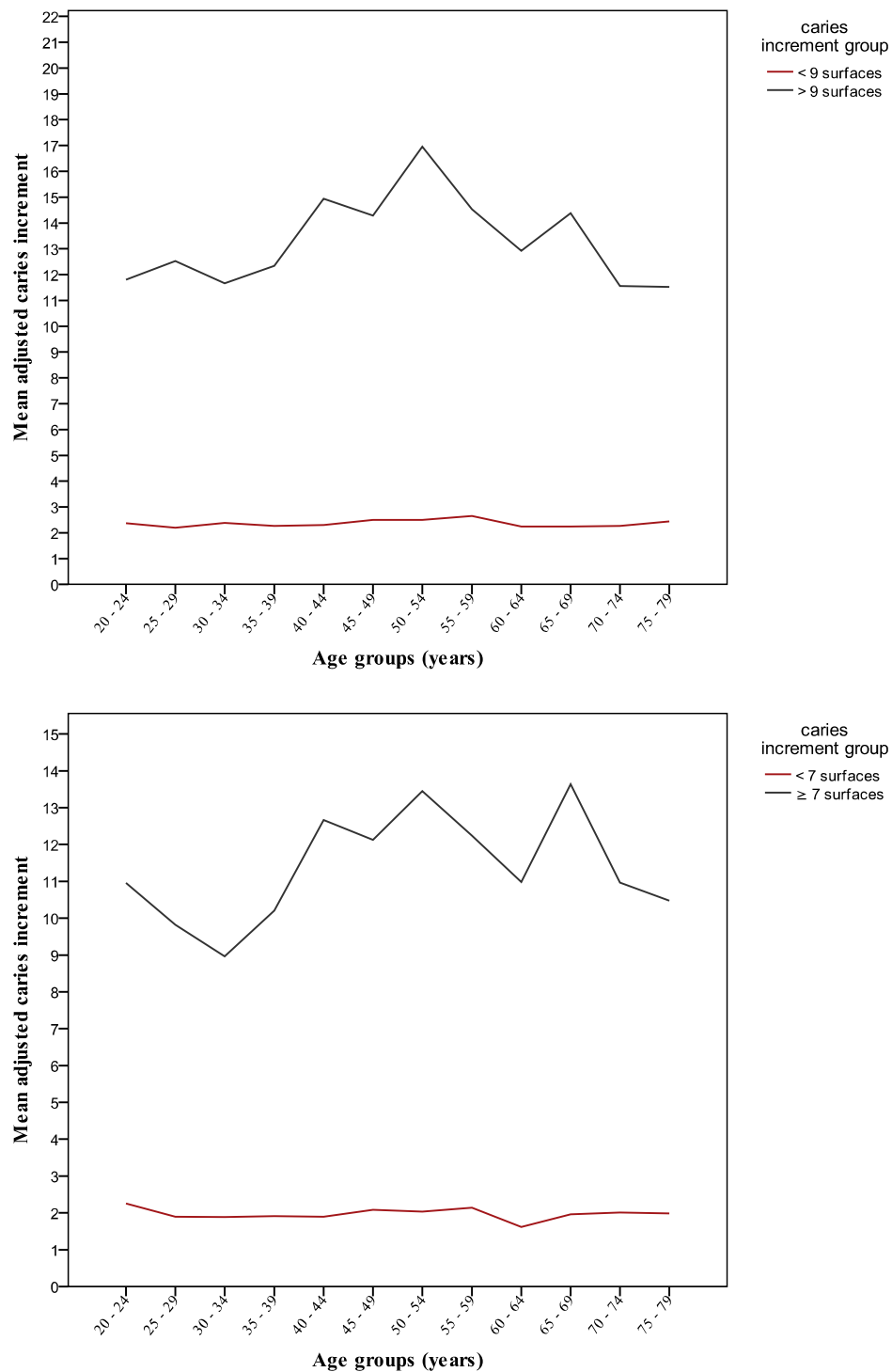
Table 14: Total amount of surfaces of half-mouth 5-year caries increment in the total sample and its fraction regarding the different sizes of the high caries increment groups.

Group label and size	N	Caries increment (DMFS)
All patients	2,565	9,511 (100 %)
25 % high caries increment group	669	6,571 (69 %)
17 % high caries increment group	454	5,351 (56 %)
10 % high caries increment group	292	**4,110 (43 %)**
5 % high caries increment group	139	2,492 (26 %)

4.1.6 Influence of baseline DMFS on 5-year caries increment

The mean baseline DMFS was significantly higher ($p < 0.001$) in the 10 % caries increment risk group (mean $\pm$SD: 33.71 $\pm$12.37 DMFS vs. 28.32 $\pm$14.02 DMFS; and the median DMFS was 36 vs. 28), which showed that caries experience in the past was correlated with caries increment. At this point a reminder should be allowed that by definition participants with a baseline DMFS $\geq$ 56 were excluded from the study sample as they could not be categorized into the 10 % high caries increment group. Therefore, the x-axis in the upcoming figures ends at a baseline DMFS of 55. Figure 16 and Figure 17 clearly display that participants with almost any baseline caries experience may be affected by high caries increment, which indicates that low caries experience is no guarantee for low caries increment. Nonetheless, the probability of high caries increment rose with rising DMFS, which means that low baseline DMFS scores appear to be protective against high caries increment. Moreover, the distribution of participants according to the baseline DMFS in the total sample had a tendency to be shaped like a quadratic function, whereas the distribution of the high caries increment group according to the baseline DMFS was not. Comparing the influence of the baseline DMFS on a larger group at risk of high caries increment, exemplary the 25 % risk group, this relationship was even more obvious (Figure 17). At last, the high prevalence of caries in these dentate adults can be observed as well from these figures, which has been published in detail elsewhere [Splieth et al. 2003].

Figure 16: Number of participants in the top 10 % caries increment group (≥ 9 surfaces of caries increment) compared to the rest (< 9 surfaces of caries increment) according to the baseline DMFS.
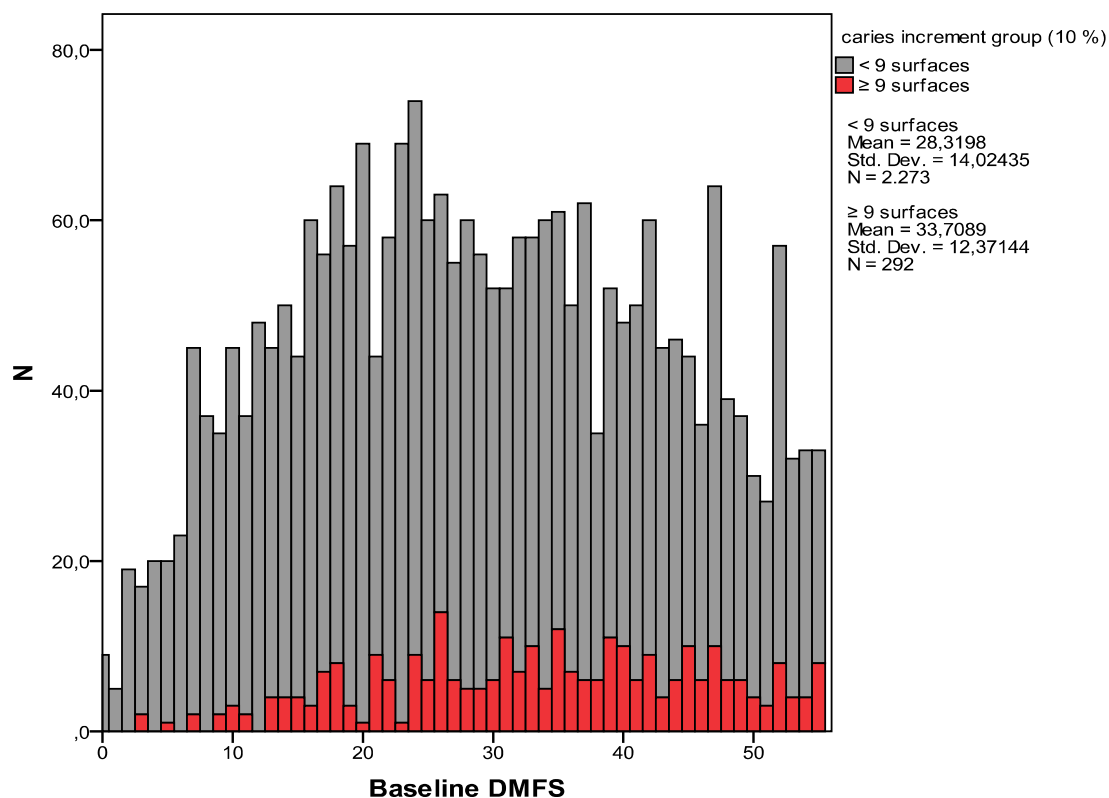
Figure 17: Number of participants in the top 25 % caries increment group (≥ 5 surfaces of caries increment) compared to the rest (< 5 surfaces of caries increment) according to the baseline DMFS.
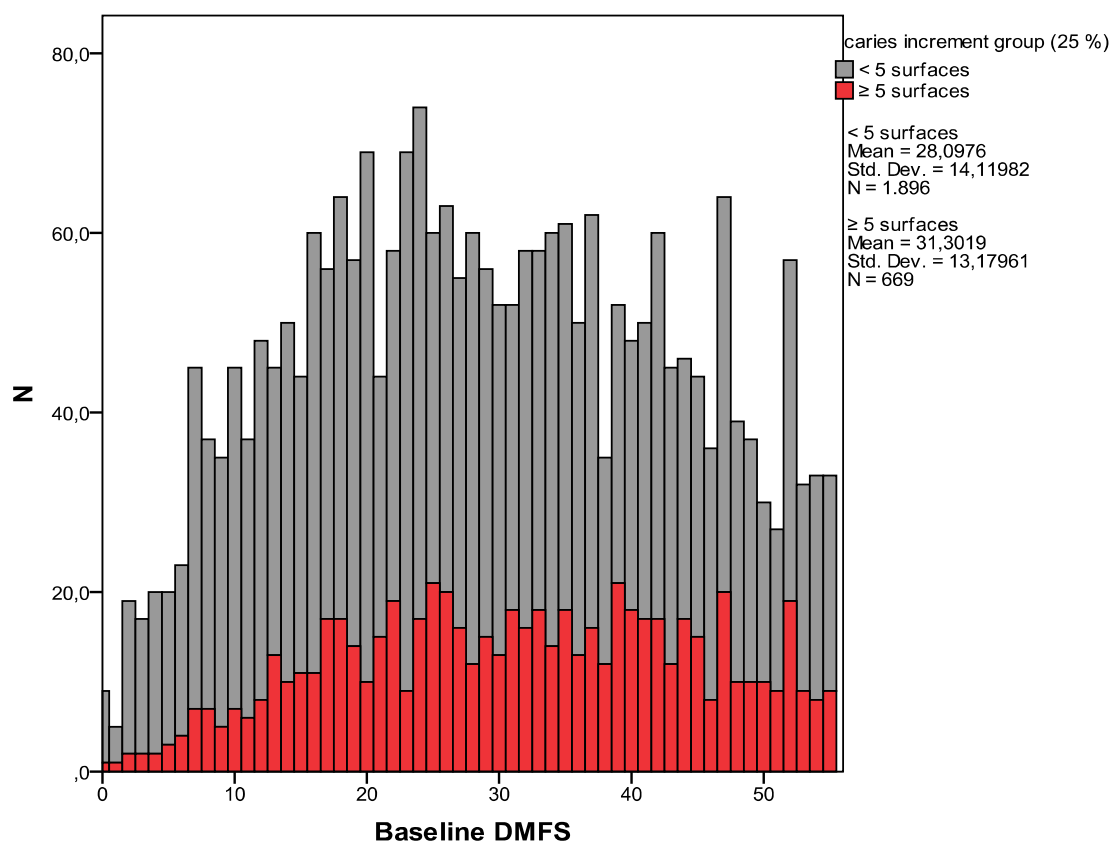
4.2 Analytic statistics

4.2.1 Binary logistic regression models

For the model building process in the binary logistic regression the inclusion criterion for a variable was set at α = 0.15. The variable was then only included to the binary logistic regression model, if via the backward inclusion a significant change in the Likelihood Ratio (LR) was achieved.

4.2.1.1 Simple prediction model

The simplest forecast model for high caries incidence included only gender, household income and the age. The risk age was categorized as ≥ 40 years and the household income as < 2150 DM per month. Men had an odds ratio (OR) of about 1.5 and low income an OR of 1.8 (Table 15). This model achieved an area under the ROC-curve of 0.675. The sensitivity and specificity for this model were depending on the gender each only slightly higher than 60 % (Figure 18).

Table 15: Simple model for the prediction of high caries increment (≥ 9 surfaces in 5 years) in dentate adults (N = 2,565) in Pomerania including the factors age group, gender and household income which are presented with odds ratios (95 % CI).

Simple prediction model	Sig.	OR (95 % CI)
Gender (male)	0.001	1.53 (1.14 - 1.88)
Income (lowest third)	< 0.001	1.79 (1.36 - 2.36)
Age (≥ 40 years)	< 0.001	3.75 (2.70 - 5.22)

AUC = 0.675

4.2.1.2 Prediction model including all associated factors

The best prediction model for high coronal caries increment (Table 16) in this population of dentate German adults applied the factors: gender, age, income, pain associated dental visit, self-perception of teeth, smoking, baseline caries experience (DMFS and the adjusted DMFS, which was squared and centred). In this study sample, men had an OR of 1.8 and, therefore, a 1.8 times higher risk of being in the high caries increment group than women. Similarly, people with a low income had an OR of about 1.7. The self-perception of teeth being not good or bad was associated with an OR of 2.2. Baseline smokers had an OR of 1.4 to belong to the high caries increment group. Nevertheless, all these significantly associated variables only have a small OR, as they

range barely from slightly above 1 till an OR of 2, besides the age which accounted for the highest OR with a 3-fold higher risk. High baseline DMFS prevailed almost a similar OR than low DMFS. Still, higher baseline caries experience showed to be a significant predictor of caries increment. The prediction model was even more exact if instead of a dichotomous variable for the age, all 5-year age groups were applied. For an easier prediction model all the 13 five-year age groups were summarized in this one variable (< 40 vs. ≥ 40 years). This model produced an area under the ROC of 0.727.

Table 16: Prediction model of high caries increment (≥ 9 surfaces in 5 years) in dentate adults in Pomerania (N = 2,565) presented with odds ratios (95 % CI) for the included exposing variables.

Prediction model	Sig.	OR (95 % CI)
Gender (male)	< 0.001	1.79 (1.37 - 2.34)
Age group (≥ 40 years)	< 0.001	3.02 (2.12 - 4.30)
Income (< 2150 DM)	< 0.001	1.69 (1.24 - 2.24)
Pain-associated dental visit (yes)	0.005	1.64 (1.16 - 2.31)
Self-perception of teeth (not good/bad)	< 0.001	2.17 (1.66 - 2.84)
Smoking (current)	0.020	1.38 (1.05 - 1.81)
Baseline DMFS (high)	0.002	1.08 (1.03 - 1.14)
Baseline DMFS (squared & centred) *	0.013	1.00 (0.99 - 1.00)

AUC = 0.727

* The variable baseline DMFS (squared & centred) is used for adjustment and mentioned only for the sake of completeness.

The model predicted high caries increment on a similar level (OR and AUC comparable) when the variable school education (< 10 vs. ≥ 10 years) was included instead of the household income (< 2150 DM), as both are markers for the socio-economic status. This is presented in the next prediction model, which also considers gender-dependent correlations (Table 17).

4.2.1.3 Prediction model separated by gender

In men, the variables smoking, low school education, pain associated dental visit and high baseline caries experience were significantly correlated with higher caries increment ($p \leq 0.012$), whereas in women neither of these variables had a significant association with high caries increment (Table 17).

Table 17: Prediction model of high dental caries increment (≥ 9 surfaces in 5 years) separated by gender presented with OR and 95 % confidence interval. The factors marked with bold letters show gender-dependent differences, as they only show significant influence in males.

Prediction model separated by gender		Sig.	OR (95 % CI)
Male	Self-perception of teeth (not good/bad)	< 0.001	1.99 (1.38 - 2.86)
	Pain-associated dental visit (yes)	**0.001**	**2.14 (1.38 - 3.31)**
	Smoking (current)	**0.008**	**1.62 (1.13 - 2.30)**
	School education (< 10 years)	**0.012**	**1.59 (1.11 - 2.28)**
	Age (≥ 40 years)	< 0.001	2.56 (1.58 - 4.15)
	Baseline DMFS (high)	**0.003**	**1.10 (1.03 - 1.18)**
	Baseline DMFS squared & centred *	0.019	1.00 (0.99 - 1.00)
Female	Self-perception of teeth (not good/bad)	< 0.001	2.04 (1.39 - 3.01)
	Pain-associated dental visit (yes)	**0.560**	**1.19 (0.67 - 2.09)**
	Smoking (current)	**0.990**	**1.00 (0.67 - 1.51)**
	School education (< 10 years)	**0.940**	**1.02 (0.66 - 1.57)**
	Age (≥ 40 years)	< 0.001	2.63 (1.57 - 4.42)
	Baseline DMFS (high)	**0.160**	**1.06 (0.98 - 1.14)**
	Baseline DMFS squared & centred *	0.220	1.00 (0.99 - 1.00)

* The variable baseline DMFS (squared & centred) is used for adjustment and mentioned only for the sake of completeness. For details on the AUC see Table 19.

Male current smokers had a risk of 1.6 to be in the high caries increment group, whereas female smokers had basically the same risk as female ex- or never-smokers. Moreover, men with a low school education had an OR of 1.6, in contrast to women with lower school education whose risk is not significantly different from the reference group. Furthermore, male participants who visited the dentist symptom related showed a statistically significantly higher risk of caries increment, with an OR of about 2.1. This factor showed again no statistically relevant association for women. These findings confirmed gender-dependent associations to the caries increment. High baseline DMFS was also associated with a higher OR for high caries increment in men while in women this association was not significant.

4.2.2 Caries prediction: sensitivity, specificity and AUC

All single variables presented in Table 18 had very low sensitivities but quite high specificities in predicting high coronal caries increment ($\geq$ 9 surfaces, top 10 % caries increment risk group). Nevertheless, only the ones optimizing the prediction were used for the prediction model (Table 19).

Table 18: Sensitivity and specificity of the single variables predicting high caries increment ($\geq$ 9 surfaces) in an adult population (N = 2,565) in North-East Germany.

Variable predicting high caries increment	Sensitivity (%)	Specificity (%)
Gender (male)	13.6	90.7
School education (< 10 years)	17.0	90.8
Self-perception of teeth (not good/bad)	17.0	90.8
Registered at a certain dentist (no)	19.3	89.0
Self-reported general health (not good/bad)	16.0	89.4
Pain-associated dental visit (yes)	18.2	89.6
Age ($\geq$ 40 years)	15.3	95.0
Smoking (current)	13.4	89.6
Income (< 2150 DM)	12.8	91.1

The model for coronal caries prediction in dentate adults presented in paragraph 4.2.1.2 with the factors gender, age group, income, pain associated dental visit, self-perception of teeth, smoking and baseline caries experience (DMFS) produced an area under the Receiver Operating Characteristic curve of 0.75 for men in contrast to only 0.68 for women (Table 17). This is considerably higher than 0.675 which was the AUC for the simplest not gender-differentiated forecast model including only the three factors: age, gender and income.

The gender-dependent stepwise change of the area under the curve (AUC) in the model building process with the addition of the significantly associated variables one by one is depicted in Table 19. For a better visual understanding the correlating graphs are presented as well (Figure 18).

Figure 18a/b: ROC-curves depicting the probabilities and the different AUC of the prediction models applied stepwise in the model building process for the prediction of high caries increment in males (a) and females (b). The cluster with its crossings of the vertical and horizontal lines indicates the false positive rate (1 - specificity) and its corresponding sensitivity.

Diagonal segments are produced by ties.

Diagonal segments are produced by ties.
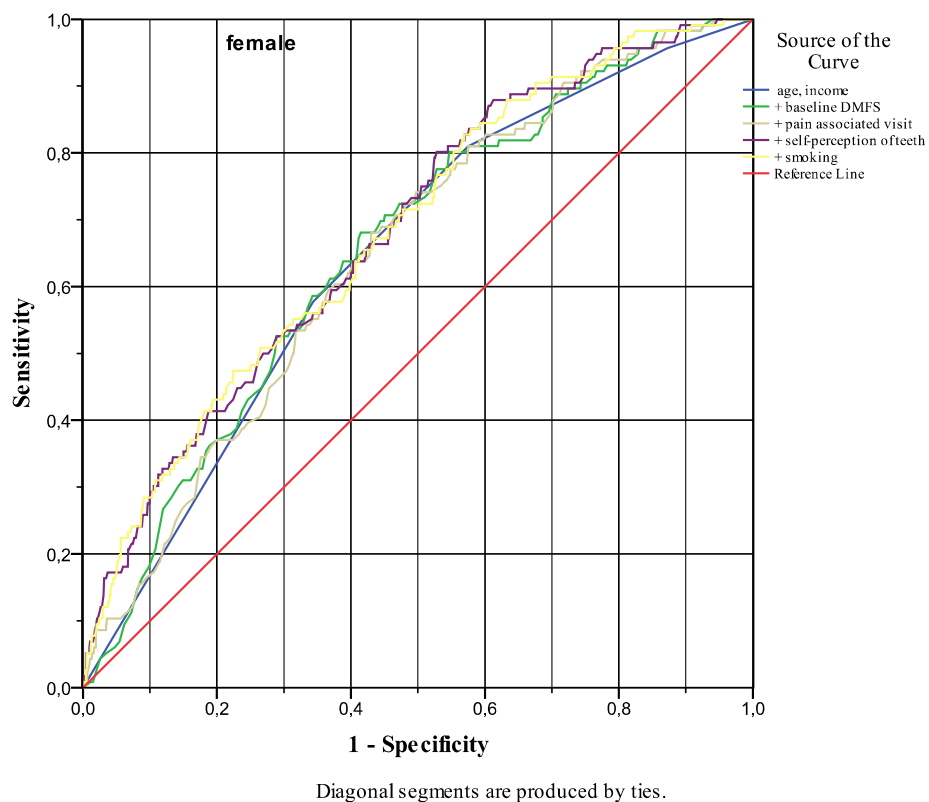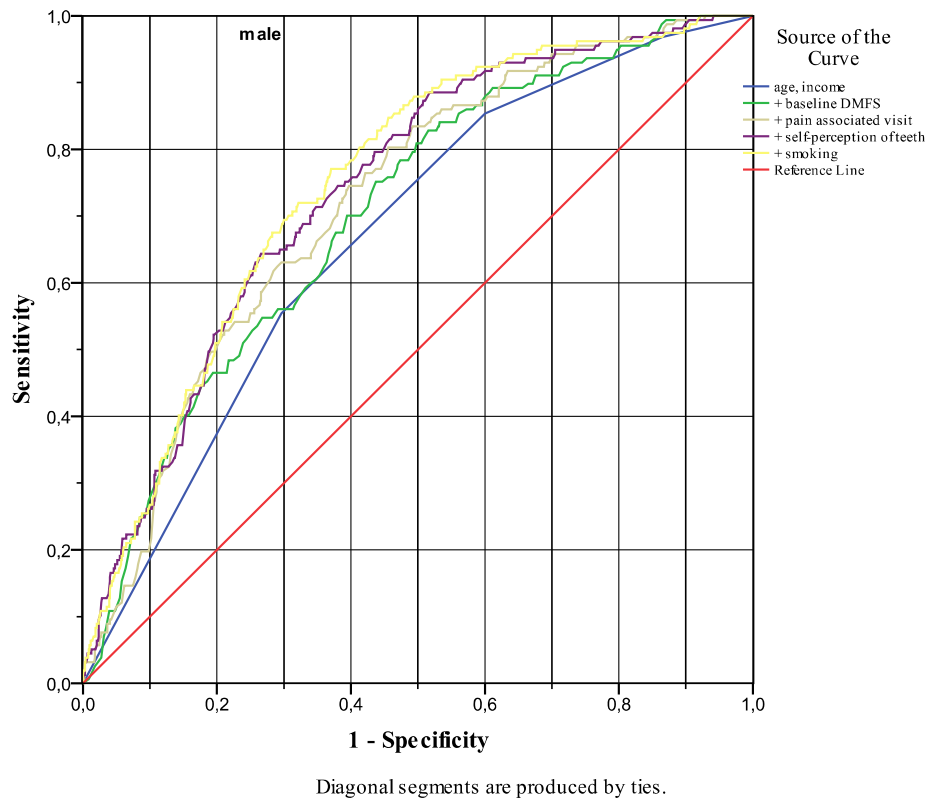
For each model the sensitivity with its corresponding specificity can be obtained from Figure 18, the highest sum (sensitivity + specificity) is at the point of the graph which is located the closest to the upper left corner. For males the highest sum of sensitivity and specificity was achieved in the area of a false positive rate (1 - Specificity) between 0.3 - 0.4, which corresponded depending on the best prediction model to a sensitivity of 75 %. For females the highest sum of sensitivity and specificity was achieved in the area of a false positive rate (1 - Specificity) 0.45 of which corresponded in the best prediction model to a sensitivity of 68 %. The highest AUC in the model building process was 0.75 for men and 0.681 for women (Table 19).

Table 19: The gender-dependent stepwise change of the area under the curve (AUC) in the model building process are shown for males and females separately. Variables resulting in a significant improvement of the model are marked with *.

Prediction model		AUC	95 % CI
Male	Age (≥ 40 years), income (< 2150 DM) *	0.670	0.628 - 0.712
	+ baseline DMFS (high) *	0.705	0.664 - 0.746
	+ pain associated dental visit (yes) *	0.722	0.682 - 0.761
	+ self-perception of teeth (not good/bad) *	0.740	0.702 - 0.779
	+ smoking (current) *	0.750	0.713 - 0.788
Female	Age (≥ 40 years), income (< 2150 DM) *	0.647	0.598 - 0.697
	+ baseline DMFS (high)	0.657	0.608 - 0.705
	+ pain associated dental visit (yes)	0.651	0.602 - 0.699
	+ self-perception of teeth (not good/bad) *	0.681	0.632 - 0.730
	+ smoking (current)	0.681	0.632 - 0.730

4.2.3 The high risk person

The persons at highest risk for high caries increment would have been male smokers older than 40 years with a low school education/low income, a low self-perception of teeth who visit the dentist only symptom-based. However, this person does not exist in the study sample. Male smokers older than 40 years of age belonged to 23 % to the high caries increment group, which in total consisted only of 11.4 % of the population. But only 256 of the 2,565 participants carried these attributes. Nevertheless, these 3 factors already doubled the chance to identify a person at risk for high caries increment (Table 20).

Table 20: Number of male smokers older than 40 years from the study sample according to the affiliation to the high or low caries increment group (total N = 2,565; males N = 1,246)

Caries increment group	Threshold	N	%
Low	< 9 DMFS	198	77.3
High	≥ 9 DMFS	58	22.9
Total		256	100

Sensitivity: 19.8 % (in total); 34.3 % (within males)

Specificity: 91.3 % (in total), 81.6 % (within males)

Moreover, if the factor smoking was exchanged with the variable of a low self-perception of teeth the chance for a correct identification rose from 1:5 to almost 1:3 (Table 21).

Table 21: Number of men older than 40 years with a low self-perception of teeth from the study sample (N = 2,565; males N = 1,246) according to the affiliation to the high or low caries increment group.

Caries increment group	Threshold	N	%
Low	< 9 DMFS	137	72.9
High	≥ 9 DMFS	51	27.1
Total		188	100

Sensitivity: 17.5 % (in total), 30.2 % (within males)

Specificity: 94.0 % (in total), 87.3 % (within males)

4.3 Summary of the main results

Caries incidence was a highly relevant problem in this adult population from North-East Germany as 3/4 of the participants had at least one surface affected by caries within this 5-year time period. The mean 5-year caries increment in this study sample was about 7 surfaces (full-mouth) and within the high caries increment group even 28 surfaces (full-mouth). This shows that caries increment was clearly polarized. The high caries increment group (≥ 9 surfaces of caries increment in half-mouth) making up for about 10 % of the total sample had more than 40 % of the total number of surfaces affected by caries increment. The remaining 90 % had still 60 % of the caries increment.

High caries increment was statistically significantly associated with male gender, age ≥ 40 years, lower school education, current smoking, pain-associated dental visit, baseline caries experience and a non-satisfying self-perception of teeth. The smoking habit, school education and pain-associated dental visit were gender-dependent factors, as they only showed to be highly relevant for the prediction of high caries increment in men. Each of the factors included in the model had an OR of about 1.5 - 2. This means that single male smokers with a low school education, who were dissatisfied with the look of their teeth and visited the dentist only symptom-related characterize the high risk person, though this person does not exist in the study sample.

The simple prediction model (gender, age, school education/income) led to an AUC of 0.675, which meant only a poor prediction. The gender adjusted model including all the presented markers resulted in a fair to good prediction (AUC = 0.75) on an epidemiological level for men.

5 Discussion

5.1 Discussion of the method

5.1.1 Study design and sample

The Study of Health in Pomerania has many strong points. First of all, the longitudinal design with a 5-year time spread and the large number of participants in the follow-up (SHIP-1, N = 3,300) is very unique in general, but especially in coronal caries incidence studies. Secondly, a randomized stratified sample was selected according to age and gender in order to obtain a representative sample of the population in Mecklenburg-Vorpommern, which might be taken as precursor for upcoming demographic changes in Germany. As the population of this county is older in average compared to the total population in Germany [Statistical institute Germany 2009], this might hold true. This is the case, because especially people seeking for jobs moved away since the reunification of Germany. These were mostly younger adults often with children, as the number of school children in M-V had decreased above average [Statistical Institute M-V 2011] (Table 2). Previously, the study population has been considered to be representative of the population in (North-East) Germany [Mundt et al. 2011, John et al. 2001]. Unfortunately, a vast amount of drop-outs had to be noted, though the response is still relatively high compared to other so called representative cohort studies as high recruitment efforts were undertaken [Haring et al. 2009]. First of all, out of the 7,008 subjects contacted at the first stage subjects 126 died (Figure 6). The subjects who moved away predominantly had a higher education and a better general health. As a result, they have higher chances of lower caries prevalence and increment, because caries experience and increment not only in this study was found to be significantly lower with higher social status, but also in another recent survey in Germany [RKI 2009].

Moreover, the subjects who died were very likely older and sicker, which posed them at the same time at higher risk of high caries prevalence and increment. But as for obvious reason no oral data was available in these participants, this can only be extrapolated, but not be proven. Still, these subjects were regarded as neutral drop-outs as they were not considered in the net sample.

The response of the net sample was 68.8 %, which resulted in the total study sample of SHIP-0 (N = 4,308). The distribution throughout all age groups and gender

was shown in Table 1. Nevertheless, one can only speculate on other traits of these non-responders. Most likely they were not neutral drop-outs: The fraction of drop-outs in males was slightly higher than in females (31.8 % vs. 30.6 %), which means that drop-outs exhibit a rather high caries increment. Furthermore, they were slightly older, which was also associated with higher caries prevalence and increment in this study.

Looking at the higher response rate in the follow-up (76.6 %) and the response proportion of 83.6 %, which was considered very satisfactory [Haring et al. 2009], still, one has to accept that about one quarter of the sample was lost. Once again migration (N = 130) and death (N = 231) were relevant factors, leading to the same conclusion as mentioned above. Moreover, as the participants available in SHIP-0 had already shown to have an interest taking part in such a study (positive selection), they are less likely to lose interest. However, 647 active non-responders had to be noted. Subjects living alone, with a low educational level, female sex, smoking habit, a late recruitment in SHIP-0 or unemployment were most prone for attrition in this 5-year time frame, which showed that in spite of high recruitment efforts selection bias still occurred [Haring et al. 2009].

High educational level predicted lower caries increment in this adult population, and this was found to be predictive of a higher response, too. Likewise, smokers belonged more often to the drop-out group [Haring et al. 2009], and they were also more frequently present in the drop-out group, which were excluded at the last step before statistical analyses (Table 7). Socio-demographic factors identified as predictors of caries incidence were, therefore, at the same time predictors of non-response [Haring et al. 2009]. This means that the fraction of subjects with supposedly higher mean caries increment (e.g. low education and smoking) dropped out and one can speculate that the average caries incidence in the population of this region was even higher than observed.

The participants with missing (oral) data (N = 116) were excluded as no statistical analysis on caries increment was possible. They were more likely subjects with high caries prevalence and increment, as being aware of the unsatisfactory oral situation, embarrassment might have led them to the decision of non-consenting to the oral examination. Dental anxiety or displeasing memories of a dental examination might be further reasons. The selection of the study sample for statistical analyses excludes also the edentulous for obvious reasons. They belong to a group at very high risk of caries increment, but with no further caries increment possible, this group would

bias the findings. Furthermore, all subjects with a baseline DMFS > 55 were excluded for the risk modelling process as per definition of the caries increment risk group ($\geq$ 9 surfaces of caries increment in 5 years in the half-mouth design) they could not be categorized to the high caries increment group, although they would very likely belong to the high risk participants similarly like the edentulous. Therefore, the drop-out analysis was performed and presented in the chapter material and methods (3.9).

Due to the mentioned drop-outs at the different stages, the final sample of this caries incidence and caries prediction study was significantly younger, healthier and had a higher educational level compared to the randomized stratified sample drawn in the beginning and also in comparison with the participants in SHIP-0. Participants with a baseline DMFS > 55 (including edentulous) were also significantly older, rather current smokers and had a lower school education than all participants in SHIP-0 (Table 7, Table 8). This showed that the drop-outs again had a lower social status. Interestingly, they had a better self-perception of their teeth, as they might find their total/partial dentures to have good aesthetics. Moreover, the mean age differed highly significantly between men and women (Table 8). The study sample, therefore, was younger and statistical adjustments should be considered for the long-term follow-up to compensate this selection bias and to ensure a representative sample for the current population in Mecklenburg-Vorpommern. Still, as the median age in the ageing population of the whole of Germany was clearly younger with 41 years in 2000 [Statistical Institute Germany 2009], the study sample might account for the entire (ageing) German population in the future. In this case, the prediction model developed in this study might prove very valuable for the identification and the prediction of the high caries increment group in Germany.

However, in spite of a high total number of participants (N = 2,565) and a very high response proportion in SHIP-0 and SHIP-1, the drop-outs still had a relevant impact on the results as the social gradient remained. As presented, the study sample underwent certain selection bias at baseline and the survival of the subjects also correlated with socio-demographic factors [Haring et al. 2009], which were also found to be predictors of high caries increment.

In SHIP only German citizens had been investigated [Community Medicine Research Net 2012] while the fraction of foreigners or Germans with immigrant background in the county was clearly lower than in the whole of Germany [Statistical Institute Germany 2011]. Factors as immigrant background and ethnicity were,

therefore, not considered in this study, which excluded by selection the rising fraction of German adults with immigrant background [Statistical Institute Germany 2011] and might, consequently, slightly reduce the applicability to the entire population of Germany.

Nevertheless, with these robust and easily applicable prediction models (Table 15, Table 17, Table 19), the risk of high caries increment can be identified. This applies in particular as the total adult population in Germany presents similar levels of caries experience [Splieth et al. 2003] compared to this study sample. Moreover, this means that the relevance of certain ethnic and age group specific factors should be considered as small and, therefore, not critical.

5.1.2 Variables and categories

5.1.2.1 Caries experience and increment (DMFS vs. DMFT and adjustment)

In order to be able to compare the findings of this study, an analysis at the surface level (DMFS) was used, as many epidemiological studies use this index [Oral health database 2011, Tanaka et al. 2009]. The recordings of the caries experience on the tooth level (DMFT) were too high in SHIP-0 and SHIP-1 to gain a realistic view on the caries increment. Very likely caries incidence in adults occurred from e.g. an occlusal filling to an approximal-occlusal filling or to a crown. This cannot be exhibited by the index DMFT, as the number of affected teeth remains constant. On average, only very few healthy teeth were left to be affected by caries increment in this study sample of dentate adults [Splieth et al. 2003], as already about half of the total surfaces had caries experience (4.1.6). This would have biased and shifted the results on caries increment towards people with lower DMFT scores.

Moreover, the advantages and disadvantages of the DMFT/S index as a frequently used index are known and quite obvious. Mainly, it is an easy obtainable and well-reproducible variable in order to compare caries experience in populations, because dental examiners achieve generally (and also in this study) high inter- and intra-examiner kappa values (3.3). Nevertheless, the need for restorative treatment might be underestimated [Pitts 1997]. Caries diagnostics using a modified DMFT index including radiographs showed about 1.5 higher caries prevalence than without X-rays [Becker et al. 2007]. Moreover, in dental practices or for clinical trials, the diagnosis of coronal caries can be based on a combination of visual and tactile measures, radiographs as bitewings, fibre-optic transillumination, electronic caries monitor and

quantified light-induced fluorescence [Pretty 2006], each having different strength and weakness and, therefore, a combination very likely leads to a more exact and higher amount of diagnosed caries [Pretty 2006, Pitts 1997]. None of these further diagnostic methods was applied in this study, because they are unpractical and are not recommended by the WHO [1997] for epidemiological oral health surveys.

On the one hand, using the DMFS index the approximal surfaces are most prone to diagnostic error in a clinical examination, but on the other hand, as this was a longitudinal study, the underestimation likely happened in both examinations and its effect eradicates itself, measuring only the increment. Therefore, the impact of an underestimation of coronal caries due to the lack of additional caries diagnostics was probably marginally in this study, especially keeping in mind that the participants underwent their dental treatment in dental practices, where generally this diagnostic measure and dental treatment were performed, if necessary. This is reflected by the very low DS component [Splieth et al. 2003].

The author is aware that in a recently published systematic review [Preisser et al. 2012] on dental caries indices in epidemiological studies recommendations were given concerning the presentation of caries prevalence and incidence. These so-called zero-inflated count regression models were originally developed to eliminate the potential inaccuracy in the description of the caries prevalence and its distribution as inherited in the traditional models [Preisser et al. 2012 review] as e.g. used in this study. Interestingly, Preisser et al. [2012] found that the results were often interpreted imprecisely or incorrectly, which supported the decision to present data on caries the traditional way (e.g. mean DMFS ±SD). Moreover, the type of the distribution of caries prevalence (approximately a normal curve of distribution) and the generally high caries prevalence were further reasons (Figure 16).

All of these influencing factors show that the choice of measuring the caries increment on a surface level with the DMFS index was well taken.

5.1.2.2 Primary outcome variable: caries increment

Any measure for caries increment is based on several assumptions. Moreover, in collecting data mistakes occur, although e.g. kappa values for caries diagnostics are very high (intra-examiner 0.9 - 1.0; inter-examiner 0.93 - 0.96). With high (baseline) caries prevalence, which was the case in SHIP-0 [Splieth et al. 2003] and SHIP-1 diagnostic errors are very likely. Additionally, the necessity for adjustment according to Beck et al. [1995] becomes evident as negative caries increment is not possible by

definition of the DMFS as shown in Figure 8 depicting the net caries increment. Preliminary assumptions may cause, on the one hand, an overestimation of the true caries increment if the crude caries increment (CCI) is used and on the other hand may lead to an underestimation in case the net caries increment (NCI) is used. Moreover, in other caries prediction studies the caries increment was adjusted the same way [Sánchez-Garcia et al. 2011]. In this study sample, the mean values for the crude caries increment and the adjusted caries increment were very similar. This would have left the option to use only the crude caries increment, but due to all the previously mentioned factors, the measure of caries increment applied in this study was still adjusted to the intermediate estimate called adjusted caries increment [Beck et al. 1995].

Despite much statistical adjustment the caries increment was not adjusted to the length of the time period between the two oral examinations in SHIP-0 and SHIP-1, which stands in accordance to other published longitudinal studies using SHIP-data [Mundt et al. 2011, Haring et al. 2009]. As this time adjustment is not possible using the logistic regression this influencing factor had to be passed over. The adjustment of the time period between the two examinations could have only been realized with the Poisson regression, which does not produce probabilities needed for the ROC-curves. However, as the time period of 5 years is already quite long, few additional months or even a year might not make a relevant difference in the selection of the participants at high risk of caries increment, especially considering the large number of participants and the high threshold (≥ 9 surfaces) for the high caries increment group. Still, this aspect as generally done has to be accepted, lacking better alternatives.

Beyond doubt, in some cases a more detailed knowledge on the different components of the DMFS-index might have been useful for better differentiation, but the adjustment of each of the components was not performed and, therefore, no detailed data was presented on the different components. The single components (DS, MS and FS) would have made a more specified interpretation possible: DS is the indicator for the need of treatment, as it stands for decayed surfaces. It has been found to be very low in Germany [RKI 2009, Micheelis and Schiffner 2006], as well as in this study sample [Splieth et al. 2003]. DS therefore, played a minor role for the DMFS and was for that reason not the main concern of this research on the prediction of caries incidence. Moreover, MS stands for missing surfaces and depicts the severity of caries, or with age the low threshold for extraction due to periodontal reason [Splieth et al. 2002]. Unfortunately, the threshold for tooth-extractions for periodontal reasons has been

found to be low in Germany as the attachment level of extracted teeth with low caries experience was between 50 - 70 % [Splieth et al. 2002]. At last, filled surfaces (FS) show the level of dental care and make up for the highest part of the index hand in hand with MS, depending on the age of the adult participant. Despite this limitation, one needs to keep in mind that the aim of the study was neither the identification of the risk factors or predictors for the incidence of tooth-loss (MT) [Houshmand et al. 2012, Mundt et al. 2011] nor to predict individuals with open cavities (DS). Moreover, in a recent incidence study (also SHIP) in almost the same study sample used for statistical analyses, caries was found to be the best predictor for incident tooth loss in young adults (20 - 39 years) in contrast to periodontal parameters for older adults [Houshmand et al. 2012]. This means that with age and, therefore, especially in older adults the cause for tooth loss shifts from caries to periodontal disease. This obviously has an influence on the DMFT/S as the cause for the extraction (periodontal disease or caries) can hardly be obtained in the aftermath. This suggests that in younger adults carious lesions were the main reason for an increment of the DMFS (mostly FS and MS component). Whereas with higher age the increment of the FS component was still due to caries, while the MS component increased rather due to periodontal disease. This stands in accordance with findings in Denmark, where the proportion of MS/FS in elderly was found to be higher than in younger adults [Krustrup and Petersen 2007]. Furthermore, poorly contoured fillings or prosthetic restorations (crowns, bridges, etc.) provide a niche for plaque accumulation and may, therefore, also be a potential risk factor for marginal periodontal disease [Geurtsen 1990]. Still, tooth loss could also mean that the caries experience had been more severe or that the choice of dental therapy like endodontic treatment had not been available for these cohorts and, therefore, led to higher MS.

5.1.2.3 High caries increment group

The choice to put the threshold at 9 surfaces of caries increment for the high caries increment group was based on several factors. First of all, a group of about 10 % is small enough to call it a high risk group. Secondly, these subjects, as caries increment was found to be polarized, have more than 40 % of the total number of surfaces affected by caries incidence (Table 14). This displays a clinically relevant amount of carious surfaces affected, but still a justifiable small group size for an adequate cost- and time-effective preventive strategy being significantly smaller than the threshold of 30 % to start population based prevention [Hausen 1997]. Moreover, the interpretation

of the OR is more powerful. With lower prevalence of an event (e.g. here 10 % high caries increment group) the values for OR and RR converge and, therefore, can be considered almost equivalent at this level [Sistrom and Garvan 2004]. Furthermore, in preliminary analyses the prediction (ROC, AUC) for a group size of 10 % showed undoubtedly better results than for a risk group size of 25 %. Amongst others, this enforced the decision to define the group at risk of high caries increment to the smaller size of about 10 %. Due to this defined size of the risk group the study sample was adjusted. This led to the exclusion of some participants of the supposedly high caries risk group (edentulous or baseline DMFS > 55), who per definition could not be categorized into the high caries increment group. These drop-outs as assumed and already presented above (3.9, 5.1.1) had other characteristics in the significantly exposing factors as they were older, had lower school education and were rather current smokers. This consequently would have had an interfering impact on the results (Table 7, Table 8). Thus, this group which exhibited high caries prevalence already at the beginning of the study confirmed the findings for males in the high caries increment group.

5.1.2.4 Half-mouth design

According to Gülzow and Maeglin [1964] data on caries prevalence in epidemiological studies does not differ regarding the way of the recording (half-mouth vs. full mouth), due to the symmetrical distribution of caries. Obviously, caries affected surfaces can be collected a lot quicker in a half-mouth design, and as in the pilot phase also no significant differences had been proven [Splieth et al. 2004, Hensel et al. 2003], this design was chosen for this large scale examination. Still, the presentation of data on caries increment from a half-mouth design leads to a lower comparability to other studies. Nevertheless, for an easy comparison, the mean values of the caries increment only need to be doubled. Unfortunately the standard deviation of these mean values cannot be computed without the original data. Nonetheless, reminding that the main objective of the study was to predict the group or at best the individuals with the highest risk for high caries increment on an epidemiological level, the exact values for the standard deviation are of secondary interest. Moreover, the prediction of the exact increment in an individual person stays an open goal. Thus, it remains a task that experts think to be barely possible [Hausen et al. 1997].

5.1.2.5 Initial caries lesions

Unfortunately, the factor initial caries as a marker of caries activity could not be used in this study as it has not been recorded. The variable "enamel defect" was collected, but it only included carious defects (DS) in enamel instead of non-cavitated lesions and it was rarely present [Splieth et al. 2003]. After the caries decline, a documentation of initial active lesions with surface breakdown seems to be very important in children to prevent the impression that the very low caries values express freedom of caries activity. Data on coronal caries should register at least active initial lesions such as the Nyvad index [Nyvad et al. 1999], which proposes a more distinct level of detection, especially of carious processes within the enamel. In adults with the current high levels of restored lesions, the D-component plays a marginal role and even the differentiation between carious defects in enamel and dentine revealed very few lesions confined to enamel. Active initial lesions in adults had enough time to develop into defects during the 5-year course of the study. Thus, the argument, that the DMFT/S lacks to reveal if the caries process is active or inactive, is valid for cross-sectional studies, but not relevant for longitudinal settings as in the present study. Nevertheless, active lesions (white spot or initial stage decay) may have shown to be a good predictor of caries incidence as they are the early sign of the clinically visible active carious process [ICDAS 2012]. This concept differs from the idea of predicting the disease via the disease, which has been shown to be very successful, especially in children [Alm et al. 2008, Tagliaferro et al. 2008, Reisine and Psoter 2001, Hausen 1997]. Furthermore, using caries activity as the predicting factor is an approach of primary prevention in contrast to measures of secondary prevention using the caries experience as the risk marker or predictor.

5.1.2.6 Selection of other variables

The selection of the other predominantly socio-medical variables used in the prediction model mostly do not need to be discussed in detail. Age (5-year age group) and gender are self-explaining. The level of school education, self-perception of teeth, the pain-associated dental visit and being at a certain dentist are based on self-report (yes/no or good/not good). These questions very likely were answered correctly as no evidence or hint for a biased answer was present and these questions did not touch socially difficult topics. Contrarily, the number of participants having "problems with alcohol" was very likely to be underestimated as the embarrassment or the regression connected to the answer though anonymously made remains obvious. At first, nobody easily admits to

have problems with the consumption of alcohol, sometime not even to oneself. Secondly, harm reductions in the self-perception of alcohol use are usual. For example a large part of students in the USA reported not consuming alcohol at the last socialisation, while only a tiny fraction of their college students had not drunk [Haleem and Winters 2011]. Therefore, undoubtedly, a discrepancy in the self-perception of drinking is present. This might also be an explanation that this variable was not found to be statistically correlated to high caries incidence. Moreover, the variable smoking was simplified to the highest degree (current vs. never/ex-smoker). In preliminary analyses, no better outcome was generated when cigarette smoking was differentiated to the exact number of cigarettes. In addition, the prediction model was aimed to be kept as easy as possible, which could only be realized by simple dichotomous variables.

5.1.2.7 Statistical tests and quality of the prediction model

As stated in material and methods significances were tested according to the type of the data. All these statistical parameters especially the chi square test (χ^2), the t-test, the ANOVA and the odds ratios (OR) are frequently used in epidemiological studies [UNCCPHP 2012]. Moreover, a valuable criterion for the quality of the prediction model is the area under the curve (AUC) of the ROC. Therefore, the AUC was calculated using the binary regression, being the model resulting in probabilities needed for the creation of ROC-curves [Hanley and McNeil 1982]. Moreover, the OR can be considered quite similar to the relative risk when prevalence is low (10 % or less) [Sistrom and Garvan 2004], which was the case as in this study the size of the high caries increment group (11.4 %) was very close to it.

5.2 Discussion of the results

5.2.1 Caries prevalence and increment

In this study caries was still a highly relevant problem in German adults of all ages. Adults had high levels of caries experience in SHIP-0 and SHIP-1. Moreover, a very high proportion (77.2 %) of adults in this study sample had caries incidence during the observation period of 5 years. Additionally, a mean 5-year caries increment of 3.7 surfaces (median 2) in the half-mouth design should be considered as highly relevant from a socio-medical point of view, because this means an average caries increment of almost 2 completely healthy teeth in each adult of this population. The 10 % of the population with the highest caries increment had even an increment of more than 9

surfaces in the half-mouth design. This leads to an estimate caries increment of at least 18 surfaces (full mouth), which again means that in summary the surfaces of 4 completely healthy teeth were affected by caries within 5 years in this high risk group. Contrarily to the caries experience (DMFS) the caries increment was clearly polarized in this adult population. Especially considering that 1/4 of the sample had 2/3 of the caries increment and 10 % of the participants had about 40 % of the total number of surfaces affected by caries increment. These findings stand in accordance to studies on caries incidence in children in which about 1/3 to 1/4 of the population portrays 2/3 to 3/4 of the total caries [Peres et al. 2008]. Moreover, a high socio-economic level showed to be clearly protective of caries incidence in the permanent dentition in school children [Chankanka et al. 2011], similarly to findings in this study. This goes along with Ferro et al. [2012] who conclude that the "socio-economic status is still a predictor for dental decay in the Italian 14-year-olds."

Future research needs to analyse if the caries increment of this population in Mecklenburg-Vorpommern actually represents the caries incidence in the German population, because many factors mentioned suggest that this study even underestimates the real caries increment. Nevertheless, the validity of the predictors remains for this population. Moreover, one has to consider that the demographic change combined with the large decline of caries prevalence in adults will have an important effect on caries incidence. This can already be seen in this study as younger adults (20 - 39 years) had less caries increment, which can be interpreted as slower progression of the carious processes possibly due to more effective preventive measures. As no national caries decline in children and adolescents was observed in the GDR before reunification of Germany [Künzel 1988], none of the adults in this study benefited from improving caries prevention during childhood as data collection for SHIP-0 began already in the late 90s. Thus, the observed lower caries increment in young adults has to be a post-unification effect. After reunification a caries decline in children of more than 30 % could be observed which was accounted to a "broader availability of fluorides" and a "high level of individual dental curative and preventive care" [Künzel 1997]. Consequently, the upcoming generation in (North-)East Germany with declining caries experience in childhood [DAJ 2010] will profit from these measures also in adulthood, where further caries reductions can be anticipated. In the last national health survey (DMS IV) the reference group for adults (35 - 44 years) had a clearly lower mean DMFT than in the previous national survey (DMS III) [Micheelis

and Reich 1999, Micheelis and Schiffner 2006], which shows that the caries decline has reached German adults. Though only a hypothetical scenario for Germany, the so-called cohort-effect very likely will occur as these effects can be observed in other countries like the USA [Mjör et al. 2008], which started prevention decades before Germany [Splieth 2004]. With the demographic change and the ageing of the population [Statistical institute Germany 2009], hand in hand with the improved caries prevention in childhood [DAJ 2010], the adults of tomorrow will not prevail anymore the situation of caries experience and increment depicted in this study. This is especially plausible as every dental restoration runs the risk of subsequent damage of neighbouring healthy surfaces, which could be drastically reduced in the future. Therefore, the need for prosthetic and restorative dentistry per person could decrease along with the declining DMFS and the decreasing population in Germany. Nevertheless, more remaining teeth have a higher risk to be affected by periodontal disease and with the ageing population in Germany [Statistical Institute Germany 2009] these teeth also have a longer expected function period.

5.2.2   The influence of age and caries experience on caries increment

The mean age at baseline in the high caries increment group was significantly higher with 51.8 ±13.1 years vs. 44.5 ±14.3 years in the reference group (p < 0.001, ANOVA, Table 11). Nevertheless, the variation of caries increment should be observed within at least two different age groups (young adults and older adults). This factor was simplified into a dichotomous variable as all the adult age groups $\geq$ 40 years had significantly higher mean caries increment than the younger adults (Figure 13).

In accordance to expert opinions on the general caries decline [Bratthall et al. 1996], the caries progression of this study sample decreased with younger age in the time frame between SHIP-0 and SHIP-1. This correlation between age and caries progression after the introduction of caries prevention programs for children has been proven already by Friis-Hasché [1994], as every dental restoration leads to further caries increment as no restoration is ever-lasting. Even though caries progression slowed down, caries prevalence and increment in these young adults (20 - 39 years) was still on a relevant and high level (Table 9).

In middle-aged adults and seniors (40 - 79 years) of this study most likely the increase of the DMFS in this 5-year period was not only due to new carious lesions but also to the replacement of fillings (mean lifespan 7.7 years) and prosthetic restorations (mean lifespan > 10 years) [Splieth and Fleßa 2008] e.g. for the replacement after tooth

loss, which could have been also due to periodontal reasons [Splieth et al. 2002]. This means that one should always be aware that DMFT/S scores may increase not only due to new caries lesions, but also due to prosthetic work as for the replacement of missing units with bridges or the replacement of fillings, which were found to have a median longevity around 8 - 10 years [Mjör et al. 1990].

Especially for people with frequent social contact, as most adults of this age are, aesthetic teeth and an attractive smile play an important role [Van der Geld et al. 2007] assuming that this counts similarly for the function of these teeth. Furthermore, "tooth loss can be disabling and handicapping" and may have a profound impact on people's lives [Fiske et al. 1998]. Therefore, prosthetic dentistry is undertaken. Interestingly, the drop-outs had a higher self-perception of teeth (3.9), which shows that total and partial dentures might even achieve better aesthetics than the own teeth. One further major reason for the high caries prevalence in the study region has been accounted to the German oral health care system [Splieth et al. 2003] and the fact that until the reunification in Germany fluoridated toothpaste was barely available [Treide 1984]. More importantly, these participants have not had the chance to obtain and learn caries preventive measures during childhood as the IP programme (individual prophylaxis in dental offices in Germany) was not introduced till 1989 for 12-year-olds and not until 1993 for 6-year-olds by the health insurances [Pieper and Momeni 2006]. Therefore, they might undertake shorter or less successful prophylaxis at home, which is obviously also more difficult with a higher rate of dental restoration. Moreover, they might still carry the thought that the dentist is responsible for their oral health, as still a lack of knowledge on the prevention of oral diseases exists [Aggarwal et al. 2010].

Due to the definition of the DMFS index, baseline caries experience correlated with higher age in study sample. Moreover, baseline caries experience (dmfs/DMFS) has been proven to be a predictor for caries incidence in children [Tagliaferro et al. 2008, Fontana and Zero 2006, Gilbert et al. 2000, Powell 1998]. In elderly, the number of remaining teeth was shown to be predictive [Fure 2004], but no significant correlation could be observed in this study. The concept to predict the disease (caries incidence) with the disease (caries experience) works, but is by far not satisfying for a preventively orientated dentist. Obviously, the factor baseline caries experience has an impact on the caries increment, as it shows whether the person has been able to deal with the disease in the past. Adults with a low baseline DMFS belonged mostly to a group with no or a low risk of high caries increment (Figure 16, Figure 17), but not

automatically. In case a risk factor changes (diet, brushing behaviour, periodontal disease, etc.), these adults have the highest number of surfaces at risk for future caries.

In daily practise, dentists often use caries experience as an indicator for caries increment in children [Sarmadi et al. 2009], which has been identified to be its best predictor [Messer 2000, Van Palenstein Helderman 1998]. The present study showed that this association is also valid for adults.

5.2.3 The influence of gender-dependent variables on caries increment

Men showed significantly higher mean caries increment in this study (Table 10, Figure 13), whereas women on the contrary have higher DMFS/T scores in general [Armfield et al. 2009, RKI 2009] and also at baseline [Splieth et al. 2003]. This is probably due to a higher frequency of dental visits and earlier restorative dental care [Astrøm et al. 2011], but maybe also due to other factors like hormones, lower salivary production or food cravings during pregnancy [Jindal et al. 2011]. In the German oral health survey, adults (35 - 44 years), who visit the dentist control-based have slightly higher caries experience. Generally, the number of decayed surfaces (DS) is very low, because they are treated "immediately" in Germany. Moreover, the size of fillings in adults usually is larger than the primary caries lesion due to the material used for restoration and due to the concept "extension for prevention" declared by G.V. Black at the beginning of the 20th century [Garg and Garg 2010]: A small mesial caries, for example, will end up as a two-surface filling on the mesial and the occlusal surface. Moreover, women also have a higher degree of dental restoration, as they rather regularly attend the dentist and, therefore, more often than men. In this study the factor pain-related dental visit was significantly associated with high caries increment in men, while in women it was not (Table 17), which confirms that women rather regularly attend the dentist, while men do not and, therefore, visit the dentist rather pain-related [Schouten et al. 2006]. This can be also anticipated from the DMS IV, in which symptom-related dental visit was associated with higher caries experience in adults and seniors [RKI 2009], but unfortunately, gender-dependent differences of this factor were not published. In this study, the effect of the educational level on caries incidence was also only present in men (Table 17). This means that men were more prone to belong to the high caries increment group (mostly low education/income and current smokers). In comparison women rather take care of themselves, even if they smoke or if they are not as well educated, because their demand for an aesthetic appearance remains due to socio-cultural influence [Fox 1997]. Moreover, this shows, that women are rather

capable to adapt and compensate these influences and maintain a better oral hygiene than men. Additionally, not only in Germany lower educational status was found to be significantly higher in adults [RKI 2009] but also, e.g. in Denmark [Krustrup and Petersen 2007]. Nonetheless, as the study sample originates from a specific region in Germany, the influence of the socio-economic factors on caries incidence in adults needs further proof in other populations. These findings were already shown in SHIP/Germany [Mundt et al. 2011] and in the NHANES/USA [Wu et al. 2011]. Furthermore, to enforce the impact of socio-economic factors, unemployment being a predictor for active non-response [Haring et al. 2009] is generally correlated with lower financial status (monthly income), which was shown to be also significantly associated with higher mean caries increment in this study (Table 11).

Likewise, men with a lower socio-economic status tend to have a lower conscious for (oral) health (e.g. smoking), which was reflected in the higher caries increment. Interestingly, smoking women also compensate this unhealthy behaviour and might perform a better oral hygiene due to socio-cultural influences [Fox 1997].

Moreover, the influence of smoking on periodontal disease has been shown [Al-Habashneh et al. 2009, Micheelis and Schiffner 2006], which might be another way to explain the impact of smoking on the DMFS increment, as with age and a low threshold in the attachment loss for tooth extraction the MS component increases as well.

The differences in the mean caries increment maintain highly significant even without the consideration of the gender-dependent variables such as education, smoking, pain associated dental visit (Table 10, Figure 13, Table 17). This suggests that women are rather capable to compensate unhealthy life-style and learn to overcome the tilted social gradient. For that reason, the prediction of the subjects being incompetent in oral health works truly better in men than in women.

5.2.4 High risk prevention or population-based prevention

In this study the presented ROC-curves show that the diagnostic tests meaning the predictive models are far from being ideal (AUC = 1), but with an AUC of 0.75 reach a fair to good level [Hanley and McNeil 1982]. The statistical measurements in this study showed for males with an AUC of 0.75 (sensitivity: 30.2 %, specificity 87.3 %) a similar level compared to a study performed on the prediction of root caries, which resulted in an AUC of 0.75 and while displaying a low sensitivity of 15.6 % and a high specificity of 97.8 % [Sánchez-García et al. 2011]. Nevertheless, one has to keep in mind, that the sensitivity and the specificity strongly depend on the prevalence of the

disease and the selected cut-off points. In this case the "prevalence" is roughly equivalent to the 10 % of the participants belonging to the high caries increment group. With a larger risk group of caries incidence at hand the positive predictive value rises automatically, which displays the precision of the test detecting the subjects belonging to this group. Likewise, the positive predictive values increase with rising sensitivity and specificity by definition [Fletcher and Fletcher 2005].

One key question remains: whether a high sensitivity or rather a high specificity in caries prediction is set as a goal. First of all, it is of utmost importance to detect all the ones in the high caries increment group, meaning a high sensitivity, yet a lower sensitivity leading to caries prevention for some subjects not belonging to the high caries increment group is not harmful to their health. On the contrary, considering, that most adults in this study sample (75 %) had caries increment during this time period of 5 years, additional preventive measures would be helpful for any of them. Evidently, concentrating only on risk-specific prevention, with lower sensitivity the costs for prevention will increase for insurances, the state or the performing authority, as the group size receiving intensive prophylaxis grows. Alternatively, a high specificity helps in this case to minimize the size of the risk group. In this way the group at high risk of caries increment can be narrowed down from both sides. Nevertheless, none of the presented models (Table 15, Table 16, Table 17) achieved a sum for the sensitivity and specificity > 160 as demanded by Kingman [1990] for a high accuracy of such a risk model.

Experts still debate whether prevention should be population-based or target only the high risk group. According to Hausen [1997], prevention should target an entire population if the risk group is larger than 30 %, which obviously depends on the definition of the population at risk. Moreover, Batchelor and Sheiham [2002], in contrast to Burt [1998] and Hausen [1997], found out, that in spite of the polarized distribution of caries in most countries of the Western World caries prevention should always be population-based as "strategies limited to individuals 'at risk' would fail to deal with the majority of new lesions" [Batchelor and Sheiham 2002]. Disregarding the unsatisfying sensitivity and specificity for prediction but looking at the very high caries experience, incidence and increment in this population, this already calls rather for a population-based prevention, especially considering that 90 % of the participants still had about 60 % of the total number of surfaces affected by caries increment (Table 14). Although the life-long perspective for preventive measures can be extremely cost-

effective [Splieth and Fleßa 2008] the high caries experience of this study sample "reflects the structure of the German national health coverage system and the need for intensified preventive measures for adults" [Splieth et al. 2003]: This shows, that very little has been achieved in population-based caries prevention in German adults. In case of a politically rather unrealistic, but still reasonable scenario of a national caries preventive approach in adults, very likely a similar process of caries reductions could be achieved as already observed in German children [DAJ 2010], or in adults of other countries like Sweden [Hugoson et al. 2000] or the USA [Winn et al. 1996] in which population-based caries prevention was started many years ago. As also seen e.g. in British children [Schou and Wight 1994], the caries levels decrease and become more polarized after a dental health campaign. Consequently, the distribution of caries experience and increment in German adults will very likely become even more polarized, while the total number of surfaces or teeth affected by caries decreases step by step.

Population-based prevention for adults could work by offering group prophylaxis e.g. in companies. This is comparable to group prevention for children in schools. Alternatively, the liquidation of caries preventive measures in dental practice could be enforced, according to the individual prophylaxis (IP), which exists for children. Moreover, as presented by Sheiham and Watt [2000], oral health promotion could also work through the "common risk factor approach" as "conventional oral health education is not effective nor efficient". The risk factor approach gives attention to common risk factors of chronic diseases and should be seen as an oral health policy "within the context of a wider socio-environmental milieu" [Sheiham and Watt 2000]. This means a major public health action on the conditions, which generally resolve in unhealthy behaviours across the population, is necessary, instead of a high-risk approach [Watt 2005]. A general public health promotion should address the underlying determinants ("causes of the causes") and, therefore, copes with the inequalities in oral health [Watt and Sheiham 2012, Sheiham 2000]. Furthermore, the efficacy of caries prevention in high risk children has been low [Källestål 2005], and suggests that also in high risk adults the implementation of preventive measures works less successful as hoped.

In spite of the call for a population-based prevention for adults, in dental practices an easy risk screening – like the presented prediction model – on caries risk backs up and helps to come to a reasonable therapeutic decision. Especially,

considering that the intuition of the dentist and the caries experience have previously been shown to be the best working predictors [Stößer 1998]. Consequently, an individual intensive prophylaxis with a higher frequency and a higher effort should be undertaken seeking oral and also socio-environmental factors. Still, one has to acknowledge, that the long-term influence of social factors make a more valid prediction than aetiological factors as they influence the life-style a life long [Mundt et al. 2007].

For the state and health insurances, an early identification of high risk individuals might save money as for the prevention less money might be spent than for the restoration [Splieth and Fleßa 2008]. In contrast, the private health insurances choosing their clients themselves could apply this model and might increase the fees for the risk subjects. Nonetheless, one should be aware that the role of medical insurance in dentistry is decreasing and, besides preventive measures, the costs will be privatized [KZVBW 2006]. In Germany, many adult patients pay parts of the total costs in dentistry already themselves. This accounts for prophylactic treatment as well as prosthetic therapy. Still, the aim of a financially well-situated and social country like Germany should be a less polarised distribution of the caries experience and incidence as well as a generally tremendously lower mean caries increment in adults.

In conclusion, a population-based preventive approach would be indicated for adults in Germany at first. This call is mainly based on the maintaining high caries prevalence and incidence, while the prediction of high caries increment works only on a fair to good level. Obviously, also ethically a population-based oral health policy is less complicated, as anybody is being offered the same chance for oral health, but political boundaries still have to be overcome. Specific, risk-based programmes seem to be more appropriate as a second step when a further caries decline and an increase in the polarisation can be detected.

5.2.5 Caries prediction

No single subject in the study sample had all the factors, which correlated with higher risk of caries incidence. Nonetheless, already 2 - 4 of these factors increase the OR for being in the high caries increment group tremendously. The more factors the participants have the higher the overall risk. Still, neither of these variables alone nor several factors together make a prediction of high caries increment in an individual possible. At the highest, a hypothetical male person in this study having all statistically significant correlating factors of high caries increment would have an OR which is by

far smaller than 228, which is demanded in order to be able to have such an impact on the ROC-curve that the prediction of caries incidence in an individual adult would be possible [Wang et al. 2006, Ware 2006]. Such an OR ($\geq$ 228) corresponds to a sensitivity of 0.80 and a specificity of 0.90 [Wang et al. 2006, Ware 2006].

Still, the variables smoking, school education, and pain-associated dental visit have a very remarkable impact on the OR as they show interactions with the variable gender. Interestingly, as presented earlier these factors correlate significantly in men, but not in women. Therefore, these variables should be of special interest in the prediction of high caries increment in men.

Though, the prediction of high caries increment cannot be applied for an individual of this study sample, the few variables (gender, age and income/school education) included in the simple model pose already a good basis for the prediction of high caries increment on a population level. All the other variables have a smaller impact on the improvement of the prediction, which also showed to be gender-dependent, as only in males a further significant improvement was found. In accordance to Wang et al. and Ware [both 2006], one has to admit that risk stratification regarding processes of a multi-factorial disease is still very difficult to realize. Therefore, efforts need to be undertaken to find markers and predictors which provide a better basis for prognostic evaluation in an individual patient or for a prediction of caries incidence on a tooth level or even surface level.

In a recent study performed in Mexico, a similar AUC (0.75) was obtained in the prediction of root caries [Sánchez-García et al. 2011]. Moreover, similarly to this study (compare Figure 18, Table 18) the values for the sensitivity (15.6 %) and specificity (97.8 %) have been problematic [Sánchez-García et al. 2011]. Likewise, in the prediction of caries progression in children, an AUC ranging between 0.70 - 0.79 could be achieved [Fontana et al. 2011]. Furthermore, in another study using the total Cariogram for caries prediction in children a sensitivity of 0.73 and specificity of 0.6 could be achieved resulting in and AUC of 0.751 [Petersson et al. 2010]. Whereas, the reduced model without the factors *Streptococcus mutans*, buffer capacity and secretion rate had a sensitivity of 0.9 and only a specificity of 0.2, which lead to a significantly lower ($p < 0.05$) AUC of 0.723. As previously mentioned, in children caries experience has been identified as the best predictor of caries increment, while for no single diagnostic tool or factor the specificity and sensitivity of the test is reliably high for caries prediction in an individual [Messer 2000, Van Palenstein Helderman 1998]. In

that sense compared to children, the prediction of caries incidence works equally well or unsatisfactory in this adult population: The prediction of risk groups can easily be performed, but on an individual level, the accuracy is questionable making also the allocation for risk-specific preventive programmes a difficult task.

6 Conclusions

The findings of this representative sample can be generalized with minor limitations to the entire population of Germany. By nature, forecast models can impossibly predict precisely, but offer a reasonable scenario for the future.

The depiction of high caries prevalence and increment in these adults is biologically plausible as none of them benefited from measures of fluoride prevention during childhood and their existing restorations lead subsequently to further damages and increment of coronal surfaces.

The presented prediction model offers a concept for an easy screening to identify a group of adults at high risk of high caries increment using the medical history for a caries risk assessment. Only few easily obtainable markers as the age, gender, socio-economic status, caries experience, smoking, pain-associated dental visit and the self-perception of teeth may lead to an identification of a large part of the group at risk of high caries increment. Interestingly, the prediction via these factors works quite well for men while only fairly for women.

Nevertheless, as caries prevalence and increment were high, a population-based caries prevention policy for adults as well as the prolongation of the IP programme existing for children, would be very reasonable. Risk-specific intensified preventive approaches might follow later on. This is also ethically less complex as the entire population is being offered the same chances for oral health.

Upcoming generations, who benefited from the established caries prevention in childhood, will most probably in adulthood display clearly lower caries experience than the adults of this study sample. Therefore, along with the demographic change the demand for prosthetic and restorative dentistry will decline in the long run with caries being still prevalent, but more polarized according to the socio-economic status.

Still, further research is needed to prove this prediction model in daily practice as well as in other populations, in order to come closer to the aim of a successful caries prediction.

7 Summary

The objective of this study was to determine risk indicators predicting high coronal caries increment in adults (20 - 79 years) living in North-Eastern Germany based on the longitudinal data obtained from the "Study of Health in Pomerania - baseline" (SHIP-0) and the 5-year follow-up (SHIP-1). In children, caries predictors have been well investigated. Especially, high caries experience and low socio-economic status have been found to be significantly associated with caries incidence [Twetman and Fontana 2009]. Few cohort studies have been performed in adults investigating long-term caries predictors. Mostly in adult populations only data on short-term studies restricted to specific age groups (e.g. seniors) or data on predictors of root caries are available.

In this 5-year longitudinal caries incidence study a population-based study sample stratified according to age and gender was selected at random from the study region in North-East Germany. The response in SHIP-0 was 68.8 % leaving 4,308 participants in the baseline examination (1997 - 2001). The response in the 5-year follow-up SHIP-1 (2002 - 2006) was 76.6 % leaving 3,300 subjects in the cohort study. After excluding participants with missing oral data, edentulous, subjects with a baseline DMFS > 55 or older than 79 years, 2,565 participants were included for statistical analyses.

The data collection consisted of four parts: oral health examination, medical examination, computer-aided interview and a self-administrated questionnaire. The oral health examination was conducted according to WHO criteria [1997] by eight licensed dentists. In caries diagnostics Cohen's kappa reliability coefficients of 0.9 - 1.0 (intra-examiner) and 0.93 - 0.96 (inter-examiner) were achieved in the final quality control. The DMFS was obtained and presented in a half-mouth design, as no statistically relevant right-left difference was found in the pilot phase. The caries increment was adjusted according to Beck et al. [1995] and the high caries increment group was defined as the participants with ≥ 9 surfaces of caries increment in the half-mouth design in a time period of 5 years and led to a group size of 11.4 %. Descriptive and analytic statistics (binary logistic regression) were performed using the programme PASW Statistics 18 with the support of a professional mathematician of the University of Greifswald. A drop-out analysis was carried out and revealed that drop-outs were significantly older, had a lower school education, were more frequently current smokers, but had a better self-perception of their teeth.

The majority of the study-population (76 %) had caries incidence during this 5-year period. Moreover, caries increment showed a polarized distribution, as the high caries increment group (≥ 9 surfaces in half-mouth, 11.4 % of the sample) comprised 40 % of the total number of newly carious, filled or missing surfaces. The variables male gender, age ≥ 40 years, lower school education or lower income, current smoking, pain-associated dental visit, baseline caries experience and a non-satisfying self-perception of teeth showed a statistically significant long-term influence on high caries increment. Baseline caries experience was also significantly higher in the high caries increment group. Whereas, no variable associated with periodontal disease nor diabetes, nor self-reported problems with alcohol, nor the type of medical insurance (state or private), nor being a club member was found to have statistically significant influence on the mean caries increment. The simple prediction model (gender, age, income) made only a poor prediction possible (AUC = 0.675), whereas the final gender-adjusted model including all significantly associated variables allowed already a fair to good prediction on an epidemiological level for men (AUC = 0.750). The factors smoking, school education and pain-associated visit had gender-dependent associations, which means, that they only had a significant impact on the prediction of high caries increment in men. Probably, less educated women or female smokers still had a higher drive for health and aesthetics as they live in the socio-cultural environment of our Western world. More so, the odd ratios (OR) for being in the high or low caries increment group ranged between 1.5 and 2 for the following dichotomous variables: pain-associated dental visit, gender, school education, smoking, self-perception of teeth.

In conclusion, caries incidence remains a relevant challenge in German adults. The prediction of high caries increment using the presented prediction model is possible on a fair to good level when applied on an epidemiological level. Furthermore, the prediction via socio-economic and medical factors appears to be a promising approach as they showed a long-term influence on the life style. Still, the combination of the mostly gender-dependent factors did not predict caries incidence on an individual level. Especially, considering that generally high caries prevalence and increment was found in this study sample, population-based, preventive strategies for adults should be implemented before risk-specific approaches are used. Further drastic caries decline and a more polarized distribution are very likely to occur in future adult generations in Germany.

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9   List of figures

10 List of tables

11 List of abbreviations and glossary

AIDS: Acquired Immune Deficiency Syndrome

ANOVA: analysis of variance

AUC: The Area under Curve summarizes the findings of the ROC by presenting the probability that a classifier will rank a randomly chosen positive instance higher than a randomly chosen negative. It can rank between 0.5 and 1.

BMI: body mass index

BOP: bleeding on probing

CAL: clinical attachment loss

CCI: crude caries increment

CI: confidence interval (95 %)

CMR: Community Medicine Research net

Decrement: decrease of the disease in the population

dmfs/t: decayed missing filled surfaces/teeth in the deciduous dentition

DMFS: decayed missing filled surfaces – measurement of caries experience, excluding wisdom teeth and teeth extracted for another reason than caries

DMFT: decayed missing filled teeth – measurement of caries experience, excluding wisdom teeth and teeth extracted for another reason than caries

DS: decayed surfaces

DT: decayed teeth

DMS: Deutsche Mundgesundheitsstudie (German Oral Health Survey)

e.g.: for example [exempli gratia]

FS: filled surfaces

FT: filled teeth

GDR: German Democratic Republic

HbA1c: Glycated haemoglobin – used to identify the average plasma glucose concentration over prolonged periods of time

HIV: human immunodeficiency virus

IgA: immunoglobulin A

IgG: immunoglobulin G

Incidence: amount of people who got the disease in a period of time

Increment: increase of the disease within a time period

IP: individual prophylaxis for children in dental practices in Germany

LR: Likelihood ratios are used for assessing the value of performing a diagnostic test. They use the sensitivity and specificity of the test to determine whether a test result usefully changes the probability that a condition/disease exists.

MS: missing surfaces

MT: missing teeth

M-V: Mecklenburg-Vorpommern

N: number of participants

NCI: net caries increment

NSAOH: National Survey of Adult Oral Health (in Australia)

OR: The odds ratio describes the strength of association between two binary variables. An OR of 1.0 means no association, a higher OR poses a risk, a lower OR is protective.

Prevalence: amount of people with the disease in the total population

Predictor: a factor associated with the increment of the disease (longitudinal study)

PSU: primary sampling units

RCI: root caries index

RDFS: root decayed filled surfaces

Risk factor: a factor associated with the disease in a cross-sectional study

ROC: The Receiver Operating Characteristic (ROC-curve) depicts the true positive rate vs. the false positive rate for a binary classifier system. It was chosen to evaluate the strength of the prediction.

RR: relative risk

SD: standard deviation

Sensitivity: the percentage of sick people who are correctly identified as sick

SHIP-0: Study of Health in Pomerania - baseline

SHIP-1: Study of Health in Pomerania - 5-year follow-up

SiC: Significant caries index – The mean DMFT of the one third of the study group with the highest caries score. The index is used as a complement to the mean DMFT value in order to describe the polarisation of caries

Sig.: significance

Specificity: the percentage of healthy people who are correctly identified as healthy

SD: standard deviation

Vs: versus

WHO: World Health Organization