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ORIGINAL ARTICLE

The impact of oral rehabilitation on oral health-related quality of life in patients receiving radiotherapy for the treatment of head and neck cancer

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Abstract
Objectives To analyze the influence of dental treatment on oral health-related quality of life (OHRQoL) in head and neck cancer patients.
Materials and methods This study included the data of 116 patients who underwent radiotherapy (RT) because of head and neck cancer. For each patient, the variables age, sex, tumor site, irradiation technique, dose on the spared parotid gland, concomitant chemotherapy, and denture status were documented. OHRQoL was determined using the OHIP-G14 questionnaire. Patients were divided into subgroups according to denture status: none or fixed partial dentures (none/FPD), removable partial dentures (RPD), and full dentures (CD). OHIP summary scores were determined and tested for clinical relevant differences with respect to the different variables. The association between OHRQol and the variables was assessed using linear regression.
Results No clinically relevant influence on OHRQoL was found for gender, irradiation technique, and chemotherapy. Patients with tumors located in the oral cavity had a significantly higher OHIP score than patients with other tumor sites ($p < 0.001$). None/FPD and RPD patients had higher values than those found in a normal population, but did not differ significantly from each other ($p = 0.387$).
Conclusions In contrast to tumor site, teeth and type of denture seem to have a limited effect on OHRQoL in head and neck cancer patients.
Clinical significance Prosthetic treatment in head and neck cancer patients do not lead to the same improvement in OHRQoL as found in the normal population. This might be taken into account especially if extensive dental treatment is intended.

Keywords Oral health-related quality of life · Head and neck cancer · Radiotherapy · Tumor site · Dental status

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Introduction

The treatment of malignant tumors with associated side effects is often accompanied by a distinct reduction in quality of life (QoL). Tumor therapeutic measures focused on the head and neck area can frequently lead to impairment within the oral cavity [1, 2]. The treatment of these chronic side effects is the role of the dentist. Ideally, the dentist will take care of both the dental treatment after radiotherapy (RT) and the control of any dental infections prior to RT [3, 4]. Generally, the most important consideration in the control of infectious sources is the necessity and extent of the extraction of teeth in order to prevent the development of radiation caries and osteoradionecrosis (ORN) of the jaw.

An ORN of the jaw is an unwanted adverse effect of therapeutic irradiation of tumors of the head and neck areas. Its subsequent treatment can lead to the complete loss of the jaws and a considerable reduction in chewing, speaking, and

swallowing functions. Functional limitations and disfiguring facial deformities often occur and result in psychological stress and social marginalization. According to accepted theories, a substantial cause for ORN (in addition to the irradiation dose) is teeth destroyed by radiation caries [5]. Affected or decayed teeth may be an entry port for pathogenic germs into the bone that induce its necrosis. From the current point of view, it appears almost incomprehensibly that it was usual to extract all teeth before RT in the past [6].

However, the approach to preventing later complications by the extraction of questionable teeth is inconsistent with the need to preserve as many teeth as possible. The preservation of teeth is desirable because the patients' quality of life generally declines with a reduction in the number of teeth [7]. However, it is unclear how much importance patients with head and neck cancer attribute to the number of teeth and the kind of prosthesis used in terms of their subjectively perceived QoL.

The European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire is an established method for evaluating QoL in oncology [8]. This questionnaire covers all aspects of health-related quality of life (HRQoL). However, the EORTC questionnaire is not commonly used in dentistry because the results obtained are not suitable for use in dental therapeutic decision-making.

A commonly used questionnaire with a greater relevance for use in dental therapeutic decision-making is the Oral Health Impact Profile (OHIP). This questionnaire evaluates a subset of the HRQoL, the oral health-related quality of life (OHRQoL). The original English language (OHIP-E) was developed in 1994 and includes 49 questions (items) [9]. The 49 items can be divided into 7 subscales: functional limitations, pain, psychologically discomfort, physically discomfort, psychologically limitations, social limitations, and discrimination/disability. In 2002, a German version was established (OHIP-G) [10]. The OHIP questionnaire has been translated into over 10 languages and is recognized worldwide.

OHIP-G is the only validated tool for measuring OHRQoL in adults in German-speaking regions. A shorter version (OHIP-E14) has been produced from the original extensive version; this has been translated into German (OHIP-G14) and verified [11, 12]. It comprises over 95 % of the information contained in the original extended version. The OHIP-G14 is divided in to 7 subscales, each of which comprises two questions. Representative data for the wider population exist for OHIP-G14, making it possible to use this questionnaire not only for monitoring but also for comparison with the wider population [13]. OHIP can be used to evaluate the quality of dental treatment [14]. The OHRQoL can also be used as an indicator of the degree of patient suffering and to determine when dental prosthetic treatment is required. The results of the OHRQoL can determine when prosthetic intervention is unlikely to contribute significantly to an improvement.

It is unclear if patients suffering from head and neck cancer attribute the same significance to teeth and dentures as patients from the "normal" population. Although head and neck cancer patients are often included in a single cohort in investigations, they represent a heterogeneous population in terms of the size of the tumor sites. This can result in a diverse range of therapy-related side effects following RT with modern irradiation techniques. However, the real impact of tumor site and irradiation technique on OHRQoL is still largely undetermined.

Radiogenic xerostomia is regarded as one of the most important factors in reducing OHRQoL in head and neck cancer patients. Salivary flow can vary by up to 30 % physiologically, which makes the classification of radiogenic xerostomia difficult. Measurement of the irradiation dose on the spared parotid gland has become established as an alternative to determining xerostomia in recent years [15, 16].

The aim of the present study was to evaluate OHRQoL in long-term survivors after RT for head and neck cancer and to compare the results with a normal population. Along with oncological therapeutic factors such as the irradiation technique used, the dose used on the spared parotid gland, the tumor site, and requirement of concomitant chemotherapy, other factors that may affect OHRQoL, such as age, sex, and dental situation, were also evaluated.

The following hypotheses were tested: OHRQoL in head and neck cancer patients is worse than OHRQoL in the normal population. Furthermore, OHRQoL in head and neck cancer patients is influenced by the irradiation technique used, a concomitant chemotherapy, the dose on the spared parotid gland, the tumor site, and the dental situation. In addition, OHRQoL in head and neck cancer patients is influenced by age and sex.

Patients and methods

One hundred and thirty-one patients who underwent high irradiation therapy for head and neck cancer between January 1, 2003, and January 31, 2013, at the Department for Radiotherapy at the University Hospital of Halle were included in this study. Patients were part of a prospective long-term clinical study granted by the German Cancer Aid association (grant no. 106386 and 108429) investigating therapy-related side effects of modern irradiation techniques in head and neck cancer patients [15, 17]. The criterion for inclusion was a diagnosis of a primary tumor in the nasopharynx, oropharynx, uvula, tongue base, oral cavity, cheek/parotid gland, or larynx/hypopharynx. The study protocol was reviewed and approved by the appropriate local institutional review board and conducted in accordance with the Declaration of Helsinki on Ethical Principles for Medical Research.

Surgery

Primary surgery of the tumor and neck lymph nodes was performed on patients with early and locally advanced tumors who were in good general condition.

Radiotherapy

Three-dimensional treatment planning following three-dimensional conformal RT (3D-CRT, from 2003 to 2013) or intensity-modulated RT (IMRT, from 2006 to 2013) was performed for all patients. Treatment planning was based on a computer tomography (CT) scan of the head and neck regions using a slice thickness of 5 mm (Lightspeed; General Electric, Fairfield, USA). Patients were immobilized using a custom-made thermoplastic head–neck–shoulder mask. Two planning systems (Helax TMS version 6.1 and Oncentra Masterplan version 1.5 / 3.0; Nucletron, Veenendaal, Netherlands) were used for the 3D treatment planning.

The 3D-CRT was performed using a standardized six to seven portal arrangement as described in a previous investigation [18]. Patients receiving 3D-CRT were treated with 6 and 10 MV photons using a linear accelerator (Primus and Oncor; Siemens Medical Solutions, Erlangen, Germany). IMRT was performed using the step-and-shoot approach with seven or nine equidistant 6 MV beams and five to eight subsegments, respectively. The treatment technique was similar to the one described by Georg et al. [19]. The planning strategy was to cover 95 % of the planning target volumes (PTVs) with 95 % of the prescribed dose using a maximum dose to the spinal cord of 45 Gy. Irradiation planning was performed according to reports 50 and 62 of the Commission on Radiation Units and Measurements (ICRU) [20, 21]. Planning, performance, and quality assurance were performed according to ICRU report 83 [22]. The PTVs and both parotid glands, the mandibular, and the oral mucous membrane were outlined on the transversal slices of the planning CT scans. The goal was to minimize the mean dose to the contralateral parotid while maintaining a homogeneous dose distribution to the target volumes. No effort was made to spare the submandibular or minor salivary glands. The mean dose and the partial volumes receiving specified doses were determined for each gland using a dose–volume histogram (DVH). The DVH was transformed using an algorithm initially proposed by Lyman [23]. Mean doses received by the ipsilateral and contralateral parotid glands were calculated for each patient.

Chemotherapy

Concomitant radiochemotherapy was used in all cases with high-risk factors such as pT3 and pT4 stages, two or more involved lymph nodes, extracapsular nodal spread, or incomplete microscopic resection of the margin of the carcinoma. Diagnosis and treatment were performed by a specialist in radiotherapy at the University Clinic Halle.

Oral treatment

Prior to radiotherapy

The majority of the patients in this study were referred to the Department of Dental, Oral and Maxillofacial Medicine for dental infectious source control prior to RT, from 2003 onwards. The recommendations of the German Society for Dental and Oral Medicine were used as the basis for dental treatment [3]. A dental assistant at the University Clinic of Prosthodontics performed the initial examination. In coordination with a medical or dental assistant from the University Clinic of Oral and Maxillofacial surgery, the extent of the treatment required was determined and performed as described in a previous publication in order to prevent ORN [16].

After radiotherapy

All patients were advised to take part in a dental follow-up program. Quarterly, patients were offered free professional tooth cleaning during which a dental check up was performed. If the patient requested adjustment of old or the manufacture of new dentures, treatment was performed either with the cooperation of their family dentist or at the Department of Prosthodontics at the Martin-Luther-University in Halle-Wittenberg. During the first year after RT, the patients were provided with provisional dentures; this was to reduce the risk of treatment failure because of recurrence and to enable better risk assessment of the residual teeth. After 1 year, permanent dentures were made. In cases of pronounced xerostomia and rapid onset of tooth decay, protective crowning was considered. In cases where removable partial dentures were planned, attempts were made to use mucosa as support as little as possible. Particular attention was given to a hygienic design and cleanability of the dentures. If invasive intervention (e.g. tooth extraction, periodontal treatment) became necessary, it was performed under antibiotic prophylaxis and wounds were, if possible, primarily closed.

For patients who were unable to tolerate conventional removable dentures, the treatment option of implantation was considered and the course of isodoses at the prospective implant position was evaluated. In cases of isodoses over 50 Gy, implantation was not advised but not refused either [24]. After accurate diagnostics, implants were inserted under antibiotic prophylaxis solely by an experienced oral and maxillofacial surgeon at the Department of Oral and Maxillofacial Surgery at Martin-Luther-University under inpatient conditions. As far

as possible, bone augmentation was avoided. When it was absolutely necessary to perform bone augmentation, autologous bone was used. Wounds were primarily closed. The healing period was at least 6 months. Prosthetic restoration of the implants was performed at the Department of Prosthodontics at Martin-Luther-University. In order to prevent or, where not practicable, to reduce harmful stresses acting on the implants, primary interlocking was intended.

OHRQoL

For assessment of OHRQoL, patients that had received RT at least 2 years prior to undertaking the questionnaire were selected. Prosthetic restorations, if necessary, had been completed at least 1 year prior to undertaking the questionnaire. The OHIP-G14 was used as the questionnaire [12]. Patients who could not complete the questionnaire because of comprehension or language difficulties were excluded. Each OHIP item elicits information about how frequently subjects had experienced a specific impact in the previous month. The OHIP-G is a self-administered questionnaire which follows a standard ordinal format ("never" = 0, "hardly ever" = 1, "occasionally" = 2, "often" = 3, and "very often" = 4). Average scores were determined for each patient.

Existing standard values differentiate between age and denture status. Therefore, patients were divided into subgroups according to denture status: none or only fixed partial dentures (none / FPD), removable partial dentures (RPD), or full dentures (CD). The "none/FPD" category was used if the patient had all their teeth except the molars. In cases where teeth were missing due to agenesis (for example the lateral incisors or after orthodontic treatment, the first premolars), the same category was used if the first molars existed as well as for patients whose missing teeth were replaced by a fixed partial denture that excluded the molars.

Statistical analysis

The OHIP item scores obtained from the patients' responses were compared. Descriptive statistics were determined for age, sex, tumor site, irradiation technique, dose on the spared parotid gland, necessity of additional chemotherapy, and denture status. We determined the average scores for the ordinal responses and assessed whether these differed significantly with respect to sex, tumor site, irradiation technique, necessity of additional chemotherapy, and denture status using the Mann–Whitney U test or the Kruskal–Wallis test. Linear regression was used to assess the association between the OHIP summary scores and age, sex, tumor site, irradiation technique, dose on the spared parotid gland, necessity of additional chemotherapy, and denture status. Regression results were adjusted according to the tumor site, "hypopharynx/larynx" or "none/FPD". Statistical analysis was performed using the IBM SPSS Statistics 22 (IBM Inc., Chicago, IL, USA) with the probability of a type I error set at 0.05.

Results

Patients' characteristics

Data from 116 patients were included in the analysis. Fifteen patients were excluded whose questionnaires were incompletely or incorrectly filled out (more than one of the four possible answers ticked). The patients had a mean age of 57.7 years at the timing of radiotherapy (range 24 to 79 years). Males constituted 75 % of the study group.

The doses received by the spared parotid gland were between 0.96 and 70 Gy, (mean 25.4 ± 13.6 Gy). A total of 57 patients (49.1 %) were treated with IMRT, and 55 patients (47 %) received concomitant chemotherapy. The oral cavity was the most common tumor site (32.8 %). Only one patient had a uvula tumor site (0.9 %). A detailed breakdown is shown in Table 1.

Forty-four patients had no dentures or FPD (38 %), 30 patients had CD (25.9 %), and 42 patients had RPD (36.1 %).

OHRQoL

In this study, the average OHIP score was 19.2 ± 16.1.

The effect of age, irradiation technique, and the requirement for additional chemotherapy on OHRQoL score

No clinically relevant difference was found in the average OHIP scores for men and women (19.9 ± 15.9 vs. 16.9 ± 16.6; $p = 0.308$). Average OHIP scores for patients irradiated with IMRT did not differ significantly from those in patients irradiated with 3D-CRT (20.2 ± 16.2 vs. 18.3 ± 16.0; $p = 0.604$).

Table 1 Distribution of patients with regard to tumor site

Tumor site	Number of patients (% of total, $n = 116$)
Nasopharynx	6 (5.2 %)
Oropharynx	31 (26.7 %)
Uvula	1 (0.9 %)
Tongue base	6 (5.2 %)
Oral cavity	38 (32.8 %)
Parotid gland	9 (7.8 %)
Hypopharynx/larynx	25 (21.6 %)

Patients who had to undergo additional chemotherapy did not have a significantly higher average OHIP scores when compared to patients that had not received additional chemotherapy (20.5 ± 17.3 vs. 18.1 ± 15.0; $p = 0.660$).

OHRQoL according to tumor site

Table 2 shows the mean OHIP based on the patients' tumor site. The highest mean score was found for patients with an oral cavity tumor site (28.5 ± 14.4). Patients with tumors located in the nasopharynx had the lowest values (6.8 ± 10.8). Only one patient had a uvula tumor site (Table 2).

The mean OHIP scores of the patients with tumors located in the oral cavity were significantly larger compared to those of the patients with other tumor sites ($p < 0.001$).

OHRQoL according to denture status

The average values of none/FPD and RPD patients were higher than those found in a normal population, but did not differ significantly from each other ($p = 0.387$). A detailed breakdown of the data is shown in Table 3.

The influence of different variables on OHRQoL score

Due to the limited number of patients and tumor localizations, the tumor sites oropharynx, tongue base, and uvula were combined as a single group for linear regression. Of all the variables considered, only the oral cavity as tumor site had a significant influence on the mean OHIP score (Table 4).

Discussion

Typically, OHIP scores in a representative normal population show a tendency to increase with age and decreasing number of natural teeth, with scores ranging between 10 and 34 points [12]. With the exception of patients with complete dentures, patients who had undergone RT due to head and neck cancer had a worse mean OHRQol summary score than the representative normal population. So the working hypothesis that OHRQoL in head and neck cancer patients is worse than in the normal population can be confirmed.

Table 2 OHIP summary scores according to the different tumor sites

Region	Number of patients	Mean OHIP score (SD)
Nasopharynx	6	6.8 (10.8)
Oropharynx	31	16.7 (16.5)
Uvula	1	48
Tongue base	6	18.3 (17.4)
Oral cavity	38	28.5 (14.4)
Parotid gland	9	11.6 (5.8)
Hypopharynx/larynx	25	12.9 (14.1)

Women tended to have a lower OHRQoL score than men. Thus, the hypothesis that OHRQoL is influenced by sex can be confirmed. However the relatively low proportion of women (25 %) in the study has to be taken into account when interpreting this finding. When compared to the representative normal population, only 12.5 % of subjects had no significant decrease in OHRQoL score as opposed to 43.9 % that reported a significantly higher score. Therefore, it appears that denture status is less important than the tumor site and its corresponding irradiation area. This may be explained to degree by the manifestation of RT-related side effects being largely dependent on the affected region. This assumption is supported by the findings of Chigurupati et al. that showed that resection defects and postoperative RT had the most marked negative impact on QoL in patients with head and neck cancer [25]. In our investigation, OHIP summary score increased by 0.083 points for each additional Gy applied to the spared parotid gland. Therefore, the hypothesis that OHRQoL is influenced by the dose on the spared parotid gland can be confirmed.

The OHIP summary scores in the normal German population depend on age and denture status. In our study, younger patients showed greater discrepancies than older patients (−0.20 points per year). Thus, the hypothesis that OHRQoL is influenced by age can be confirmed. In contrast to normal population values, the differences in OHIP summary score between the three categories of denture status were not significant ($p = 0.387$, Table 3). This may indicate that in head and neck cancer patients, the tumor site and associated side effects have a greater influence on OHRQoL than both the denture status and the type of denture. Thus, the hypothesis that OHRQoL in head and neck cancer patients is influenced by the dental situation that has to be rejected, whereas the hypothesis that OHRQoL is influenced by the tumor site can be confirmed.

Generally, the effect of denture status and the associated prosthetic restoration type influence OHRQoL is ambiguous. Own teeth, fixed partial dentures, or dentures with an optimal retention are often associated with a positive OHRQoL score [14, 26]. In our investigation, patients mentioned that they would use their removable dentures only occasionally despite the presence of partial or complete edentulous arches. What impact this aspect had on the correlation between denture status and OHIP summary score is unclear. Bortoluzzi et al. reported that a significant proportion of their study group did not wear prosthetic dentures for financial reasons [27]. Their study tested a potential association between OHRQoL and the number of own teeth. The results confirmed that although edentulous arches without prosthetic treatment existed, there is a significant correlation between an increasing number of natural teeth and better life quality. This finding has been supported by other studies [28].

Table 3 OHIP summary scores according to denture status and representative normal values

Denture status	Number of Patients	Mean OHIP score (SD)	Mean OHIP score of the representative normal population [12]	Number of patients with OHIP-SS = 0	Number of patients with OHIP-SS > standard values
None/FPD	44	16.7 (15.5)	10–12	7	24
RPD	42	21.2 (16.4)	15–19	5	21
CD	30	20.1 (16.7)	21–34	3	6

No clinically relevant influence on OHRQoL in long-term survivors of head and neck cancer was found for irradiation technique (3D-CRT vs. IMRT) and additional chemotherapy. Thus, the hypothesis that OHRQoL in head and neck cancer patients is influenced by the irradiation technique or a concomitant chemotherapy was rejected. It could be that the positive influence of the more precise irradiation provided by IMRT was masked by the considerable differences in OHRQoL associated with variation in tumor site.

For patients who underwent RT due to head and neck cancer, own teeth, and type of denture seem to have a limited effect on OHRQoL. Tumor site, especially tumors located within the oral cavity, has the greatest impact on OHRQoL. As a consequence, dentists cannot assume that the manufacture and fitting of prostheses lead to the same improvement in OHRQoL as found in the normal population [29]. This aspect should always be taken into account during dental treatment if extensive prosthetic treatment is intended. It is conceivable that complicated treatments to address extreme situations, such as implants to restore the essential functions of the masticatory system such as speaking or swallowing, may be an exception [30]. Future investigations are merited to determine whether patients with gum defects benefit comparatively more from prosthetic rehabilitation than patients with tumors located in other anatomical regions [31, 32]. These patients were not part of the current cohort, so this aspect should be evaluated in future investigations that compare OHRQoL prior and after prosthetic rehabilitation.

It could be speculated that a further optimization in irradiation techniques and a concomitant reduction in side effects, such as difficulty in swallowing, impaired sense of taste, xerostomia, and speech difficulties, could lead to a change in OHIP summary scores to the level of the normal population [33]. If this is the case, teeth and dentures may become increasingly important in terms of their impact on OHRQoL. In a group of patients suffering from head and neck cancer, who did not have to undergo RT, it has been shown that dentures had a positive influence on OHRQoL particularly if a serious illness was present [34].

However, several methodical factors limited the results of our study. The patients ranged from 24 to 79 years of age and were older than the patients in the study of John et al., whose results were used as reference values [12]. Although patients' age was normally distributed, a slight shift in favor of older patients was determined. This might be explained by the relatively small number of patients and the rising incidence of cancer as people grow older.

Additionally, the timeframe between RT and the questionnaire reply has to be taken into account. The study of John et al. did not give information on how long dentures were

Table 4 Multiple linear regression analysis of OHRQoL results

Variable	B-coefficient	*p* value	95 % Confidence interval	
			Lower limit	Upper limit
Females	−2.32	0.50	−9.13	4.50
Age	−0.20	0.15	−0.48	0.08
IMRT	0.29	0.92	−5.71	6.29
Chemotherapy	3.92	0.21	−2.22	10.06
Dose on the spared parotid gland	0.08	0.47	−0.15	0.31
CD[a]	3.81	0.32	−3.67	11.28
RPD[a]	4.59	0.17	−1.98	11.17
Nasopharynx[b]	−6.09	0.40	−20.25	8.07
Tonsil, uvula, tongue base[b]	6.28	0.11	−1.49	14.05
Oral cavity[b]	16.75	<0.01	9.06	24.43
Parotid gland[b]	1.47	0.83	−11.83	14.76

[a] vs. none/FPD

[b] vs. hypopharynx/larynx

finished before patients were asked to answer the questionnaire [12, 35]. Due to the aspect that parotid glands recover in the first 2 years after radiotherapy, only patients whose RT was finished more than 2 years previously were included into this study. Prosthetic rehabilitation was finished at least 1 year before questionnaire reply giving the patients enough time to arrange themselves with the new situation [14].

Furthermore, surgical and prosthetic treatment before and after RT was solely conducted by experienced oral and maxillofacial surgeons and dentists. Particular attention was given to the prevention of iatrogene ORN. Invasive treatment was avoided if possible. If surgical intervention was urgently required, it was performed with the greatest care to damage the vulnerable irradiated tissues as little as possible. Prosthetic treatment considered the individual structural anatomical characteristics and intended to restore masticatory function with minimal irritation of the supporting tissues. After prosthetic rehabilitation, patients were quarterly reexamined and dentures, if necessary, were adjusted.

The minimal important difference (MID) of OHIP-G14, the smallest difference in score that indicates clinical significant changes in OHRQoL, was proven to be two points [7]. However, taking the relatively high standard deviation into account, not every difference in OHIP summary score of almost two points was considered as clinical significant in this study. Further clinical trials with a significantly higher number of patients are needed to analyze, for example, the differences in OHRQoL in patients with cancer located in the oral cavity depending on the irradiation technique used.

Conclusion

In our study, patients who underwent RT due to head and neck cancer had worse OHRQoL than the population average. This suggests that tumor site has a greater impact on OHRQoL than the number of own teeth or the kind of prosthetic treatment employed. With future development in irradiation technique, it could be assumed that therapy associated side effects will be further reduced and OHIP summary scores of patients suffering from head and neck cancer will tend towards the level of the normal population. Teeth and dentures could then become increasingly important in regard to their impact on OHRQoL.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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Ethical approval The study protocols were approved by the medical faculty's ethics committee at the Martin-Luther-University Halle-Wittenberg and conducted in accordance with the Declaration of Helsinki on Ethical Principles for Medical Research.

Informed consent For this type of study, formal consent is not required.

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