IQWiG Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen

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Relevance of the condition of the opposite dentition[1]

Executive Summary

[1] Translation of the executive summary of the final report "Relevanz der Beschaffenheit der Gegenbezahnung" (Version 1.0; Status: 20.4.2009). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

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Executive summary

Background

In its letter of 15 March 2005, the Federal Joint Committee (G-BA) in accordance with § 91 Para. 6 SGB V commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to perform a scientific evaluation on the relevance of the condition of the opposite dentition when fitting a fixed denture. The commission is based on the Decision in No. A.3 of the general section of the Guidelines for Fixed Contributions dated 08.12.2004 (G-BA guidelines in accordance with § 91 Para. 6 SGB V "on determining the diagnoses and basic care provision for which fixed contributions in accordance with §§ 55, 56 SGB V are to be made", valid since 01.01.2005), and the question whether insured individuals can be guaranteed adequate, appropriate and efficient care as prescribed under law.

Research question

The contract wording and the subsequent specifications define the aim of the investigation, which is as follows: Comparison of the functionality of fixed and removable dentures as test interventions in relation to the condition of the opposite dentition and their prosthetic care with regard to the following patient-relevant outcomes: (i) "survival of denture", (ii) "change in dietary habits", (iii) "oral health-related quality of life" to include patient satisfaction and phonetic rehabilitation, which are parameters relevant to quality of life, and (iv) "denture cleaning and aftercare required".

Methods

Systematic literature searches were carried out in the following databases: CENTRAL, MEDLINE, EMBASE, BIOSIS, SciSearch, CCMed, DARE and HTA (search period from 1982 until September 2007). In addition, a manual search was carried out in German dental journals and the search was extended topic-specifically to the following databases: CDSR, CDMR, CDMS, NHS EED, CINAHL, AMED, CAB abstracts, GLOBAL Health, ISTPB + ISTP/ISSHP, Medikat, and the publisher databases of Karger (secondary search), Kluwer, Springer, Thieme and Hogrefe (secondary search). Finally, the opportunity to cite additional topic-relevant studies was provided in July 2008 when interested parties were invited to submit written comments on a preliminary version of the report (preliminary report).

Randomized controlled trials (RCTs) together with prospective and retrospective studies without control group were included for the patient-relevant outcomes, provided the patients were included in the study consecutively and the confounding variables were adequately monitored. Also included in the assessment were case reports and case series with a sample

size of at least 10 and of adequate biometric quality to avoid any bias in selection. The minimum observation time for all studies was 6 months. In this way, the success of prosthetic measures in relation to the opposite dentition could be determined with sufficient certainty in the longer term as well.

The literature screening was carried out by 2 reviewers independently of each other. After assessing the quality of the studies, the results from the individual studies were collated according to therapy goals and outcomes, and compared and described. IQWiG's preliminary benefit assessment, the preliminary report, was published on the Internet and interested parties invited to submit written comments.

Results

Initially, a total of 25 papers were identified that met the inclusion criteria. After more detailed screening, 8 studies had to be excluded from the assessment, as they contained no separate data on the condition of dentition. In 5 out of 17 papers definitely included, there were pre-publications with no additional relevant information. In 8 of the 17 studies there was information about the "survival of denture" outcome, in 5 studies information on the "change in dietary habits" outcome, in 4 studies information on the "oral health-related quality of life" and "patient satisfaction" outcome, and in 9 studies information on the "denture cleaning and aftercare required" outcome, whereby 11 studies reported on 1 outcome, 3 studies on 2, and 3 studies on 3 outcomes. Five publications reported only on fixed dentures, 3 publications only on removable dentures, 1 publication on fixed and removable dentures, 1 publication on fixed partial dentures and complete dentures, 3 publications on removable partial dentures and complete dentures, 1 publication on removable dentures and fully dentulous patients and 3 publications on removable partial dentures and complete dentures as well as fully dentulous patients. There were control interventions in 9 papers; however, in 8 cases they represented interventions that did not meet the inclusion criteria (i.e. complete dentures or fully dentulous patients). This ultimately resulted in indirect comparisons being carried out on the test interventions of fixed versus removable dentures in relation to opposite dentition.

The overall study and publication quality of the relevant studies was for the most part inadequate. There was only 1 prospective trial on the topic under investigation that could be described as randomized controlled, but it provided no information on the randomization technique used. The 6 prospective studies identified revealed unequal periods of observation and flaws in how study discontinuations were dealt with. The 3 retrospective studies also revealed considerable flaws in the quality of studies and publication. It was a similar story for the 7 prevalence studies identified, although here it was mainly the selection methods of the patient population that was inadequately described. If study data had to be deduced from a manually drawn chart without precise figures, then that attested to large flaws in the quality of studies and publication in those studies concerned.

"Survival" outcome

Of the 8 studies identified for the "survival" outcome, 1 had no detectable flaws, 2 had minor and 5 had major flaws in the biometric quality of the studies and publication. A comparison between the survival of fixed and removable dentures was only possible for one opposite dentition variant (complete dentures in opposite arch).

Only one trial, described as randomized controlled, contains data on the survival of fixed and removable dentures when fitting the opposite arch with a complete denture. The validity of this trial is reduced through the following biometric flaws: (1) no data on the Kennedy classes of the intervention arches; (2) incomplete data on prognostic factors and comorbidity; (3) unequal teeth gaps in the group with fixed denture: 44.4 % teeth gaps in 2 to 3 teeth, 25.9 % in 4 to 5 teeth, 29.7 % in 9 to 11 teeth; (4) no data on teeth gaps for the group with removable denture; (5) drop-out rate of 18.9 % over a follow-up period of 5 years; (6) detailed description of randomization procedure is missing (only mentioned as a term), so should rather be classed as a non-randomized controlled trial; (7) no significance level given (p value) in the sub-group analysis. Consequently, a significant difference cannot be considered as detected in the 5-year survival rate of fixed dentures (95.2 %) and removable dentures (100 %) with a complete denture in the opposite arch.

Data on the survival of fixed tooth-borne dentures with differing condition of opposite dentition were found in 2 studies: in one publication, the 3-year survival rate with natural opposite dentition is given as 93%; in the above-mentioned randomized controlled trial, the 5-year survival rate with complete denture in the opposite arch is given as 95.2%. Apart from other differences in the study design and setting, a direct comparison between these 2 trials is limited by the different follow-up periods, since one of the publications gives no survival rates for shorter periods.

Data on the survival of fixed implant-supported dentures with differing condition of opposite dentition were found in 2 additional trials: the 3-year survival rate with natural opposite dentition is given as 97.8% in one publication; the survival rate for fixed implant-supported dentures in the opposite arch after an average of 44.5 months is given as 100% in the other publication. Apart from other differences in the study design and setting, a direct comparison of these data does not appear to have much value, since the follow-up period in one of the studies does not indicate survival rates for shorter periods.

No conclusions can be drawn on the basis of the existing data regarding whether the condition of the opposite dentition influences the survival of fixed or removable dentures. Only two trends can be deduced: the first one towards removable dentures compared to fixed dentures with a fully edentulous opposite arch fitted with a removable prosthesis and the second, weaker trend towards implant-supported dentures compared to conventionally fixed dentures with natural opposite dentition or with a removable denture in the opposite arch.

"Dietary habits" outcome

There were major flaws in the quality of the biometric studies and publication in all 5 studies that contained data on the change in dietary habits in fixed and removable dentures in relation to the condition of the opposite dentition. As no evaluable data were found on dietary habits in patients fitted with a fixed denture, it was not possible to compare with dietary habits in patients fitted with a removable denture.
Data on the relevance of opposite dentition for removable dentures could only be drawn from one trial. The validity of this trial is reduced due to the following biometric flaws: (1) unequal residual dentition in the intervention arch: on average 17.4 teeth in the opposite natural dentition group, 11.8 teeth in the removable partial denture group, 5 teeth in the complete denture group; (2) no data on the Kennedy classes in the intervention arches; (3) no data on prognostic factors or on comorbidity; (4) only male patients between 67 and 68 years of age; (5) unequal age of prostheses: 35 % less than 2 years old, 48 % between 2 and 9 years old, 17 % over 10 years old; (6) data collection instrument based on 6 hard and 6 soft meals not validated; (7) basing the analysis as a percentage on the trial participant who experienced the lowest overall restriction in his/her dietary habits (= 100 %) appears unsafe. In another trial, all patients interviewed possessed natural dentition in the opposite arch, so that different dentition constellations could not be compared.
The existing data does not allow any conclusions to be drawn on whether the condition of the opposite dentition influences dietary habits when a fixed or removable denture is fitted. The data in another trial show that, in the case of removable dentures only, no or little difference can be determined in relation to the opposite dentition when eating soft or hard food.

"Quality of life and patient satisfaction" outcome

Out of the 4 identified trials, 1 displayed minor flaws and 3 major flaws in the biometric quality of the studies and the publication. It was only possible to compare the satisfaction between a fixed and removable denture with one opposite dentition variant (complete denture in opposite arch).

One trial described as randomized controlled contained data on patient satisfaction for fixed and removable dentures when fitting the opposite arch with a complete denture. Due to the biometric flaws already described in the results for the "survival" outcome, this trial should be designated non-randomized. A significant difference ($p < 0.05$) is indicated in patient satisfaction regarding stability in general and during chewing with fixed (77.8 % and 85.2 % of patients respectively were satisfied) and with removable denture (61.5 % and 53.9 %, respectively). This effect cannot be viewed as proven due to the biometric flaws. However, the fact that fixed prostheses have greater stability than removable ones appears reasonable.

Data on general patient satisfaction with removable dentures and differing condition of opposite dentition were found in one trial: the percentage of satisfied patients with removable partial denture in the opposite arch was 37 % (n = 102), and complete denture in the opposite arch 65 % (n = 147). However, due to the variable sampling size and the unequal age of prosthesis (1 to 15 years), a comparison of these data would not appear to be worthwhile.

Based on the existing data, it is not possible to draw any conclusions on whether the condition of the opposite dentition influences patient satisfaction when fitting fixed or removable partial dentures.

"Cleaning and aftercare required" outcome

Data on denture cleaning and aftercare required when fitting fixed and removable dentures were included in 9 publications. Of these trials, 1 showed no detectable flaws, 1 minor and 7 major flaws in the biometric quality of studies and publication. It was only possible to compare the maintenance required for fixed and removable dentures for one opposite dentition variant (complete denture in the opposite arch). As no analysable data were found on prosthesis cleaning or aftercare required in fixed dentures, it was not possible to make a comparison with the prosthesis cleaning or aftercare required in removable dentures.
Only 1 randomized controlled trial contained data on the maintenance required for fixed and removable dentures when the opposite arch was fitted with a complete denture. However, as already mentioned above, it contained biometric flaws that reduced its validity. Consequently, a significant difference could not be proven in the level of repair required for fixed dentures (22.2% of prostheses) and removable dentures (26.9/23%) when a complete denture was fitted in the opposite arch.
In another trial, data were found on the level of repair required of removable dentures with differing condition of opposite dentition: the number of repairs required within a period of 16 months was 72 for natural opposite dentition, 8 for removable partial dentures in the opposite arch and 18 for removable complete dentures in the opposite arch. However, due to the non-documented sample size of the individual subgroups and the unequal age of prosthesis (1 to 6 years), a comparison of these data would not appear to be worthwhile.

No conclusions could be drawn on the basis of the existing data as to whether the condition of the opposite dentition influences denture cleaning and aftercare when fitting a fixed or removable denture.

Conclusions

This report assesses the relevance of the condition of the opposite dentition when fitting fixed and removable dentures. There is currently no proof of sufficient certainty regarding the relevance of opposite dentition in removable and fixed dentures for any of the following patient-relevant outcomes: "survival of denture", "change in dietary habits", "oral health-related quality of life" – condensed into "patient satisfaction" – and "denture cleaning and aftercare required".

No evidence-based statements could be generated as to whether, and if so how, the condition of the opposite dentition has a bearing on the decision to fit a partially edentulous arch with a fixed or removable denture. There were only a few indications of more patient satisfaction in favour of the fixed denture in combination with the opposite dentition variant of complete

denture in the opposite arch. However, these indications are based on a small number of methodologically weak studies, and this is characteristic of the field of prosthetic dentistry, as the report shows.

Key words: denture, dental prosthesis, bridge, opposite arch, partially edentulous arch

The full report (in German) is available on www.iqwig.de/index.623.html