THE CAPABILITY OF MODERN GLASS IONOMER CEMENTS (GICS) TO REPLACE DENTAL AMALGAM IN WEST EUROPEAN HEALTHCARE SYSTEMS IN THE LIGHT OF INTENDED PHASE-OUT OF MERCURY-ADDED PRODUCTS. A CRITICAL APPRAISAL

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The work reports on the use of the high-viscosity glass ionomer cements approach as a possible clinical alternative for other direct restorations.

Key words: *glass ionomer cements; direct restorations.*

The development and the introduction of conventional glass ionomer cements (GIC) in the mid-1970s was driven by the hope to provide a viable alternative solution for the replacement of dental amalgam as the direct restorative material of first choice in the molar region. Unfortunately, both the general quality and the clinical longevity of these early chemically curing restorative materials turned out to be inferior only, thus leading to cautious assessments of GIC materials. With the advent of high-viscosity glass ionomer cements (hvGIC), materials providing advanced characteristics became available; one of these materials was Fuji IX GP Extra (GC, Tokyo, Japan), reintroduced under the brand name Equia Fil (GC) in 2007 and modified to glass hybrid restorative system (ghRS; Equia Forte, GC) in 2015. These developments have regenerated the hope to replace dental amalgam, particularly in the light of the intended amalgam phase-out, and several single group studies as well as randomized controlled trials (RCT) have shown promising initial results with the use of Equia Fil (GC). Up to now, however, no concluding overview on this material is available from the available literature, and potential analyses of clinical data require documentation. Thus, the present work reports on the use of this hvGIC/RC approach as a possible clinical alternative for other direct restorations.

Objectives. The first aim is to present the state of knowledge on currently used hvGIC/RC in Class I and II cavities. The second aim is to investigate the abrasive wear of hvGIC and ghRS in comparison with well-established controls, a conventional GIC (Ketac Fil; 3M Espe, Seefeld, Germany), and a hybrid composite resin (G-ænial Posterior; GC). By determining the possible differences, it was hypothesized that abrasion of hvGIC or ghRS would not be significantly different from other conventional materials ($H_{0\text{-}1}$), and that abrasive wear would not be influenced by the recommended adhesive coating ($H_{0\text{-}2}$) after standardized testing by means of a chewing simulator. These null hypotheses were tested against the alternative hypotheses of a difference (H_A).

Objects and Methods. To evaluate the available literature on this therapeutic approach, and to focus in particular on the clinical performance of the hvGIC/RC combination a reproducible search strategy was developed. This search included the Cochrane Library, and Ebsco, Embase, PubMed, and Scopus databases. As basic search terms ”glass ionomer cements”, “EQUIA” and ”resin coat” as well as

“composite resin” or “amalgam” were used. The main aim was to screen for randomized clinical trials (RCTs); thus, prospective studies including control groups focusing on the clinical performance were considered primarily relevant for the current systematic evaluation. Moreover, relevant abstracts published with dental meetings were reviewed. Selection criteria included all available randomized clinical trials focusing on hvGIC/RC (either published as full-texts or abstracts until December 2020). Moreover, single-group studies using the hvGIC/RC approach were included. The data collection and analysis were conducted by screening of titles and abstracts, data extraction, and quality assessments of full-texts according to Oxford scoring.

The second aim of the present investigation was to evaluate the volumetric abrasive wear of a high-viscosity glass ionomer cement (hvGIC; Equia Fil) and a glass hybrid restorative system (ghRS; Equia Forte), each being recommended as amalgam alternatives. Both materials were applied with or without their respective resinous coating, and were compared with a conventional GIC (Ketac Fil) and a hybrid composite resin (CR; G-ænial Posterior). For these purposes 78 acrylic mandibular second molars (ANA-4; Frasaco, Tettnang, Germany) featuring a standardized occlusal Class I cavity (being centrally located, with a mesiodistal diameter of 6.5 mm, a buccolingual diameter of 3.5 mm, and a depth of 3.5 mm) were used. The sample cavities were divided into six equal groups. Subsequently, 54 artificial cavities were restored with either Equia Fil (GC; n = 26) or Equia Forte (GC; n = 26) each, while half of these restorations were coated with Equia Coat (GC; n = 13) or Equia Forte Coat (GC; n = 13), respectively; the other half of the hvGIC and ghRS fillings remained uncoated (n = 13 each). The remaining 26 standardized cavities, representing the controls, were filled with either Ketac Fil (3M Espe; n = 13) or G-ænial Posterior (GC; n = 13). Before and after chewing simulation (30,000 cycles at 40 N), each sample underwent optical scanning procedures (Omnicam). A comparison of the total wear using a fluorescence-aided identification technique (OraCheck) followed, and differences (α=5%) between groups were compared by means of MANOVA.

Results. In the first part of the present research the PubMed search resulted in 60 clinical reports, while Embase provided 19 publications; retrieval via Scopus also led to 19 articles, and the search at Ebsco resulted in 5 reports. Also the Cochrane Library was screened, and 2 articles were found. Furthermore, 12 abstracts reporting interim results and to 2 hand-searched papers reporting on single-group studies were identified, while 7 additional abstracts reporting on 2 RCTs in progress could be found, thus resulting in a total of 124 papers and abstracts. After review of all full-texts and abstracts, 99 documents were excluded. After subordinating 18 records focusing on interim or laboratory results a total of 5 full-texts and 2 abstracts representing the longest observation periods of 7 independent trials were identified and considered for further analysis. Screening as well as data extraction and assessment of full reports according to three Oxford criteria (1 – randomization; 2 – blinding; 3 – reported analysis of dropout rates) resulted in 2 RCTs considered for evaluation, and these were rated as low quality reports with high risk of bias. In total, the 7 studies reported on some 500 Class I cavities treated. All studies except one (including the single-group studies) documented high survival rates of up to 100% for

the hvGIC/RC approach, even after five and six years. The included RCTs compared the hvGIC/RC combination either to glass ionomers, or to composite resins, and these comparisons did not reveal any significant differences after two, three, or after up to five years; however, significant differences were observed between hvGIC/RC and GIC as well as between hvGIC/RC and composite resin after six years. All in all, some 800 Class II cavities were studied in 6 (of the 7 studies). As with the Class I restorations, survival rates were high in all studies, and ranged to some 90 % after four years. Again, the included RCTs did not reveal any significant differences between hvGIC/RC restorations and the respective control groups, with even fewer failures in the follow-up intervals for pooled Class I and Class II fillings. However, there was a clear tendency for breakdown of large Class II restorations from their marginal ridges leading to replacement needs, and this was observed with other reports as well.

In the second part of the present research the data were normally distributed. Since the indenter was initially placed in the centre of the sample surface, this region was constantly exposed to the highest recurrent load during the simulated masticatory movements, thus consequently resulting in advanced mechanical wear of the central contact surface. Spallings and macroscopically visible surface defects have been detected exclusively with the conventional GIC specimens. The mean (± SD) restorative material-based abrasion of the tested resin composite was negligible (0.07 ± 0.02 mm3). In contrast, the conventional GIC clearly underperformed with regard to wear loss (12.73 ± 4.81 mm3), and revealed the highest wear rates of all investigated materials ($p < .0001$). In the hvGIC (5.34 ± 2.06 mm3) and the ghRS groups (5.90 ± 1.36 mm3), abrasive loss was comparable ($p > .050$). Interestingly, no influence ($p > .050$) on wear resistance could be revealed with the respective resinous coatings (hvGIC: 4.92 ± 2.15 mm3; ghRS: 5.19 ± 1.45 mm3). Here, the resinous surface coatings were completely abraded at the end of the 30,000 cycles.

Conclusions. When summarizing the available data regarding the hvGIC/RC approach, the total number of successfully reported cases (in all studies, and with follow-up periods of up to six years) was high, thus suggesting that the hvGIC/RC combination presented in the current review deserves further surveillance, at least for permanent restorations of Class I and small Class II cavities. However, quality of the included studies was considered perfectible, and it should be re-emphasized that primary supporting scientific evidence should be available before introducing new materials or techniques into clinical dentistry. Within the limitations of the laboratory part of the present study, the following conclusions can be drawn. Concerning the abrasive wear, the significant underperformance of conventional GIC compared with composite resin and hvGIC/ghRS materials (coated or non-coated) became clearly recognizable. Resinous coating of modern GIC does not appear to be an effective protection against abrasive wear in the short or medium term, and our findings suggest that both hvGIC and ghRS are susceptible to abrasive wear. Thus, the clinical use of the latter should not be generally excoriated, but ought to be restricted to applications where their bioactivity is expected to be beneficial, where high compressive and flexural strengths are not considered necessarily mandatory, and where abrasive stress would seem avoidable.

References

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