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# Long-term clinical performance of experimental glass-ionomer cement with the bi-functional fluid

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## Abstract

**Introduction**. Glass-ionomers have the ability to chemically bond to enamel and dentin, and are characterized by long-term fluoride release and absorption of fluoride from surrounding sources.

**Objective**. The aim of the presented long-term clinical trial was to evaluate and compare the three-year clinical performance of the experimental glass-ionomer cement 'SJZ/W' with the bi-functional fluid placed in carious and non-carious cavities.

**Material and methods**. Seventy restorations were made in adult patients of both genders. Clinical evaluation was performed at baseline and yearly intervals after placement using Ryge's scale, considering the surface structure, anatomical form of the restoration and marginal integrity.

**Results**. Immediately after placement, 70 restorations were assessed, 65 of which were subject to clinical evaluation after a year, 63 subject to clinical evaluation after 2 years, and 3-year evaluation was made for 55 restorations. The material showed minor changes in evaluated parameters and no differences were detected between their performance at baseline, and after three years only in anatomical shape. No post-operative sensitivity was recorded.

**Conclusion**. The examined glass-ionomer 'SJZ/W' provided an acceptable clinical performance over a three-year period.

## Key words

glass-ionomer, clinical evaluation, Ryge's scale

## INTRODUCTION

Glass-ionomer cements used in restorative dentistry are organic and bio-ceramic materials featured by high bio-tolerance and bio-functionality. Although they were introduced in dentistry more than 40 years ago, research on their composition and properties continues to this day. These materials have a wide range of application: they may be used as bases, fissure sealants, root canal sealers, for temporary and final restorations and core build-up [1, 2]. Various possibilities of using glass-ionomer cements are associated with their advantages: due to fluoride release they can prevent secondary caries, as a result of chemical bonding to tooth structure they provide a durable marginal integrity, and the favourable coefficient of thermal expansion of these materials enables good margin adaptation [3, 4]. There is the evidence that the chemical preparation of hard tooth tissues, especially dentin, allows for better adhesion of glass ionomer cements [5]. However, many researches are still carried out to assess the impact of the chemical composition of conditioners on the quality of restorations or bases made of glass-ionomer cements. Regardless of these obvious advantages, there are also some limitations in the use of glass-ionomer cements due to their weaker mechanical strength, fragility, unsatisfactory polishability and imperfections in terms of aesthetics [6, 7, 8]. For these reason, attempts are still being made to create a material meeting all the expectations of dentists and patients.

As a result of research carried out in the Department of Bioceramics of the Institute of Ceramics and Building Materials in Warsaw, Poland a technology has been developed to manufacture a glass-ionomer cement – 'SJZ/W', with the bi-functional liquid. The cement includes a powder, which is an innovative mixture of particulated aluminosilicate glass with a high content of strontium and barium, polyacid, bond modifier, and colouring pigments. The liquid, a 25% aqueous solution of polyacrylic acid, is used both to mix with the powder and to remove the smear layer formed during the preparation of cavities, which is functional for future dentists. Glass-ionomer cement for restoring hard tooth tissues is recommended for filling class III and V cavities (especially of non-carious origin) and carious lesions in elderly patients, wedge-shaped defects, cavities of class I and II in primary teeth, and to cover cracks and enamel erosions. Due to its high fluoride content, it is advised for the treatment of initial carious lesions, or in patients with high susceptibility to dental caries. For protection against moisture, the surface of the restoration should be covered with a layer of protective varnish just after placement of the material into the cavity. The material was tested before in *in-vitro* conditions at the Department of Bioceramics and fulfilled all mechanical parameters.

The aim of the presented prospective 3-year clinical trial was to evaluate the *in-vivo* clinical behaviour of restorations made with 'SJZ/W' glass-ionomer.

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## MATERIALS AND METHOD

Clinical examination under the implemented project included adult patients of both genders, aged 19–74 years (mean age – 43.68 years) selected from a pool of patients referred for outpatient treatment in the Department of Conservative Dentistry and Endodontics at the Medical University of Lublin. The research project was approved by the Ethics Committee in Lublin under Authorization No. KE-0254/155/2009. Before starting treatment procedures, a physical examination of each patient was carried out to qualify them for participation in further therapeutic proceedings. Clinical examinations included people who did not report allergy to synthetic polymers. Before commencement of the treatment, the patients were informed about the purpose, nature and risks of the research, learned about the 'Information for Research Participants', and gave their informed, written consent to participate in the study according to forms required by the Local Ethics Committee. Patients with the following factors were included: good general condition and periodontal health; exclusion criteria were: aged below 18 years, pregnancy, periodontal diseases, systemic diseases, disabilities, heavy occlusal contact, bruxism, lack of opposite tooth to the tooth which was planned to be restored, xerostomia, smoking and allergies.

During the clinical trial, 70 restorations made of glass-ionomer cement colours A3 and A2 were placed. Among the 70 reconstructions, material was inserted into 41 cavities of non-carious origin, and in 29 carious cavities, including 19 class I cavities according to Black without occlusal forces (within the anatomical pits in the upper incisors, the fissures on the palatal surfaces of the upper molars and buccal surface of lower molars), 1 class III cavity, 7 class V cavities and 2 in the case of root caries. In terms of clinical diagnosis, non-carious cavities were recognized as *abrasio* and carious cavities were divided into: *caries superficialis* – 2, *caries media* – 23 cases, *caries profunda* – 2 cases and *caries atypica* – 2 cases. Carious cavities were prepared with a minimally invasive technique and in cavities of non-carious origin, cleansing of tissues without mechanical preparation was performed. In order to remove the smear layer created during caries removal and for improving the adhesion of the cement, a bi-functional liquid was applied to the prepared dentin. After 10 s, the cavities were extensively washed with water and gently dried with compressed air in order to avoid excessive desiccation of the tissue. In the course of material preparation, 3 scoops of powder to 1 drop of bi-functional liquid were used. During the preparation phase, the material was mixed with a spatula on a plate. Preparation time of cement did not exceed 20 seconds.

The cement was placed in the cavities in less than 90 s after the start of mixing, using standard dental instruments. At the setting phase of the cement, the cavities and material were protected from moisture. The restoration was protected with the varnish directly after its placement and dried for 10–15 s with a gentle stream of air. After hardening time, the final finishing of the restoration was performed, and the varnish was again applied to the surface of the material. The Clinical Trial Protocol assumed a 4-fold clinical evaluation of the restorations, i.e. directly after filling the cavities, and after 12, 24 and 36 months. Immediately after placement, 70 restorations were assessed, 65 of them were subject to clinical evaluation after a year, 63 after 2 years, and a 3-year evaluation was made for 55 restorations. Finally, 15 of the original restorations could not be evaluated because either the patient did not return or had moved away. Additionally, the reason of the lack of evaluation was tooth extraction or prosthetic treatment (a crown).

In order to obtain objective results, evaluation of the restorations was carried out according to the established order with the use of a 4-level Ryge`s scale, taking into account [9]:

- the surface structure (criteria: colour, smoothness, gloss, discolouration):
  0 – smooth surface of the restoration, well-chosen colour of the restoration, no discolouration;
  1 – slightly rough surface, but it is possible to restore smoothness by polishing, or possibly when the restoration was placed to excess – correction at the first follow-up visit;
  2 – very porous surface, highly discoloured; the restoration cannot be corrected;
  3 – broken-off surface, highly discoloured, the restoration should be immediately replaced;

- anatomical shape (criteria: restoration of anatomical shape, nodules and shear surface):
  0 – restoration with the appropriate anatomical shape; reproduced nodules, shear edges, points of contact and occlusal contacts preserved;
  1 – restoration with a badly modeled shear edge, partial contact points of occlusion but correction is possible;
  2 – restoration badly modeled, inadequate occlusion, inability to correct the restoration
  3 – restoration incorrectly modeled, traumatic occlusion;

- marginal adhesion (criteria: presence of a marginal fissure, discolouration, cracks, damage to the edges of the filling, secondary caries):
  0 – no marginal fissure, micro-leakage and discolouration of hard tissues of the tooth around the restoration;
  1 – visible superficial damage to the edge of the restoration and discolouration of hard tissues of the tooth along the restoration,
  2 – damage to the edge of the restoration, visible dentin or base, possible discolouration of hard dental tissues;
  3 – loose restoration, tooth wall breaking-off, marginal secondary caries, need for immediate replacement.

The numerical Ryge's scale allows for comparison of the quality of restoration in the subsequent control examinations and tracking its changes over time. Parameters were evaluated on a scale 0–3 on a specially prepared patient's examination sheet. Restorations that were rated 0 (very good – ideal condition) and 1 (satisfying – requiring minor corrections) were considered clinically acceptable. Restorations with the rating 2 (need for deferred replacement of the restoration) or 3 (unacceptable – restoration needs to be replaced immediately) were considered clinically unacceptable.

The obtained results, starting from the baseline point until after 3 years of clinical observation, were analyzed statistically with the Cochran's Q test ($p<0.05$) (Tab. 1).

**Table 1.** Clinical evaluation of examined glass-ionomer restorations according to Ryge's scale

| Evaluated parameters acc. to Ryge scale | | No. of fillings | Grade | | | | Cochran's Q Test |
|---|---|---|---|---|---|---|---|
| | | | 0 | 1 | 2 | 3 | |
| Structure of surface | Baseline | 70 | 70 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | NS |
| | 12 months | 65 | 58 (89.23%) | 7 (10.77%) | 0 (0%) | 0 (0%) | **p<0.001** |
| | 24 months | 63 | 43 (68.25%) | 20 (31.75%) | 0 (0%) | 0 (0%) | **p<0.01** |
| | 36 months | 55 | 38 (69.09%) | 16 (29.09%) | 1 (1.82%) | 0 (0%) | |
| Anatomical shape | Baseline | 70 | 70 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | |
| | 12 months | 65 | 65 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | |
| | 24 months | 63 | 62 (98.41%) | 1 (1.59%) | 0 (0%) | 0 (0%) | NS |
| | 36 months | 55 | 52 (94.54%) | 1 (1.82%) | 2 (3.64%) | 0 (0%) | |
| Marginal adaptation | Baseline | 70 | 70 (100%) | 0 (0%) | 0 (0%) | 0 (0%) | **p<0.002** |
| | 12 months | 65 | 55 (84.61%) | 10 (15.38%) | 0 (0%) | 0 (0%) | **p<0.004** |
| | 24 months | 63 | 52 (82.54%) | 11 (17.46%) | 0 (0%) | 0 (0%) | **p<0.004** |
| | 36 months | 55 | 45 (81.82%) | 10 (18.18%) | 0 (0%) | 0 (0%) | |

## RESULTS

Clinical evaluation of the quality of set restorations ranked by the Ryge's scale was carried out at baseline, namely directly after setting and finishing the restorations. The examined parameters – surface structure of the restoration, anatomical shape and marginal integrity – in 100% of the cases received the highest rating – 0. Based on the initial clinical trial (phase 0), it was stated that all of the restorations with 'SJZ/W' material had a smooth surface, a proper anatomical shape, and their marginal integrity did not raise objections.

After 12 months of restoration placement, the surface smoothness was rated very well (score 0) for 58 restorations, anatomical shape for 65, and marginal integrity for 55 restorations. Rating 1 ranked by the Ryge's scale was obtained by 16 restorations: 7 restorations lost smoothness of the surface, and in the case of 10, a slight superficial damage to the edge of the restoration was noted. In the case of 1 restoration, score 1 ranked by the Ryge's scale, concerned both the surface structure and marginal adhesion. Restorations that scored 1 in the study, were slightly corrected and re-polished. After 12 months of follow-up assessment, none of the examined restorations produced an unacceptable rating (2 and 3 according to the Ryge's scale). The presence of secondary caries was not noted.

24 months after the material placements, surface smoothness was rated very well (score 0) for 43 restorations, anatomical shape in 62 (98.41%), and marginal integrity in 52 restorations. The rating 1 ranked by the Ryge's scale was obtained by 29 restorations: 20 restorations lost the smoothness of the surface, 1 restoration lost the appropriate anatomical shape, and in the case of 11, slight superficial damage to the edge of the restoration was noted. In the case of 3 restorations, rating 1 ranked by the Ryge's scale concerned both surface structure and marginal adhesion. Restorations that scored rating 1 in the study were slightly corrected and re-polished.

36 months after the applications, surface smoothness was rated very well (score 0) for 38 restorations, anatomical shape for 52, and marginal integrity for 45 restorations. Score 1 ranked by the Ryge's scale was obtained by 20 restorations: 16 restorations lost the smoothness of the surface, 1 restoration lost the appropriate anatomical shape, and in the case of 10 – slight superficial damage to the edge of the restoration was noted. In the case of 4 restorations, score 1 ranked by the Ryge's scale concerned both surface structure and marginal integrity, and in the case of 1 restoration – both surface structure and anatomical shape. Restorations that scored 1 in the study were slightly corrected and re-polished. Three restorations scored 2 according to the Ryge's scale, i.e. they needed deferred replacement: 1 restoration lost surface smoothness and 2 restorations lost proper anatomical shape.

During the performed medical procedures and observation period there were no post-operative sensitivity and general

side-effects or allergic reactions in any of the patients, doctors or staff coming into contact with the glass-ionomer material 'SJZ/W' in the immediate follow-up.

The selected clinical situations of performed restorations are presented on Figs. 1–4.

**Figure 1.** Class V glass-ionomer 'SJZ/W' restoration in the cervical region (abrasion cavity) in tooth 33 – baseline situation. Patient 45 years old, gender – female, Ryge's scale – grade 0

**Figure 2.** Class V glass-ionomer 'SJZ/W' restoration in the cervical region (abrasion cavity) in tooth 33 – after 12 months. Patient 46 years old, gender – female, Ryge's scale – grade 0.

**Figure 3.** Class V glass-ionomer 'SJZ/W' restoration in the cervical region (abrasion cavity) in tooth 33 – after 24 months. Patient 47 years old, gender – female, Ryge's scale – grade 0

**Figure 4.** Class V glass-ionomer 'SJZ/W' restoration in the cervical region (abrasion cavity) in tooth 33 – after 36 months. Patient 48 years old, gender – female, Ryge's scale – grade 0

## DISCUSSION

Since the introduction of the first glass-ionomers into the dental market, a number of developments and improvements in their composition have been made, however it still has the ability to chemically bond to enamel and dentin, and is characterized by long-term fluoride release and absorption of fluoride from surrounding sources [10]. The success of long-term maintenance of restorations depends largely on the joint between the material and tooth tissues and marginal adhesion [5].

The previously performed initial clinical study after material setting allowed for evaluation of the applied glass-

ionomer 'SJZ/W' [11]. The high ratings obtained on the performance characteristics of the tested material are worth emphasizing, in particular: the ability to model the surface of the restoration in the unset material, lack of adhesion of the material to dental instruments, good adhesion to cavity walls, ease of condensation and placing of the cement into the cavity [11].

There are limited studies on the clinical evaluation of the restorations made with glass-ionomer materials in permanent teeth [12, 13, 14, 15, 16, 17]. In the presented study, immediately after filling the cavities, all the restorations (100%) in all categories were rated very good. After one-year observation of restorations made with glass-ionomer cement, nearly 90% of the restorations had excellent surface structure, 100% restorations had the correct anatomical shape, and approximately 85% of the restorations had marginal adhesion without reservations. Other restorations required minor corrections and obtained a satisfying score. In a study evaluating glass-ionomer Ketac Molar restorations in class I and II cavities according to Black, in permanent posterior teeth after a 12-month observation, the correct shape of the filling surface was noted in 63% of the restorations, and 35% of the restorations scored a good rating. A proper marginal seal was found in 26% of cases, 68% were rated good, and 6% of restorations required a deferred replacement because of unsatisfactory marginal sealing [14]. However, all restorations in this work had been exposed to occlusal forces, which certainly affected the value of the evaluated parameters.

Interesting results were obtained in assessing another glass-ionomer restoration (Ketac Fil) after 2 years of their placement in patients irradiated due to head and neck cancer [13]. No secondary caries were noted at the margin of the restoration, only the lack of given shape. The material damage could have been due to desiccation, which is the effect of xerostomia after irradiation. On the other hand, the lack of secondary caries was probably the result of the action of fluoride from the glass-ionomer and additional topical applications with fluoride gels which also interface with the structural integrity of glass-ionomer cement [18]. Additionally, Ketac Fill is a glass-ionomer cement that uses maleic acid for its setting, and therefore becomes prone to acidic erosion [19]. The current study also did not reveal any secondary caries after 2 years of observation. A characteristic and very important feature of glass-ionomer cements is not only the content of fluoride, but also the fluoride re-charging ability – they can uptake fluoride from external sources (e.g. water, food, toothpaste), store and release them when the fluoride concentration in hard tooth tissues decreases. For this reason, they enable remineralization and have long-term anti-carious activity [20, 21, 22, 23].

To prevent water imbalance during the maturation of glass ionomer, the kit with the experimental glass-ionomer 'SJZ/W' provided by the manufacturer contains a protective varnish that is applied to the cement just after placing the restoration into the cavity. Because the varnish remains on the surface of the restoration for some time, and depends on the patient occlusion conditions and the tooth brushing technique, and that the chemical maturation time of glass-ionomers requires a longer isolation, covering the restorations twice is recommended, even after finishing the restorations. This procedure appears to be justified in the light of studies by other authors who noticed that the follow-up visit or the treatment of adjacent teeth might result in exposure of 'fresh' glass-ionomer restoration to desiccation [24]. There are also a few clinical studies comparing glass-ionomers with and without coating [16, 17]. One has shown that the 36-month performance of posterior restorations of Fuji IX GP Extra coated with G-Coat Plus was equivalent to that of a resin composite. Although this was not statistically significant, there was a trend that G-Coat Plus can protect Fuji IX GP Extra against wear – 28% of restorations showed wear slightly more than adjacent enamel [17]. In the presented study, similar results were found after 3-years of observation, 29.09% of restorations showed only slight change with the surface structure.

One of the disadvantages of glass-ionomer cements is its insufficient polishability and not always satisfactory cosmetic result. In the current study, however, satisfying polishability and the resulting smoothness of restorations was achieved, which may indicate a reduced accumulation of plaque in the course of 'using the restorations' [5, 6, 7]. Immediately after its application into the cavity, the tested cement 'SJZ/W' was opaque and matt, but over time its appearance improved and became similar to the material of the tooth in terms of transparency (Figs. 1–4). Other authors obtained similar results. The change in colour match over time of the glass-ionomer restorations is consistent with expectations, as it is generally found that conventional GICs will improve in translucency as the cement matures [25]. The maturation of the material is important from the point of view of aesthetics and durability of restorations made of glass-ionomer cements because of the problem of loss of water and then its re-absorption into the mass of the material. Dentists must follow 2 principles: protection of restorations against moisture in the first minutes of setting of the material when, with the involvement of calcium ions, unstable salts are formed which are readily dissociated in water, and protection against drying of restorations in the second setting step, i.e. during the final maturation of cement, according to some authors lasting up to 6 months. Most authors emphasize that the most critical, however, is the first day during which it is absolutely essential to isolate the restoration, and even after a day water absorption is less important for the quality of the restoration; its loss, however, is still a major problem which makes continuous observations expedient [5, 24, 25].

## CONCLUSION

To summarize, it can be concluded that the glass-ionomer 'SJZ/W' showed acceptable clinical results in the 3-year follow up.

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