Clinical evaluation of gallium alloy as a posterior restorative material

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Abstract This study evaluated 30 gallium alloy (Gallium alloy GF) and 31 amalgam (Dispersalloy) restorations over a period of 8 months in both Class I and Class II cavity preparations in 28 human subjects. At baseline, all gallium alloy and amalgam restorations were considered acceptable (Alfa) in terms of caries, anatomic form, marginal adaptation, surface texture, and bulk fracture. Postoperative sensitivity was reported in 67% of the gallium alloy restorations and in 29% of the amalgam restorations. At 8 months, 61% of the gallium alloy restorations were rated Beta for marginal adaptation, and all restorations exhibited tarnish and corrosion. With a few exceptions, the amalgam restorations were rated Alfa for those criteria. Three gallium alloy restorations had to be replaced during the evaluation period because of severe postoperative sensitivity and 39% of gallium restorations still presented some sensitivity at 8 months. Additional problems exhibited by gallium restorations were tooth fractures, tooth cracks, and marginal whitening. (Quintessence Int 1996;27:315-320.)

Clinical relevance Gallium alloy GF restorations exhibited high rates of corrosion and postoperative sensitivity after 8 months of clinical service and were considered unacceptable for clinical use.

Introduction Amalgam has been widely used for many years as a posterior restorative material, and its good clinical performance has been extensively demonstrated. However, drawbacks to amalgam restorations include lack of adhesion to mineralized dental tissues, lack of esthetics, and the unavoidable use of mercury, which may be regarded a harmful component to the patient’s health.

The use of gallium to replace mercury in dental restorations was suggested in 1928. Waterstrat reviewed several studies that were conducted by the National Bureau of Standards in an attempt to characterize and improve gallium-based alloys for restorative purposes. Those studies showed that several alloy systems were potentially useful because of their mechanical and physical properties; however, at that time, none of them had been subjected to either extensive biologic experimentation or clinical trials. Comparative studies among palladium-gallium, gold-gallium, and amalgam alloys have shown that the first two alloys had mechanical properties similar or even superior to the last.

As a result of those studies, one gallium alloy has been recently introduced in the market (gallium alloy GF, Tokuriki Honten). It is claimed to be more useful as a restorative material than conventional amalgam and resin composite. Data available from in vitro studies have demonstrated the material to have acceptable mechanical properties for posterior restorative purposes. Few biologic studies of gallium alloy GF are available. Masuhara et al have demonstrated
the clinical safety of the gallium alloy GF in acute and subacute toxicity tests. Hagiwara et al. have shown that gallium alloy GF is not mutagenic.

Because the material is currently marketed, it is important to comparatively evaluate its performance in a clinical trial. This study compared the gallium alloy GF with a high-copper, disperse-phased amalgam alloy for its suitability as an alternative to amalgam in Class I and Class II restorations in human subjects.

Method and materials

The materials used in this study were the gallium alloy GF (batch No. 9037020922) and Dispersalloy amalgam alloy (Johnson & Johnson Dental, batch No. IC 151). Dispersalloy is a dispersion alloy containing silver-copper eutectic particles. Gallium alloy GF is prepared by mixing a powder containing 50% silver, 25.7% tin, 15% copper, 9% palladium, and 0.3% zinc with a liquid consisting of 65% gallium, 18.95% indium, 16% tin, and 0.05% silver and palladium. Both materials were manipulated according to their manufacturer's instructions.

Dispersalloy was mixed at a powder-liquid ratio of 1:1 (w/w) and triturated (Varimix II, LD Caulk) for 12 seconds at low speed. Gallium alloy GF was provided pre-encapsulated, and care was taken to precisely follow the steps recommended by the manufacturer to obtain the final alloy. It was triturated for 7 seconds at low speed. The materials were immediately carried to the cavity preparations after trituration.

A total of 61 restorations, 31 Dispersalloy and 30 gallium, were placed in both Class I and Class II cavity preparations (ratio 1:2) in both molar and premolar teeth (ratio 1:1) in 28 subjects. Adult male patients were selected from the military police headquarters based on their need for Class I and Class II posterior restorations. The purpose of the study was explained to all the selected patients and, on agreement, they signed a consent form. Only teeth in occlusal function and with at least one approximal surface of the Class II restoration in contact with the adjacent tooth were selected for the study. The teeth were randomly assigned to be restored with either one of the materials. Local anesthesia was administered to all patients, and all the restorations were placed under rubber dam. The cavity preparations were standardized according to the following design:

1. Facial and lingual walls, slightly convergent occlusally, were prepared with a No. 245 carbide bur.

2. Pulpal and gingival walls were prepared flat and perpendicular to the long axis of the tooth.

3. A gingival margin trimmer was used to bevel the axiopulpal line angle and to finish the gingival cavosurface angle.

4. Proximal retention grooves were provided in dentin at lingual and facial walls with a No. 699 fissure bur.

The restorations were inserted by two operators, and at least one restoration of each alloy was placed in the same patient. The restorations were polished in accordance with the manufacturer's instructions 1 week after placement. The Dispersalloy restorations were polished with Shofu rubber points and the gallium restorations were polished with the rubber points provided by the manufacturer, under water coolant. Clinical evaluations were performed in accordance with criteria described by Cvar and Ryge at baseline (after polishing) and 8 months after placement. The restorations were directly evaluated by two independent, calibrated evaluators and consensus was obtained for any disagreement. The restorations were evaluated for secondary caries, anatomic form, marginal adaptation, surface texture, postoperative sensitivity, and bulk fracture. When the restoration could not be examined, it was considered "lost to follow-up." Each restoration was photographed after polishing at the baseline evaluation and at the 8-month recall.

Results

Thirty-one Dispersalloy and 30 gallium restorations were evaluated at baseline. All the restorations were rated Alpha for all the criteria analyzed (Fig 1a). Twenty (67%) teeth restored with gallium and nine (29%) teeth restored with Dispersalloy were reported to be sensitive at baseline. One week after placement, one of the gallium restorations had to be replaced at baseline, at the request of the patient, because of the severity of the postoperative sensitivity.

Before the scheduled first recall at 8 months, two additional gallium restorations and one Dispersalloy restoration had to be replaced because of persistent postoperative sensitivity. At 8 months recall, 26 gallium and 28 Dispersalloy restorations were available for reevaluation (retrieval rates of 87% and 90%, respectively). Table 1 summarizes the results obtained at 8 months' recall. Three of the 26 gallium restorations were not considered in the reevaluation because they presented tooth fracture associated with the restorations (Fig 2).
Table 1 Evaluation scores assigned to the two alloy restorations at the 8-month recall.

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Gallium (n = 23)</th>
<th>Dispersalloy (n = 28)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A</td>
<td>B</td>
</tr>
<tr>
<td>Caries</td>
<td>23</td>
<td>0</td>
</tr>
<tr>
<td>Anatomic form</td>
<td>18</td>
<td>0</td>
</tr>
<tr>
<td>Marginal adaptation</td>
<td>9</td>
<td>14</td>
</tr>
<tr>
<td>Surface texture</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Bulk fracture*</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
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* The score C was assigned for partial bulk fracture, and the score D was assigned for complete bulk fracture.

At 8 months, almost all Dispersalloy restorations were rated Alpha for all the criteria investigated. One restoration was rated Beta for surface texture and another was rated Beta for marginal adaptation (Table 1). Five of 23 gallium restorations (28%) presented bulk fractures (two partial fractures and three complete fractures) and 18 (78%) were rated Alpha for anatomic form. Nine gallium restorations (39%) had adequate marginal adaptation, while 14 (61%) were rated Beta for the same criteria. All gallium restorations were rated Charlie for surface texture. Severe tarnish and corrosion were the most frequent observations with gallium restorations (Figs 1B and 3). This result was also observed in the restorations associated with the tooth fractures (not considered in the reevaluation). No caries was associated with the restorations at the 8-month recall.

Postoperative sensitivity was still associated with nine gallium and one Dispersalloy restoration after 8 months. The three fractured teeth with gallium restorations were also reported to be sensitive. In addition to the tooth fractures observed, three teeth restored with gallium alloy exhibited cracked enamel originating at the margins of the restorations (Fig 3). These cracks were not seen at the baseline evaluation.

An interesting observation was that six (21%) of 28 gallium restorations presented marginal enamel whitening (Fig 3), similar to the appearance of secondary caries. Because of the high degree of postoperative sensitivity, tooth fractures and cracking, marginal whitening, and intense tarnish and corrosion, the authors decided to terminate the study at the 8-month recall. All the gallium restorations were then replaced by dispersalloy restorations. During this procedure, whitening of the internal walls of the cavities was observed in most of the teeth with gallium restorations (Fig 4). No statistical analysis was performed, because the gallium restorations were considered unacceptable after 8 months.

**Discussion**

The increasing concern regarding the potential harm to human health of mercury released from dental amalgam restorations has led to the development of alternative restorative materials that do not contain mercury and yet provide adequate properties to be used as a posterior restorative material. In 1990, a gallium-based alloy was approved for clinical use by the Japanese government. Since then, several laboratory studies have become available on the physical, chemical, and mechanical properties of gallium-based alloys. Mechanical properties, such as compressive strength and creep, have been reported to be comparable to those of currently available high-copper amalgams. However, poor corrosion resistance has been exhibited by gallium-based alloys immersed in different experimental solutions. The high rate of corrosion observed in laboratory studies was confirmed in the present clinical trial. After the short period of 8 months, remarkable corrosion and tarnish were observed in all of the gallium alloy restorations.

Attempts to improve the corrosion behavior of gallium alloys are evident in the most recent studies. Henson et al have recently investigated the corrosion behavior, during static immersion in saline, of an experimental gallium alloy that does not contain tin. After 6 weeks, they found that the absence of tin in the experimental alloy did not reduce the corrosion rate of the alloy. The corrosion process seems to take place by...
Fig 1a  Two restorations at baseline. (G) Gallium alloy GF; (D) Dispersalloy.

Fig 1b  The same two restorations at the 8-month recall. Note the remarkable difference in the corrosion behavior of the restorations. Enamel cracks that were not seen at baseline (arrowheads) were associated with the gallium (G) restoration (compare with Fig 1a). There was marginal breakdown (arrows) of the G restoration. The margin was not in direct occlusal contact with the opposing tooth.

Fig 2  Tooth fracture associated with a gallium (G) restoration (8 months). The fractured piece of the tooth was supported by thick, healthy dentin (*). (D) Dispersalloy.

Fig 3  Gallium (G) and Dispersalloy (D) restorations after 8 months. Observe the advanced corrosion of the gallium restoration as compared to the Dispersalloy restoration. (arrowheads) Whitening of the enamel margins associated with the gallium restoration.

Fig 4  During the replacement of the gallium restorations after the 8-month recall, the whitening of the margins was observed to extend over the internal walls of the cavities.
initial degradation of the component grains (such as beta-tin and gallium-copper) located on the surface. This increases the exposed surface area and exposes the grain boundary areas, thus enhancing the corrosion to an advanced crevice-corrosion process. This phenomenon could explain the observation that “chunks” of the restoration seemed to have been degraded and corroded away from the surface (see Fig 4). The bulk fractures were probably a result of reduced strength of the material because of intense corrosion.

Postoperative sensitivity was surprisingly frequent in this study. Gallium alloy GF has shown good biocompatibility and cytotoxicity levels similar to those of dental amalgams in in vitro studies. Conversely, the present clinical findings that 67% of the gallium restorations presented postoperative sensitivity could be related to the rate of postsetting expansion of the gallium alloy. According to Okabe et al, it is on the order of 64.1 μm/cm, which is far above the maximum accepted by the current American Dental Association specification for dental amalgam (about 20 μm/cm). This high rate of expansion may also have contributed to the tooth fractures observed (see Fig 2). Although the three fractured teeth were reported to be sensitive at 8 months’ recall, they were not included in the results because we could not rule out the fact that the sensitivity was due to the exposure of dentin after the fracture.

The persistent sensitivity could also have been caused by differences in the electric potential between the two alloys. No cavity varnish was used with the gallium restorations, as recommended by the manufacturer. In many instances, amalgam and gallium restorations were placed in adjacent teeth. No cavity varnish or liner is used with gallium alloys because it is thought that the liner might prevent adhesion of the alloy to cavity walls; however, such adhesion is not likely to occur at intraoral temperatures.

Postoperative sensitivity could also have been caused by the exothermic reaction of the gallium alloy. We believe, however, that this was not the case. Gallium alloy GF is a result of several modifications that were made in the earlier formulations of gallium alloys, rendering a very stable palladium-gallium alloy system that reacts with the liquid gallium-tin eutectic alloy without excessive exothermic heating.

Whitening of the margins was also observed in gallium restorations. Furthermore, on removal of the gallium restorations, the whitening of the margins was observed to extend over the internal walls of the cavity (see Fig 4). Working in vitro with corrosion tests, Waterstrat identified the formation of a white gelatinous compound formation on gallium alloys. According to his work, the whitening could be the result of a slow formation of that gelatinous compound that ultimately crystallizes as white gallium oxyhydroxide [Ga(OH)]. This reaction is accompanied by blackening of the surface of the alloy, which is caused by residual palladium or palladium-rich intermetallic compound. Although whitening of the margins may be clinically misinterpreted as secondary caries, its real clinical significance regarding the integrity of the margins is yet unknown.

Gallium alloy restorations were considered unacceptable by the authors at the time of the recall; therefore, the study was terminated after 8 months of follow-up. The high degree of postoperative sensitivity, presence of cracks, whitening of the margins, and intense tarnish, corrosion, and marginal breakdown were the main reasons for this decision. These observations are in agreement with the findings of Yamashita et al, who reported similar surface deterioration of experimental gallium alloy restorations in a noncomparative clinical trial. As far as postoperative sensitivity resulting from postsetting expansion is concerned, a new gallium-based alloy (Galloy, SDI) that has been shown to have significantly reduced expansion rate is currently available.

We believe that efforts should be directed toward the development of a more corrosion-resistant gallium alloy before it can be recommended and approved for clinical use. Parallel studies are also being conducted to improve the current formulations of dental amalgams to reduce the amount of mercury released from the restorations.

Acknowledgments

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References


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