Amalgam to be phased out completely by 2025.

an interview with **Bart Dopheide**, GC Europe.

Bart Dopheide graduated *as a dentist from the University of Groningen (the Netherlands) in 1987. He has worked in management roles in the dental industry in Europe and internationally for more than 30 years. The focus of his activities were the marketing and development of a broad range of materials for dentists and technicians. He held leading positions in cross-functional teams that introduced the MI concept, high-viscosity glass ionomers, composites and glass hybrids in Europe. Currently, he is general manager, responsible for the scientific services activities of GC in Europe*

This Thursday, negotiators from the Parliament and Council reached a provisional political agreement on the Commission's proposal to address the remaining uses of mercury in products in the EU in line with its Zero Pollution Ambition. Last year, the European Council had made an official proposal to ban the use of amalgam for any dental treatment in its member states as of the 1st of January, 2025. The use of dental amalgam for children and pregnant or breastfeeding women, had already been banned in the EU since 2018, apart from a few strict exceptions.
Now, this agreement has to be adopted by Parliament and Council, after which the new law will be published in the EU Official Journal and enter into force 20 days later. With this new legislation in sight, the need for alternative solutions is once again highlighted. Mr. Bart Dopheide, General Manager Scientific Services at GC Europe, glimpses into a future where amalgam is gone for good.

The EU Commission wants to ban dental amalgam by 2025. Why is this happening?

The reason for the phase out of amalgam is the mercury that is inside. Once an amalgam restoration is set and bound within the alloy, the release of mercury is negligible. However, even though mercury naturally occurs in the environment, in its free and unbound form, it is toxic and a severe hazard for the environment. An important example occurred amid the 20th century, when mercury-tainted industrial wastewater poisoned thousands of people in Minamata in Japan, leading to severe health damage. The global agreement on the phase out of mercury, the Minamata Convention, was named after this tragedy.

Dental amalgam is the largest remaining intentional use of mercury in Europe, estimated at around 40 tons. The consequential environmental impact does not only manifest in waste – even though amalgam separators prevent the mercury dump in the wastewater. Mercury pollution may occur during any stage from the production of amalgam capsules, their preparation, placement, and removal, to amalgam fillings in the deceased, especially when the remains are cremated.

40 tons, that is a huge number. Thus, we can assume that still many dentists are using amalgam. What will this mean for dentistry?

Some countries have already banned amalgam completely; Nordic countries have played a pioneering role here. Nevertheless, in some countries, amalgam remains important, mainly because of the health insurance coverage policies, where it's still considered an affordable and durable material. Recently, some countries started to remove it from the national reimbursement programs. However, in many countries, amalgam is still widely advocated, even though it's acknowledged that a phase-down is necessary for the environment, and they focus on thorough and sensible waste management. These EU countries that have not yet adjusted their reimbursement system to cover alternatives, may postpone the phase-out up until 30 June 2026, to avoid negative repercussions for low-income EU citizens who might otherwise not be able to afford adequate dental treatment in these countries. The phase-out in countries that already prohibited amalgam, has taught us that a policy change is feasible. Especially because several alternatives exist nowadays. Interestingly, even before the phase down, other direct restoratives gained importance, not for environmental reasons, but mainly because of their increased aesthetic appeal and minimally invasive potential.

Dental amalgam has been used successfully to restore teeth for more than a century. Nowadays, several, viable and less invasive options are available.

So, you think dentists are ready to completely abandon amalgam? Are current alternatives sufficient to cover all needs?

Currently, there are several viable, mercury-free alternatives on the markets, but of course, we need to ensure that all requirements are met, also from the patient's perspective. This is something GC has anticipated since many years. Prof. Dr Falk Schwendicke, the current Director of the Polyclinic for Dental Conservation and Periodontology at the LMU Clinic in Munich, has conducted a series of cost-effectiveness studies with his team. In these studies, he conducted direct comparisons between EQUIA Forte glass hybrid restorations and composite restorations. Composite is considered the 'gold standard' for direct restorations nowadays.

Although this is an excellent alternative, in some cases, the higher technique sensitivity and costs could be a drawback. In this research, both initial and retreatment were taken into account. The conclusion was that glass hybrids had more potential in terms of cost-effectiveness. Such studies are very important considering the transition to alternatives to be covered by social security systems and private healthcare, to make oral healthcare affordable for everyone. The conclusions from the World Health Organisation correspond to these findings; composites as well as glass ionomers and their hybrids are being considered essential medicines.

Either way, amalgam won't be replaced by just one material, but several materials.

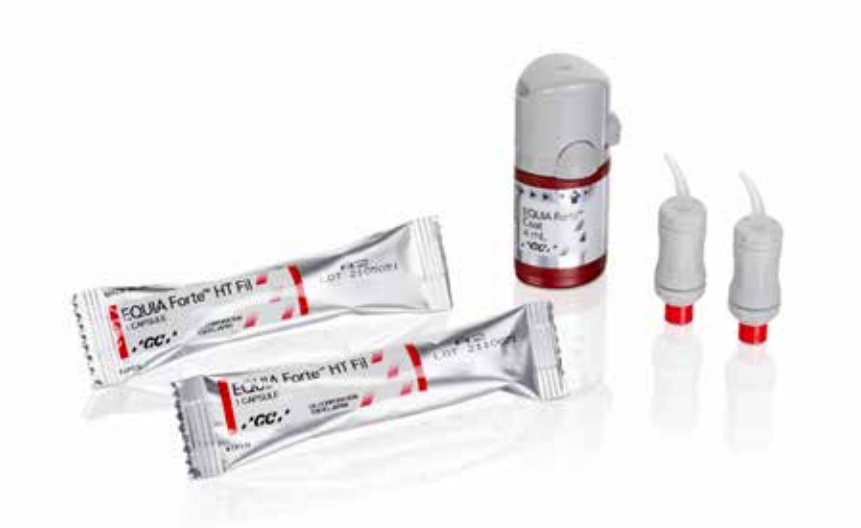
So, what determines which material should be selected in which case?

This is always a multifactorial decision. Three years ago, the management board of Foundation Nakao initiated the "Restorative options decision tree" to support the amalgam phase-down by providing dentists with clear alternative options. It comprises a consensus of experts to guide the selection of restorative materials. All key aspects are considered, from mechanical and clinical properties to patient comfort, expectations, and financial consequences. Such a tool facilitates and objectifies decision making, without losing sight on all important factors, whether physical, practical, or economical.

Tremendous advances in materials science have been made. Nowadays, we even have very strong direct options for large restorations, such as fibre-reinforced composites. The everX series of composites exists in two viscosity levels, both adding strength and fracture toughness. In large cavities, such as after endodontic treatment, these types of composites are recommended.

Another important evolution are the newest low-viscosity composites such as G-ænial Universal Injectable. This composite is as least as strong or even stronger than contemporary paste composites. This has opened many new ways of working, all contributing to the ease of placement. All these advances have it made possible to imagine a world without dental amalgam, so I am very confident that prospects in dentistry and our future smiles are looking bright.

In case of interest in GC's alternative options, more information can be found on the dedicated webpage: https://campaigns-gceurope.com/amalgam-alternative/



Left: EQUIA Forte HT has shown to be a cost-effective alternative that has become a popular amalgam alternative. Right: MO restoration on a first molar with EQUIA Forte HT. Courtesy of Dr. Zeynep Bilge Kütük, Türkiye

References

1. Mercury: deal with Council to phase out the use of dental amalgam. https://www.europarl.europa.eu/news/en/press-room/20240205IPR17416/mercury-deal-with-council-to-phase-out-the-use-of-dental-amalgam
2. Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2017/852 of the European Parliament and of the Council of 17 May 2017 on mercury as regards dental amalgam and other mercury-added products subject to manufacturing, import and export restrictions. Register of commission documents. https://ec.europa.eu/transparency/documents-register/detail?ref=COM(2023)395&lang=en
3. Schwendicke F, Müller A, Seifert T, Jeggle-Engbert LM, Paris S, Göstemeyer G.J Dent. 2021 Jul;110:103689. doi: 10.1016/j.jdent.2021.103689. Glass hybrid versus composite for non-carious cervical lesions: Survival, restoration quality and costs in randomized controlled trial after 3 years.
4. Schwendicke F, Rossi JG, Krois J, Basso M, Peric T, Turkun LS, Miletić I.J Dent. 2021 Apr;107:103614. doi: 10.1016/j.jdent.2021.103614. Cost-effectiveness of glass hybrid versus composite in a multi-country randomized trial.
5. Foundation Nakao Decision tree. https://zingtree.com/deploy/tree.php?z=embed&tree_id=510390943

Case 2:

The second case shows the clinical situation of a 59-year-old female patient with partial edentulism in the lower jaw and whose further mandibular treatment consisted of a cast partial denture (Fig. 10). An extension of the incisal defects to clean, caries-free dentine was carried out according to the procedure presented in case 1. Figure 11 illustrates the cavities of different depths (already under rubber insulation), Figure 12 illustrates the phosphoric acid conditioning (37.5 %, "Total Etch", Gel Etchant, Kerr) and Figure 13 illustrates the resulting "frosty" etching pattern of the melting surfaces.

The narrow type of microbrush as used in case 1 was too large to transport the adhesive into the depth without too much pressure on the remaining lateral enamel walls. For this reason, a classic brush (Mirabrush regular, Hager & Werken) was used in this case (Fig. 14). Here, too, after the light polymerisation of the adhesive, the injectable, low-viscosity restorative material G-ænial Universal Injectable could be injected in shade A3.5 selected for this case. Just as in case 1, a fine type 45 cannula was used for the application of the injectable material (Fig. 15). Figure 16 shows the fully polymerised incisal edge restauration of the mandibular front still under rubber dam, Figure 17 shows the same situation after the adjustment of the protrusion sheets and the polishing - now already with the mandibular model cast prosthesis reinserted. Figures 18 and 19 show the stable and aesthetic final result again after a further check-up after 5 months. This restoration result also corresponded exactly to the patient's ideas and her desire for a simple, minimally invasive, yet aesthetic incision edge restoration.

Fig. 10: Preoperative situation of a patient with incisal defects that is only partially edentulous in the lower jaw.

Fig. 11: The prepared incisal edges revealed cavities of different depths.

Fig. 12: Total-etch phosphoric acid conditioning.

Fig. 13: The "frosty" etching pattern of the enamel surfaces.

Fig 14: Application of the universal adhesive with a classic brush.

Fig. 15: Application of the injectable low-viscosity restorative material.

Fig. 16: The fully polymerised incisor edge abutments of the mandibular front still under rubber dam.

Fig. 17: Situation after adjustment of the protrusion sheets and polishing.

Fig. 18: The stable and aesthetic final result with a further check-up after 5 months.

Fig. 19: View with additional lingual contrastor for better visualisation of the incisal edge areas.

Discussion:

The combination of materials presented here is certainly just one of many. The primary selection was made based on the handling properties: There was a lot to be said for the use of a stable, injectable low-viscosity restoration material. It is pleasing to note that – after reviewing the literature published on the material in peer-reviewed journals so far – no compromises have to be made in terms of physical properties with regard to the material quality: With regard to abrasion behaviour in a 2-body wear test, the "injectable" restorative material G-ænial Universal Injectable used surpasses both Filtek Bulk Fill and the new G-ænial A'CHORD[12]. In another study on mechanical properties[3], G-ænial Universal Injectable showed comparable Vickers surface hardness to SonicFill (Kerr). In the same study, G-ænial Universal Injectable was found to have the lowest surface roughness and the lowest abrasion-related volume loss after thermal cycling loading in a chewing simulator. Beautifil Injectable X and SonicFill 2 showed statistically significantly higher roughness values and abrasion-related volume losses. The study revealed (as expected) a highly significant correlation between the roughness values and the determined volume loss ($p = 0.001$, $R 2 = 0.9803$). Another study confirmed these data: G-ænial Universal Injectable, together with G-ænial Universal Flo, showed the smoothest surfaces after finishing and polishing, and therefore the lowest adherence of S. mutans[15].

Thus, the selection of the restorative material presented here would definitely be on a secure basis and at the same time benefit from the handling properties that are perfectly suited for this indication.

For the further prevention of further, possibly unnoticed parafunctional progression, the adjustment of a mandibular anti-bruxism splint is a useful follow-up measure[2,11].

Literature:

1. Arnold M, Paqué F. The anatomy of mandibular incisors and canines zm 2018; 108, 2110-2117.
2. Burian, G.; Erdelt, K.; Schweiger, J.; Keul, C.; Edelhoff, D.; Güth, J.-F. In-Vivo-Wear in Composite and Ceramic Full Mouth Rehabilitations over 3 Years. Sci. Rep. 2021, 11, 14056.
3. Elsahn NA, El-Damanhoury HM, Shirazi Z, Saleh ARM. Surface Properties and Wear Resistance of Injectable and Computer-Aided Design/Computer Aided Manufacturing-Milled Resin Composite Thin Occlusal Veneers. Eur J Dent 2023; 17: 663-672.
4. Ernst CP. Light polymerization. In: Frankenberger, R.: Adhäsive Zahnheilkunde, Deutscher Zahnärzte-Verlag, Cologne 2013, pp. 35-80.
5. Ernst CP, Price RB, Callaway A, Massek A, Schwarm H, Rullmann I, Willershausen B, Ehlers V. Visible Light Curing Devices - Irradiance and Use in 302 German Dental Offices. J Adhes Dent 2018; 20: 41-55.
6. Ernst CP. Keep your eyes open when buying lamps. ZMK 2019; 35; 14-20.
7. Ernst CP. Veneer restorations after orthodontic pretreatment: A multidisciplinary treatment approach. ZMK 2023; 39: 414-430.
8. Ernst CP. Leadership roles. ZMK 2023; 39: 484-503.
9. Ferracane F, Watts DC, Barghi N, Ernst CP, Rüeggeberg FA, Shortall A, Price R. The efficient use of light curing equipment – a guide for dentists. ZMK 2014; 30 (4): 166-180.
10. Frankenberger R, Dudek M-C, Krämer N, Winter J, Roggendorf MJ. The 10 most popular mistakes in adhesive technique. DZZ 2022; 77: 238-244.
11. Hardan L, Mancino D, Bourgi R, Cuevas-Suárez CE, Lukomska-Szymanska M, Zarow M, Jakubowicz N, Zamarripa-Calderón JE, Kafa L, Etienne O, Reitzer F, Kharouf N, Haïkel Y. Treatment of Tooth Wear Using Direct or Indirect Restorations: A Systematic Review of Clinical Studies. Bioengineering 2022; 9: 346.
12. Lassila L, Novotny R, Säilynoja E, Vallittu PK, Garoushi S. Wear behavior at margins of direct composite with CAD/CAM composite and enamel. Clin Oral Investig 2023; 27: 2419-2426.
13. Ludovichetti FS, Lucchi P, Zambon G, Pezzato L, Bertolini R, Zerman N, Stellini E, Mazzoleni S. Depth of Cure, Hardness, Roughness and Filler Dimension of Bulk-Fill Flowable, Conventional Flowable and High-Strength Universal Injectable Composites: An In Vitro Study. Nanomaterials 2022 7; 12(12): 1951.
14. Manhart J. Aesthetic analysis for composites in the anterior region. Determination of tooth color and individual characteristics. Lower Saxony Dental Journal 2022 (1): 18-27.
15. Vulović S, Stašić JN, Ilić J, Todorović M, Jevremović D, Milić-Lemić A. Effect of different finishing and polishing procedures on surface roughness and microbial adhesion on highly-filled composites for injectable mold technique. J Esthet Restor Dent 2023; 35: 917-926.