Technical Advantages of Mercury-Free Dentistry

1. Availability and Feasibility of Non-Mercury Alternatives

The availability of superior non-mercury alternatives has enabled the virtual phase out of amalgam use in entire countries in Europe. For example, Sweden[1] and Norway[2] have phased out amalgam use. Finland[3], the Netherlands[4], and Denmark[5] use amalgam for only 1% of all fillings. In fact, according to the latest report, fully 70% of the EU Member States – 17/27 – are reported to have less than 10% amalgam use or have filed phase out plans.

The use of non-mercury alternatives to amalgam is not only feasible; it is supported by the European public, recognized by industry, and already practiced many dentists. The European Commission's' online public consultation resulted in over 85% support for phasing out amalgam.[6] The manufacturers are focused on alternatives, having even hosted a conference themed "The Demise of Amalgam". The majority of dentists practice mercury-free dentistry, and all dentists (certainly all under age 70) know how to use mercury-free fillings.

A recent survey of the market shares of mercury-free fillings in Germany (Annex I) impressively shows how modern and user-friendly alternative products for permanent fillings have been established on the market while the number of fillings per year continue to decline. [7]

Clearly and indisputably, the non-mercury alternatives to amalgam are available and feasible.

2. Mercury-free fillings are more minimally-invasive than amalgam

It is well-established that amalgam damages healthy tooth matter, weakens tooth structure, and fractures teeth:

- "However, some significant disadvantages are associated with amalgam that are not encountered with resin based composite. These include…strict preparation requirements for depth and mechanical retention; and its non-adhesive nature."[8]

Mercury-free materials like composite offer the invaluable benefits of preserving tooth structure and strengthening teeth:

The majority of cavities are small and can be filled time-saving with single layer composites, compomers or glass-ionomers

The majority of cavities are small cavities of one or two surfaces (statistically 70% in Germany in 2018[9]) which can be fast and easily filled by using minimal invasive single-layer composites, composer or glass ionomers.

Since the use of these materials is less invasive and allows a longer survival of the tooth, they should be **the first choice for small cavities.**

This also complies with the World Dental Federation which recommended in September 2018 to reduce and if possible, avoid the use of amalgam particularly in lesions that are suitable for other restorative materials, especially in first restorative treatment and young patients. [10]

Using amalgam causes large cavities reducing the healthy tooth structure and poses a greater challenge to the dentist when they have to be replaced. The consistent use of the minimally invasive therapy from the beginning would therefore reduce the number of large cavities in the long term.

In any case, even large cavities can nowadays be handled just as well with alternative materials as with amalgam.

A further assessment of the feasibility and benefits of non-mercury alternatives to dental amalgam is attached with images (Annex II)

3. Mercury-free fillings can be placed as fast as amalgam

It generally does not take dentists any more time to place a composite than it does an amalgam:

- According to a 2012 BIOIS report prepared for the European Commission, "it has been shown that the time needed to carry out a Hg-free [mercury-free] restoration has reduced significantly as dentists have gained more experience in the handling of Hg-free materials, so that there is currently no (or minor) time difference to perform Hg-free restorations compared to amalgam."[11]

As mentioned before, small cavities can be fast and easily filled by using minimal invasive single-layer composites, compomers or glass ionomers.

For **large cavities with three or four surfaces,** even in the masticatory load-bearing posterior region dentists have nowadays the choice between several modern non-metallic alternatives or a combined technique with a comparable lifetime to amalgam.

A standard technique is the combination of glass ionomer cement and composites. It saves material costs, reduces shrinkage stress and increases marginal seal. The self-adhesive glass ionomer cement replaces the missing dentin as a cavity base and the composite covers the base to increase the durability. This cost-effective and durable combination of glass ionomer cements and composites is suitable for medium to large cavities with sufficient enamel limitation in the posterior region.

Another alternative to traditional incremented composites are the new generation of optimized bulk fill composites. Given that these new composites are placed in-bulk, restoring the complete cavity or most of it, depending on the type of bulk-fill composite, the placement is time-saving and therefore cost-effective.

Direct composite restorations in the posterior dentition have become an indispensable element of modern dentistry. The performance of these restorations has been conclusively proven in many clinical studies. This procedure is usually carried out in a layering technique. Aside from the possibilities that highly aesthetic composites offer in the application of polychromatic multiple-layer techniques, there is also a great market demand for the simplest and quick and therefore economical composite- based materials for posterior teeth. These products are offered in the category of bulk-fill composites.

4. Mercury-free fillings can last as long – or longer – than amalgam

According to the current guideline of the DGZ (Deutsche Gesellschaft für Zahnerhaltung, German society for tooth preservation) on composite restorations in the posterior region from 2016, alternative restorations can be successfully used in the posterior region according to the current data situation for the restoration of class I and II cavities[12]. The results of a comprehensive review have shown that the annual failure rate of composite fillings in the posterior region (2.2%) is statistically not different from that of amalgam fillings (3.0%)[13]. For not only time-consuming high-end restorations for the posterior region, but also a simpler, faster and therefore more cost-effective basic restoration, bulk fill composites with optimized curing depths have been available on the market for some time now. They allow clinically acceptable posterior fillings to be placed in a more economical procedure than the 2 mm layering technique with traditional hybrid composites[1415].

The following table shows the survival rates of composite restorations in the posterior region in long-term clinical studies with at least a 4 years observation periods (1990-2015)[16]
(AFR = Annual Failure Rate)

Author	Year	Observation period (years)	Compositgroup	AFR (%)
Manhart et al. (not yet published)	2016	10	Bulkfill Composit Hybridcomposit	1.8
Pallesen and Van Dijken [17]	2015	30	HybridComposit light-curing 2 Hybridkomposite chemically curing	1.4 1,1/0,8
Pallesen and Van Dijken [18]	2015	27	2 Hybridcomposites light-curing Hybridkomposit chemically curing	1,7/1,8 1,4
Van Dijken and Pallesen [19]	2013	6	Hybridcomposit Nano-Hybridcomposit	1,7 2,3
Van Dijken and Pallesen [20]	2011	7	Hybridkomposit without Lining Technik Hybridkomposit with Lining Technik	2,3 2,0
Da Rosa Rodolpho et al. [21]	2011	22	Hybridcomposit (70vol% Filler) Hybridcomposit (50vol% Filler)	1,5 2,2
Manhart et al. [22]	2010	4	Bulkfill Composit Hybridcomposit Kompomer Underfilling	2,7 0,6 0,2
Van Dijken [23]	2010	12	Hybridkomposit (closed sandwich technique) Hybridkomposit (only Class I Restauratioen)	0,2
Opdam et al. [24]	2010	12	Hybridcomposit Amalgam	1,68 2,41
Van Dijken et al. [25]	2009	5	Hybridcomposit Hybridkomposit with Präpolymerisaten (low shrinkage)	2,9 2,1
Lindberg et al. [26]	2007	9	Compomer/Hybridcomposit (Open Sandwich Technique) Hybridcomposit	1,0 1,37
Van Dijken et al. [27]	2005	4	Hybridcomposit Calcium aluminate cement	1,9 19
Pallesen and Quist [28]	2003	11	Hybridcomposit Composit-Inlays	1,5 1,5
Gaengler et al. [29]	2001	10	Hybridcomposit	2,58

5. Mercury-free fillings are safer than amalgam

Amalgam never faced the regulatory scrutiny that new dental materials go through: Amalgam came into use more than a century ago, before any effective government safety regulations for new medical devices existed. Many current regulatory schemes permit the continued use of this mercury-added product under "grandfather" clauses that excuse older products from meeting current regulatory standards (or any standards at all). Today, a new product this toxic would have to overcome far more regulatory hurdles well before it reached the market – and any serious health, safety and environmental concerns would be addressed during this rigorous process. As a result, any risky products – especially one comprised of a known neurotoxin—are unlikely to receive regulatory approval, well in advance of reaching the market. In Europe it is even more unlikely now that the new Medical Devices Regulation (MDR) (EU 2017/745)[30] is going into effect. MDR will enter into force on 26th Mai 2021 in all EU Member States, provide an optimised uniform regulation for the marketing of medical devices, and enhance the focus on product quality and safety. Detailed documentation, including raw materials, will be required. In conclusion, MDR will ensure the safety of new dental filling materials. If the manufacturer of a device has a current "approval", this remains valid for the time being, but **its validity ends at the latest on 27 May 2025**. There is reason to believe that dental amalgam would not meet these requirements.

Considering that amalgam consists of 50% mercury, it is no surprise that the industry was failing to introduce effective safety standards for products on the market. Usually, the safety is made transparent to consumers by applying uniform standards which are indicated on the package leaflet. In the case of dental amalgam, a standard for tolerable release rates of mercury was delayed for decades. Due to the Minamata Convention and the EU mercury regulation, standards for encapsulated and non-encapsulated amalgam fillings have finally been initiated (ISO 23325, ISO 20749 and ISO 24234). However, since these new standards refer to a purely mechanical test method of the corrosion resistance and accept a wear rate of 20%, they are not suited to prove the safety of amalgam. If the immersion procedure or the potentiostatic procedure (as had been defined in the now ignored Technical Specifications of ISO/TS 17988 Dentistry - Corrosion test methods for dental amalgam) had been applied, consumers would at least have had the opportunity to verify the quality of the filling by a saliva-, vapour- or tension test.

Amalgam's known risks keep increasing while no harm from mercury-free fillings has been found in half a century: No study has proven that mercury-free fillings pose a risk – and new developments make it even less likely that they ever will. For example, the share of hybridfiller and organic matrix in a composite filling is today 15-25% organic matrix and 75-85% inorganic filler. The share of hybrid fillers can actually exceed 86% without containing nanoparticles[31]. This high proportion increases the strength of the filling while reducing the potential release of the organic matrix. However, new research has concluded that amalgam's mercury poses even more risks than were known at the time of SCENIHR's 2015 opinion. For example, *Bjorkman et. al.* (2018) found that "The results from this study support the hypothesis of increased risk of perinatal mortality of children born by women with many amalgam fillings."[32] And *Yin et. al.*(2016) "found that dental surface restorations significantly contributed to the blood concentrations of THg and IHg in both periods of study, as well as MeHg in 2011–2012, after adjusting covariates such as age, education, race/ethnicity, gender, smoking, and fish consumption history" – meaning that it is now clear that amalgam's elemental mercury can convert to methylmercury in the human body and put people (especially individuals already exposed to other sources of methylmercury like high fish diets) at

even more risk, especially if they are already exposed to other sources of methylmercury (like high fish diets or mercury-based skin creams).[33]

While mercury poses many risks to both health and the environment, **the European Center for Environmental Medicine would like to direct the Secretariat's attention specifically to the problem of amalgam use in people with kidney impairments** because so many studies, governments, and industry sources – especially in the European Union, but also beyond – have warned against the use of amalgam in people with kidney impairments.

Kidney disorders affect millions of Europeans. According to the European Renal Association-European Dialysis and Transplant Association (ERA-EDTA), 10% of Europeans are affected by chronic kidney disease.[34] This means that approximately "70 million Europeans (850 million people worldwide)[35] have lost some of their kidney function and are at high risk of becoming dependent on renal replacement therapies (dialysis or transplantation)."[36] Making the problem even worse, many people – especially low-income individuals with less access to healthcare – do not even realize they have a kidney impairment because the disease has few "alarm signals" until it reaches an advanced stage and there is a lack of public awareness about the disease.[37] The ERA-EDTA says this lack of awareness extends to the medical community. These facts raise particular problems for amalgam use:

- With so many people who have undiagnosed kidney impairments (or who will develop kidney disease later), how can dentists ensure that they are not using amalgam in this vulnerable population?

- If even medical doctors are unaware of kidney disease, how can dentists – who are not licensed or trained to practice medicine – be depended upon to decide which patients with kidney impairments, with undiagnosed kidney impairments, or with higher risk of developing kidney impairments should receive amalgam?

Below are examples of studies, governments, and even industry warning against amalgam use in people with kidney impairments, indicating that use of non-mercury alternatives to amalgam would be a clear benefit to the health of this vulnerable population.

Studies support the conclusion that dental amalgam should never be used in people with kidney impairments:

- *European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), Final opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users (29 April 2015), http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_046.pdf, p.36, 43, 75:*
  The European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) explained that "decreased kidney function (decreased renal clearance) is likely to decrease the ability to eliminate mercury and other substances via the urine."[38] It concluded that "use of amalgam restorations is not indicated in primary teeth, in patients with mercury allergies, and persons with chronic kidney diseases with decreased renal clearance."[39]

- *Barregard L, Fabricius-Lagging E, Lundh T, Mölne J, Wallin M, Olausson M, Modigh C, Sallsten G., Cadmium, mercury, and lead in kidney cortex of living kidney donors: Impact of different exposure sources. Environ Res. 2010; 110(1): 47-54:*

As explained in the abstract, Barregard *et al.* (2010) found that "Kidney Hg increased by 6% for every additional amalgam surface, but was not associated with fish consumption…. Dental amalgam is the main determinant of kidney Hg."[40]

- *Wael I. Mortada, Mercury in dental restoration: Is there a risk of nephrotoxicity, J. NEPHROL (2002), http://www.ncbi.nlm.nih.gov/pubmed/12018634:*
  Mortada *et. al.* (2002) explained that "A total of 101 healthy adults (80 males and 21 females) were included in this study. The population as grouped into those having amalgam fillings (39 males and 10 females) and those without (41 males and 11 females). Hg was determined in blood, urine, hair and nails to assess exposure. Urinary excretion of beta2-microglobulin (beta2M), N-acetyl-beta-D-glucosaminidase (NAG), gamma-glutamyltransferase (gammaGT) and alkaline phosphatase (ALP) were determined as markers of tubular damage. Albuminuria was assayed as an early indicator of glomerular dysfunction. Serum creatinine, beta2M and blood urea nitrogen (BUN) were determined to assess glomerular filtration….From the nephrotoxicity point of view, dental amalgam is an unsuitable filling material, as it may give rise to Hg toxicity…in these exposure conditions, renal damage is possible…"[41]

- *Ritchie KA et. al., Mercury vapour levels in dental practices and body mercury levels of dentists and controls, British Dental Journal (2004), https://www.researchgate.net/publication/8118038_Mercury_vapour_levels_in_clinical_practices_and_body_levels_of_dentists_and_controls:*
  Ritchie *et al.* (2004) found that the urinary mercury levels found in dentists can be over four times that of the control group: "A large and highly significant difference was found between urinary mercury levels of dentists and controls, with the geometric mean urinary mercury for dentists being 4.17 times that for the control group (95% CI = 3.36 to 5.19)....There was, amongst dentists, a significant correlation between the number of amalgam fillings they placed and removed in a week and urinary mercury concentration ($r = 0.38$, $P < 0.001$, and $r = 0.29$, $P<0.001$)."[42] It also found that dentists were significantly more likely than non-dentist control subjects to report having disorders of the kidney: "....dentists were significantly more likely to have suffered from kidney disorders (6.5%) than control subjects (0.6%),...".[43]

Governments – in the EU and beyond – support the conclusion that dental amalgam should not be used in people with kidney impairments:

- *European Commission, Final Report: Review of the Community Strategy Concerning Mercury (October 2010), https://ec.europa.eu/environment/chemicals/mercury/pdf/review_mercury_strategy2010.pdf , p.187:*
  According to a report prepared for the European Commission, in Germany "It is recommended not to use dental amalgam on children, pregnant and nursing women, people with kidney problems, when in contact with other metals, such as braces, and in people with mercury sensitivity."[44]

- *Ministero della Salute (Italy), Divieto di utilizzazione, importazione e immissione in commercio, sul territorio italiano degli amalgami dentali non preparati sotto forma di capsule predosate e precauzioni ed avvertenze da riferire nelle istruzioni per l'uso degli amalgami dentali posti in commercio in Italia. (G.U. Serie Generale , n. 261 del 09 novembre 2001), http://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=14407&completo=true*

"evitare per prudenza la posa e la rimozione dell'amalgama in pazienti con allergia per l'amalgama, gravidanza, allattamento, bambini sotto i sei anni d'eta', pazienti con gravi nefropatie" (translated as "prudently avoid the installation and removal of the amalgam in allergy patients, pregnancy, breastfeeding, children under six years of age, patients with severe kidney disease)[45]

- *Health Canada, The Safety of Dental Amalgam, https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/dent_amalgam-eng.pdf:*
  According to Health Canada's Position Statement on Dental Amalgam, "Amalgam should not be placed in patients with impaired kidney function."[46]

- *National Health & Medical Research Council, Dental Amalgam – Filling You In (2002), https://web.archive.org/web/20040611002357/http://www.health.gov.au/nhmrc/publications/pdf/d18.pdf:*
  Australia's National Health and Medical Research Council brochure *Dental Amalgam – Filling You In* warned people with kidney impairments to avoid amalgam: "Very small amounts of mercury are released from the surface of dental amalgam fillings, mainly as mercury vapour. Grinding teeth, chewing and tooth-brushing all increase the amount of mercury released. Some of the vapour is breathed out, but some is breathed in, or dissolves in saliva and is swallowed. In this way, some mercury can reach the rest of the body and accumulate in certain organs, particularly the kidneys….Because high levels of mercury exposure may affect the kidneys, people with kidney disease may be more concerned than others to minimise exposure to mercury."[47]

Industry supports the conclusion that dental amalgam should never be used in people with kidney impairments:

- *Professor Gottfried Schmalz, Webinar: What dentists need to know about the Minamata Convention on Mercury, https://www.fdiworlddental.org/news/20190501/webinar-what-dentists-need-to-know-about-the-minamata-convention-on-mercury (emphasis added)*
  "….the scientific advisory committee of the EU (SCENIHR) in 2015 concluded that current evidence does not preclude the use of amalgam for the general population with no allergy to amalgam components or *with no renal disease*."[48]

- *World Dental Federation (FDI), Policy Statement on Dental Amalgam Phase Down (September 2018), https://www.fdiworlddental.org/resources/policy-statements/dental-amalgam-phase-down (emphasis added):*
  "FDI supports the following practices in the phase down of dental amalgam….Reduce and if possible avoid the use of amalgam particularly in: lesions that are suitable for other restorative materials, especially in first restorative treatment and young patients; *patients with special medical conditions, such as severe renal disease* or patients with allergic reactions to amalgam or (erosive) lichenoid contact lesions in the oral mucosa; except when deemed necessary by the dental practitioner based on the specific needs of the patient. "[49]

- *Canadian Dental Association, Dental Amalgam FAQs, http://www.cda-adc.ca/en/oral_health/faqs/dental_amalgam_faqs.asp*
  "Can dental amalgam be safely used with every patient? No….Health Canada suggests that alternatives should be considered for patients with impaired kidney function. Although dental

amalgam itself is not linked to such conditions, there is evidence that total body burden of mercury is of particular concern with these patients."[50]

6. Mercury-free fillings are safer for the environment

A report by UNEP shows that, per capita, the European Union largest user of dental mercury in the world – consuming at least 90 tons in 2010.[51] While this is due in part to more universal dental care than is available in other regions, the stark reality is the E.U. is the #1 dental mercury polluter; as this AMAP/UNP report shows, all other regions consume significantly less dental mercury[52]:

Once in the environment, SCHER has confirmed that dental amalgam in the environment can methylate (forming the most toxic form of mercury, methylmercury), that as a result "the acceptable level in fish is exceeded" under some circumstances, and thus there is "a risk for secondary poisoning due to methylation."[53]

The use of Dental Amalgam is critical for the chemical status in water bodies

The European Environmental Agencies State of Water Report (2018)[54] highlights, that across Europe mercury is the main contributor for failure to achieve good chemical status in the highest number of water bodies: out of a total of 111,062 surface water bodies, 45,973 are not achieving good status for mercury equating to about 41% of all surface water bodies in Europe. If the widespread pollution by ubiquitous priority substances, including mercury, were omitted, the proportion of water bodies failing to achieve good chemical status would fall to 3% (as opposed to 46%).

Additionally, dental amalgam appears to be the main contributor to releases of mercury from urban wastewater treatment plants (UWWTP) to water bodies.

A report (BIOis 2012[55]) on behalf of the European Commission suggested to ban dental amalgam since it seems necessary to achieve mercury-related requirements of the EU legislation (the Water Framework Directive (2000/60/EC), Decision 2001/2455/EC and Directive 2006/11/EC on dangerous substances and Directive 2008/105/EC on priority substances).

Meanwhile, mercury-free composites and glass ionomers are safe for the environment:

- European Commission Scientific Committee on Health and Environmental Risks (SCHER): "Due to the low mammalian toxicity of these compounds, indirect risks to human health from release of the alternatives [to amalgam] without mercury are estimated as low."[56]

- According to a 2012 study by the Health Care Research Collaborative of the University of Illinois at Chicago School of Public Health, the Healthier Hospitals Initiative, and Health Care Without Harm, "there is no current evidence of significant personal or environmental toxicity" from the non-mercury alternatives.[57]

- A briefing note from EurEau says: **The available evidence suggests that microplastics at current concentration levels do not pose a risk to human health and waste water is not a source of microplastics.** Only a minor share of the total microplastics released from various sources enter waste water infrastructure. Conventional WWTPs can efficiently remove up to 80-95% of microplastics, mostly in the preliminary and primary treatment steps. [58]

- **The BPA molecule can be readily metabolized by many microbial communities and BPA-degrading strains have been isolated from water, soil and biomass from wastewater treatment systems.** BPA degradation in the environment is mainly due to bacterial metabolism, though, the activities of fungi and algae in BPA degradation are also discussed. The metabolites produced during degradation of BPA under aerobic conditions have been exhaustively studied and several BPA degradation pathways have been proposed. Some information is also presented on the enzymes and genes that are involved in BPA degradation. The role of species composition and adaptation of the microbial community to BPA removal is discussed, as well as environmental factors that may influence the efficiency of BPA degradation. A summary of this information will help readers better understand the fate of BPA in the environment, how BPA degradation by different groups of microorganisms proceeds and finally, how to design treatment lines to ensure efficient BPA removal.[59]

- **BPA, BPAF, and BPS are also adsorbed to the sludge in a WWTP, but are there readily biodegradable and degraded quick in soils with a half-time of less than 1 day**. Pressures to ban bisphenol A (BPA) has led to the use of alternate chemicals such as BPA analogues bisphenol S (BPS) and bisphenol AF (BPAF) in production of consumer products; however, information on their environmental fate is scarce. In this study, aerobic degradation of BPA, BPAF, and BPS at 100 μg/kg soil and 22 ± 2 °C was monitored for up to 180 days in a forest soil and an organic farm soil. At each sampling point, soils were extracted three times and analyzed by liquid chromatography high resolution mass or time-of-flight mass spectrometry. Based on compound mass recovered from soils compared to the mass applied, BPS had short half-lives of <1 day in both soils similar to BPA. BPAF was much more persistent with observed half-lives of 32.6 and 24.5 days in forest and farm soils, respectively. To our knowledge, this is the first report on BPAF degradation. For all three compounds, half-lives were longer in the higher organic carbon (OC) forest soil which correlates well to sorption studies showing higher sorption with higher OC. Metabolites identified for all three bisphenols support degradation pathways that include meta-cleavage as well as ortho-cleavage, which has not been previously shown.[60]

[1] BIO Intelligence Service (2012), *Study on the potential for reducing mercury pollution from dental amalgam and batteries*, Final report prepared for the European Commission-DG ENV, https://ec.europa.eu/environment/chemicals/mercury/pdf/mercury_dental_report.pdf, p.58.
[2] Personal communication, email from Eirik H. Steindal, Senior Advisor, Norwegian Climate and Pollution Agency, 13 December 2012
[3] Ministry of Social Affairs and Health, *Plan for the Abolition of Dental Amalgam by 2030* (2019), http://julkaisut.valtioneuvosto.fi/bitstream/handle/10024/161728/STM_rap_59_19_Plan%20for%20the%20abolition%20of%20dental%20amalgam%20by%202030.pdf?sequence=1&isAllowed=y. p.23
[4] UNEP, *Lessons from Countries Phasing Down Dental Amalgam Use* (2016), https://wedocs.unep.org/bitstream/handle/20.500.11822/11624/Dental.Amalgam.10mar2016.pages.WEB.pdf; Mercury Policy Project Report to the United Nations Environment Program Chemicals Branch Division of Technology, Industry and Economics (UNEP) on "Phasing Down Dental Amalgam: Country Case Studies"; Project Account Number: MC/4030-09-04-2204, December 30, 2012.
[5] Ministry of Environment and Food of Denmark, *Overview of Danish legislation and actions in connection with the phasing out of dental amalgam*, https://circabc.europa.eu/ui/group/19e66753-84ca-4e4e-a4a1-73befb368fc2/library/67c149f5-c04a-4310-a828-42f0fdf78e71/details
[6] https://ec.europa.eu/eusurvey/publication/MinamataConvention
[7] https://www.kzbv.de/kzbv-jahrbuch-2019.media.381dcb7f99745a1edf1e2c179a5624b3.pdf
Conservation services, KZBV Yearbook 2019, p. 100
[8] Christopher D. Lynch, Kevin B. Frazier, Robert J. McConnell, Igor R. Blum and Nairn H.F. Wilson, *Minimally invasive management of dental caries: Contemporary teaching of posterior resin-based composite placement in U.S. and Canadian dental schools*, J AM DENTA ASSOC 2011; 142; 612-620, http://jada.ada.org/content/142/6/612.abstract
[9] https://www.kzbv.de/kzbv-jahrbuch-2019.media.381dcb7f99745a1edf1e2c179a5624b3.pdf
Conservation services, KZBV Yearbook 2019, p. 100
[10] Dental Amalgam Phase Down, Policy Statement, Adopted by the FDI General Assembly September, 2018 in Buenos Aires, Argentina, https://www.fdiworlddental.org/resources/policy-statements/dental-amalgam-phase-down
[11] BIO Intelligence Service (2012), *Study on the potential for reducing mercury pollution from dental amalgam and batteries*, Final report prepared for the European Commission-DG ENV, p.67.
[12] Federlin, M., et al., composite restorations in the posterior region. S1 Recommendation for action (long version). AWMF register number: 083-028; as of October 2016; valid until: October 2021 German Dental Journal, 2017. 72(1): p. 75-82.
[13] Manhart, J., et al., Review of the clinical survival of direct and indirect restorations in posterior teeth of the permanent dentition.Oper Dent, 2004. 29(5): p. 481-508.
[14] Manhart, J., H.Y. Chen, and R. Hickel, Three-year results of a randomized controlled clinical trial of the posterior composite QuiXfil in class I and II cavities.Clin Oral Investig, 2009. 13(3): p. 301-7.
[15] Burke, F.J., et al., The current status of materials for posterior composite restorations: the advent of low shrink.Dent Update, 2009. 36(7): p. 401-402.
[16] Federlin, M., et al., composite restorations in the posterior region. S1 Recommendation for action (long version). AWMF register number: 083-028; as of October 2016; valid until: October 2021 German Dental Journal, 2017. 72(1): p. 75-82.
[17] Pallesen U, van Dijken JW: A randomized controlled 30 years follow up of three conventional resin composites inClass II restorations. Dent Mater 2015; 31: 1232–1244
[18] Pallesen U, van Dijken JW: A randomized controlled 27 years follow up of three resin composites in Class II restorations. J Dent 2015; 43: 1547–1558
[19] van Dijken JW, Pallesen U: A six-year prospective randomized study of a nano-hybrid and a conventional hybrid resin composite in Class II restorations. Dent Mater 2013; 29: 191–198
[20] van Dijken JW, Pallesen U: Clinical performance of a hybrid resin composite with and without an intermediate layer of flowable resin composite: a 7-year evaluation. Dent Mater 2011; 27: 150–156
[21] Da Rosa Rodolpho PA, Donassollo TA, Cenci MS et al.: 22-year clinical evalua-tion of the performance of two poste-rior composites with different filler characteristics. Dent Mater 2011; 27: 955–963
[22] Manhart J, Chen HY, Hickel R: Clinical evaluation of the posterior composite Quixfil in class I and II cavities: 4-year follow-up of a randomized controlled trial. J Adhes Dent 2010; 12: 237–243
[23] van Dijken JW: Durability of resin composite restorations in high C-factor cavities: a 12-year follow-up. J Dent 2010; 38: 469–474
[24] Opdam NJ, Bronkhorst EM, Loomans BA, Huysmans MC: 12-year survival of composite vs. amalgam restorations. J Dent Res 2010; 89: 1063–1067
[25] van Dijken JW, Lindberg A: Clinical effectiveness of a low-shrinkage resin composite: a five-year evaluation. J Adhes Dent 2009; 11: 143–148
[26] Lindberg A, van Dijken JW, Lindberg M: Nine-year evaluation of a polyacidmodified resin composite/resin composite open sandwich technique in Class II cavities. J Dent 2007; 35: 124–129
[27] van Dijken JW, Sunnegardh-Gronberg K: A four-year clinical evaluation of a highly filled hybrid resin composite in posterior cavities. J Adhes Dent 2005; 7: 343–349
[28] Pallesen U, Qvist V: Composite resin fillings and inlays. An 11-year evaluation. Clin Oral Investig 2003; 7: 71–79
[29] Gaengler P, Hoyer I, Montag R: Clinical evaluation of posterior composite restorations: the 10-year report. J Adhes Dent 2001; 3: 185–194
[30] https://ec.europa.eu/growth/sectors/medical-devices/new-regulations_en
[31] VOCO, *x-tra fil Light-curing posterior filling material*, https://www.voco.dental/en/products/direct-restoration/composites/x-tra-fil.aspx
[32] *Bjorkman L, Lygre GB, Haug K, Skjærven R (2018) Perinatal death and exposure to dental amalgam fillings during pregnancy in the population-based MoBa cohort. PLoS ONE 13(12): e0208803. https://doi.org/10.1371/journal. pone.0208803*
[33] *Yin et. al., Associations of blood mercury, inorganic mercury, methylmercury and bisphenol A with dental surface restorations in the U.S. population, NHANES 2003–2004 and 2010–2012, Ecotoxicity and Environmental Safety (2016)*
[34] European Renal Association-European Dialysis and Transplant Association, *Chronic Kidney Disease – a Challenge for European Healthcare Systems*, http://www.era-edta2015.org/press/1_150526_18.00_Press%20Release_CKD_Challenge.pdf
[35] European Renal Association-European Dialysis and Transplant Association, The hidden epidemic: Worldwide, over 850 million people suffer from kidney diseases, http://web.era-edta.org/uploads/180627-press-era-asn-isn.pdf
[36] European Renal Association-European Dialysis and Transplant Association, *Chronic Kidney Disease – a Challenge for European Healthcare Systems*, http://www.era-edta2015.org/press/1_150526_18.00_Press%20Release_CKD_Challenge.pdf
[37] European Renal Association-European Dialysis and Transplant Association, *Chronic Kidney Disease – a Challenge for European Healthcare Systems*, http://www.era-edta2015.org/press/1_150526_18.00_Press%20Release_CKD_Challenge.pdf

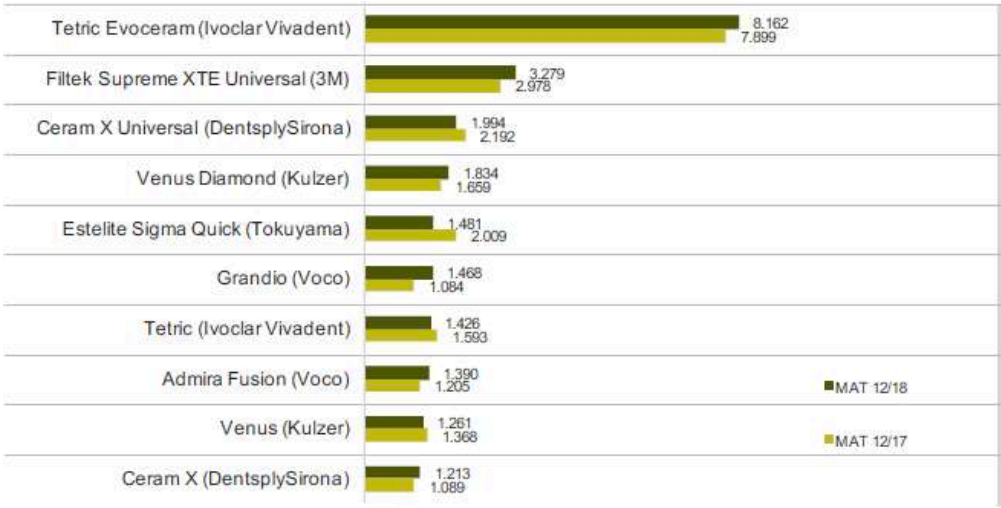
[38] European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), *Final opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users* (29 April 2015), http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_046.pdf, p.36
[39] European Commission Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), *Final opinion on the safety of dental amalgam and alternative dental restoration materials for patients and users* (29 April 2015), http://ec.europa.eu/health/scientific_committees/emerging/docs/scenihr_o_046.pdf, pp.43, 75
[40] Barregard L, Fabricius-Lagging E, Lundh T, Mölne J, Wallin M, Olausson M, Modigh C, Sallsten G.. Cadmium, mercury, and lead in kidney cortex of living kidney donors: Impact of different exposure sources. Environ Res. 2010; 110(1): 47-54:
[41] Wael I. Mortada, *Mercury in dental restoration: Is there a risk of nephrotoxicity*, J. NEPHROL (2002).
[42] Ritchie KA et. al., *Mercury vapour levels in dental practices and body mercury levels of dentists and controls*, British Dental Journal (2004).
[43] Ritchie KA et. al., *Mercury vapour levels in dental practices and body mercury levels of dentists and controls*, British Dental Journal (2004).
[44] European Commission, *Final Report: Review of the Community Strategy Concerning Mercury* (October 2010), https://ec.europa.eu/environment/chemicals/mercury/pdf/review_mercury_strategy2010.pdf, p.187.
[45] Ministero della Salute (Italy), Divieto di utilizzazione, importazione e immissione in commercio, sul territorio italiano degli amalgami dentali non preparati sotto forma di capsule predosate e precauzioni ed avvertenze da riferire nelle istruzioni per l'uso degli amalgami dentali posti in commercio in Italia. (G.U. Serie Generale , n. 261 del 09 novembre 2001), http://www.trovanorme.salute.gov.it/norme/dettaglioAtto?id=14407&completo=true
[46] Health Canada, *The Safety of Dental Amalgam*, https://www.canada.ca/content/dam/hc-sc/migration/hc-sc/dhp-mps/alt_formats/hpfb-dgpsa/pdf/md-im/dent_amalgam-eng.pdf
[47] National Health & Medical Research Council, *Dental Amalgam – Filling You In* (2002), https://web.archive.org/web/20040611002357/http://www.health.gov.au/nhmrc/publications/pdf/d18.pdf
[48] Professor Gottfried Schmalz, *Webinar: What dentists need to know about the Minamata Convention on Mercury*, https://www.fdiworlddental.org/news/20190501/webinar-what-dentists-need-to-know-about-the-minamata-convention-on-mercury (emphasis added)
[49] World Dental Federation (FDI), *Policy Statement on Dental Amalgam Phase Down* (September 2018), https://www.fdiworlddental.org/resources/policy-statements/dental-amalgam-phase-down (emphasis added)
[50] Canadian Dental Association, *Dental Amalgam FAQs*, http://www.cda-adc.ca/en/oral_health/faqs/dental_amalgam_faqs.asp
[51] AMAP/UNEP Technical Report for the Global Mercury Assessment" (2013), http://www.amap.no/documents/doc/technical-background-report-for-the-global-mercury-assessment-2013/848, p.103
[52] AMAP/UNEP Technical Report for the Global Mercury Assessment" (2013), http://www.amap.no/documents/doc/technical-background-report-for-the-global-mercury-assessment-2013/848, p.103
[53] SCHER, *Opinion on Environmental Risks and Indirect Health Effects of Mercury from Dental Amalgam* (2014), http://ec.europa.eu/health/scientific_committees/environmental_risks/docs/scher_o_165.pdf, page 4
[54] European Environmental Agency Report No 7/2018, European waters: Assessment of status and pressures 2018 https://www.eea.europa.eu/publications/state-of-water
[55] BIO Intelligence Service (2012), *Study on the potential for reducing mercury pollution from dental amalgam and batteries*, Final report prepared for the European Commission-DG ENV, https://ec.europa.eu/environment/chemicals/mercury/pdf/mercury_dental_report.pdf, p.58.
[56] SCHER, *Opinion on the environmental risks and indirect health effects of mercury in dental amalgam* (2008), http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_089.pdf, page 16
[57] Health Care Research Collaborative of the University of Illinois at Chicago School of Public Health, the Healthier Hospitals Initiative, and Health Care Without Harm, *Mercury in Dental Amalgam and Resin-Based Alternatives: A Comparative Health Risk Evaluation* (June 2012), http://www.noharm.org/lib/downloads/other/Mercury_in_Dental_Amalgam.pdf, p.6
[58] http://www.eureau.org/resources/briefing-notes/3940-briefing-note-on-microplastics-and-the-water-sector/file
[59] BPA removal from wastewater: Chapter 4. Microbial Biodegradation and Metabolism of BPA , Abstract https://www.springerprofessional.de/bisphenol-a-removal-from-water-and-wastewater/15782874; https://www.sciencedirect.com/science/article/pii/S0048969719332474 , biodegradation in an ordinary WWTP with activated sludge seems to be around 75% https://ars.els-cdn.com/content/image/1-s2.0-S0048969719332474-ga1_lrg.jpg
[60] Aerobic Soil Biodegradation of Bisphenol (BPA) Alternatives Bisphenol S and Bisphenol AF Compared to BPA Abstract https://www.ncbi.nlm.nih.gov/pubmed/2911046

Market share of mercury-free fillings Germany 2018

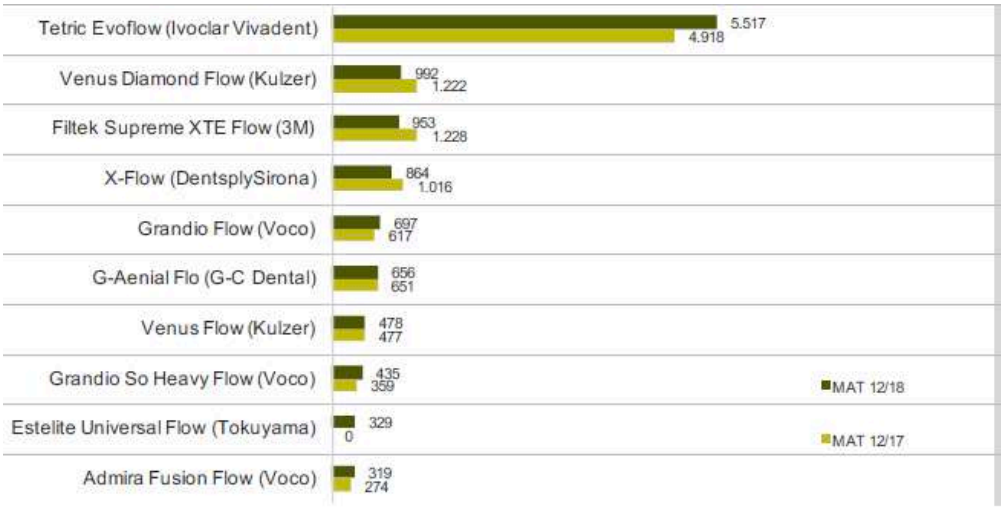
based on
GfK German Dental Market Report (DDM)
Management Report (MMR) | MAT 12/18 |

GfK Consumer Health | Dental | Februar 2019 |

MS= Market Share; Change in market share in percentage points over the previous year

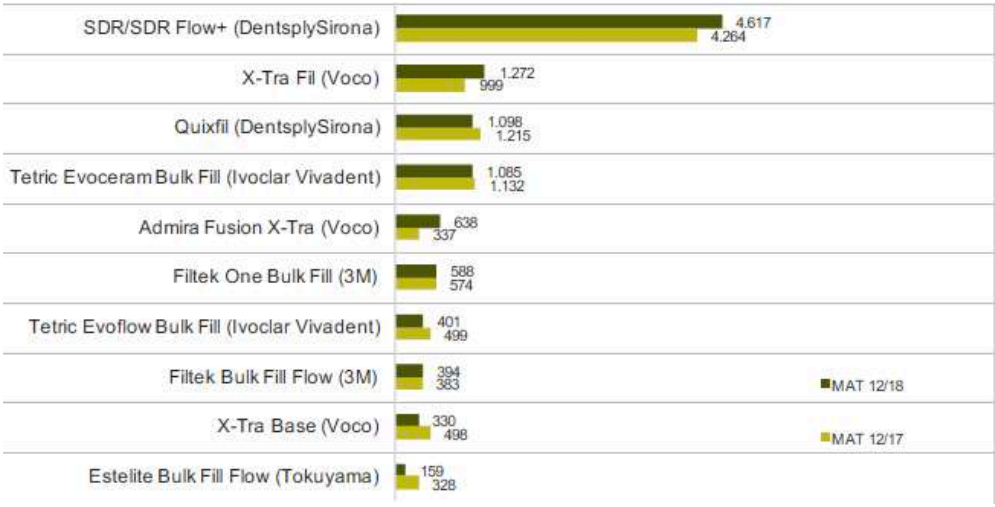


Light-curing composites: not flowable | MS: 36,6 mio € / 2018|(1%)|Leading products	Sales +/- %	Market share %
Tetric Evoceram (Ivoclar Vivadent)	3%	22%
Filtek Supreme XTE Universal (3M)	10%	9%
Ceram X Universal (DentsplySirona)	-9%	5%
Venus Diamond (Kulzer)	11%	5%
Estelite Sigma Quick (Tokuyama)	-26%	4%
Grandio (Voco)	35%	4%
Tetric (Ivoclar Vivadent)	-10%	4%
Admira Fusion (Voco)	15%	4%
Venus (Kulzer)	-8%	3%
Ceram X (DentsplySirona)	11%	3%



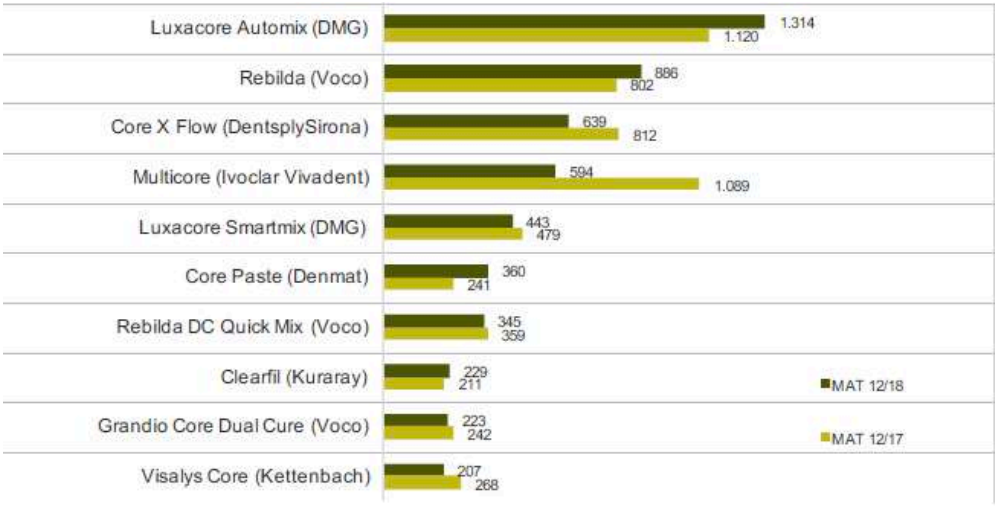
Light-curing composite: flowable | MS: 15,0 mio € / 2018 |(6%)|Leading products	Sales +/- %	Market share %
Tetric Evoflow (Ivoclar Vivadent)	12%	37%
Venus Diamond Flow (Kulzer)	-19%	7%
Filtek Supreme XTE Flow (3M)	-22%	6%
X-Flow (DentsplySirona)	-15%	6%
Grandio Flow (Voco)	13%	5%
G-Aenial Flo (G-C Dental)	1%	4%
Venus Flow (Kulzer)	0%	3%
Grandio So Heavy Flow (Voco)	21%	3%
Estelite Universal Flow (Tokuyama)	0%	2%
Admira Fusion Flow (Voco)	16%	2%

Bulk Fill Materials | MS: 11,2 mio € / 2018 |(0%)|Leading products



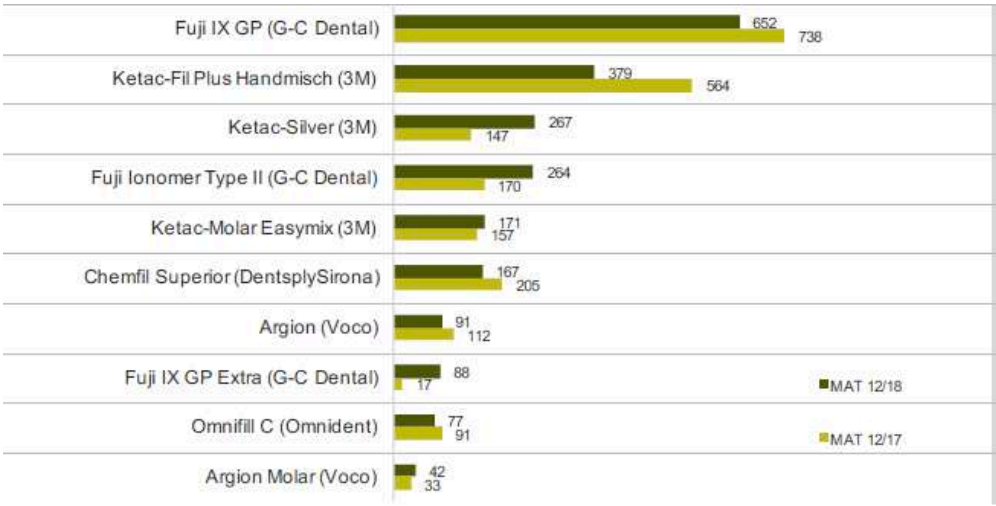
	Sales +/- %	Market share %
SDR/SDR Flow+ (DentsplySirona)	8%	41%
X-Tra Fil (Voco)	27%	11%
Quixfil (DentsplySirona)	-10%	10%
Tetric Evoceram Bulk Fill (Ivoclar Vivadent)	-4%	10%
Admira Fusion X-Tra (Voco)	89%	6%
Filtek One Bulk Fill (3M)	2%	5%
Tetric Evoflow Bulk Fill (Ivoclar Vivadent)	-20%	4%
Filtek Bulk Fill Flow (3M)	3%	4%
X-Tra Base (Voco)	-34%	3%
Estelite Bulk Fill Flow (Tokuyama)	-52%	1%

Self-curing composites | MS: 6,3 mio € / 2018 |(-8%)|Leading products



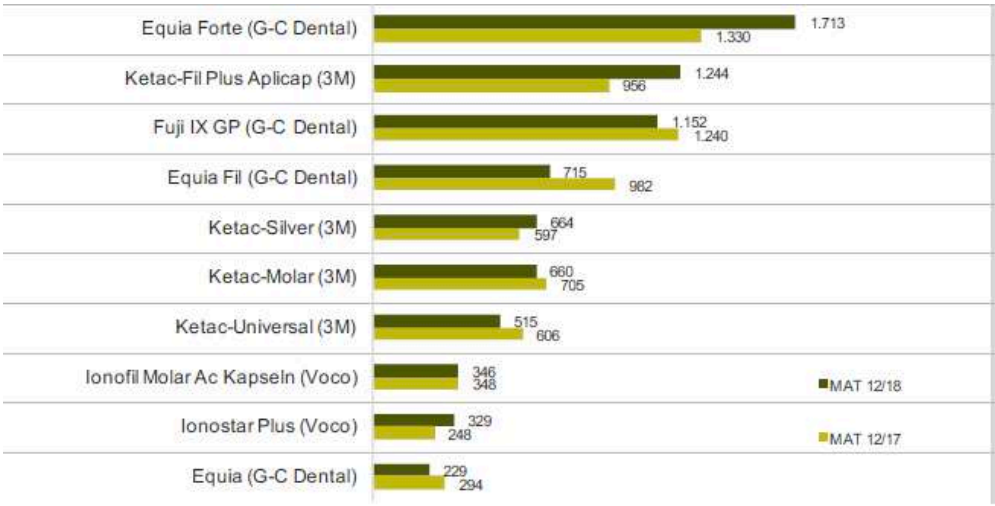
	Sales +/- %	Market share %
Luxacore Automix (DMG)	17%	21%
Rebilda (Voco)	10%	14%
Core X Flow (DentsplySirona)	-21%	10%
Multicore (Ivoclar Vivadent)	-45%	9%
Luxacore Smartmix (DMG)	-7%	7%
Core Paste (Denmat)	49%	6%
Rebilda DC Quick Mix (Voco)	-4%	5%
Clearfil (Kuraray)	9%	4%
Grandio Core Dual Cure (Voco)	-8%	4%
Visalys Core (Kettenbach)	-23%	3%

Glass ionomer cement : powder | MS: 2,3 mio € / 2018 |(-6%)|Leading products



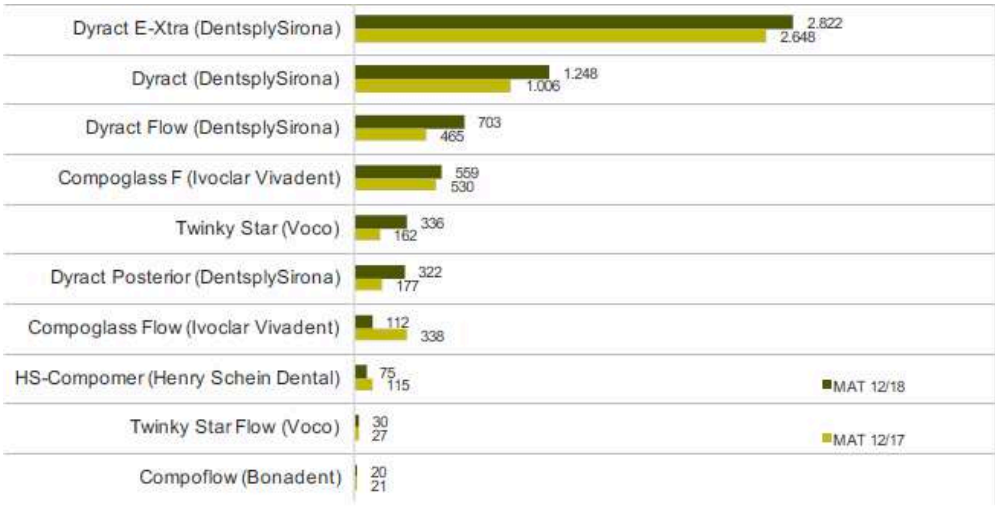
	Sales +/- %	Market share %
Fuji IX GP (G-C Dental)	-12%	29%
Ketac-Fil Plus Handmisch (3M)	-33%	17%
Ketac-Silver (3M)	81%	12%
Fuji Ionomer Type II (G-C Dental)	56%	12%
Ketac-Molar Easymix (3M)	8%	7%
Chemfil Superior (DentsplySirona)	-19%	7%
Argion (Voco)	-19%	4%
Fuji IX GP Extra (G-C Dental)	>100	4%
Omnifill C (Omnident)	-15%	3%
Argion Molar (Voco)	27%	2%

Glass ionomer cement : capsules | MS: 8,2 mio € / 2018 |(1%)|Leading products



	Sales +/- %	Market share %
Equia Forte (G-C Dental)	29%	21%
Ketac-Fil Plus Aplicap (3M)	30%	15%
Fuji IX GP (G-C Dental)	-7%	14%
Equia Fil (G-C Dental)	-27%	9%
Ketac-Silver (3M)	11%	8%
Ketac-Molar (3M)	-6%	8%
Ketac-Universal (3M)	-15%	6%
Ionofil Molar Ac Kapseln (Voco)	-1%	4%
Ionostar Plus (Voco)	33%	4%
Equia (G-C Dental)	-22%	3%

Compomers | MS: 6,2 mio € / 2018 |(13%)|Leading products



	Sales +/- %	Market share %
Dyract E-Xtra (DentsplySirona)	7%	45%
Dyract (DentsplySirona)	24%	20%
Dyract Flow (DentsplySirona)	51%	11%
Compoglass F (Ivoclar Vivadent)	6%	9%
Twinky Star (Voco)	>100	5%
Dyract Posterior (DentsplySirona)	82%	5%
Compoglass Flow (Ivoclar Vivadent)	-67%	2%
HS-Compomer (Henry Schein Dental)	-35%	1%
Twinky Star Flow (Voco)	14%	0%
Compoflow (Bonadent)	-7%	0%

Assessment of the feasibility and benefits of non-mercury alternatives to dental amalgam

by
Christer Malmström, DDS, Sweden

1. Myth: Composite fillings are taking longer than amalgam fillings to make.

(0) = No difference.
(+) = Composite fillings a little faster.
++ = Composite fillings faster, much faster.
(-) = Amalgam fillings a little faster.
- - = Amalgam fillings faster, much faster.

Facts about how to make an amalgam or a composite filling:

a.	If needed, Dental anaesthesia and cofferdam takes the same amount of time. No difference.	0
b.	Drilling the cavity. Less drilling for composite, a little faster than amalgam.	(+)
c.	If needed, put on matrix strip and wedge. No difference.	0
d.	Cavity cleaning. No difference.	0
e.	Mix and isolate for amalgam. Etch and bond for composite.	(-)
f.	Do the filling. Mix, put in and condense amalgam. Insert composite and light cure.	0
g.	If needed, take off matrix strip and wedge. No difference.	0
h.	Model chewing surface and check chewing. No difference.	0
i.	Polishing the surface to completed filling. Amalgam can only be polished after 24 hours.	++

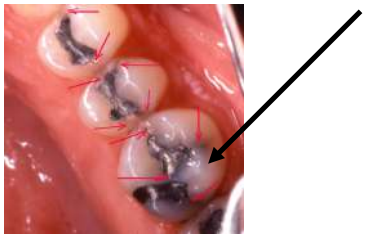
Final comments.
Composite fillers do not take longer than amalgam.
With a little experience, they go faster even if you cheat and fail to polish the amalgam.

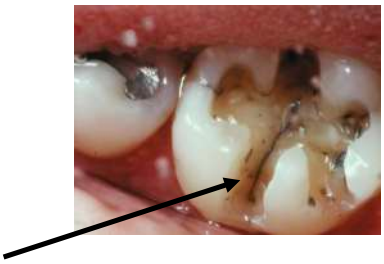
2. Myth: There are long-term facts about amalgam that show how good it is, long-term facts are missing about composites.

Facts: There are many long-term studies that show that composite fillings are as good or better than amalgam fillings, I think you already have them.
About long-term studies on amalgam unfortunately, they are often censored if they are negative.
But there are some.

All metals or alloys that corrode, expand, (basic facts in metallurgy).

Amalgam fillings corrode, expand and crack teeth. If you have amalgam in the mouth you see cracks after a couple of years in the enamels around the filling.





The dangerous cracks are not seen until a cusp or large parts of the crown is fractured. Then you can see cracks in the dentin, under the filling or inside the cusps that remains.
If the crack goes down into the dentin and reach the pulp it leads to necrosis of the pulp (then a root filling or extraction of the tooth is needed)

If the crack goes deeper it can split the tooth into two parts.
Fractures may occur after one or two years, but become common after 8-10 years. Often, the first fracture comes in the sixth tooth from the front. The cause is, it was often the first amalgam filling.

It is easy to see the difference between how a gold filling looks (that does not corrode) and an amalgam filling that corrodes. You see the cracks around the amalgam filling and the discoloration of tooth by corrosion products from amalgam.

C**onclusion:** Amalgam are more expensive in long-term follow-ups.
Fractures can force you to make a crown or extract the tooth and make a bridge or prosthesis instead. You don't have these problem with composite filling.

3. Myth: Composite are more expensive to make.

Facts: As you see in statement 1. It takes about the same time to make an amalgam as to make a composite. If you have a little experience, composite is faster.

The difference in material costs is 1-2 EUR. Compared with the total cost of 45 - 50 EUR, it is irrelevant.

For amalgam you need a mixer and to take care of the excess of amalgam and an amalgam separator to take care of the waste.

For Composite you need a lamp.
If there are any difference amalgam is more expensive.

4. Myth: To evaluate the quality of composite fillings, if different for different materials, investigations are needed.

Facts: All the major manufacturers have excellent materials. The most important thing for good quality of fillings is not the material but the one that makes the filling. Practically all dentists can make excellent fillings if they care about the patient.
If you work as a dentist many years, you will discover over time that only a very few dentists how do not make good fillings, regardless of the material. All the other dentists make excellent fillings, regardless of manufacturer of the material they use.

The materials are so good today that their quality has much, much less impact on the quality of the filling than the dentists' knowledge and morals have.
To improve the quality of the filling, improve knowledge of the dentist.