Resin-based composite (high-viscosity)

Section: 30. Dental medicines and preparations

EMLc | Codes ATC: En attente

Indication	Dental caries Code ICD11: DA08.0
Type de médicament	Chemical agent
Type de liste	Liste de base
Additional notes	*of any type for use as dental filling material
Formulations	**Local > Topical > Other:** Single-use capsule or multi-use syringe
Historique des statuts LME	Ajouté pour la première fois en 2023 (TRS 1049)
Sexe	Tous
Âge	Aussi recommandé pour les enfants
Équivalence thérapeutique	La recommandation concerne ce médicament spécifique
Renseignements sur le brevet	Patents have expired in most jurisdictions Lire la suite sur les brevets.
Wikipédia	Resin-based composite (high-viscosity)

Recommandation du comité d'experts

The Expert Committee acknowledged the large global burden of dental caries and noted the work undertaken by WHO in developing a global oral health action plan, in which targets have been set that by 2030, 50% of countries will include essential dental preparations that are on the EML/EMLc in their national essential medicines lists, and 90% of countries will have implemented measures to phase down or will have phased out the use of dental amalgam as stipulated in the Minamata Convention on Mercury. The Committee noted that the available evidence indicated that resin-based composites were effective and safe for use as dental sealants (low-viscosity forms) and as filling materials (high-viscosity forms) in the prevention and treatment of dental caries. The Committee also noted that resin-based composites may have functional and aesthetic advantages compared with glass ionomer cement, however they required more specialized expertise and facilities for application. The Committee noted that the evidence suggested that resin-based composites were not as effective as dental amalgam when used as a filling material but considered that the availability of alternatives to dental amalgam was important to enable parties to the Minamata Convention on Mercury to achieve the mandated phase down of dental amalgam use to reduce environmental mercury pollution. The Committee noted that limited information was available on the cost and cost–effectiveness of resin-based composites. They may be more expensive than other prevention and treatment options. The Committee considered that having more treatment options available could increase access and affordability at the country level. The Expert Committee therefore recommended the inclusion of resin-based composites on the core list of the EML and EMLc for use as sealant and filling material in the prevention and treatment of dental caries.

Contexte

Resin-based composites have not previously been considered for inclusion on the Model Lists. Glass ionomer

cement was added to the Model Lists in 2021 as a dental sealant and filling material for the prevention and treatment of dental caries. The Expert Committee took into consideration that dental sealants, including glass ionomer cement, have been shown to be highly effective in the prevention and treatment dental caries. The main advantage of glass ionomer cement over other sealants was the simplicity of application, making it suitable for use in atraumatic restorative treatment by dentists and other health professionals in primary care, and community and field settings outside of specialized dental clinics. The Committee noted that while other types of sealants or fillings, such as resin-based products, are at least as effective as glass ionomer cement sealants and may have better mechanical properties (e.g. adherence to the tooth), they require more specialized expertise and application techniques and conditions. Glass ionomer cement was considered particularly suitable for people who are unable to tolerate conventional invasive dental treatment, such as young children, elderly people and patients with mental health conditions who may have difficulty cooperating (1).

Pertinence pour la santé publique

The WHO global oral health status report, using the latest available data of the Global Burden of Disease Study 2019, estimates that oral diseases affect close to 3.5 billion people worldwide. Dental caries is the most widespread oral disease with more than 2.5 billion untreated cases. This includes more than 2 billion estimated cases of caries in permanent teeth (global average prevalence of 29%) and 514 million estimated cases of caries in primary (deciduous) teeth (global average prevalence of 43%). Among the 194 WHO Member States, 134 have prevalence figures greater than 40% for caries in primary teeth. More than three quarters of cases of untreated caries teeth are found in middle-income countries. Over the past 30 years cases of untreated caries have increased and surpassed the demographic population growth during the same period (2). Untreated dental caries may cause pain and infection, and may lead to systemic infections requiring hospitalization and complex treatment. The high prevalence and severity of untreated dental caries in children can contribute to low body mass index and stunting (3–5). Additionally, dental caries results in significant absenteeism in schools and workplaces (6,7). Good oral health is essential for healthy aging (8). The burden of dental caries varies significantly across populations within and between countries, with a clear socioeconomic gradient showing higher disease burden in deprived and disadvantaged communities, who also have limited access to prevention and oral health services (2,9). Caries affects people throughout their lives, with varying patterns of burden across age groups – starting in early childhood, increasing notably in adolescence and continuing to rise in adulthood (10).

Bénéfices

Resin-based composites as sealants A 2017 Cochrane systematic review of 38 randomized controlled trials (7924 participants) evaluated the effectiveness of dental sealants for preventing dental caries in children and adolescents (11). For the comparison of resin-based composite sealants versus no sealant, there was moderate quality evidence that resin-based sealants were superior to no sealant for preventing caries in first permanent molars in children aged 5–10 years at 2 years of follow-up (odds ratio (OR) 0.12, 95% confidence interval (CI) 0.08 to 0.97; seven randomized controlled trials, 1322 participants). The superior effect was maintained over 48 and 54 months of follow-up, however the quality and quantity of the evidence declined. For comparisons of glass ionomer sealants versus resin sealants, the trials identified in the review reported inconclusive results for relative effectiveness, although they generally indicated that resin-based sealants had better retention rates at 24 months follow-up and beyond. A 2022 Cochrane systematic review of nine randomized controlled trials (1120 participants) evaluated the effectiveness of different dental sealants for preventing dental caries in primary teeth of children aged 18 months to 8 years (12). Data were not pooled due to differences in study design (e.g. age of participants and duration of follow-up). The incidence of development of new caries lesions was typically low across the different sealant types evaluated; however, the authors concluded that the certainty of the evidence for the comparisons and outcome of caries incidence was low or very low. A study with 200 participants reported an advantage of resin-based sealants over glass ionomer sealants for complete or partial retention at 24 months (OR 0.20, 95% CI 0.11 to 0.36) (13). A 2020 Cochrane systematic review of 11 randomized controlled trials (3374 participants) compared pit and fissure sealants versus fluoride varnish for preventing dental caries in permanent teeth of children and adolescents (14). For the comparison of resin-based sealants versus fluoride varnish, it was

uncertain whether one was better than the other in preventing caries in first permanent molars at 2–3 years of follow up (OR 0.67, 95% CI 0.37 to 1.19; four randomized controlled trials, 1683 participants). There was low-certainty evidence from one study (542 participants) of a small advantage for resin-based sealant over fluoride varnish for the outcomes of decayed, missing and filled permanent surfaces increment at 2 years (mean difference (MD) –0.09, 95% CI –0.15 to –0.03) and decayed, missing and filled permanent teeth increment at 2 years (MD –0.08, 95% CI –0.14 to –0.02) (15). There was very low-certainty evidence from one study (75 participants) of a benefit for sealant at 4 years in preventing caries (risk ratio (RR) 0.42, 95% CI 0.21 to 0.84) and at 9 years (RR 0.48, 95% CI 0.29 to 0.79; 75 children) (16). Resin-based composites as filling material A 2021 Cochrane systematic review of eight randomized controlled trials compared the efficacy as measured by restoration failure or survival at 3 years follow-up of direct composite resin fillings versus amalgam fillings for permanent posterior teeth (17). Data were combined from two parallel-group trials (921 participants) for the primary meta-analyses. There was low-certainty evidence that composite resin restorations had a greater risk of failure compared with amalgam restorations (RR 1.89, 95% CI 1.52 to 2.35), and were at higher risk of secondary caries (RR 2.14, 95% CI 1.67 to 2.74). There was also low certainty evidence that composite resin restorations were not more likely to result in restoration fracture (RR 0.87, 95% CI 0.46 to 1.64). The authors noted that composite resin materials have improved substantially in the years since the trials informing the primary analyses were conducted, and that the global phase-down of dental amalgam with the Minamata Convention on Mercury was an important consideration for decision-making when choosing materials for dental restorations. A 2015 systematic review of 17 clinical studies evaluated the long-term clinical performance of composite resin restorations placed in anterior teeth (18). Among a total of 1821 restorations evaluated, the total failure rate was 24.1%. Annual failure rates varied from 0 to 4.1%, and survival rates varied from 53.3% to 100.0% across the studies.

Torts

The 2021 Cochrane systematic review comparing composite resin fillings with amalgam fillings for permanent posterior teeth found very low-certainty evidence suggesting that there may be no clinically important differences in the safety profile of amalgam compared with composite resin dental restorations (17). A 2015 systematic literature review examined allergic reactions to dental materials, considering both patients and providers. In the case of resin-based composites, the main potential allergen is the metacrylate compound. However, reports of allergic reactions specifically to resin-based composite fillings or dental sealants were rare. Reactions are typically localized, such as erythema (redness) of the surrounding gum, and subside after the removal of the resin-based composite material (19). A study based on data from the Norwegian Mother and Child Cohort Study found no increased risk for adverse birth outcomes associated with placement of resin-based composite fillings during pregnancy (20).

Rapport coût/efficacité

Evidence on the cost and cost–effectiveness of resin-based composites as dental sealant and filling material is limited. A study in Chile modelled the cost–effectiveness of different caries preventive programmes versus no intervention from a societal perspective (26). Health outcomes were measured as dental caries averted over a 6-year period. Costs were estimated as direct treatment costs, programmes costs and costs of parental productivity losses as a result of each dental caries prevention programme. Four programmes (salt fluoridation, water fluoridation, milk fluoridation and fluoridated mouthrinses) showed net social savings for dental caries averted. Programmes using fluoride gel application, dental sealants and supervised toothbrushing were associated with costs per diseased tooth averted of US$ 21.30, US$ 11.56 and US$ 8.55, respectively. A multicountry randomized controlled trial evaluated the cost–effectiveness of glass ionomer cement versus resin composites in the treatment of dental caries from a payers perspective (27). Overall costs were lower for glass hybrid than resin composites in Croatia, Serbia and Türkiye, but differences in costs between interventions were minimal in Italy. The overall survival time for restorations over 3 years was not significantly different between interventions. A cost-comparison study of dental filling procedures using amalgam and resin composite fillings was done in nine European countries (28). Mean unit costs for dental amalgam and resin composite fillings were €2.03 and €4.75, respectively.

Directives de l'OMS

WHO plays an important role in global coordination of the work on phasing down the use of dental amalgam and the introduction of good-quality alternative materials for restorative dental care (21). A 2022 WHO briefing note on the prevention and treatment of dental caries with mercury-free products and minimal intervention provided updated guidance on resin-based composites (22). The publication lists the following benefits of using resin-based composites: • effective against caries, with good durability in small-to-moderate restorations, and more durable than glass ionomer cement for large, multisurface, load-bearing restorations; • minimally invasive and protective of more of the natural tooth structure than conventional methods; • improved health and quality of life through reductions in infection, pain, tooth damage and the need to fill future cavities, thereby reducing financial burdens for individuals and health systems, and reducing school and work absenteeism; • aesthetic benefits, as composite resin can match the colour and translucency of natural teeth; • environmental and public health benefits as a mercury-free alternative to dental amalgam; • safe, cost-effective and potentially widely available; and • suitable for use in primary care facilities by trained dentists. The 2011 World Health Assembly resolution on oral health (23) and the 2022 draft global strategy on oral health (24) highlight the urgent need to intensify preventive efforts, particularly for dental caries. To address this issue, the draft global oral health action plan was prepared, which includes a target that 50% of countries will include dental preparations that are listed in the WHO Model Lists on their national essential medicines lists by 2030 (25).

Disponibilité

Resin-based composites are available through medical and dental retailers for professional use and are reported to be available globally. For public dental services, procurement of supplies such as resin-based composite is generally undertaken by the service administrators (e.g. health ministry or other agencies).

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