Glass ionomer cement

Essential medicine status

Section: 30. Dental medicines and preparations

EMLc | ATC codes: Pending

Indication	Dental caries ICD11 code: DA08.0
Medicine type	Chemical agent
List type	Core (EML) (EMLc)
Additional notes	Powder (fluoro-alumino-silicate glass) contains: 25-50% silicate, 20-40% aluminium oxide, 1-20% fluoride, 15-40% metal oxide, 0-15% phosphate, remainder are polyacrylic acid powder and metals in minimal quantities. Liquid (aqueous) contains: 7-25% polybasic carboxylic acid, 45-60% polyacrylic acid.
Formulations	Local > Dental > Powder + liquid: Single-use capsules: 0.4 g powder + 0.09 mL liquid ; Multi-use bottle: powder + liquid
EML status history	First added in 2021 (TRS 1035)
Sex	All
Age	Also recommended for children
Therapeutic alternatives	The recommendation is for this specific medicine
Patent information	Patents have expired in most jurisdictions Read more about patents.
Wikipedia	Glass ionomer cement

Expert Committee recommendation

The Expert Committee noted that dental caries of permanent teeth affects 2.3 billion people worldwide and more than 530 million children suffer from caries of primary teeth. Inequalities throughout the life course and across populations in low-, middle- and high-income countries were also noted, with the highest burden in countries with limited resources for prevention and control. In those settings, primary oral health care is often limited by a lack of essential supplies such as filling material, leading to an unnecessary focus of treatment on tooth extraction, even when a tooth-saving filling would still be an option. The Expert Committee also considered Resolution EB148/1 of the WHO Executive Board adopted in January 2021, in which Member States requested WHO to develop technical guidance on environmentally friendly and less invasive dentistry to support countries with their implementation of the Minamata Convention on Mercury, including supporting preventative programmes. The Committee noted that high-viscosity glass isomer cement has caries-preventive properties due to continued capture and release of fluoride ions that remineralize carious tooth structures and have a bacteriostatic effect. In addition, glass isomer cement results in lower rates of recurring caries compared with composite resin or amalgam fillings, and reduces the incidence of new cavities in other teeth. The Expert Committee took into consideration that dental sealants, including glass ionomer cement, have been shown to be highly effective in preventing dental caries. The main advantage of glass ionomer cement over other sealants is the simplicity of application. This makes glass ionomer cement suitable for use in atraumatic restorative treatment for dental caries by dentists and other health professionals in primary health care, and community and field settings outside of specialized dental clinics. The Committee noted that while other types of sealants or fillings (e.g. resin-based products) are at least equally as effective as glass ionomer cement sealants and potentially have better mechanical properties (e.g. adherence to the tooth), they require more specialized expertise and application techniques and conditions (e.g. need for electricity). Glass ionomer cement is 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. In certain conditions, glass ionomer cements are indicated for everyone. From the mechanical and optical perspectives in dentistry, better material alternatives are available, namely resin composites or ceramics. However, these alternatives are sensitive to the application technique and are costly compared with glass ionomer cements. The Expert Committee, therefore, recommended including glass ionomer cement in the core list of the EML and EMLc in the new section for dental preparations on the basis of its relevant benefits in the prevention of dental caries and its advantages in atraumatic restorative treatment due to its ease of application, making it suitable for use in a wide range of settings. The Committee considered that inclusion of glass ionomer cement on the Model List, in alignment with WHO's technical guidance on oral health, will support countries to deliver an expanded range of interventions that will benefit the oral health of their populations.

Background

Glass ionomer cement has not previously been considered for inclusion on the Model Lists. Preventing caries with dental sealant Clinical application of glass ionomer cement as a dental sealant can be performed as a preventive intervention without any caries present. The procedure can be carried out in a dental clinic or in a community setting such as in a school. The therapeutic effect does not require long-term retention of the bulk material, so monitoring is not essential. Minimal training for a dental assistant, dental therapist, dental nurse, dental hygienist or dentist is required, but non-dental health care workers have also been successfully trained to apply dental sealants. Glass ionomer cement should be applied early after eruption of both primary and permanent molars. Treatment is done once per erupting molar tooth; for example, sealing four permanent first molars at around 6 years and sealing four permanent second molars at around 12 years. Treating carious lesions with a filling Glass ionomer cement can be used to fill cavities using the atraumatic restorative treatment procedure and is endorsed by WHO for caries management across the life course (1,2).

Public health relevance

The 2017 Global Burden of Disease Study estimated that oral diseases affect close to 3.5 billion people worldwide, with caries of permanent teeth being the most common condition. Globally, 2.3 billion people are estimated to suffer from caries of permanent teeth and more than 530 million children suffer from caries of primary teeth (3). Most caries are untreated. The caries burden is very unequal across populations within and between countries, with a clear socioeconomic gradient showing higher disease burden in deprived and disadvantaged populations who at the same time have less access to care, including preventive care (4). Caries is a disease of all age groups with an onset in early childhood and continued increase over the life course. Most significant increases in incidence are observed in adolescent age groups. A high prevalence and severity of untreated dental caries is associated with low body mass index and stunting; it also leads to considerable absenteeism in school and the workplace. Good oral health is also vital for healthy ageing, playing a crucial role with regard to nutrition. Globally, prevalence and incidence of untreated caries changed little between 1990 and 2017 (3), while the total number of individuals affected significantly increased due to population demographics, particularly in low- and middle-income countries. As most tooth decay is untreated, all forms of prevention are essential, including fluoride toothpaste and other forms of fluoride delivery, and dental sealants. After the onset of the carious process and cavitation, simple, cost-effective options for dental fillings need to be available to improve access and affordability of restorative dental care, and to avoid tooth extraction as the only other treatment option. The Minamata Convention on Mercury requests a phase-down of dental amalgam, the current most commonly used dental filling material, due to its mercury content (5,6). In view of the burden of untreated caries and the need to expand coverage of basic dental services in the context of universal health coverage, the availability of glass ionomer cement as an alternative dental filling material is very important (5,7). Moreover, glass ionomer cement is one of the public health tools to provide appropriate levels of fluoride for dental health and to address early childhood caries (1,8,9). Glass ionomer cement is a dental material with widespread global use for treatment and prevention of dental caries. It has caries-preventive properties due to continued capture and release of fluoride ions that remineralize carious tooth structures and have a bacteriostatic effect. Glass ionomer cement results in lower rates of recurring caries compared with composite resin or amalgam fillings; its use also reduces the incidence of new cavities in other teeth. The simplicity of application makes glass ionomer cement suitable in primary health care and field settings, as it does not require specialized equipment including curing lights. Furthermore, since the application of glass ionomer cement does not require extensive dental training, it can be used to provide people living in rural and remote areas and otherwise disadvantaged populations with access to dental care for caries through the primary health care system (4).The hydrophilic nature of glass ionomer cement makes application in the field much easier where moisture control is a problem. The expected health-related positive effects of glass ionomer cement sealants and fillings include: improved quality of life through reduction of pain and infection from caries, reduced absence from school and work and substantial cost savings for health systems.

Benefits

The summary of evidence presented in the application was minimal. A review of the cited references was conducted by the EML Secretariat and a summary is provided below. A 2017 Cochrane systematic review of 38 trials (7924 participants) evaluated the effects of different types of fissure sealants in preventing caries in permanent teeth in children and adolescents (10). Within this review, three trials (905 participants) evaluated glass ionomer sealant versus no sealant and found inconclusive results. Two of the studies slightly favoured glass ionomers compared with no sealant (11,12), while the third found no significant difference between sealant and no sealant (13). The authors concluded that there was insufficient evidence to judge the effectiveness of glass ionomer sealants. However, the review found that resin-based sealants reduced caries by between 11 and 51 percentage points compared with no sealant at 24 months (10). A 2008 meta-analysis of six studies evaluated the effectiveness of dental sealants in preventing the progression of caries lesions in pits and fissures of permanent teeth (14). Four studies used resin-based sealants and two used glass ionomer cement. For the individual studies combined, the median prevented fraction was 74.2% (range 61.6–100.0%). In the two glass ionomer cement studies, the median prevented fraction was 86.5% (range 73–100%). Overall, the median prevented fraction did not vary greatly by sealant type and always exceeded 60%. The authors concluded that the sealing of caries lesions reduces the probability of lesion progression. Because non-cavitated lesions accounted for almost 90% of teeth in this meta-analysis, the evidence supporting the sealing of non-cavitated lesions was stronger than that for the sealing of cavitated lesions. A 2003 review of evidence for the use of pit and fissure sealants in preventing caries in the permanent dentition of children found that retention rates for glass ionomer cements (continued adherence of the sealant to the tooth) were lower than that of resin-based sealants, and the authors did not recommend their use (15). Guidelines developed by the American Dental Association and the American Academy of Pediatric Dentistry included a meta-analysis of 10 randomized controlled trials comparing glass ionomer sealants with resin-based sealants. The analysis found that use of glass ionomer sealants may reduce the incidence of occlusal carious lesions in permanent molars by 37% after 2 to 3 years of follow-up (odds ratio (OR) 0.71, 95% confidence interval (CI) 0.32 to 1.57) however, this difference was not statistically significant. In absolute terms, for a population with a caries baseline risk of 30%, use of a glass ionomer sealant would prevent 67 carious lesions out of 1000 sealant applications (95% CI 102 more to 179 fewer). In patients with non-cavitated occlusal carious lesions, glass ionomer sealants may increase the incidence of carious lesions by 53% (OR 1.53, 95% CI 0.58 to 4.07). Glass ionomer sealants were found to have a five times greater risk of loss of retention from the tooth compared with resin-based sealants (OR 5.06, 95% CI 1.81 to 14.13). The guideline panel determined the overall quality of the evidence for this comparison as very low owing to a serious risk of bias (unclear method for randomization and allocation concealment), inconsistency and imprecision (16). A systematic review of six trials evaluated the caries-preventive effect of high-viscosity glass ionomer and resin-based fissure sealants on permanent teeth (17). No statistically significant differences were found between treatments at 48 months (risk ratio (RR) 0.62, 95% CI 0.31 to 1.21) but a borderline significant difference in favour of high-viscosity glass ionomer sealants was seen after 60 months (RR 0.29, 95% CI 0.09 to 0.95). However, the authors of the review noted that the included trials had a high risk of bias. A randomized trial evaluated the effect of fluoride-releasing sealants on adjacent tooth surfaces in children aged 6–7 years (18). High-viscosity glass ionomer cement and resin-based sealants with fluoride were shown to protect against dental caries, with evidence that these materials also reduced the incidence of new caries on untreated teeth adjacent to the sealed tooth. A 2018 systematic review and meta-analysis evaluated the survival percentages of dental restorations of high-viscosity glass ionomer cement fillings placed in permanent teeth using an atraumatic restorative technique (19). Over the first 2 years, the survival percentages of single- and multiple-surface atraumatic restorative treatment restorations in primary posterior teeth were 94.3% and 65.4%, respectively. Over the first 3 years, the survival percentage for single-surface restorations was 87.1%. For multiple-surface restorations, the survival percentage over the first 5 years was 77%. A systematic review of 38 trials including over 10 000 tooth restorations found no statistically significant differences in failure rates between high-viscosity glass ionomer cement and amalgam restorations in single- and multiple-surface tooth cavities up to 6 years. However the trials had a high risk of bias due to inadequate randomization and allocation concealment, and a high risk of performance, detection and attrition bias (20). Findings from an indirect treatment comparison of failure rates between high-viscosity glass ionomer cement and composite resin restorations in posterior permanent teeth found no statistically significant difference between restoration types (21). However, the limitations of the indirect comparison and the lack of direct comparative data were noted.

Harms

A recent Cochrane systematic review of pit and fissure sealants versus fluoride varnishes for preventing dental decay in children and adolescents included five trials that reported adverse events – four using resin-based sealants and one using resin-modified glass ionomer (22). No adverse effects were associated with the use of either sealant type or fluoride varnishes. Various in vitro and in vivo studies of glass ionomer and resin sealants did not find any significant negative effects on pulp, dentine or gingival tissues and cells (23,24).

Cost / cost effectiveness

The average costs of dental sealant, atraumatic restorative treatment or conventional filling using glass ionomer cement are between US$ 2 and US$ 3 per application on multiple teeth (10,25,26). Average conventional fillings using other materials cost between 8 euros (€) and € 156 in Europe. However, comparability of data is limited and depends on the size and location of the filling and additional supplies or procedures included in the costing (27). A cost–benefit study in China assessed the incremental cost of four different glass ionomer cement sealant types in preventing one cavity in permanent molars of schoolchildren. Costs ranged between US$ 52 and US$ 105 per 1000 sealants (28). The authors concluded that "ease of application, minimal technical and infrastructure requirements, and cost–effectiveness make glass ionomers a practicable option for governments making decisions under economic constraints".

WHO guidelines

The WHO implementation manual on ending childhood dental caries (2) states the following in relation to glass ionomer cement. • Placement of pit- and-fissure sealants in molar teeth can reduce the development and progression of new carious lesions into dentine. Different types of sealant material have their own merits, but glass ionomer sealants, which are less demanding on technique and moisture control, are often suitable for use in young children and in community settings. • If restoration of decayed primary teeth is required, preference should be given to the use of minimally invasive techniques such as atraumatic restorative treatment using adhesive materials such as glass ionomer cement, especially when provided in community settings. These techniques do not require a local anaesthetic injection and, being less invasive, are more "child-friendly". Survival of single surface atraumatic restorative treatment restorations using high-viscosity glass-ionomer in primary teeth is high and can be comparable to that of restoration placed using a conventional approach.

Availability

The application considered that it was safe to assume that glass ionomer cement was available worldwide and regulated as a medicinal product.

Other considerations

Aspects of glass ionomer cement are standardized by the International Organization for Standardization (ISO) under standard ISO 9917-1:2007, such as testing methodology, minimum requirements, labelling and other matters (29). In the European Union, glass ionomer cement must conform to European Union Council Directive 93/42/EEC concerning medical devices and falls under Class IIa (30).

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