

PM

Nr 9/05

KEMI
KEMIKALIEINSPEKTIONEN

Mercury-free Dental Fillings

Phase-out of amalgam in Sweden

Order No. 510821
Sundbyberg, December 2005
Publisher: Swedish Chemicals Inspectorate
Order address: Telefax +46 8 735 76 98, e-mail kemi@kemi.se

Mercury-free Dental Fillings

Phase-out of amalgam in Sweden

This PM was written by Kemi & Miljö Konsulterna AB
on commission by the Swedish Chemicals Inspectorate

Preface

This study describes the current use of dental filling materials in Sweden, as amalgam use has been phased out almost totally. The study has been performed by Kemi & Miljö AB on commission by the Swedish Chemicals Inspectorate.

The European Commission presented in January 2005 a Community Strategy Concerning Mercury, with the aim to reduce mercury levels in the environment and to reduce human exposure by e.g. reducing emissions and the entry into circulation of mercury in society. One of the actions in the strategy is to consider whether regulatory measures are appropriate for the marketing and use of dental amalgam.

During the last six to seven years the use of dental amalgam in Sweden has been almost totally replaced by other filling materials. This report was commissioned in order to contribute with Swedish experiences.

Sundbyberg, December 2005

Table of Contents

Executive Summary	4
Sammanfattning	5
Introduction	6
<i>Background</i>	6
<i>Objective</i>	7
<i>Screening methodology</i>	7
What filling materials are currently used?	8
<i>Main types of filling materials</i>	8
<i>Areas of use</i>	9
<i>Shares</i>	10
<i>Supply of dental filling materials</i>	11
<i>Use of dental filling materials</i>	11
<i>Estimated total shares</i>	12
<i>Countries of origin</i>	13
<i>The Swedish market</i>	13
Conclusions	14

Executive Summary

This study describes the current use of dental filling materials in Sweden. Dental amalgam has been replaced almost totally by other materials during the last six to seven years in Sweden.

This study concentrates on materials for direct techniques since amalgam and its alternatives almost exclusively are direct technique materials.

The tracking of dental filling materials is spread on a number of business organisations, on public and private sector dental care providers and in some cases partially on authorities.

Three different sources that each represents a major part of the market were studied. The first represent 80 % of supplied filling materials, the second represent services offered to 34 % of the Swedish population and the third represent 20 % of the dentists.

The shares of dental filling materials, measured by weight, are approximately:

Composites (78 %), glassionomers (13 %), amalgam (6 %), compomers (3 %) and ceramics (less than 1 %).

Since composites are lighter than amalgam one kilo of composites will fix many more teeth than one kilo of amalgam. So if measured by the number of restored teeth the composites' share will increase and amalgam's share will decrease even further.

There is not one but a number of techniques and materials that have replaced the use of amalgam. The most commonly used materials in Sweden are composites that have replaced more or less all types of restorations where amalgam was previously used.

There is no indication that the total amount of amalgam used in Sweden is higher than the 100 kg (mercury) per year that was estimated to be used in 2003. Instead, the business organisations' tracking of amalgam has ended as amalgam has more or less become irrelevant from a business perspective.

Sammanfattning

Den här studien beskriver den nuvarande användningen av tandfyllningsmaterial i Sverige. Dentalt amalgam har ersatts nästan totalt av andra material under de senaste sex till sju åren i Sverige.

Studien behandlar material som används i direkt teknik eftersom amalgam och dess alternativ nästan uteslutande är material för användning i direkt teknik.

Uppföljning av de tandfyllningsmaterial som används är utspridd på ett antal branschorganisationer, offentliga och privata vårdgivare och i några fall delvis på myndigheter.

Tre olika källor som var och en representerar en stor del av marknaden studerades. Den första representerar 80 procent av de levererade fyllningsmaterialen, den andra representerar tandvård som erbjuds 34 procent av den svenska befolkningen och den tredje representerar 20 procent av tandläkarna.

Fördelningen av tandfyllningsmaterial, i vikt, är ungefärligen:

Kompositer (78 procent), glasjonocement (13 procent), amalgam (6 procent), kompositer (3 procent) och keramer (mindre än 1 procent).

Eftersom kompositer är lättare än amalgam så räcker ett kilo komposit till många fler lagningar än ett kilo amalgam. Om fördelningen istället baserades på antalet fyllningar skulle därför kompositernas andel bli än större, och andelen amalgam mindre.

Det är inte ett enskilt alternativ utan ett antal material och tekniker som har ersatt användningen av amalgam. De vanligaste använda tandfyllningsmaterialen i Sverige är kompositer som har ersatt mer eller mindre alla typer av lagningar där amalgam tidigare användes.

Det finns ingen indikation på att den totala använda mängden amalgam i Sverige skulle vara högre än de 100 kg (kvicksilver) som uppskattades 2003. I stället så har branschorganisationernas uppföljning av amalgam upphört eftersom amalgam mer eller mindre har blivit ointressant från ett affärsperspektiv.

Introduction

Background

Mercury can cause substantial adverse impacts on the environment and health. The number one area of mercury use is in chlor-alkali production. This use and other uses as in batteries are in steep or significant decline. Therefore use of amalgam¹ in dental care in the EU stands out as the projected top area for mercury use. Estimates from 2002 show that amalgam was the single largest application of mercury within the EU with about 70 tonnes per annum.² Since then ten new member countries have joined the EU. Amalgam use in the new member countries is probably at level with or higher than in the old member countries.³

In Sweden amalgam has been replaced almost totally by other materials during the last six to seven years. The quantities of mercury sold for amalgam are estimated to have decreased from 980 kg in 1997 to about 100 kg in 2003. The main causes for this reduction is a high awareness of the environmental and health risks among both patients and dentists, access to as well as demand for other alternatives and the agreement between the state and the county councils to phase-out use in children and young people.

Also, to make amalgam more cost-neutral against other filling materials, Parliament decided in 1999 that no financial support should be given for amalgam fillings via the national dental insurance. Since 1999 the patient gets no reimbursement from the dental insurance for amalgam fillings. The result is that the costs to the patient for an amalgam filling are as much as for a repair with composite, or even more.⁴

This study describes the use of dental filling materials in Sweden. The study was commissioned by the Swedish Chemicals Inspectorate and was executed by the Stockholm based consultancy firm Kemi & Miljö AB during October and November 2005. Kemi & Miljö has more than a decade's experience with the phase-out of mercury in the dental care sector.

¹ Amalgam is an alloy of mercury and other metals. Dental amalgam contains silver, tin and copper in addition to mercury. About half of amalgam, by weight, is mercury. Throughout this document "amalgam" means "dental amalgam" unless otherwise stated.

² Concorde East/West Sprl, 2004

³ Information from several Swedish dental filling suppliers and Thomas Andersson, the Swedish Dental Trade Association, personal communication October 31st 2005.

⁴ Swedish Chemicals Inspectorate report 2/2004.

Objective

The overall objective is to describe the use of mercury-free dental filling materials as amalgam use has been phased out almost totally.

This study firstly aims to describe the materials, their current areas of use and the product's countries of origin. The study also estimates the proportional use of the different dental materials in Sweden.

Screening methodology

Seven member companies, from a total of 40 that supply dental filling materials, have been chosen by the Swedish Dental Trade Association as suppliers of statistics on the sale of dental care products. The companies supply dental care products from a wide range of manufacturers to dental care providers in both the public and the private sector. They have been selected because of their market share, their broad product range and because of a good track record on supplying up-to-date high-quality data. The statistics from these companies is used by the Swedish Dental Trade Association to describe the current situation and new trends on the Swedish market for dental care products.

The seven companies were contacted and asked to supply data on their current sales of dental materials. One company did not provide the requested data. Statistics from one more company that is not part of the "group of seven" was added to the total supplier statistics. The company supply well over half of the amalgam that is used in Sweden. In this study the suppliers' reported sales of dental filling materials represent 80 % of all the filling materials used on the Swedish market.

Parallel sources of data for the use of dental filling materials are the dental care providers under county council responsibility, Folktandvården and Praktikertjänst AB. The Folktandvården data sample comes from two providers that offer services for 34% of the Swedish population. Other County Council Dental Service providers were also contacted but they were unable to provide the data. Praktikertjänst AB is Sweden's largest private dental care company where the owners themselves provide the dental care services. The company is run in the form of a producer cooperative and organises 20 % of all dentists in Sweden.

All sources above have been used for the description of areas of use for the dental filling materials. Examples of other sources are: the Swedish daughter company of one of the world's largest manufacturer of dental filling materials; experts at the National Board of Health and Welfare and the Swedish Social Insurance Administration.

For reasons described above, the information gathered for this report can with good confidence be said to cover the current use of dental filling materials in Sweden.

What filling materials are currently used?

Main types of filling materials

Materials that are used for the restoration of the form and function of teeth can be divided into materials used for direct and indirect techniques. In the case of direct techniques the material is introduced in a plastic state and hardens in the tooth, while in indirect techniques an impression is usually made which is used by a dental technician to make an inlay or crown. This study concentrates on materials for direct techniques since amalgam and its alternatives almost exclusively are direct technique materials.

The most common materials nowadays are different types of composites (i.e. polymer resin based materials). It is also called "the modern amalgam". Other materials used are ceramics (including porcelain) and glass ionomers⁵. Also used are combinations of materials, e.g. "compomers" that are modified composites.⁶ There are also prefabricated ceramic cones, which are pressed into composite fillings to reduce shrinkage of the filling. Finally there is amalgam which is in little and declining use and like the replacement materials is used to form a soft paste which hardens on setting.

There is constant research into the development of new materials. One example is hydrated ceramics, which form a body-compatible substance that is integrated chemically and biologically into the tissue. Another example is the mixture of ceramic powder into composite material that gives the filling increased strength.

⁵ Ordinary glass ionomer cements consists mainly of poly acrylic acid and an acid soluble glass powder (calcium-, aluminium- and fluorosilicate glass). Resin modified glass ionomer cements contains of ordinary glass ionomers mixed with some acrylate monomers for example hydroxymethylmetacrylat (HEMA).

⁶ A more correct denomination is polyacid modified composites.

Areas of use

There is a classification system that is used to define the type of restorations for the direct technique.⁷

Direct technique	Type of restoration
Class I filling	Single surface filling - filling of contacts
Class II filling	Multi surface filling - filling of contacts and of side surfaces in between molars and premolars
Class III filling	Single surface filling - filling of side surfaces in between canines and incisors
Class IV filling	Multi surface filling - filling as in class III but also on the back side of the tooth
Class V filling	Single surface filling - filling of tooth on the front side or the back side

Composites are today the main material for direct made restorations and are used for all indications, classes I-V, in permanent teeth and in milk teeth with low or medium high caries activity. The exceptions where composites are not used are veneers and real large restorations where indirect techniques are used.

Glassionomers are mainly used for temporary restorations in milk teeth including class II cavities. Also used for class III and class V fillings of milk teeth and permanent teeth. Glassionomers are sometimes used for temporary restorations in class I and class II fillings of permanent teeth with high caries activity and restorations near crowns.

In children and young adults where caries activity is expected to be low or medium high, *compomers* can also be used as material mostly for class I and II restorations. In addition the materials are used for class V restorations and as a lining material. Compomers are also sometimes used for temporary fillings used during extend periods.

⁷ The description is based on multiple sources, among them are Agneta Ekman and Ulf Örtengren, National Board of Health and Welfare.

Amalgam is used for all types of fillings except for class III fillings. Amalgam is almost totally phased out as filling material and is almost exclusively used for major class II fillings of permanent teeth. The last follow-up survey for 2003, based on data from 21 of 25 responsible authorities showed that the use of amalgam had halved since 2002. Amalgam's share of fillings was stated to be only 0.05% of the total number of fillings in children and young people. A majority of the responsible authorities state that amalgam was no longer used at all in the case of children and young people.⁸

Gold is mainly used, with indirect techniques, in crowns but also in direct techniques to restore attacks of caries next to existing gold fillings, as gold inlays in class II cavities. *Ceramics* (including porcelain) are mainly used with indirect techniques in crowns, but prefabricated ceramic inlays are also used in direct techniques together with composites to prevent shrinkage.

Shares

Since 1996 the Swedish authorities no longer track the use of dental materials. During this period the Swedish Dental Trade Association has stopped collecting data that is specific enough for extracting the supply and use of dental materials. A further complication is that the flow of materials used for direct techniques, such as composites, mainly is recorded at dental clinics, their associations and their suppliers. This flow is not recorded in a consistent way if recorded at all.

For this study it has therefore been necessary to use data from a lot of different sources which all have slightly different assumptions. The description below is at present the best available presentation even if it inevitably is patchy.

Below is a presentation of two main groups and their supply or use of dental materials in Sweden.

⁸ Redovisning av uppdrag angående uppföljning av avveckling av amalgam i barn- och ungdomstandvården, Dnr. 00-5700-2002. Socialstyrelsen 2002.

Supply of dental filling materials

The first group is a sample of Swedish suppliers of dental materials. The data presented below represent 80 % of the dental filling materials supplied to the Swedish market.

Table 1 the suppliers' answers

Type of material	Average share, by weight	Span*
Composites	81 %	65-91 %
Glassionomers	11 %	0-16 %
Compomers	5 %	0-11 %
Amalgam	1 %	0-11 %

* The lowest and the highest share reported from suppliers for each type of material.

Use of dental filling materials

The second group is from the user side. The Folktandvården data below is from the public sector dental care. The sample represents services offered for 34 % of the Swedish population. The Praktikertjänst AB data below is from a company for private sector dentists that organise 20 % of all, private and public, dentists in Sweden.

Table 2 Folktandvården's answer

Type of material	Average share, by weight	Span*
Composites	80 %	62-86 %
Glassionomers	14 %	12-21 %
Compomers	2 %	No span
Amalgam	4 %	0-16 %

* The lowest and the highest share reported for each type of material.

Table 3 Praktikertjänst AB's answer

Type of material	Share, by weight
Composites	76 %
Glassionomers	13 %
Compomers	3 %
Amalgam	7 %

Estimated total shares

There is a good correlation for the shares of the different materials among all the sources. By making an average from the two user data sources it is clear that the probable shares of dental filling materials, measured by weight, are:

Composites (78 %)

Glassionomers (13 %)

Amalgam (6 %)

Compomers (3 %)

Ceramics is also used so much that it can be measured but it represents less than 1 % of all filling materials used.

These figures are confirmed by the suppliers' data. The exception is amalgam. Amalgam has an even smaller share in the suppliers' statistics. The explanation for this may be that some of the suppliers' statistics are originally deducted from value and not from weight directly.

It is important to keep in mind the difference in weight of the materials, especially the difference in weight between the lighter composites and the heavier amalgam. One kilo of composites will fix many more teeth than one kilo of amalgam. So if measured by the number of restored teeth the composites' share will increase and amalgam's share will decrease even further.

Countries of origin

Composites that represent the great bulk of filling materials used in Sweden are mainly manufactured in Germany and neighbouring Switzerland and Liechtenstein. For the world market there is the European production as well as substantial amounts that are being produced in the United States and Japan. In this study glassionomer manufacturing was reported to take place in the European Union and in Japan. Amalgam manufacturing was reported to take place in Russia, Bulgaria, former Yugoslavia, the United States and the European Union including Sweden. Ceramics manufacturing was reported to take place mainly within the European Union.

The Swedish market

Manufacturing of filling materials in Sweden is very limited.⁹ One exception is compomers, but the ingoing components are originally sourced outside of Sweden such as the European Union, the United States and Japan. Ceramics that is sometimes used is also manufactured on a small scale in Sweden.

There are two companies that manufacture amalgam in Sweden. They have been granted exemption from the Swedish export ban on mercury to export dental amalgam until 31 December 2006. Most of the amalgam production is exported for the European market. The two companies supply about 70-80 % of the amalgam used in Sweden. Around forty companies distribute or supply alternatives to dental amalgam on the Swedish market. Seven of these companies distribute amalgam.¹⁰

⁹ Several sources including, suppliers contacted for data on current use of filling material and Swedish manufacturers of amalgam.

¹⁰ Mats Holme, The Swedish Dental Trade Association and Lars Bengtsson at Nordiska Dental AB, personal communication October 31st 2005.

Conclusions

There is not one but a number of techniques and materials that have replaced the use of amalgam. The most commonly used materials in Sweden are composites that have replaced more or less all types of restorations where amalgam was previously used.

The tracking of dental materials is spread on a number of business organisations, on public and private sector dental care providers and in some cases partially on authorities. This makes it difficult to get a clear picture on the total amounts that are used of the different materials.

By comparing data from different sources it is estimated that the shares of dental filling materials, measured by weight, are:

Composites (78 %), glassionomers (13 %), amalgam (6 %), compomers (3 %) and ceramics (less than 1 %).

Since composites are lighter than amalgam one kilo of composites will fix many more teeth than one kilo of amalgam. So if measured by the number of restored teeth the composites' share will increase and amalgam's share will decrease even further.

There is no indication that the total amount of amalgam used in Sweden is higher than the 100 kg (mercury) per year that was estimated to be used in 2003. Instead, the business organisations' tracking of amalgam has ended as amalgam has more or less become irrelevant from a business perspective.



Swedish Chemicals Inspectorate • P.O. Box 2 • SE 172 13 Sundbyberg • Sweden
Phone + 46 8 519 411 00 • Fax + 46 8 735 76 98
e-mail kemi@kemi.se • www.kemi.se