

## COCHRANE-REVIEW

# Ingen evidens for fyldningsmaterialer i primære tænder

Cochranes forfattere finder det foruroligende, at der kun findes få evidensegnede studier af fyldningsmaterialer i primære tænder. De mener, at der er akut behov for kvalificerede undersøgelser

Winnie Brodam

Et studie fra 1999 sammenlignede det kliniske resultat af æstetiske kroner med konventionelle stålkrøner hos 11 børn. Et andet studie fra 1999 sammenlignede resinmodificeret glasionomer med amalgam hos 40 patienter over en etårig periode. Og et tredje studie, også fra 1999, sammenlignede compomer med amalgam på 30 patienter, som fik foretaget klasse II-restaureringer.

I ingen af de tre inkluderede undersøgelser fandt man forskelle i succes af forskellige materialer.

Cochranes forfattere finder det foruroligende, at mængden af randomiserede, kontrollerede studier (i dette tilfælde med en minimumsopfølgningstid på seks måneder) er så lille. Og de påpeger, at der er akut behov for kvalificerede studier, som undersøger og sammenligner forskellige fyldningsmaterialer.

### Kommentar af professor, dr.odont. Ivar Espelid, Institutt for klinisk odontologi ved Universitetet i Oslo:

– Det var med spænding, at jeg begyndte læsningen af denne rapport, for det er et område af stor interesse. Fyldninger i primære tænder skal holde i en begrænset periode, og det kan være udfordrende at behandle materialerne optimalt i en urolig barnemund. Derfor er det af stor klinisk interesse at få at vide, hvad der fungerer bedst nu, hvor amalgam er udfaset i Skandinavien.

Cochrane-reviewets målsætning var ambitiøs:

Fyldningsmaterialer skulle sammenlignes mht. holdbarhed, smerter og æstetik, og desuden skulle fyldningsterapi sammenlignes med alternativerne ekstraktion eller ingen behandling. Det er ikke overraskende, at kun tre studier tilfredsstillede inklusionskriterierne – ingen af dem havde i øvrigt ekstraktion eller ingen behandling som alternativ.

Reviewet kan ikke hjælpe os til at vælge fyldningsmateriale i primære tænder, for studierne viser ikke signifikante forskelle. Desuden var der store frafald i de inkluderede studier, så observationstiderne kom kun op på to år. Det er min erfaring, at studier af fyldningers holdbarhed bør strække sig over mindst tre år.

Randomiserede kliniske studier er svære at gennemføre. Ethiske hensyn indebærer, at patienten skal tilbydes en behandling med det materiale, der afprøves, som er lige så god som den behandling, der ellers ville blive udført.

Et alternativt studiedesign er anvendt af Vibeke Qvist og andre, hvor mange klinikere lægger deres fyldninger med det materiale, de selv vælger. Ulempen er, at de studier kræver et betydeligt antal fyldninger (flere tusinde) for at kunne analyseres med henblik på faktorer, der påvirker fyldningers funktion og holdbarhed.

Det er svært ikke at være enig i Cochranes konklusion: Der er stort behov for forskning på området. Men ellers er der ikke meget at hente i reviewet.

## Abstract

### Background

Childhood caries (tooth decay) consists of a form of tooth decay that affects the milk teeth (also known as baby or primary teeth) of children. This may range from tooth decay in a single tooth to rampant caries affecting all the teeth in the mouth. Primary teeth in young children are vital to their development and every effort should be made to retain these teeth for as long as is possible. Dental fillings or restorations have been used as an intervention to repair these damaged teeth. Oral health professionals need to make astute decisions about the type of restorative (filling) material they choose to best manage their patients with childhood caries. This decision is by no means an easy one as remarkable advances in dental restorative materials over the last 10 years has seen the introduction of a multitude of different filling materials claiming to provide the best performance in terms of durability, aesthetics, symptom relief, etc when placed in the mouth. This review sought to compare the different types of dental materials against each other for the same outcomes.

### Objectives

The objective of this review was to compare the outcomes (including pain relief, survival and aesthetics) for restorative materials used to treat caries in the primary dentition in children. Additionally, the restoration of teeth was compared with extraction and no treatment.

### Search strategy

Electronic searches of the following databases were undertaken: the Cochrane Oral Health Group's Trials Register (up to January 2009); CENTRAL (The Cochrane Library 2009, Issue1); MEDLINE (1966 to January 2009); EMBASE (1996 to January 2009); SIGLE (1976 to 2004); and conference proceedings on early childhood caries, restorative materials for paediatric dentistry, and material sciences conferences for dental materials used for children's dentistry (1990 to 2008). The searches attempted to identify all relevant studies irrespective of language.

Additionally, the reference lists from articles of eligible papers were searched, handsearching of key journals was undertaken, and personal communication with authors and manufacturers of dental materials was initiated to increase the pool of suitable trials (both published and unpublished) for inclusion into this review.

### Selection criteria

Randomised controlled trials (RCTs) or quasi-randomised controlled trials with a minimum period of 6 months follow up were included. Both parallel group and split-mouth study designs were considered. The unit of randomisation could be the individual, group (school, school class, etc), tooth or tooth pair. Included studies had a drop-out rate of less than 30 %. The eligible trials consisted of young children (children less than 12 years) with tooth decay involving at least one tooth in the primary dentition which was symptomatic or symptom free at the start of the study.

### Data collection and analysis

Data were independently extracted, in duplicate, by two review authors. Disagreements were resolved by consultation with a third review author. Authors were contacted for missing or unclear information regarding randomisation, allocation sequence, presentation of data, etc. A quality assessment of included trials was undertaken. The Cochrane Collaboration statistical guidelines were followed for data analysis.

### Main results

Only three studies were included in this review. The Fuks 1999 study assessed the clinical performance of aesthetic crowns versus conventional stainless steel crowns in 11 children who had at least two mandibular primary molars that required a crown restoration. The outcomes assessed at 6 months included gingival health (odds ratio (OR) 0.3; 95 % confidence interval (CI) 0.01 to 8.32), restoration failure (OR 3.29; 95 % CI 0.12 to 89.81), occlusion, proximal contact and marginal integrity. The odds ratios for occlusion, proximal contact and marginal integrity could not be estimated as no events were recorded at the 6-month evaluation. The Donly 1999 split-mouth study compared a resin-modified glass ionomer (Vitremmer) with amalgam over a 36-month period. Forty pairs of Class II restorations were placed in 40 patients (21 males; 19 females; mean age 8 years +/- 1.17; age range 6 to 9 years). Although the study period was 3 years (36 months), only the 6- and 12-month results are reported due to the loss to follow up of patients being greater than 30 % for the 24- and 36-month data. Marks (1999a) recruited 30 patients (age range 4 to 9 years; mean age 6.7 years, standard deviation 2.3) with one pair of primary molars that required a Class II restoration. The materials tested were Dyract (compomer) and Tytin (amalgam). Loss to follow up at 24 and 36 months was 20 % and 43 % respectively. This meant that only the 24-month data were useable. For all of the outcomes compared in all three studies, there were no significant differences in clinical performance between the materials tested.

No studies were found that compared restorations versus extractions or no treatment as an intervention in children with childhood caries.

### Authors' conclusions

It was disappointing that only three trials that compared three different types of materials were suitable for inclusion into this review. There were no significant differences found in all three trials for all of the outcomes assessed. Well designed, randomised controlled trials comparing the different types of filling materials for similar outcomes are urgently needed in dentistry. There was insufficient evidence from the three included trials to make any recommendations about which filling material to use.

Yengopal V, Harneker SY, Patel N, Siegfried N. Dental fillings for the treatment of caries in the primary dentition. Cochrane Database of Systematic Reviews 2009, Issue 2. Art. No.: CD004483. DOI: 10.1002/14651858.CD004483.pub2