

Class 2 Cavity Preparations and Restoration Performance

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Thesis

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Preface

This thesis is presented as a monograph. The main part of the experimental results and discussions has been published in *Acta Odontologica Scandinavica* 1987-1991:

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Jokstad A. The dimensions of the everyday class II cavity preparations for amalgam. *Acta Odontol Scand* 1989;47:89-99.

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Jokstad A, Mjör IA. Cavity design and marginal degradation of the occlusal part of class II amalgam restorations. *Acta Odontol Scand* 1990;48:389-97.

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Jokstad A, Mjör IA. Replacement reasons and service time of class II amalgam restorations in relation to cavity design. *Acta Odontol Scand* 1991;49:109-26.

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1. Introduction

The physical and mechanical properties and the chemical stability of modern dental materials suggest a relatively long clinical service period for restorations in the oral environment. However, there is an apparent lack of correlation between properties recorded in-vitro and in-vivo performance of dental materials (Academy of Dental Materials, 1989). Clinical experience and surveys of failures show that many restorations need to be replaced after a relatively short time (Anusavice, 1989a). Once the restoration fails, it is important that the cause of, or the sequence of events leading to, the failure is established, to avoid another replacement in the future. Studies of amalgam restorations in extracted teeth show that restoration failures often can be related to faults made by the operators (Healey & Philips, 1949).

Many clinical studies show that the short and long term clinical performance of restorations is dependent on several clinical parameters (Anusavice, 1989a; Academy of Dental Materials, 1989). Morphological aspects of the cavity that is prepared to receive the filling material are probably also important, but experimental data to prove this assumption are lacking.

Short term clinical studies show that certain features of the cavity morphology may initiate restoration failures. An example is the increased margin fractures of amalgam restorations when fissures are present along the cavosurface margins (Jørgensen & Wakumoto, 1968). Other important factors are the cavity margin angle (Mathewson et al., 1973) and morphology (Elderton, 1975), cavity depth (Jokstad, 1991), and cavity width (Osborne et al., 1980). However, the cavity design as an etiological factor in the fracturing of restoration margins remains controversial (Mjör & Espevik, 1980; Smales et al., 1990; Osborne & Gale 1990). Another example is the increased occlusal wear in restorations placed in wide compared to narrow cavities, which is especially apparent in restorations made from polymeric materials (Leinfelder, 1991).

Many factors will be decisive for the service period of the restoration, e.g., the material quality, the handling of the materials and the oral environment of the patient. Several systems for evaluating restorations after short- or long-term clinical service include criteria that may not correlate with the service period or the replacement reasons of the restoration (Elderton, 1977). However, few clinical studies have addressed the relationship between short term discrepancies and long term clinical observations. An exception is margin fractures, which may (Lemmens et al., 1987; Letzel et al., 1990; Osborne et al., 1991), or may not (Hamilton et al., 1983; Moffa, 1989; Osborne & Norman, 1990; Smales et al., 1991) correlate with the restoration service period.

Much clinical data derive from trials carried out in a dental school environment. In these studies, the operators are often selected, and specially trained to insure optimal handling of the materials (Norman et al., 1990). Furthermore, the patients are often dental students, dental school staff or dentists with above average oral hygiene (Letzel et al., 1989). Controlling the operators and their working environment, the patients, and the size and intra-oral location of the restorations reduce confounding, when comparing different materials or products. However, the data from such studies do not reflect the situation in the "real-world" dental practice (Stanford, 1988; Tyas, 1991). This is especially apparent when technique-sensitive materials are involved (Anusavice, 1989b). In general practices, treatment times are constrained, the diagnostic threshold for replacement may vary with the patient load, and there are no economic incentives to produce higher clinical standards than above acceptable (Drake et al., 1990). In general, there is lack of data on the clinical performance of dental materials and on the quality of dental service given by dentists in general practices, and especially on the interaction between clinical performance of restorations and quality of service (NIDR, 1991).

The replacement of existing restorations represents a significant work load in dental practices. Estimates of the proportion of replacement to the total number of restorations in adult patients vary between 54%-73% for amalgam, and slightly higher for tooth-colored restorations (Mjör, 1981; Grøthe, 1985; Bronkhorst, 1988). The economic consequence is that the yearly expenditures on "replacement dentistry" are reported to be GBP 200 millions in UK in 1981 (Merrett & Elderton, 1984), USD 5 000 millions in USA in 1984 (Maryniuk, 1990), and NLG 600 millions in the Netherlands in 1988 (Bronkhorst, 1988). Most of these restorations are made from amalgam (ADA, 1980). The prevailing type of amalgam restoration is the class 2 restoration in the posterior teeth (Kroeze, 1989; Jokstad et al, 1990). Thus, the greatest impact on the patients' and national dental services' expenditures would be to increase the clinical service time of this amalgam restoration type. The present study, consequently, focus on the clinical performance and causes for the replacement of the class 2 amalgam restoration.

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2. Aims

The aims of this thesis have been divided into three parts. Part I comprises a literature review. Part II is a prospective 5-year clinical study of margin fractures of class 2 amalgam restorations inserted by 7 clinicians. Part III is a 10-year retrospective follow-up of the reasons for failure and service period of the restorations investigated in Part II. In all three parts, particular emphasis has been placed on the effect of the cavity designs on the clinical performance of the restorations. Specific aims were developed within each study parts.

Part I

The first part of this study aimed to review the literature on

- the relationship between class 2 cavities in detail, and amalgam restoration performance, and
- various systems for evaluating class 2 cavity designs.

Part II

The aims of the 5-year prospective study were to:

- develop a system for an assessment of various aspects of class 2 cavity preparations for amalgam restorations.
- develop a method for recording the outer and inner outline of restorations, with emphasis on measuring the dimensions in the isthmus area.
- validate the use of a routine impression technique for scoring margin fractures in long term studies.
- record margin fractures ("ditching") of class 2 amalgam restorations inserted under routine conditions by general practitioners, and assess the relationship between margin fractures and quantitative and qualitative features of the cavity preparation, material properties and patient variables

Part III

The aims of the retrospective 10-year study were to:

- record the service period and the replacement reasons of class 2 amalgam restorations made under routine conditions by general practitioners and
- relate the service periods and the replacement reasons of the restorations retrospectively to patient, dentist and material variables, and quantitative and qualitative features of the cavity preparation.

3. Review of class 2 cavity designs for amalgam restorations

In vitro studies

The morphology of cavities that is prepared to receive a dental material is probably one of many important parameters that are decisive for the clinical performance of restorations (Anusavice, 1989a). However, it is difficult to conduct experimentally designed clinical studies with the aim to establish this relationship numerically. The main reason is the necessity of an extensive observation period, resulting in problems such as patient dropout, patient representativity, change of the clinician's diagnostic abilities, or perception of replacement criteria. Furthermore, there are statistical problems, since it is impossible to assure an independence among the clinical variables which affect the restoration prognosis. Finally, apparent ethical reasons restrict the possibilities to conduct optimally designed clinical studies. It is, therefore, not surprising that the present-day perception of the "optimal cavity design" for amalgam restorations is mainly the result of observations obtained in in vitro studies. Different comprehensive review articles describe the impact of in vitro study results on opinions on the optimal cavity preparation (Markley, 1951; Knight, 1966; van Achter, 1967; Rodda, 1972; Welk & Laswell, 1976; Sigurjons, 1983; O'Hara & Clark, 1984; Robinson, 1985; Lund, 1985; Laswell & Welk, 1985; Hunter & Hunter, 1989; O'Hara & Clark, 1990).

The aim of this review is to present the methodologies and the results from in vitro studies which have focussed on the association between the clinical performance of class 2 amalgam restorations and the cavity design. The paper is limited to studies on class 2 cavities for amalgam. All references in the text to cavities and restorations are, therefore, restricted to class 2 cavities and amalgam restorations, although the terms "class 2" and "amalgam" are not used repeatedly in the text. The relevant cavity or restoration class is included in the text only when references are made to studies where other cavity classes or different materials have been used.

Summary of methods

In vitro studies which have focussed on the association between the performance of restorations and features of the cavity preparation can be

categorized into biophysical stress analyses and other types of laboratory studies (Table I.1).

Table I.1. In vitro studies focussed on the association between the cavity design and the clinical performance of class 2 amalgam restorations.

I. Biophysical stress analyses

1. Static, slow strain or impact loading until fracture
2. Static, slow strain and deformation measurement
3. Photoelastic modeling (PEM)
4. Finite element modeling (FEM)

II. Other laboratory studies

1. Biocompatibility
 2. Adaptation
 - Optical methods
 - Microleakage
 - Artificial caries
 3. Physical properties of amalgam
-

Biophysical stress analyses have mainly focussed on the fracture strengths of the restoration and/or the tooth. One frequent study aim has been to compare different dental materials or tooth filling techniques. Other biophysical stress analyses have elucidated possible effects of features of the cavity design on the development of restoration discrepancies, such as extrusion of the restoration or the restoration margins on the proximal and the occlusal surface, increased microleakage or loss of adaptation, or margin fractures. The second group of in vitro studies have addressed the relationship between cavity design factors and adaptation to the cavity wall, and the physical and mechanical properties, of the amalgam.

Biophysical stress analyses

Biophysical stress analyses can be categorized into four methods. Two of the methods employed measure the mechanical behavior under loading of unrestored teeth, restored teeth, or restorations placed in metal casts. The traditional and most popular method is irreversible; a recording is made of the level of compressive loading upon fracture of the tooth or the restoration. The method is fast, inexpensive and relatively uncomplicated. Thus, the literature abounds with reports including data on the fracture strengths of prepared and unrestored teeth, restored teeth, or restorations in tooth models. However, only few of these focus on the effects of the cavity design (Burke, 1992). Both static, dynamic, and impact loading data have been reported (Table I.2).

Table 1.2. Slow strain or impact loading studies focussed on class 2 restoration/tooth strength as a function of cavity design factors.

Investigators Tooth strength	Purpose
Vale, 1956	Assess the relationship between the size of the cavity and the weakening effect on the remaining tooth in upper premolars
Mondelli et al., 1980	Establish the fracture strength of maxillary premolars prepared with three different buccolingual widths of occlusal preparations
Larson, Douglas & Geistfeld, 1981	Compare the effect of O and MOD cavities on the strength of teeth, and compare the effect of cavities that are narrow occlusally and those that are wide
Blaser et al., 1983	Compare the strength of intact and prepared teeth with varying widths and depths.
Eakle & Braiy, 1985	Test the significance of sharp vs. rounded internal forms as predisposing factors in tooth fracture by measuring the forces required to fracture premolars with MOD cavities
Restoration strength	
Lampshire, 1950	Test and evaluate those principles that are already being used in primary molars, and suggest which principles should be advantageous to be included in a preparation
Mahler, Terkla & Johnson, 1961	Determine the validity of methods for evaluating restorative design
Terkla & Mahler, 1967	Determine if the increased strength afforded by interproximal axial retention grooves prevent fracture of clinically placed restorations
Johnson , 1972	Test if amalgam exhibits plastic deformation when subjected to repeated impact forces of low magnitude, and to assess the value of retentive grooves in resisting this deformation
Mondelli & Vieira, 1972	Measure the strength of amalgam restorations with and without pins placed in Cr-Co models of mandibular first molars with flat occlusal surface
Galan Jr, Phillips & Swartz, 1973	Assess the influence of cervical retention grooves and avosurface margin bevels on margin deformation and extrusion proximally
Mondelli et al., 1974	Determine the fracture strength of restorations placed inn 4 different cavity designs, and the influence of retentive grooves proximally
Crockett et al., 1975	Determine the vertical and horizontal forces required to fracture or displace restorations for 4 cavity design conditions in steel blocks
Yates, Hembree & McKnight, 1976	Compare the difference in fracture strength of restorations made from 3 alloys inserted in cavities with and without acute line angles in the proximal box

Amorim et al., 1978	Determine the influence of 4 types of axiopulpal line angles and proximal grooves on the fracture strength of restorations placed in Cr-Co models
Alexander et al., 1980	Compare the difference in fracture strength of restorations made from 3 alloys inserted in cavities with and without an acute axiopulpal line angle
Sturdevant et al., 1987	Evaluate the fracture and dislodgement resistance of estorations made from 4 alloys and placed in 5 different designs in Ni-Cr replicas
Summitt et al., 1992	Examine the effect of groove location and length on resistance form providede to very conservative class 2 amalgam restorations

Restored tooth strength

Re, Norling & Draheim, 1982	Assess the effect of varying the buccolingual width of MOD restorations on fracture strength of mandibular molars
El-Sherif et al., 1988	Evaluate the effect of the isthmus width on the fracture strength of restoration in maxillary premolars
Staninec, 1989	Compare the retention of bonded amalgam restorations to undercut-retained restorations under simulated occlusal loads
Caplan, Denehy & Reinhardt, 1990	Determine the effects of proximal retention grooves on compressive strength of teeth restored with composite resin and amalgam restorations
Purk et al., 1990	Compare the compressive strength of the marginal ridge of restored teeth receiving different preparations and materials

Margin ridge strength in alternative cavity designs

Hill & Halaseh, 1988	Assess the ability of glass-ionomer cements and amalgam to support undermined enamel ridges of teeth with tunnel preparations
Covey, Schulein & Kohout, 1989	Measure the resistance to fracture of the marginal ridge in teeth prepared with modified preparations in maxillary third molars

In spite of the frequent use of the compressive loading method, few reports have used identical procedures for choice of tooth and loading parameters, which make inter-study comparisons of the results difficult (Table I.3).

Table I.3. Methodological parameters of slow strain loading studies focussed on class 2 restoration/tooth strength as a function of cavity design factors.

Tooth strength without restoration assessed by static loading until fracture

	-----Tooth-----			-----Load-----			
	<u>Tooth</u>	<u>Prep</u>	<u>No</u>	<u>Size</u> <u>mm</u>	<u>Speed</u> <u>mm/min</u>	<u>Position</u>	<u>Angle</u>
Mondelli et al. 1980	P	1 & 2	10x10	4	.5	Central	0°
Larson et al. 1981	U1P	O/MOD	5x12	4.8	20 lbs/s	Central	0°
Blaser et al. 1983	U1P	MOD	5x20	4.8 Rod	10	Rod	0°
Eakle & Braly 1985	U1P	MOD	2x15	3.2	20	Central	0°

Restoration strength assessed by static loading until fracture

	-----Tooth-----			----Material---		-----Load-----			
	<u>Tooth</u>	<u>Prep</u>	<u>No</u>	<u>Type</u>	<u>Set</u> <u>hours</u>	<u>Size</u> <u>mm</u>	<u>Speed</u> <u>mm/min</u>	<u>Position</u>	<u>Angle</u>
Mahler et al. 1961	Die/U1P	DO	4x20	1 amal	168	1.6	12.7	Fossa	6°
" "	U1P	DO	4x20	1 amal	168	1.6	12.7	Fossa	6°
Terkla & Mahler 1967	Die/L2P	MO/DO	2x20	1 amal	168	1.6	12.7	Central	n/s
Mondelli/Vieira 1972	Die/LM	MOD	4x40	1 amal	1-168	2.4	.5	Centr/Fossa	0°
Mondelli et al. 1974	Die/LM	4xMO	4x4x10	1 amal	>24	2.4	.5	Centr/Fossa	0°
Crockett et al. 1975	Die/M	MO/Box	4x10	1 amal	>24	2	.5	Ridge	n/s
Yates et al. 1976	Die/1M	MO	3x15x2	3 amal	>24	1.5	.5	Fossa	0°
Amorim et al. 1978	Die/LM	MO	4x10	1 amal	>24	2.4	.5	n/s	n/s
Alexander et al. 1980	Die/1M	MO	3x15x2	3 amal	>24	1.5	.5	Fossa	0°
Sturdevant et al. 1987	Die/UP	MO/Box	5x4x15	4 amal	>24	3rod	.1	Fossa	10°

Restored tooth strength assessed by static loading until fracture

	-----Tooth-----			----Material---		-----Load-----			
	<u>Tooth</u>	<u>Prep</u>	<u>No</u>	<u>Type</u>	<u>Set</u> <u>hours</u>	<u>Size</u> <u>mm</u>	<u>Speed</u> <u>mm/min</u>	<u>Position</u>	<u>Angle</u>
Vale 1956	UP	MOD	n/s	1 amal	n/s	4.8	n/s	Central	0°
Re et al. 1982	LM	MOD	4x10	1 amal	n/s	5.6	1	Central	0°
El-Sherif et al. 1988	UP	MO	10x10	1 amal	n/s	5	n/s	Central	0°
Hill & Halaseh 1988	P	Tunnel	4x16	1 amal	168	2.5	10	Fossa	0°
Covey et al. 1989	U3M	Tunnel	4x20	1 amal	168	1.5/lead	.5	Ridge	0°
Staninec 1989	L3M	MO/Box	4x13	1 amal	336	n/s	5	Fossa	45°
Caplan et al. 1990	M	MO	5x10	1 amal	>24	5x1-lead	.5	Ridge	0°
Purk et al. 1990	UPM	Cl.1/2	4x25	1 amal	>24	.9	.5	Ridge	0°
Summitt et al. 1992	UPM	MO/DO	5x12	1 amal	>1000	1.2	1	Ridge	13.5°

Restored tooth strength assessed by impact or alternate loading until fracture

<u>Model</u>	-----Tooth-----			-Material-		-----Load-----			
	<u>Tooth</u>	<u>Prep.</u>	<u>No</u>	<u>Type</u>	<u>Set</u>	<u>Size</u> <u>mm</u>	<u>Load</u> <u>g</u>	<u>Cycles</u> <u>x1000</u>	<u>Position</u> <u>/Angle</u>
Lampshire 1950	x2Die	L2M	18xMO	2x3x3	1 am	>24	1.5	205*4cm	* Fossa/0°
Johnson 1972	Plastic	U1M	MO	2x16	1 am	>24	1.5	500*1mm	* Ridge/0°
Galan Jr et al. 1973	Die	L1M	MOD	5x5x4	5 am	3/168	1.5	844/cm2	8 Fossa/0°

* Until fracturing occurred

A more sophisticated method, using strain gauges bonded to the tooth surfaces, enables the calculation of strain on the external surface of the tooth in a sound state, prepared and unrestored, or in the restored state (Table I.4). The method is regarded as semi-reversible, since the effects of the cavity design on the mechanical behavior of the tooth/restoration can be successively monitored. Since the original sound tooth serves as a control, pairwise comparisons of the strain values are possible. The results from some of these studies have also been reviewed by Douglas (1985) and by Hood (1991).

Table I.4. Strain measurement studies focussed on class 2 restoration/tooth deformation as a function of cavity design factors.

Investigators	Purpose
Stress in the tooth	
Grimaldi & Hood, 1973	Assess the lateral deformation of cusps in prepared teeth, using a technic with linear voltage differential transformers (LVDT) presented by Grimaldi (1971)
Hood, 1973	Assess the extent of tooth deformation from the use of matrix bands
Jørgensen, Matono et al. 1976	Study the deformation of selected types of cavities in axially loaded teeth with and without restorations, using a light microscope
Powell, Nicholls & Schurtz, 1977	Measure the elastic displacement of tooth structure under the action of a matrix band, using photographs
Powell, Nicholls & Molvar, 1980	Determine the deformation of teeth by matrix bands and amalgam condensation, using photographs
Morin, DeLong & Douglas, 1984	Measure deflection of the cusps of premolars after the use of 3 bonded and 1 non-bonding restorative materials
Douglas, 1985	Investigate the possibility for a range of materials and techniques to improve the fracture resistance of teeth, using a technic with strain gauges presented by Malcolm(1973)
Krainau et al., 1987	Measure the deformation of cavity walls under the influence of matrix bands, using a granulation optical method
Morin et al., 1988a	Examine the behaviour of the tooth under a variety of restorative conditions, including effects of different materials, cavity designs and restorative techniques, using a methodology described previously by Morin et al. (1984).
Assif, Marshak & Pilo, 1990	Measure deflection of the cusps of premolars during and after amalgam therapy

Stress in the restoration

Granath & Hiltcher, 1970	Find out whether variations of the cavity buccolingual shape had any effect on the avulsive tensile stresses arising on loading of the occlusal edges in relation to the horizontal support and the physical properties of silver amalgam
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Stress in the restoration/tooth interface

Granath & Möller, 1975	Determine if the cavity width influence microleakage, using a compression device
Granath & Svensson, 1991	Study in detail the effects of cavity size and form on elastic outward bending of separated buccal and lingual walls in premolars, with special reference to the variation in form when a given amount of tooth substance is removed.

Measurements of the stresses internally in a class 1 amalgam restoration have also been described, using a microtransducer inside the restoration (Watkins, 1971). However, there are no further publications on this method, and the report included no data on the effects of the cavity design per se on the internal stress development.

The photoelastic modeling method (PEM) and the finite element method (FEM) enable analyses of the distribution of stresses in a model under specific load conditions. In PEM, stresses are estimated from measurements of the temporary double refraction that certain transparent isotropic materials develop under stress. The first PEM analyses in dentistry appeared in 1949 (Noonan, 1949), and the theoretical basis of PEM was reviewed by Mahler & Peyton (1955), and by Granath (1963a). Both two- and three-dimensional PEM studies have been used to identify the stress distribution in models or idealized models of the tooth, the restoration, or both the tooth and the restoration (Table I.5). The results from several of these PEM-studies have been reviewed by Granath (1965) and by Craig & Farah (1977).

Table I.5. Photoelastic modelling (PEM) studies focussed on stresses in class 2 restoration/tooth as a function of cavity design factors.

Investigators	Purpose
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Noonan, 1949	Present an introduction of the application of PEM, and determine the advantage of one cavity form over another with regard to minimizing stress
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- Granath, 1963b Investigate by studying stress distributions how different factors can increase the separation of the cavity wall from the restoration
- Robinson, 1966 Demonstrate that wedging effects from dental restorations are liable to bring stresses in the tooth substance

Stress in the restoration

- Haskins, Haack & Ireland 1954 Determine what effects different class 2 designs would have on the stresses in the restoration
- Guard, Haack & Ireland 1958 See which cavity form that provides for the best stress distribution in deciduous teeth, at least the width of the isthmus from the axial wall
- Holliger, 1958 Demonstrate the value of photography in qualitative PEM
- Granath, 1964a Study the stress distribution as influenced by the gingival wall inclination and location.
- Craig et al., 1967 Study the stress distribution of several inlays and modifications, and to investigate the effect of different loading sites in accordance with occlusal loading and by the pulpoaxial line angle configuration.

Stress in the tooth and the restoration

- Mahler, 1958 Determine where the maximum tensile stress occurs in the restoration and in the tooth, and the effect that design variables have on these stresses, using a lateral extensometer
- Granath, 1964b Study the stress distribution when a specified one- pointload was applied on the restoration
- Schreiber & Motsch, 1968 Reexamine the stress distributions in the tooth and the restoration in relation to the shape of the cavity
- El-Ebrashi et al. 1969a Investigate the stresses in different proximal margins and to measure, quantitatively, the effect of modifications in the design of the different preparations on the stresses in the restorations.
- El-Ebrashi et al. 1969b Investigate the stresses as a function of the convergence angles of axial walls, and the effect of increasing that angle on the factors for concentration of stress.

Stress in the tooth/restoration interface

- Granath, 1964c Determine the bending stresses in the tooth and the restoration, combined with a lateral extensometer technic
- Granath & Edlund, 1968 Study the influence of the pulpoaxial line angle morphology on stresses in the isthmus region using 3 different force vectors, combined with a lateral extensometer.

Stress in the tooth, restoration and interface

- Tanner, 1972 Establish the importance of some methodological variables as they relate to PEM design studies.

FEM was introduced in restorative dentistry by Farah (1972). The methodology and theoretical principles of FEM have been discussed by Peters (1981). FEM is based on computerized-numerical modeling, where estimations of stress are calculated as functions of various parameters such as size, elastic moduli and Poisson's ratio of the components in the models, and the values and directions of force vectors. The advantage of FEM is that the method enables the determination of estimates of both the state of the stress and the extent of deflection of the different components in a model of the tooth and/or the restoration. Results from FEM are almost identical with the results from PEM (de Vree et al., 1983). Results from two-- and three-dimensional FEM studies were reviewed by Morin et al. (1988a) (Table I.6).

Table I.6. Finite element modelling (FEM) studies focussed on stresses in class 2 restoration/tooth as a function of cavity design factors.

Investigators	Purpose
Stress in the tooth	
Farah, Hood & Craig, 1974	Investigate the accuracy of a model system and its application to the study of stresses and displacements in the cavity floor under simulated loading
Khera et al., 1988	In a three-dimensional model of a premolar study stress distributions in a normal tooth and the effect of different cavity designs on the same tooth
Stress in the tooth and restoration	
Morin et al., 1988b	Validate FEM models, and determine the effect various restorative techniques have on the ability to dissipate strain
Stress in the tooth/restoration interface	
Farah, Hood & Craig, 1975	Study stresses induced in a class 1 amalgam restoration supported by bases of varying materials and thicknesses
Farah, Dennison & Powers, 1977	Study the effect of lateral wall taper and cavosurface bevel on the stress distribution under the occlusal portion of a cast gold restoration
Derand, 1977	Determine the internal stresses and calculate the rate of deformation at the margin of a class 2 amalgam restoration
Stress in the tooth, restoration and interface	
Farah & Craig, 1974	Examine the distribution of stresses in a first molar with three cavosurface margin configurations
Wright & Yettram, 1978	Estimate the stress and distortion of tooth tissue caused by the setting and the thermal expansion of amalgam
Peters, 1981	Analyze the influence of an alternative cavity design on the overall force distribution in a restored tooth

de Vree et al., 1983	Compare results and validate the calculations obtained from PEM calculations with FEM, given certain assumptions
de Vree et al., 1984	Study the influence of a modified cavity design on the overall force distribution throughout the restored tooth

As for the compressive loading method studies, there is a wide range of methodological parameters that differ in the various reports using PEM and FEM (Table 1.7). Both mesiodistal and buccolingual, including axio-symmetric idealized sections in FEM, models of the tooth and/or the restoration have been used. Loading points have varied between singular or two-point loading, with forces up to 2900 Newton and angles between -10° and 65°.

Table 1.7. Methodological parameters of PEM and FEM studies focussed on stresses in class 2 restoration/tooth as a function of cavity design factors.

Photoelastic modeling

Investigators	Model		Load			
	Struct	Section	Points	Position	Angle	Newton
Noonan, 1949	Tooth	BuccLing	1	Central	0°	240 & 420
Granath, 1964b	Tooth	BuccLing	1	Central	0°	200
Schreiber & Motsch, 1968	Tooth	BuccLing	1	Central	0°	2000
Tanner, 1972	Tooth	BuccLing	1	Central	0°	110
Robinson, 1966	Tooth	BuccLing	Inlay forced into cavity			120
Granath, 1963b	Tooth	BuccLing	2	Cuspslope	45°	100 & 200
Tanner, 1972	Tooth	BuccLing	2	Cuspslope	45°	22 & 88
Mahler, 1958	Tooth	BuccLing	2	Cusptip	45°	330
Schreiber & Motsch, 1968	Tooth	BuccLing	2	Cusptip	45°	2000
Tanner, 1972	Tooth	BuccLing	2	Cusptip	45°	22 & 88
Guard et al. 1958	Restor.	BuccLing	1	Central	0°	704
Granath, 1964b	Restor.	BuccLing	1	Central	0°	300
Schreiber & Motsch, 1968	Restor.	BuccLing	1	Central	0°	2000
Tanner, 1972	Restor.	BuccLing	1	Central	0°	110
Tanner, 1972	Restor.	BuccLing	2	Cuspslope	45°	22 & 88
Tanner, 1972	Restor.	BuccLing	2	Cusptip	45°	22 & 88
Haskins et al. 1954	Restor.	MesDis	1	Central/fossa	0°	720
Holliger, 1958	Restor.	MesDis	1	Fossa	0°	705-1050
Granath, 1964a	Restor.	MesDis	1	Fossa	0°	150
Craig et al., 1967	Restor.	MesDis	1	Central/fossa	0°+45°	530
Granath & Edlund, 1968	Restor.	MesDis	1	Ridge	-10°	1380
Granath & Edlund, 1968	Restor.	MesDis	1	Fossa	0°	1150
El-Ebrashi et al., 1969a	Restor.	MesDis	1	Cent/Fos/Rid	0°	440
El-Ebrashi et al., 1969b	Restor.	MesDis	1	Cent/Fos/Rid	0°	220 & 660
Mahler, 1958	Restor.	MesDis	2	Central+ridge	45°	330
Granath, 1964a	Restor.	MesDis	2	Fossa+ridge	15°	350

Granath, 1964c	Restor.	MesDis	2	Fossa+ridge	10°	2900
Granath & Edlund, 1968	Restor.	MesDis	2	Fossa+ridge	10°	2690
Granath, 1964c	Interface	BuccLing	1	Central	0°	1150/2300
Tanner, 1972	Interface	BuccLing	1	Central	0°	110
Tanner, 1972	Interface	BuccLing	2	Cuspslope	45°	22 & 88
Tanner, 1972	Interface	BuccLing	2	Cusptip	45°	22 & 88
Granath & Edlund, 1968	Interface	MesDis	1	Ridge	-10°	1380
Granath & Edlund, 1968	Interface	MesDis	1	Fossa	0°	1150
Granath, 1964c	Interface	MesDis	2	Fossa+ridge	10°	2900
Granath & Edlund, 1968	Interface	MesDis	2	Fossa+ridge	10°	2690

Finite element modeling

<u>Investigators</u>	<u>-----Model-----</u>		<u>-----Load-----</u>			
	<u>Structure</u>	<u>Section</u>	<u>Points</u>	<u>Position</u>	<u>Angle</u>	<u>Newton</u>
Farah et al., 1974	Tooth	ax-BuccLing	1	Central	0°	24 & 48
Derand, 1977	Restor.	BuccLing	1	Cusptip	0°	150
Farah et al., 1975	Interface	ax-BuccLing	1	Central	0°	540
Farah et al., 1977	Interface	ax-BuccLing	2	Cuspslope/tip	0°+15°	222
Farah & Craig, 1974	Tth/Int/Res	ax-BuccLing	2	Cuspslope	20°	440
Wright & Yettram, 1978	Tth/Int/Res	ax-BuccLing	Thermal/setting expansion estimates			
Peters, 1981	Tth/Int/Res	ax-BuccLing	1	Central	0°	200
de Vree et al., 1983	Tth/Int/Res	ax-BuccLing	1	Central	0°	200
de Vree et al., 1984	Tth/Int/Res	ax-BuccLing	1	Cuspslope/tip	0°	500
Morin et al., 1988b	Tooth/Rest.	BuccLing	2	Cuspslope/tip	45°+65°	6500/11750
Khera et al. 1988	Tooth	3-Dimension	1	Central	0°	200

Other laboratory studies

One basic requirement of a tooth filling material for dental use is good biocompatibility. The importance of designing in vitro biocompatibility tests that reflect the true clinical situation is well recognized (Mjör, 1988). In vitro tests using cell cultures that incorporate dentin thickness as an important methodological parameter have, therefore, been developed (Meryon, 1988). However, it is difficult to extrapolate the results from these in vitro tests to potential relationships between pulp complications and specific details of the cavity design. An exception is perhaps estimating the risk of pulp complications as a function of the cavity depth. There are to the author's knowledge no reports on this association related to amalgam restorations.

Another important property of a tooth filling material is the ability to adapt closely to the cavity walls (Table I.8), to prevent toxic substances from the oral environment reaching the pulp, reduce hypersensitivity and avoid secondary caries (Pashley, 1990). Clinical, optical, ultrasound or laser techniques have been used to measure the geometrical adaptation of restorations (Roulet 1991). Indirect methods, such as microleakage tests and caries development

in artificial environments, are also being used for assessing the adaptation of restorations. The literature abounds with microleakage studies using dyes, radioactive isotopes, air pressure, bacteria and neutron activation analysis (Ben-Amar, 1989; Taylor & Lynch, 1992, Cox, 1992). However, the studies that include amalgam as the experimental or control material concentrate on microleakage in class 5 restorations. Few studies describe the microleakage along restorations placed in class 2 cavities, and even fewer studies present data on the relationship to cavity design factors. Also the number of studies on the association between artificially produced secondary caries along amalgam restorations and details of the cavity preparation are sparse. Only 3 studies have been presented, and the restoration types used in these studies were class 5 and not class 2 restorations (Table 1.8).

A third important requirement of a tooth filling material is the resistance to degradation in the oral environment. The resistance to degradation decreases if the physical and mechanical properties of the amalgam are compromised by inadequate cavity designs. There are only two reports that have addressed this problem.

Table 1.8. In vitro experiments assessing the relationship between cavity design details and potential clinical restoration failure.

Investigators	Purpose
Effects on adaptation, measured geometrically	
Charbeneau & Peyton, 1957	Assess the clinical significance of cavity wall irregularities on adaptation, geometrically in light microscope
Heim, 1962	Determine whether amalgam can be condensed into retentive grooves and compare the adaptability of amalgam into round and acute grooves
Jørgensen & Wakumoto, 1968	Describe margin defects of occlusal amalgam restorations and correlate these defects with occurrence of secondary caries
Azar et al. 1968	Develop a method of evaluating line angle adaptation and study the influence of acuity on the adaptation of amalgam
Symons, Wing & Hewitt, 1987	Examine the adaptation of amalgam to the cavosurface margins, geometrically in a light microscope
Symons, Wing & Hewitt, 1987	Examine the adaptation of amalgam to walls and retention sites in cavity preparations, geometrically in a light microscope
Hannig & Albers, 1989	Compare roughness and adaptation of 6 different alloys after using interproximal finishing strips subsequent to the condensation procedures
Wöstmann & Lütke-Notarp, 1991	Assess the limits between "acceptable" and "unacceptable" margin discrepancies
Duncalf & Wilson, 1992	Compare the adaptation and condensation of the proximal

section of amalgam restorations placed in class 2 preparations of conventional and conservative designs in natural teeth

Effects on adaptation, measured by microleakage tests

- Menegale, Swartz & Phillips, 1960 Determine the influence of cavity-wall texture on the restoration adaptation, by the use of a Ca45 isotope microleakage technique
- Grieve, 1971 Investigate if smooth cavity margins allow better adaptation, measured geometrically and by microleakage
- Khera & Chan, 1978 Measure the amount of dye microleakage as a function of finishing and cavosurface margin continuity
- Hormati, Khera & Kerber, 1981 Measure the difference in microleakage of a dye at the entry and exit side walls on the proximal surface
- Reich, Stadlbauer & Völkl, 1987 Assess the influence of cavosurface finishing and the margin quality proximally on microleakage after thermocycling
- Schaller, Klaiber & Trunk, 1988 Assess the effect of cavosurface finishing and the use of different liners on the microleakage of a dye
- Khera, Askarieh & Jakobsen, 1990 Measure the effect of alloy and cavosurface finish on the amount of microleakage at different levels along the proximal cavity walls
- Haller, Klaiber & Tens, 1991 Study the effect of different cavity wall finishing methods on microleakage in class 1 and class 2 amalgam restorations

Effects on adaptation, measured by artificially produced caries tests

- Kidd, 1976 Produce in vitro artificial lesions in relation to restorations, and describe the histological features of the lesions
- Heintze & Mörnstad, 1980 Study the development of artificial caries around amalgam restorations, using the acidified gel technic
- Torii et al., 1989 Test the resistance to secondary caries of amalgam restorations bonded by adhesive liners, using a bacterial medium

Loss of restoration

- Bouschor & Martin, 1976 Measure the amount of tensile force necessary to remove amalgam restorations from MOD cavity preparations made in molars

Effects on physical and mechanical properties

- Winkler, 1971 Measure the surface hardness of amalgams in relation to the cavity size in extracted teeth
- Stachniss, Darwish & Hoppe, 1977 Relate the angle between the axial and gingival walls proximally, and the hardness and homogeneity of the amalgam in the angles

Discussion of methods

Biophysical stress analyses

In order to evaluate the effects of cavity design factors on stress developments in the tooth and the restoration a technique should ideally (1) distinguish small, but clinically significant, differences in design and (2) predict the magnitude of force to cause fracture (Mahler et al., 1961). These investigators reported after using the compressive loading method that the morphology and physical properties of natural teeth strongly influenced the fracture values. Consequently, minor differences in cavity design create stress level differences in the tooth and the restoration that too small to be detected when using natural teeth. Goel et al. (1990) have suggested that the fracture potential of teeth besides the morphology of the cusp and incline angles also may depend on microscopic aspects of the tooth.

In order to avoid the inter-tooth strength variations, metal dies have been used with standardized morphological details to study the effects of cavity design factors on the fracture strength. Initially, it was believed that the tooth structure only to a minor degree supported the restoration (Mahler et al., 1961). Several studies used brass castings, into which amalgam restorations were placed. In general, higher values of the fracture strengths were obtained when the restorations were placed in metal dies compared to in teeth. Probable explanations were the enhanced support of the rigid walls, or an adhesion between amalgam and brass. Thus, it could be concluded that the method using metal dies do not enable the discrimination of fracture strengths between designs exhibiting low resistance to fracture (Mahler et al. 1961). Subsequent studies were based on dies made from plastic (Johnson, 1972), steel (Crockett et al., 1975), chrom-cobalt (Mondelli & Vieira, 1972) and chrom-nickel (Sturdevant et al., 1987). In all cases, the numerical differences between the strength of the restorations placed in teeth and in dies remained, indicating that other mechanisms besides adhesion and surface roughness were present. Another failure of the using the die method is the lack of predicting the magnitude of force to cause fracture. Farah et al. (1976) have suggested that the superior modulus of elasticity of die alloys over dentin yield unrealistic results. The more closely the materials' elastic moduli match that of the dental tissues or model material, the more effective is the transfer of tensile stress (van Noort, Cardew & Howard, 1988). Thus, although using dies allow comparative measurements of the effects of cavity design factors on the restoration strength, the loading levels do probably not represent the stresses generated *in vivo*.

Either when using natural teeth or dies, there are many methodological problems associated with the compressive loading technique. One problem is

to precisely monitor the loading centricity due to the occlusal morphology of the tooth (Watts et al., 1987). Some studies, either intentionally or unintentionally, have recorded the adhesive strength between the restoration and the tooth instead of the cohesive strength of the tooth filling material. It is also probable that the results have been influenced by, e.g., alloy type, type of liner and the handling procedures of these dental materials. Other variables of the compressive loading method are the speed, the size and the diameter of the crosshead ball or rod, and the choice of teeth. Finally, the load position and -angle are also critical parameters. Due to the large variation of all these variables in the reports (Table 1.3), it is difficult to make valid comparisons of the results.

However, there are even more severe limitations of the compressive loading method. It is destructive, it lacks discrimination, large numbers of teeth are required for statistical validity, and the averaging of results often hides valuable information (Hood, 1991). Furthermore, the forces needed to fracture the teeth often exceed the maximum bite force generated by humans (Helkimo & Ingervall, 1978; Gibbs et al., 1986). The forces are also much higher than needed to fracture tooth cusps (Libermann et al., 1990; Reagan et al. 1989), or marginal ridges (Covey et al., 1989; Caplan et al., 1990; Purk et al., 1990) in sound teeth. In addition, the method does not mimic the complex isometric and isotonic load applications encountered in the working occlusion (Krejci et al., 1990). Finally, the fractures observed in these tests (Re & Norling, 1981; Re et al. 1981), are atypical from the fractures observed clinically (Snyder, 1976; Bell et al., 1982; Burke, 1992). In conclusion, it can be seriously questioned if the static compressive measurement method is a valid method for estimating the behavior of restorations and restored teeth in vivo (Mahler et al., 1961; Eames & Lambert, 1982; Howard, 1982).

The disadvantage of the strain gauge method is that strain measurements on the exterior of the tooth give no indication of the strain distribution in the dental tissues, the restoration and the tooth/restoration interface. However, by interpolating strain values measured on the external surfaces with FEM, the internal stresses can be estimated with good accuracy (Morin et al., 1988b).

The main advantage of PEM and FEM is that the methods enable assessments of both the dimension and the location of the stresses that develop internally in teeth, in tooth/restoration interfaces and within restorations. A further advantage of PEM is the possibility of the direct observation of the distribution of internal stresses throughout the entire model. However, the observed stress levels may at best be regarded as semi-quantitative. More numerical data on internal stresses were obtained when the PEM was combined with a lateral extensometer (Mahler, 1958; Granath, 1964c; Granath & Edlund, 1968). The disadvantage of the PEM technic is that the results may be confounded by the experimental variables. One prerequisite

of PEM is that the materials in the models are homogeneous, isotropic and elastic, which is not the case with enamel and dentin (Haskins et al., 1954). These investigators also observed that the effects of the cavity design variables on the stress levels varied with the location of the applied load. Furthermore, Mahler & Peyton (1955) listed three considerations that they considered important: the direction and magnitude of the applied force, the mode of support of the model, and the pulpal and external shape of the model. Later studies focussed on the necessity of using materials in the models with similar ratios of the elastic moduli as in vivo (Granath, 1964a; El-Ebrashi et al., 1969a). On the other hand, a subsequent study showed that the effects of several of these methodological variables on the results were slight (Tanner, 1972). A further question is to what extent the quality of the adaptation, as well as the movement and the friction between the different materials used in the PEM models may have influenced the results (de Vree et al., 1983). It is, therefore, probable that FEM enables more realistic modeling than PEM, since the different components of the structures under study may be assigned separate values of the elastic modulus, Poisson ratio etc. FEM calculations may also incorporate different vectors for anisotropic materials, such as dentin, which should theoretically yield more correct stress estimates than PEM models. Another advantage of using FEM is that calculations of the internal strain distributions can be limited to specific areas of interest, e.g., in a bonding resin layer or at the dentino-pulpal interface.

A limiting factor of the data from in vitro biophysical analyses is that the results are difficult to verify experimentally in vivo. One major parameter is that the mechanical behavior of a restored tooth depends on the state of adaptation of the tooth filling material (Peters & Poort, 1983). The morphology, width and physical properties of the tooth/restoration interfaces are at present unknown, but it is probable that there are variations among different alloys. Furthermore, biological variables such as the complicated morphology of teeth, e.g., the cusp width and angulation as well as the load direction, i.e., the intercuspitation and tooth angulation, etc. are difficult to simulate. Furthermore, the mode of loading in vivo is complex. Therefore, the assumption in FEM and PEM studies that the stresses are constant and perpendicular to the plane of interest may be questioned. Thus, PEM and FEM modeling is suitable for comparative studies of stress levels using different cavity preparation designs, dental materials or adhesive strengths, but the clinical relevance of detailed calculations of forces is questionable.

Other laboratory studies

The clinical implication of the various results from in vitro microleakage tests remain uncertain. It is probable that besides the corrosion properties and

dimensional stability of the alloy, the trituration, plasticity, condensation and burnishing technique influence the adaptative properties of amalgam (Haller et al., 1991). In addition, the margin microleakage along relatively well adapted amalgam restorations decreases over time (Kidd, 1976). The decreased microleakage is probably due to corrosion, although the actual rate and mechanisms remain controversial (Jodaikin, 1981). Thus, the general view is that the etiological significance of the cavity design and wall morphology on the margin microleakage is small (Ben-Amar, 1989; Cox, 1992).

Summary and discussion of results

Clinical longitudinal and cross-sectional studies have shown that the main reason for replacement of class 2 amalgam restorations is secondary caries (Jokstad & Mjör, 1991). The studies report replacement frequencies due to secondary caries varying between 45-70%. The next two prevailing replacement reasons, restoration bulk and margin fractures account for 20-50%. Tooth or cusp fractures are the causes for replacement of approximately 5-15%. Other reasons for replacement may be lack of proximal contact, poor contour, pulp complications or complications, overhanging dental restorations and corrosion of the filling, as used in a wide term. These replacement reasons account for 5-20% of the replacements.

The results obtained in the different in vitro studies relevant to the possible association between cavity design factors and restoration failure will be presented according to the different restoration failure reasons, and in decreasing frequency as observed clinically.

Secondary caries and features of the cavity design

Features of the cavity design that have been given particular attention include the extent of the external outline and depth, cavosurface margin quality, gingival beveling and the axiocervical location of the gingival wall.

Grimaldi & Hood (1973) suggested that increased deformation of the cusps upon loading may cause the formation of intermittent gaps at the margin between hard tissues and restoration, which increase microleakage and secondary caries. Subsequent biophysical stress analyses have supported this finding (Hood, 1991). Furthermore, these experiments have also shown that the dental tissue display hysteresis when recovering its original form (Morin et al., 1984), i.e., the recovery of the initial position of the cusps is slower after removal of the loading than the deformation upon loading. Thus, it may be hypothesized that any cavity design that favors cusp movements may increase the risk for secondary caries (Anusavice, 1989b).

It is presumed that the adaptation of the amalgam restoration to the cavity wall is inversely correlated with the risk of secondary caries. In this context, the morphology of the cavity wall is important. In a study of the restoration-cavity wall interface, a restored tooth with the restoration in situ was sectioned (Charbeneau & Peyton, 1957). The adaptation was measured geometrically in a microscope. Charbeneau & Peyton (1957) concluded that the amalgam seemed to adapt well to relatively rough cavity walls. However, no quantitative data on this adaptation were presented.

Duncalf & Wilson (1992) have recently presented some controversial data on the association between the cavity design and adaptation. According to these investigators, the restorations in the preparations of conservative design exhibited more adaptation defects, porosities and voids than did the restorations in the preparations of conventional design. The investigators concluded that it is necessary to identify and describe instruments and techniques that will facilitate the placement of restorations of amalgam in cavities with limited access.

The first microleakage study focussing on a possible effect of the cavity wall morphology was presented by Menegale et al. (1960). These investigators showed that the infiltration of a Ca^{45} isotope along the interface was higher in smooth-walled cavities, compared to in rough-walled cavities. Their observations were supported by Grieve (1971), but conflicting results have been reported later (Schaller et al., 1988; Haller et al., 1991). It is possible that the contradictory results are due to different alloys, since the optimal finishing method may differ with the type of amalgam alloy (Hannig & Albers, 1989; Khera et al., 1990). It has also been suggested that for a given finishing method, the adaptation can be satisfactory at one location, but poor elsewhere along the margin (Khera et al., 1990). Another explanation of the diverging results is that the microleakage may have been influenced by the flexibility of the cavity walls, i.e., indirectly by the cavity design (Granath & Möller, 1975; Granath & Svensson, 1991). On the other hand, if this theory is correct, one consequence would be that large restorations should be more prone to secondary caries. This has so far not been supported by any clinical studies.

The necessity of beveling the gingival margin is controversial. However, only one histopathologic study has been presented in the literature, and was limited to observations of class 5 restorations only (Hals & Leth Simonsen, 1972). The results showed that the development of cavity wall lesions was independent of the angle between the prisms and the enamel wall, i.e., whether the enamel wall displayed supported or unsupported prisms. Hannig & Albers (1989) studied the proximal parts of freshly restored Frasco teeth with and without gingival beveling. Gingival beveling had a detrimental effect on the restoration adaptation along the margin. The frequency of perfect margins decreased, while margins with lack of adaptation and overhanging material increased when the gingival margin was beveled.

Also the axiogingival location of the margin may be related to the risk of

secondary caries. In one in vitro study it was observed that secondary caries appeared more frequently along the coronal parts than the gingival parts on class 5 restorations (Heintze & Mömstad, 1980). However, these observations were not supported in two similar studies (Kidd, 1976; Torii et al., 1989). It is possible that the different results may be due to lack of control of the cervical parts of the teeth. Thus, SEM studies have shown that the enamel surfaces frequently display surface irregularities and microcracks in the cervical 1/3 parts of the crown (Boyde, 1972).

Restoration fractures and features of the cavity design

Conventional cavity designs: external features

Features of the cavity design that have been given particular attention include the extent of the external outline and depth, the convergence of axial walls and the extension proximally of the gingival wall.

The risk of restoration fractures is dependent on the bulk of the restoration. If the restoration is considered as a beam, it is well known that the thickness, i.e., the cavity depth, has a larger influence on the deflection or the strength than the width (Gabel, 1944). The variations in stress distributions are also related to the flexibility of the pulpal wall, which also acts as a beam. The flexibility thus depends on the length and the thickness of both the material and the dentin (Tanner, 1972), as well as the thickness and type of base material under the restoration. In principle, all features of the design that increase the restoration bulk also decrease the risk for fracture of the restorations. However, the optimal cavity preparation is to maintain as much dental tissue as possible, while creating enough bulk of the restoration to resist the intra-oral functional forces.

The relative influence of different features of the cavity design on restoration strength has been studied in different biophysical stress analyses. One early study was presented by Lampshire (1950), and the results from this study have been more or less confirmed by subsequent studies. The original data from Lampshire's study will, therefore, be presented as a reference to the subsequent biophysical stress analyses data.

Occlusal width

Lampshire (1950) reported that an increase of the cavity width from approximately 1/3 to 1/2 of the intercusp width (ICW), resulted in a higher number of loading cycles before restoration fracture. The relative gain, measured as percentage increase in loading cycles, was dependent on whether other features of the cavity design were also implemented (Table I.9). The highest increase was obtained when the cavities included proximal grooves, rounded pulpoaxial line angle and a sloping pulpal wall.

Table I.9. Relative increase (%) in loading cycles required to fracture wide compared to narrow restorations reported by Lampshire (1950).

<u>Characteristics</u>	-----Line angle design-----		
	<u>Sharp</u>	<u>Round</u>	<u>Round and sloping pulpal wall</u>
No grooves	81	40	41
Gingival groove	29	35	176
Proximal grooves	44	51	312

Only one study has confirmed Lampshire's observation of fracture strengths when the cavity width is increased (Mondelli & Vieira, 1972). These investigators compared the fracture strength of MOD restorations placed in a metal die, and recorded a 58% higher fracture strength of restorations with 1/2 ICW compared to 1/3 ICW. In contrast, Vale (1959) reported that the forces required to fracture MOD restorations in premolars with 1/3 ICW were two thirds of the forces required to break restorations with 1/4 ICW. Also El-Sherif et al. (1988) found significantly lower strength when the restoration width increased for both MO, DO and MOD restorations. Re et al. (1982) found that the differences in fracture strength were clinically negligible (5%) when comparing MOD restorations with 1/2 ICW and 1/4 ICW in molars. Obviously, different parameters in the experiments account for the variable results.

Occlusal depth

The effect of the restoration bulk on fracture strength has apparently not been studied by using the compressive loading method. One possible reason may be that the relationship seems obvious. Furthermore, only one PEM study have shown the relationship between restoration bulk and stresses (Haskins et al., 1954). However, these data were purely qualitative, and were probably included in the article as a validation of using the PEM method. These investigators reported that shallow cavity preparations permitted greater stress to develop than did those with deep occlusal steps. Granath (1964c) observed in another PEM study that the maximum tensile stress in the lower border increased with sagging support, but the maximal tensile stress never reached values near the ultimate tensile strength of amalgam. There is lack of data on the required minimum occlusal thickness of restorations. Only one study has been presented (Farah et al., 1975), and these data are semi-quantitative. The investigators concluded that if the cavity has sufficient depth for an amalgam restoration and some enamel is still present, the remaining enamel does not contribute to the mechanical failure of the restoration.

Effect of cavity type

The differences in the fracture strengths of MO/DO and MOD restorations were studied by El-Sherif et al. (1988). In premolars, the restoration fracture strengths of MO/DO restorations were almost identical with the MOD restorations, despite whether the width was 1/4 ICW (97%), 1/3 ICW (99%) or 1/2 ICW (101%).

Proximal outline

The effect of the axial wall convergence was studied by Mondelli et al. (1974). The investigators showed that MO restorations with parallel axial walls had the same fracture resistance to vertical forces as the restorations with converging walls.

It is theoretically conceivable that the axiokingival extension of the proximal part may influence the development of stress occlusally. One PEM study indicate that the amount of tensile stresses on the occlusal surface upon two-point loading may correlate with the location of the gingival wall (Granath, 1964a). Thus, restorations in cavities with cervically located gingival walls display more tensile stresses compared to restorations with gingival walls located more occlusally. The clinical significance of this observation is uncertain (Granath, 1965).

Conventional cavity designs: internal features.

Features of the cavity design of interest have been the presence or absence of proximal grooves, acuteness of the axiopulpal line angle and rounding of the pulpal wall. Some studies have also focussed on rounding the internal line angles occlusally and the angulation of the axial wall (Table I.10 - I.15).

Grooves

In Lampshire study (1950), grooves in the proximal part of the cavity increased the number of loading cycles before the restoration fractured. The relative gain, measured as percentage increase in loading cycles, was dependent on whether other features of the cavity design were also implemented (Table I.10). The highest increase was obtained in the wide cavities, which also included rounded pulpoaxial line angle and sloping pulpal walls.

Table I.10. Relative increase (%) in loading cycles required to fracture restorations placed in cavities with proximal grooves compared to without grooves reported by Lampshire (1950).

Characteristics	Gingival grooves		Proximal grooves		Additional features
	Narrow	Wide	Narrow	Wide	
No groove	40	0	408	304	Sharp pulpoaxial line angle
Gingival grooves	17	12	269	299	Round pulpoaxial line angle
	0	95	226	847	Round pulpoaxial line angle + sloping pulpal wall
Gingival grooves			264	307	Sharp pulpoaxial line angle
			217	255	Round pulpoaxial line angle
			225	386	Round pulpoaxial line angle + sloping pulpal wall

The increased strength of the restorations placed in cavities with grooves compared to those without grooves were confirmed by Johnson (1972), who observed that restorations with grooves withstood a greater number of impact cycles before fracture than those placed in cavities without proximal retention. Also other studies, using the compressive loading method, have confirmed the benefit of proximal grooves on restoration fracture strength (Table I.11).

Table I.11. The gain in fracture strength (%) of restorations placed in cavities with proximal grooves compared to in cavities without proximal grooves.

Investigators	Gain	Characteristics
Mahler et al. (1961)	60	Premolar, grooves made with bur, converging walls, rounded axiopulpal line angle
	25	Premolar, grooves made with gingival wall trimmer,
	22	Brass die, grooves made with bur,
	5	Brass die, grooves made with gingival wall trimmer,
	70	Densite model, grooves made with bur
	7	Densite model, grooves made with gingival wall trimmer
	Terkla & Mahler (1967)	19
Mondelli et al. (1974)	25	Loading on the isthmus
	13	Loading on the mesial fossa
Crockett et al. (1975)	6	Vertical loading
	2197	Horizontal loading
Amorim et al. (1978)	36	Metal dies, sharp/rounded line angles or rounded line angle + sloping pulpal wall
	53	Natural teeth, sharp/rounded line angles or rounded line angle + sloping pulpal wall
Sturdevant et al. (1987)	13	Groove from gingival floor to axiogingival line angle
	8	Groove from gingival floor to occlusal surface
Caplan et al. (1990)	38	Groove from gingival floor to axiogingival line angle
Purk et al. (1990)	2	Groove from gingival floor to axiogingival line angle
Summitt et al. (1992)	69	Groove from gingival floor to occlusal surface
	45	Small points occlusal to axiogingival line angle
	5	Groove from gingival floor to axiogingival line angle

Recent results presented by Summitt et al. (1992) suggest that the morphology of the grooves influence the results. In contrast to Sturdevant et al. (1987), these investigators found higher fracture resistance when the grooves were made from the gingival floor to the occlusal cavosurface margin. The different results were attributed to a possible influence of differences in cavity widths and depths.

Axiopulpal line angle

By rounding the axiopulpal line angle Lampshire (1950) observed that the number of loading cycles before the restoration fractured could be increased slightly. The relative gain, measured as percentage increase in loading cycles, varied with the buccolingual width of the cavity (Table I.12). The highest increase was obtained in the narrow cavities when these did not include proximal grooves.

Table I.12. Relative increase (%) in loading cycles required to fracture restorations placed in cavities with rounded axiopulpal line angles compared to without reported by Lampshire (1950).

<u>Characteristics</u>	<u>Narrow</u>	<u>Wide</u>
No proximal grooves	44	12
Gingival groove	20	26
Proximal grooves	5	10

The negligible change in restoration fracture resistance after rounding the axiopulpal line angle has been confirmed by subsequent studies using the compressive loading method (Table I.13).

Table I.13. The gain in fracture strength (%) of restorations placed in cavities with rounded compared to sharp axiopulpal line angles.

Investigators	Gain	Characteristics
Yates et al. (1976)	-3	Conventional alloy, sharp proximal line angles
	-9	High-Cu alloy, sharp proximal internal line angles
Amorim et al. (1978)	0	Metal dies, with and without proximal grooves
	0	Natural tooth, with grooves
	4	Natural tooth, without grooves
Alexander et al. (1980)	5	Conventional alloy
	3	High-Cu alloy

Also PEM studies have shown that rounding the pulpoaxial line angle makes very little difference as far as stress magnitude is concerned. It is possible that the rounding does not create an effect per se, since the procedure simultaneously provides for a slight increase in the restoration thickness (Haskins et al., 1954).

Tensile stresses develop on the occlusal surface upon two-point loading on the tooth and the restoration marginal ridge (Mahler, 1958). Mahler observed 25% lower tensile stresses on the occlusal surface when the line angle was beveled, but suggested that this result was probably more due to restoration bulk than the angle per se. Mahler also stated that the stress concentration at the line angle was not significantly deleterious. On the other hand, Holliger (1958) suggested that sharp axiopulpal line angle induce detrimental stress concentrations in the restoration along the axial wall.

Granath (1964a) found that two-point loading on the tooth and restoration marginal ridge gave lower tensile stress on the occlusal surface when the line angle was rounded compared to square, while one point loading over the axial wall resulted in higher compressive stresses at the inner vertical border of the proximal portion. Fracture inducing tensile stresses were also readily introduced when the line angle is irregular (Granath, 1964c).

Craig et al. (1967) stated that the stress concentration and development of stress is reduced with a rounded axiopulpal line angle compared to a sharp angle. Granath & Edlund (1968) showed that a sharp axiopulpal line angle causes excessive tensile and compressive stresses, but only when loaded on the marginal ridge towards the line angle.

In general, the results are conflicting. Furthermore, it is possible that all these results are irrelevant, since in all these studies the loading was vertically, which do not resemble the true clinical situation.

Pulpal floor

By rounding the pulpal floor, Lampshire (1950) observed that the number of loading cycles before the restoration fractured was increased. The increased number of loading cycles depended on whether other features of the cavity design were also implemented (Table I.14). The highest increase was obtained in wide cavities when these were made with a sharp axiopulpal line angle and included proximal grooves.

Table I.14. Relative increase (%) in loading cycles required to fracture restorations placed in cavities with with rounded pulpal floor compared to with flat pulpal floor reported by Lampshire (1950).

<u>Characteristics</u>	<u>Narrow</u>	<u>Wide</u>	<u>Additional features</u>
Round line angle	133	136	No proximal grooves
	100	308	Gingival groove
	105	459	Proximal grooves
Sharp line angle	236	163	No proximal grooves
	141	415	Gingival groove
	115	516	Proximal grooves

Although Lampshire (1950) identified a relative large gain in strength in restorations with a rounded pulpal floor, this gain was not reflected in subsequent studies using the compressive loading method:

Table I.15. The gain in fracture strength (%) of restorations placed in cavities with rounded versus flat pulpal floors.

<u>Investigators</u>	<u>Gain</u>	<u>Characteristics</u>
Mahler et al. (1961)	13	Premolars, flat pulpal wall, with grooves
	3	Brass die "
	4	Densite model "
	40	Premolars, flat pulpal wall, without grooves
	8	Brass die "
	12	Densite model "
Amorim et al. (1978)	1	Metal dies, with and without grooves angles
	6	Natural tooth, with grooves
	7	Natural tooth, without grooves

Several PEM studies have concluded that rounded pulpal floor reduce the stress in the restoration, probably due to a greater thickness of the tooth filling material and a better distribution of stress at a point where it is needed (Haskins et al., 1954; Guard et al., 1958). Mahler (1958) reported that when the pulpal wall was sloping, 20% lower tensile stress on the occlusal surface develops. Granath (1968) also advocated a rounded pulpal floor, as he felt that it was more suited than a flat one with respect to the pulpal support of the restoration. However, this last conclusion is not supported by any results from FEM studies (de Vree et al., 1983).

Axial wall morphology

The possible effect of the morphology of the axial walls on restoration bulk fractures was addressed in a PEM study by Mahler (1958). The investigator observed that restorations placed in cavities with a sloping axial wall and flat pulpal wall, developed 30% lower tensile stress on the occlusal surface upon two-point loading compared to a vertical axial wall. It was also observed that the tensile stresses on the occlusal surface increased with an increasing distance from the axial wall. Mahler suggested that the clinical implications of this finding were that the isthmus, defined as the narrowest width occlusally, should be as close to the axial wall as possible (Mahler, 1958).

Internal line angles

MO restorations in metal dies with square internal line angles had the same fracture resistance to vertical forces compared to when the line angles were rounded. This was also apparent when proximal grooves were added and when the loading location was changed (Mondelli et al., 74)

Gingival wall morphology

Two PEM studies have shown that when restorations placed in cavities with a sloping gingival floor developed higher compressive stress at the axiopulpal line angle and along the pulpal wall compared to a flat gingival wall (Holliger, 1958; Granath, 1964a). These results were made after one point loading over the axial wall. Upon two-point loading, restorations in cavities with a locked gingival wall developed more tensile stress than when the walls were flat or sloping.

Non-conventional cavity designs

Proximal box preparations versus conventional designs

Some clinicians have advocated proximal box preparation, i.e., without the occlusal extension, to avoid removing hard tissue occlusally. Early studies by Crockett et al. (1975) compared the displacement forces needed to remove the restorations. The vertical forces were comparable, and even higher (12%) when the proximal box cavities included grooves. However, the horizontal forces were lower (75% when no grooves were included and 22% when grooves were included).

One recent report, using the compressive loading method, has shown favorable results of proximal box restorations (Sturdevant et al. 1987). The investigators showed that the fracture strengths were higher for the proximal box restorations compared to conventional type restorations, when loaded with a 10 ° force on the isthmus. The fracture strengths were 25-40% higher depending on whether grooves were included or not. However, these results are in contrast to a study by Staninec (1989), who found significantly lower

values for proximal box restorations compared to conventional restorations when using a 45° loading on the isthmus (83% lower when grooves were not included, 48% lower when proximal box cavities included grooves). Clearly, the loading angle influence the results, but whether a 10 or a 45 degree angle upon loading represent the in vivo situation is not known.

In the proximal box preparations, the presence or absence of proximal grooves is the single most important cavity design factor for resisting fracture and/or loosening of the restoration, due to horizontal forces. The resistance to vertical forces is almost similar in restorations with or without grooves. Crockett et al. (1975) observed an increase of 9%, while Sturdevant et al. (1987) observed 2% increase upon 10° loading on the isthmus. However, when the loading was horizontal, Crockett et al. (1975) reported a dramatic increase of strength (8730%), while Staninec (1989) observed an increase of 203%, upon 45° loading on the isthmus.

Tunnel preparations versus conventional designs

Two studies have compared fracture strengths of the marginal ridge after tunnel preparation and restoration with amalgam. Conflicting results were obtained. Hill & Halaseh (1988) concluded that amalgam placed in a tunnel preparation did not reinforce the marginal ridge compared to a prepared but unfilled tooth. On the other hand, Covey et al. (1989) concluded that amalgam placed in a tunnel preparation reinforced the marginal ridge compared to a prepared/unfilled tooth, and even paralleled the strength of an unprepared tooth. The illustrations in the two articles showed slightly different cavity outlines. The cavity design in Hill & Halaseh's study was obliquely oriented from the occlusal surface, with parallel walls. Covey et al.'s cavities had a more triangular form with parallel axial walls, a tangential pulpal wall and an oblique occlusal wall. The cavities also looked larger. Although both studies reported almost similar fracture strengths (59 kg and 65 kg) the methodological differences of the loading procedures make further comparisons difficult. It is, therefore, not clear from these in vitro studies whether it is advisable to combine tunnel preparations with amalgam for mechanical reasons. From a cariologic view, however, it has been suggested that these preparations should preferably be filled with glass ionomer cement (Hill & Halaseh, 1988).

Margin fracture and features of the cavity design

Relatively few in vitro studies have addressed the relationship between margin fractures and specific features of the cavity design. The cavity features in this context have been the width and depth of the cavity and the restoration size relative to the remaining dental tissue, and cavosurface margin smoothness.

Also acuteness of the occlusal cavosurface angle has been studied with respect to influence on margin fractures.

The smoothness of the cavosurface margin affects the adaptation of amalgam to the cavity walls (Grieve, 1971). In general, the adaptation to the cavity walls decreases when moving from the axial walls, via the line angles, to the gingival floor (Reich et al., 1987; Symons et al., 1987). However, Furthermore, these observations may have been confounded, since the initial adaptation of amalgam along the margins is primarily dependent on the condensation technique (Jørgensen & Herø, 1988), as well as the surface treatment of the newly condensed restoration (Jeffrey & Pitts, 1989). The effect of cavosurface angle smoothness on the adaptation of amalgam, as well as on the long term influence on margin fracturing remains, therefore, uncertain.

Granath & Hiltcher (1970) stated, on basis of combined PEM and strain measurements, that slightly converging occlusal axial walls tended to reduce the avulsive tensile stresses on the loaded edges, i.e., they suggested that margin fractures increased when the margins lacked lateral support. The lack of lateral support as an etiological factor in margin fractures was also suggested by Derand (1977). Using FEM modeling, Derand (1977) suggested that stress in the restoration margins was induced by cusp deflection upon loading. Deep and wide cavity preparations induced more stress along the restoration margins, and thus more fracture during the first years of clinical service. Increasing the width of the cavity also created more stress in the restoration. Farah et al. (1977) reported a 200% higher compressive stress at the cavosurface enamel buccolingually in wide compared to a narrow restorations.

It is well known that the edge strength of amalgam is reduced when the margin angle decrease from 90 degrees (Jørgensen & Palbøl, 1965). FEM studies have shown that significant stress levels develop in wedge shaped regions of amalgam restorations at the occlusal margins when subjected to both setting and thermal expansion. It seems, therefore, evident that it should be advisable to design buccal and lingual cavity margins to have as obtuse an angle as possible (Wright & Yetttram, 1978). Another FEM study reported that a cavosurface angle of 90 °, and cavity walls built up step-wise resulted in lower concentrations of stresses, and by that in a decrease in the likelihood of breakdown of the margins of amalgam restorations (de Vree et al., 1984).

In a study of 134 extracted teeth with occlusal class 1 restorations two fracture types were identified, fracture with and without excess material. Margin fractures prevailed at intersections between restoration margins and fissures, and these were primarily of the excess type (Jørgensen & Wakumoto, 1968).

Tooth fractures and features of the cavity design

The mechanism causing tooth fractures remain unsolved. Different theories prevail, which is reflected by the methods employed to investigate the problem. Apparently, stress concentrate in the dental tissues when the width of a cavity increases (Mahler, 1958). Thus, one logical theory is that a reduction of the strength of the remaining tooth induce cusp fractures. Several studies have, therefore, focussed on the fracture strength of unrestored prepared teeth upon compressive loading.

Table I.16. The strengths of unrestored teeth with large cavities compared to teeth with small cavities. Fracture strength presented as fractions of strength of the smaller cavities.

Investigators	Fraction	Characteristics
Vale (1956)	.66	MOD, 1/3 compared to width 1/4
Mondelli et al. (1980)	.71	MOD, 1/3 compared to width 1/4
Mondelli et al. (1980)	.59	MOD, 1/2 compared to width 1/4
Larson et al. (1981)	.65	MOD, 1/3 compared to width 1/4
Blaser et al. (1983)	.76	MOD, deep, wide compared to narrow
Blaser et al. (1983)	.89	MOD, shallow, wide compared to narrow
Blaser et al. (1983)	.79	MOD, narrow, deep compared to shallow
	.69	MOD, wide, deep compared to shallow
Mondelli et al. (1980)	.58	MO, 1/3 compared to width 1/4
Mondelli et al. (1980)	.52	MO, 1/2 compared to width 1/4
Mondelli et al. (1980)	.74	MOD compared to MO/DO, Width 1/4
	.89	MOD compared to MO/DO, Width 1/3
	.84	MOD compared to MO/DO, Width 1/2

In general, the studies show that increased tissue removal decrease the fracture strength, as long as the tooth is not restored. However, the tooth filling material influences the fracture strength of the restored tooth (Morin et al., 1984). Unfortunately, it is methodologically difficult to restrict the measurements of compressive fracture strengths to only the tooth independently from the tooth filling material effect in restored teeth.

Studies using impact loading confirm the reduction of fracture strength of MOD-restored teeth compared to sound teeth (Salis et al., 1987a, 1987b). However, there are no impact load studies that have addressed the fracture strength of teeth restored with other classes of amalgam restorations.

PEM studies have shown that sharp and rounded line angles concentrated the stress in the tooth by a factor of respectively 1.2 and 1.05 relative to the stress along a flat pulpal floor (Noonan, 1949). Such differences have also been reported in other PEM studies, although the actual stress values were

not calculated (Mahler, 1958; Schreiber & Motsch, 1968). However, the clinical implication of this observation is inconclusive. One study, using the compressive loading method, has shown that teeth with conservative MOD preparation with sharp internal line angles have the same fracture strength as with rounded internal line angles (Eakle & Braly, 1985).

Peters (1981) suggested from FEM studies that the degree of convergence of the axial walls did not influence the distribution of stresses in restored teeth, provided that acute angles were avoided. This FEM study showed that the degree of adaptation of a tooth filling material to the tooth structures is the most important factor with respect to force distribution. Thus, it was suggested that the cavity geometry is of less importance as long as optimal adaptation is achieved (Peters, 1981).

One theory is that cusp fractures are the final outcome of structural fatigue caused by continuous intermittent deflections of the buccal and lingual cusps (Bell, Smith & Dupont, 1982). A theoretical model compares the extent of the deflection with the movement of a fixed cantilever beam (Hood, 1991). In this model, cusp deflections depend on the cavity depth and wall thickness, as well as the modulus of elasticity and moment of inertia of the dental tissues (Hood, 1991). It has also been suggested that the resistance to cusp deflections may be influenced by inappropriate cavity preparation, which may induce structural damage along the internal line angles of the cavity. A further consequence of the structural damage is that the threshold against fatigue fracture may be decreased (Bell et al., 1982). Thus, the theory assumes that the risk for fractures correlates with the extent of the deflection of the tooth cusps.

Deflection of cusps and features of the cavity design

Different studies report deflection of the cusps as a function of the cavity design. The cusp deflections may occur during different stages of amalgam therapy, and will be discussed accordingly.

During the matrix band placement

Hood (1973) observed that the tightening of a matrix band causes an inward movement of the cusps. For extended MODs the displacement was up to 40-65 μm , and up to 100-120 μm following pulpotomy. The ratio of the cusp deflection of teeth with extended MODs compared to minimal MODs was 2.2:1. Almost identical results were obtained by Powell et al. (1977). These investigators reported that a matrix band placed around a lower 2. molar with a MOD cavity width of 3.3 mm displaced the cusps twice as much as when the width was 1.5 mm. The maximum deflection of the cusps was approximately 25 $\mu\text{m}/\text{cm}$. A later study by the same investigators showed that a matrix band around a lower molar with a MOD cavity width of 4 mm

displaced the cusps five times more as when the width was 2.1 mm. The maximum deflection of the cusps was measured to be approximately 18 μm or 46 $\mu\text{m}/\text{cm}$ (Powell et al., 1980)

A subsequent study has shown that the deformation of cusps by a matrix is directly proportional to the thickness of the cavity walls and the depth of the cavity (Krainau et al., 1987). In this study, the maximum deflection of the cusps was approximately 4 μm or 15 $\mu\text{m}/\text{cm}$.

During condensation and/or due to volume changes during setting

One study, using external strain transducers, reported that the amount of cusp deflections recorded during and after the various stages of amalgam therapy is proportional to the volume of amalgam within the cavity (Assif et al., 1990).

Upon loading of the restoration

Grimaldi & Hood (1973) compared the cusp deflection in unrestored teeth with MO and minimal and extended MOD cavities. The deflections were approximately in the ratios 1:1.2 (MO:min. MOD) and 1:1.6 (MO:ext MOD). When the minimal MOD cavities were compared to extended MOD cavities the cusp deflections were approximately in the ratio 1:1.3. The maximum deflections for the MO restorations were 20 μm , for the minimum MODs 24 μm and 32 μm for the extensive MODs when 360 N vertical static loading was applied.

Granath & Möller (1975) reported that in an unrestored tooth with a MOD cavity, deepening and rounding the pulpal wall increased the deflection of the cusps by 50%. The maximum deflection was 21 μm , when 20 N horizontal static loading was applied.

Also a widening of the cavity as a secondary result of cusp deflections has been measured. Jørgensen et al. (1976) compared the widening of unrestored teeth with MO and MOD cavities, measured after occlusal loading with a brass rod. The widening ratio was approximately 1:1.7. If an additional class 5 restoration was placed in the tooth with the MOD cavity, the ratio increased to approximately 1:3. The maximum buccolingual widening was 15 μm at 190 N vertical static loading.

The deflection of cusps has recently received much attention after a study reported that the deflection of the cusps could be influenced by the mechanical and binding properties of the tooth filling materials (Morin et al. 1984). In addition to this finding, the investigators reported that as tooth structure was removed, the relative deformation of the unrestored tooth increased, when 74 N/s vertical loading and 3 seconds loading cycles were applied (Morin et al., 1984). Using the same method, Douglas (1985) reported that teeth with MOD restorations with 1/4, 1/3 and 1/2 widths have a coronal rigidity that is approximately .8, .6 and .2 of the sound tooth when using a first

molar, and .5 .5 and .4 when using a second molar. The same study group showed that increasingly larger cavity preparation reduce the rigidity of unrestored teeth with a marked reduction occurring when the width increases more than 1/3 width (Morin et al., 1988a). These data were also supported by FEM calculations (Morin et al., 1988b).

The effect of converging walls and a semi-circular pulpal floor on cusp deflections are uncertain. One PEM study showed that less bending stresses were produced upon cusp loading compared to in a tooth with converging or with parallel walls, a flat pulpal floor and rounded internal line angles (Granath, 1963b). The investigator suggested that in with the present experimental setup, the dentin thickness over the pulp chamber could have influenced the results (Granath, 1963b). Also three-dimensional FEM analyses indicated that teeth with a wide and deep cavity not only demonstrated higher compressive stress along the buccal and lingual cavity walls, but also tensile instead of compressive stress in the middle of the pulpal floor (Khera et al., 1988). Schreiber & Motsch (1968) also observed that the stresses at the internal line angles increased when the depth increased, i.e., when the distance between the cavity and the pulp decreased. However, the actual stress values were not calculated. However, a recent study using strain gauge measurements failed to identify other features of the cavity design besides cavity volume as significant. Using unrestored teeth with 6 different conservative MOD cavity designs, the cusp deflections varied between 2.1 - 3.5 μm , at 20 N horizontal static loading (Granath & Svensson, 1991).

Pulp complications and features of the cavity design

Pulp sensitivity may be caused by stress along the restoration/tooth interface (Robinson, 1966). This study, based on PEM, showed that stresses of a high order in the tooth are much more likely to arise because of wedging effects from dental restorations than from direct thrust. The wedging effect increases with increasing cavity width, due to the cusp deflections. Although this study focussed on the effect of gold inlays, the results are also clinically relevant to amalgam restorations (Robinson, 1966). The only other in vitro study that have addressed cavity design to pulp complications was presented by Farah et al. (1974). These investigators reported that for certain combinations of load, condenser size and cavity dimensions, the tensile strength of the dentin in the cavity floor could be exceeded followed by a failure of the cavity floor (Farah et al., 1974).

Loss of restoration and features of the cavity design

Only one in vitro study have focussed on loss of retention as a function of

cavity design Bouschor & Martin (1976). The investigators reported that the tensile strength needed to dislodge restorations is not achievable in an oral environment. Bouschor & Martin (1976) suggested, therefore, that grooves in the proximal parts of the cavities were not needed to obtain additional retention of the restoration. Furthermore, they strongly advised to avoid placing grooves, since they believed the procedure could endanger the risk of pulp exposure.

Corrosion, degradation and features of the cavity design

The homogeneity and surface hardness of the restoration are among many factors that influence the resistance towards corrosion and degradation of amalgam in the oral environment. Two studies have related these aspects to features of the cavity design. Stachniss et al. (1977) reported that the amalgam placed in cavities with acute external axiokingival line angles had lower surface hardness and more porosities in the acute angles. Winkler (1971), on the other hand, reported that the surface hardness of amalgam restorations is independent of the cavity design.

Proximal margin discrepancies and features of the cavity design

The restoration margin along the gingival margin is stressed upon vertical loading on the occlusal surface. The stress concentrates on the gingival walls, and varies with the design of the gingivoaxial line angles. One FEM study showed that a rounded gingivoaxial line angle may reduce the stress concentration factor up to 50% (El-Ebrashi et al., 1969a), compared to an acute line angle. Similar reductions in stress concentrations were observed in another FEM study, where a chamfered gingivoaxial line angle exhibited the least amount of axial, radial and shear stress at the margin, followed by the shoulder and the chisel edge geometry (Farah et al., 1974). Also a sloping axial wall influenced the stress concentrations, with a slight increase from 0-15°, and a sharp increase at 20° (El-Ebrashi et al., 1969b).

The clinical implication of the frequent development of stress along the gingival restoration margin on the short and long term restoration performance is unknown. It was previously believed that amalgam could "flow" out of the cavity gingivally in the proximal part, due to the materials's plasticity. One early PEM study reported that restorations placed in cavities with a sloping gingival floor were forced out of the cavities (Holliger, 1958). The consequence of this theory was that proximal grooves were advocated in textbooks in operative dentistry to deter overhanging proximal margins (Markley, 1951; Moore, 1992). However, several studies failed to establish any effect of proximal grooves on proximal extrusion upon loading. Johnson (1972) showed that plastic dies with

MO restorations with and without grooves showed no differences in proximal extrusion after 500 g loading and 200 000 impact cycles. The same results were reported by Galan et al. (1973), who used steel dies with MOD restorations with and without grooves. These investigators concluded also that beveling of the proximal cavosurface margin did not influence proximal extrusion. Today, it is generally accepted that creep is an inherent property of the material, and is not an effect of external mechanical factors (Mahler et al., 1973). Another possible consequence of high stress levels along the gingival margins is the enhancement of stress corrosion, with subsequent material loss and increased risk for secondary caries.

Moreover, if a tooth filling material has a low modulus of elasticity, the gingival margins of MOD restorations may be deflected horizontally upon occlusal loading. Amalgam has a relatively high modulus of elasticity. The gingival margins of amalgam restorations are, therefore, not displaced, because the material fractures before high enough stresses are reached to deflect these margins. Alternative tooth filling materials, on the other hand, with lower elastic moduli may show horizontal deflection along the gingival margins, e.g., gold-alloys (Viohl & Zimmer, 1990) and composites (Forsten, 1989) if placed in cavities with rounded gingivoaxial line angles.

In a study of margin discrepancies of 1000 amalgam restorations in extracted teeth, Wöstmann & Lötke-Notarp (1991) reported that the incidence and the mean size of margin gaps were comparable on the mesial and distal surfaces.

In vivo studies

The present body of knowledge on the clinical performance of dental materials indicates that there is a poor correlation between in vitro and in vivo findings (Wilson, 1990; Tyas, 1991). Furthermore, there is a lack of knowledge on the influence of the many dependent and independent variables on the clinical performance of restorations, e.g., the operator, the operative techniques and instrument used, the material, the location, type, size, initial quality and short term clinical performance of the restoration, and patient factors (Jacobsen, 1988). This is particularly true for the association between clinical performance of class 2 amalgam restorations and the effects of variables of the prepared cavity on the efficacy of the restoration (Jokstad & Mjör, 1987).

The aim of the following review is to present the methodologies and the results from in vivo studies that have focussed on the association between the clinical performance of class 2 amalgam restorations and the cavity design.

The paper is limited to studies on class 2 cavities for amalgam, and to publications after 1960. All references in the text to cavities and restorations are, therefore, restricted to class 2 cavities and amalgam restorations, although the terms "class 2" and "amalgam" are not used repeatedly in the text. The relevant cavity or restoration class is included in the text only when references are made to studies where other cavity classes or different materials have been used.

Summary of methods

Research methodologies

The design of clinical research projects may be classified as experimental or observational. Only studies with experimental designs can be considered as a correct inductive method, i.e., can prove any cause-effect relationships between different factors or variables. Certain requirements must be fulfilled to qualify as an experimental study. These are: the presence of control groups, a random allocation of variables, and standardized evaluation procedures and criteria. A specific aim of the study and the formulation of a hypothesis should be made prior to the study. When these criteria are not met, or observations are made of phenomena that are not manipulated by the investigator, a clinical study should be classified as observational (Hendriks, 1985).

Few *in vivo* studies in restorative dentistry focussed on clinical performance of class 2 amalgam restorations fulfil the criteria to qualify as experimentally designed (Jacobsen, 1984). This is especially apparent with regard to possible influences of features of the prepared cavity on the long term clinical performance of restorations (Table 1.17).

Table I.17. Experimental longitudinal clinical studies where aspects of the cavity preparation have been associated with restoration discrepancies or failures.

Investigators	Purpose
General performance	
Nadal, Phillips & Swartz, 1961	Determine the influence of cavity design on the incidence of bulk and marginal fracture
MacRae, Zacherl & Castaldi, 1962	Determine whether an alteration in the cavity form would influence the incidence of restoration defects in deciduous and permanent molars in children
Thomas, 1983	Develop cavity designs with maximum conservation of tooth structure and minimal proximal extension
Sturdevant et al., 1988	Test clinically 3 conservative cavity designs
Restoration fractures	
Terkla & Mahler, 1967	Determine if retentive grooves influenced the incidence of bulk fractures in mandibular second premolars
Terkla et al., 1973	Determine if retentive grooves influenced the incidence of bulk fractures and proximal extrusion of restoration margins in premolars and molars
Margin fractures	
Mathewson, Retzlaff et al. 1973,74	Evaluate the effect of alloy, retentive grooves and dentist variability on margin fracture in primary teeth
Advokaat et al., 1979,1980,1981	Study the influence of finishing and cavo-surface-angle on margin fracture
Goldberg et al., 1980	Examine the effect of operators, type of tooth, number of restored surfaces, and alloy on marginal deterioration
Leidal & Dahl, 1980	Assess the quality of two alloys after 4 years of service, and the influence of different finishing techniques
Adverse effects on the supportive tissues	
Fisher et al., 1984, Markitziu, 1987	Compare over 4 years the changes in the alveolar bone height adjacent to two dissimilar restorations

The majority of clinical studies containing information on the relationship between cavity design and restoration performance should be classified as observationally designed studies. This stringent classification is because although the studies were correctly designed experimentally to obtain information on differences between, e.g., dental materials or commercial products, the observations and descriptions of the influence of cavity design

features were not obtained by the manipulation of this variable in the original study designs.

The observational clinical studies focussed on the association between aspects of the cavity design and restoration performance can be categorized as prospective or retrospective longitudinal studies or cross-sectional studies. Retrospective studies are purely based on analyzing patient record data, or a combination of patient record data analyses and quality evaluations of restorations (Table I.18).

Table I.18. Observational longitudinal clinical studies where aspects of the cavity preparation have been correlated to restoration discrepancies or failures.

Investigators	Purpose
General performance	
Gray, 1976	Determine the failure rate of restorations placed in RAF personnel in UK
Hammer & Hotz, 1979	Establish the clinical state of restorations placed at a school clinic after 1-5 years
Crabb, 1981	Determine the cumulative failure rate of restorations placed in a dental school clinic in UK
Elderton, 1983	Determine the failure rate of restorations placed in the general dental service in UK
Paterson, 1984	Determine the failure rate of restorations placed in several general practices in UK
Meeuwissen, 1985	Determine the failure rate of restorations placed in military personnel in Holland
Hunter, 1985	Determine the failure rate of restorations placed in one general practice in Scotland
Smales & Fenton, 1985	Assess the effects of polishing on the clinical performance of a high-copper containing alloy
Ehrlich & Yaffe, 1987	Describe a conservative approach to amalgam and composite restorations of initial interproximal caries
Arthur, Cohen & Diehl, 1988	Estimate the survival of amalgam and composite restorations in a sample of military patients in USA.
Smales, 1991	Analyze material, preparation class, tooth type, patient age and operator effects on survival results and reasons for replacement of 5 alloys
Secondary caries	
Hals & Leth Simonsen, 1972	Assess the pathogenesis of secondary caries produced around amalgam restorations in vivo
Jahn, Becker & Zuhrt, 1986	Evaluate the effect of a liner on secondary caries incidence over 2 years

Otto & Rule, 1988	Determine the relationship between gingival margin depth and the frequency of recurrent caries at the gingival margin during a 2-year period.
Wundram et al., 1988	Assess the effect of caries prophylaxis over a 20 year period on restoration performance
Jahn, Hansche & Zurt, 1989	Assess and compare the secondary caries rate of amalgam and cast restorations after 2 years

Restoration fractures

Osborne, Binon & Gale, 1980	Evaluate alloys for marginal fracture at 5 years and bulk fracture at 8 years
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Margin fractures

Wilson & Ryge, 1963	Evaluate the relative importance of different manipulative technics in terms of clinical success of the restorations
Matsuda & Fusayama, 1970	Present progression of marginal fracture with an intraoral camera
Mjör & Espevik 1980	Evaluate the marginal degradation of two amalgams with different creep properties as a function of operator differences, differences in trituration time and selection of control teeth
Mahler & Marantz, 1980	Present evidence on the effects of tooth type, restoration class and size on the marginal fracture
Osborne & Gale, 1981	Evaluate the effects of alloy, tooth position and width of the preparation on marginal fracture
Berry et al., 1981	Determine whether marginal failure relates to the width of the restoration
Birtcil, Pelzner & Stark, 1981	Examine the effect of alloy type, finishing and size of the restoration on margin performance
Osborne & Gale, 1990	Evaluate effects of tooth position, restoration width and alloy brand on fracture at the margins of 13- and 14- year-old restorations
Laswell, et al., 1990	Determine the effect of tooth position and restoration width on marginal fracture

Adverse effects on the supportive tissues

Arneberg et al., 1980	Report how removal of margin overhangs affect the periodontium over 6 months
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Cross-sectional clinical studies have either been presented as replacement studies or the recording of other data from the patients' record charts. Other data on the association between restoration clinical performance and cavity design factors have been obtained from quality evaluations of restorations in situ or in extracted teeth, or detailed studies of failed restorations (Table I.19).

Table I.19. Cross-sectional clinical studies where aspects of the cavity preparation have been correlated to restoration discrepancies.

Investigators	Purpose
General performance	
Rytömaa et al., 1984	Determine the quality of fillings in 1 molars in 1 year dental students
Klausner et al., 1985	Assess the reasons for replacement of restorations by general practitioners
Klausner et al., 1987	Assess the reasons for replacement of restorations in a national survey
Secondary caries	
Budtz-Jørgensen, 1971	Compare the prevalence of secondary caries in restorations with sub- or supragingivally placed margins
Binus & Wehner, 1971	Relate secondary caries occurrence to dental materials and restoration age
Spens & Taatz, 1972	Determine if secondary caries is related to the cavity preparation or the handling of the material
Schnorr et al., 1976	Relate the rate of secondary caries to material, patient, an intra-oral location of the restorations
Eide & Birkeland, 1982	Establish the localization of secondary caries and marginal defects on restorations needing replacement
Mjör, 1985	Assess the frequency of secondary caries at various anatomical positions
Weiland et al., 1989	Analyse the causes for failures of amalgam restorations made from one specific amalgam alloy
Pütz et al., 1990	Examine the dental conditions and treatment requirements of 187 students
Restoration fractures	
Llewelyn, 1977	Assess the durability of amalgam restorations in deciduous molars
Margin fractures	
Elderton, 1975,1977a	Study the morphology of cavity and amalgam margins in vivo and define the characteristics that determine the quality of restorations as assessed subjectively by clinicians
Elderton, 1984	Measure and report CSA and AMA with respect to old and new amalgam restorations and relate the angles to the marginal integrity

Tooth fractures

Hiatt, 1973	Describe 100 cases of incomplete crown-root fractures
Snyder, 1976	Measure the incidence of cracked-tooth and fractured posterior cusps in a general practice
Bell, Smith & dePont, 1982	Examine 26 failed cusps by SEM to detect the failure etiology
Abou-Rass, 1983	Present information on 120 instances of symptomatic cracked teeth
Cavel, Kelsey & Blankenau, 1985	Evaluate factors involved in 118 cuspal fractures in a clinical survey
Hansen et al., 1990	Examine the cumulative survival rates of endodontically treated premolars and molars restored with MO/DO or MOD restorations and elucidate the fracture pattern of the fractured amalgam-restored teeth

Adverse effects on the supportive tissues

Larato, 1969	Determine whether cervical margin extension is associated with gingivitis
Gilmore & Sheiham, 1971	Assess the prevalence of overhangs, and test if these were associated with more periodontitis than sound teeth
Leon, 1976	Relate the location and marginal quality of proximal amalgam restorations to indices of periodontal disease
Grasso et al., 1979	Assess the technical quality of restorative care received in a population
Gullo & Powell, 1979	Observe the plaque accumulation and inflammation in tissue prior to and after placement of restorations with sub- or supra-gingivally located margins
Pack et al., 1990	Determine the prevalence of overhangs in two patients samples, and relate these to the periodontal status

Criteria for assessing clinical performance

Several indirect and direct methods for assessing the quality of restorations have been presented in the dental literature. However, most of these methods focus on specific features and less on the general qualitative state of the restoration. Methods have been developed for assessing the quality of the margins (Osborne et al., 1976; Mahler & Marantz, 1979; Borgmeyer et al., 1983; Bryant et al., 1985), and semi-quantitative extent of surface wear (Roberts & Söreholm 1989; Bryant, 1990), surface roughness (Smales & Creaven, 1979) and secondary caries (Tveit et al. 1991). Methods for scoring the quality of the proximal margins on bite-wing radiographs have been described by Hunkirchen (1968) and by van Amerongen & Eggink (1986). A digitized SEM analysis developed primarily for studies of composite restoration margins (Roulet, 1989), has also been applied to other types of dental materials.

When the direct standard clinical assessment of a restoration is substituted by more sophisticated methods, the aspects of restoration quality become more limited (Elderton, 1977b). A direct clinical assessment of the general qualitative state of the restorations is, therefore, usually preferred. Clinical assessments of restoration quality have been made using subjective evaluations, or according to evaluation systems with more or less concisely defined criteria. Reviews of several evaluation systems have been presented by Hammons et al. (1967), Ryge & Snyder (1973), and Elderton (1977b).

Discussion of methods

Two factors should be considered when evaluating the validity of data from clinical studies. The first factor is how the quality of the restorations were measured, i.e., directly or indirectly. Which evaluation criteria were used and, in case of replacements, were the criteria used for replacement valid? The second factor is related to the characteristic of the research methodology. Only an experimentally designed study may prove a causal relationship between independent and dependent variables. All other methods show limitations through bias or confounding. On the other hand, the data from studies that are not fully controlled are not necessarily invalid. All experimentally designed studies are performed on basis of clinical data obtained in studies with observational designs.

A frequent problem with many survival studies is that little or no information is available on the replacement reasons due to their often retrospective design. Several studies have shown that replacements are not necessarily always due to restoration failures (Anusavice, 1989), and even if they are restoration failures, the retrospective data offer no indications if these failures are related directly to the restoration, to the restorative process or to external factors (Letzel, 1989). In replacement studies, the previous history and age of the restorations is often unknown. Although the dental material is recognized, specific trade names or batch numbers are seldomly recorded. A characteristic of the study method is that the evaluation criteria are not explicit, which leaves the diagnoses to the operators involved in the study. The results do not indicate any causal relationships, and they are probably influenced by factors such as socioeconomy, patient demography and the dentist: patient ratio. The same arguments are applicable when interpreting results from quality evaluation studies of restorations. Although the evaluation criteria often are accurately described, the previous history and the clinical parameters at the time of restoration placement are unknown.

It is difficult to conduct experimentally designed prospective clinical studies, with the aim to establish a numerical relationship between the cavity

morphology and the restoration service period or replacement reasons. The main reason is that the prognosis of a restoration is dependent on many known and unknown clinical parameters that in practice are difficult to control or record. It is also difficult, if not impossible, to assure an independence among the many clinical variables that affect the restoration prognosis. Such studies also require long observation periods due to the excellent physical and mechanical properties of present-day tooth filling materials. Long observation periods are associated with problems such as patient drop-outs, patient representativity and changes in the clinician's diagnostic abilities or perception of replacement criteria. Finally, apparent research-ethical reasons restrict the possibilities to conduct experimental designed prospective clinical studies.

Summary and discussion of results

General performance and cavity design features

Experimental clinical design

MacRae et al. (1962) observed 1009 restorations in deciduous molars over 4 years. Approximately 50% of the restorations were placed in cavities with rounded and 50% in cavities with flat pulpal floors. The clinical performance of the restorations was not influenced by the morphology of the pulpal floor.

Thomas (1983) compared 100 contra-lateral Black designed (control) and under-extended (experimental) pairs of restorations. The restorations had been inserted in the mid-sixties. No secondary caries had developed either in the experimental or the control restorations after 4 years, and there were no differences between the two groups of restorations regarding other types of failures.

Sturdevant et al. (1988) reported on a clinical study using three different cavity designs, conventional conservative, proximal-box, and proximal-box with grooves. Of 44 proximal-box restorations, 6 had been displaced after 1 year. The investigators concluded that when proximal-box designs are utilized, full length retention grooves should be used to provide adequate retention.

Observational clinical design

Longitudinal

Gray (1976) reported in a study of 513 RAF servicemen that MO and DO restorations had a 50% survival rate at 10 years, while MOD restorations had a 50% survival rate at 8 years. Other investigators find no statistical differences between two- and three-surface restorations (Crabb, 1981; Elderton, 1983; Paterson, 1984). Meeuwissen (1983) reported that the differences in survival between two- and three-surfaced restorations may

depend on the intra-oral location of the restorations.

Hunter (1985) reported that MOD restorations had a longer survival time than the smaller restorations. However, it was pointed out that this result was due to a lower conversion rate of MOD restorations compared to the smaller restorations, for which conversion to larger restorations was the most important replacement reason. After correcting for this factor, no differences in survival rate between MO/DO and MOD restorations were identified.

Arthur et al. (1988) reported an estimated 66% survival rate of two-surfaced versus 64% of three-or-more surface restorations at 22 years, i.e., no difference between restoration class. A latter study included more patients, but identical conclusions were reported (Arthur et al., 1989). A recent study from Australia have reported that the survival of amalgam restorations is not influenced by the tooth type or restorative class (Smales, 1991).

Cross-sectional

Mjör (1981) reintroduced a study format used previously by Healey & Phillips (1949) and Moss (1953) for recording reasons for replacing restorations. This format has subsequently been used frequently. The reason(s) for replacement and, if possible, the age of the failed restoration are recorded and related to other clinical characteristics. The possible influence of cavity design factors on replacement reasons has not been considered in detail in these studies, and assessments of this aspect has been limited to comparisons between restoration classes (Table I.19).

Rytömaa et al. (1984) compared the quality of 767 fillings in 16 and 46 in 186 students. In both teeth, the quality of the restoration was comparable on the mesial and distal surfaces.

Alternative cavity design

Ehrlich & Yaffe (1987) placed 154 amalgam and composite restorations in tunnel cavities. After 2.5 years, 6 margin ridges had fractured, of which 5 had fractured within 6 months. No other restoration failures developed during the 2.5 years. The investigators did not describe if the failed restorations were made from amalgam or composite.

Discussion

The early dental literature on operative dentistry is replete with review articles on how to prepare ideal cavities and suggestions for handling of amalgam. These articles were mostly anecdotal, and were seldom supported by clinical data. In general, the articles described amalgam as a near-ideal tooth filling material, and that restoration failures occurred mainly due to operator faults.

One of the first reports relating restoration defects to aspects of the cavity

preparation was presented by Sweeney (1940). He observed "raising of the margins" on the proximal part of the restoration, and associated this discrepancy to lack of retention grooves in the proximal parts. In a study of 1521 defective amalgam restorations Healey & Phillips (1949) attributed only 2% of the failures to failure of the material per se. These two studies, as well as several other studies of the period suggested that careless material handling and deviations from the ideal (Black) cavity designs were common reasons for restoration discrepancies and failures (Easton, 1941; Roper, 1947; Moss, 1953; Wolcott, 1958). However, the hypotheses were not supported by the first controlled clinical studies, which appeared some years later (Nadal et al., 1961; MacRae et al., 1962; Wilson & Ryge, 1963). Further advances in dental materials research during the next years revealed that at least some of the restoration failures could be related to the physical and mechanical properties of amalgam per se (Jørgensen, 1965; Terkla & Mahler, 1967; Wing, 1971; Mahler, 1972; Taylor, 1973).

On the other hand, the hypothesis that restorations placed in a cavities prepared according to Black's class 2 design result in optimal quality and long clinical service periods, has never seriously been challenged. Although several more radical designs have appeared in the literature (Hunter & Hunter, 1989), data are limited on the clinical performance of restorations placed in these alternative cavity designs.

In restoration survival studies, the only association to the cavity design is to comparisons between two- versus three-surfaced restorations, and the data are inconclusive (Table I.18).

Secondary caries

Observational design

Longitudinal

In a Swiss study, 459 amalgam restorations, including 340 class 2 restorations, were placed in a dental school clinic and evaluated after a period varying between 1 and 5 years. Secondary caries prevailed when the margins were placed subgingivally compared to supra-gingivally placed margins (Hammer & Hotz, 1979).

Otto & Rule (1988) examined bite-wing radiographs of 375 restorations over 2 years. The restorations were categorized according to the axiokingival location of the gingival margin relative to the contact area of the adjacent tooth. The restorations with gingival margins ending occlusally to the contact area had significantly higher caries rates after 2 years. The investigators suggested that the additional length of the restoration margin was not as critical a factor as the clearing of the contact area of the adjacent tooth was.

In a recent study from Scotland, class 1 restorations in first permanent

molars of more than 2000 children aged 12 at baseline were observed over 3 years. One of the conclusions from this study was that secondary caries on the occlusal surface was more likely to develop if the margins of the filling crossed the fissures, rather than along the cusp inclines (Smith, 1990).

Cross-sectional

Budtz-Jørgensen (1971) compared the secondary caries prevalence on 341 class 5 restorations with sub- and supragingivally placed margins. The lowest rate was found when the margins were located subgingivally.

In an East-German study of 4360 restorations, the prevalence of secondary caries was lower in large compared to smaller restorations (Spens & Taatz, 1972). However, in this study, the restoration sizes were measured in square millimeters, and the axiokingival location of the margins was not described.

Another East-German study reported that secondary caries occurred more frequently occlusally. However, in this study bite-wing radiographs were not used (Schnorr et al., 1976).

Eide & Birkeland (1982) observed that in a Norwegian data-material, secondary caries prevailed along the gingival margin (60%) compared to in the line angles (19%). However, the investigators did not describe if and how this was recorded on bite-wing radiographs and clinically.

Also Mjör (1985) reported that secondary caries occurred more frequently along the gingival margin compared to other areas of the restoration margin.

In a North-American study, Klausner et al., (1987) observed that secondary caries occurred more frequently at the axiokingival line angle, followed by along the gingival margin.

Wundram et al. (1988) reported the incidence of secondary caries in Swiss children observed in epidemiological surveys from 1968/72 and 1980/84. The data showed that the incidences of secondary caries were comparable for the mesial and distal surfaces on proximal teeth.

Weiland, Nossek & Schulz (1989) categorized 441 failed restorations due to secondary caries into two groups. 58% of the cases were categorized as preparation faults, 52% to material failure. The investigators defined the preparation faults as lack of full extension of the fissures occlusally, and lack of extension into the embrasures proximally. Unfortunately, further descriptions of these "preparation faults" were omitted in the report.

A higher prevalence of secondary caries in MOD compared to DO and MO restorations has been reported in several East-German epidemiological studies (Binus & Wehner, 1971; Jahn et al., 1986, 1989). Pütz, Taege & Binus (1990) reported that 6% of all two-surfaced and 10% of all three-surfaced restorations showed secondary caries in a patient sample consisting of 187 students.

Discussion

It has been known for a long time that secondary caries develop mainly at the gingivoaxial line angles (Johnson, 1901; Darby, 1901). Several factors may explain this phenomenon. Black (1913) advised to square out the angles instead of straight axial and curved gingival walls, to obtain a better adaptation at the line angles. Pichler & Petrik (1930) believed that the predilection site was due to a faster retraction of the gingiva at these locations, and thus the loss of "the protective effect" of the gingiva. Sellmann (1944) attributed the failure to poor operator performance, in accordance with the prevailing view of the period. Similar views were expressed by Motsch (1968), who suggested that remaining demineralized enamel at these points was a common occurrence at the cavity preparation stage. Mjör & Smith (1984) suggested that caries often develop in these locations due to poor condensation of amalgam into the corners.

Black suggested in 1908 that the cavity outlines should be extended beyond the actual caries area as a method for preventing secondary caries, by having the cavosurface margins in "self-cleansing" areas. The impact of this principle is reflected in a study from 1949, where Healey & Phillips reported that 97% of 813 restorations with secondary caries developed because the "no extension for prevention" principle had been used. Even today, the procedure of placing the margin subgingivally is advocated in some textbooks in operative dentistry. The rationale of the procedure is presented in one of these textbooks (Marzouk et al. 1985): "... (1) the alkalinity of the crevicular fluid can neutralize, to some extent, acids produced from plaque activity and (2) the knife-edge relationship of the healthy free gingiva to the adjacent tooth surface will discourage food accumulation on adjacent restored surfaces occlusal to the sulcus for considerable periods during and after food ingestion... ". There are, to the author's knowledge, no scientific basis for the two hypotheses.

The procedure of extending the cavity margin gingivally is highly controversial both for cariologic and a periodontic reasons. It is therefore surprising that so few clinical studies have addressed the reality of the so-called "immune area", or "relative immune area", or "self-cleansing area", or "area of liability" (for reviews, see Mannerberg, 1969; Steffensen, 1983; Rieth, 1987).

It is uncertain how the different prevalences of secondary caries in the observational studies are influenced by the patient samples, diagnostic techniques or material related factors. In addition, it should be remembered that secondary caries is an ill defined term in the clinic (Kidd, 1989). The frequencies may, therefore, also reflect the prevalence of voids and crevices along the margin where the probe may catch (Söderholm et al., 1989; Maryniuk & Brunsen, 1989; Espelid & Tveit, 1991).

Restoration bulk fractures

Experimental design

One clinical study compared 237 restorations placed in deep and wide cavities with 64 high-mercury containing restorations and placed in narrow and shallow cavities. One bulk fracture occurred in the large cavity group, while 7 occurred in the small cavities with the different amalgam composition. Five of the fractures were seen after 1 week. Consequently, all the bulk fractures were attributed to traumatic occlusion (Nadal et al. 1961).

Two studies concluded that the presence of proximal grooves did not have any effect on the incidence of bulk fractures of 422 restorations over 2 years (Terkla et al., 1973), and on 136 restorations over 5 years (Terkla & Mahler, 1967).

Observational design

Longitudinal

One study has assessed the clinical quality of initially 113 restorations after 8 years (Osborne et al., 1980). The investigators concluded that the prevalence of bulk fractures could possibly have been influenced by the cavity design. However, they believed that this effect was minor compared to the alloys used (Osborne et al., 1980). Smales & Fenton (1985) reported data from a 3-year clinical study. Four of initially 63 pairs of restorations displayed bulk fractures, and all had been placed in cavities with very narrow occlusal sections.

Cross-sectional

Among 230 restorations placed in deciduous molars and in service between 0 and 60 months, a higher prevalence of bulk fractures was seen in DO compared to MO restorations (Llewelyn, 1977).

Klausner et al., (1985) recorded the reasons for replacements of restorations. Forty-three percent of restorations with bulk fractures were 10 years of age or older, while 80% were older than 4 years. Klausner et al. (1985) commented that if faulty occlusion or thin pulpal-occlusal section of amalgam were the principle reasons for isthmus fracture, then these fractures should have become evident at an earlier time.

Discussion

Although it is assumed that the prevalence of restoration fractures are related to restoration bulk, no clinical studies have documented such relationship. In a study of 398 bulk fractured restorations, Healey & Phillips (1949) reported that only 17% were due to insufficient bulk occlusally. The investigators explained the lack of correlation and the high prevalence of fractures among the bulky restorations to "faulty manipulation" of amalgam. However, their

suggestions were impossible to verify, since the study was purely observational, and no previous data on the placements or the history of the fractured restorations were available.

Margin fractures

Experimental design

The presence of retention grooves on the proximal surface did not influence the incidence of margin fractures in deciduous molars. This conclusion was reached after observing 91 restorations for 1 year (Mathewson et al., 1973), and 101 restorations for 2 years (Mathewson et al., 1974).

The effect of several variables, including the cavo-surface-angle (CSA) and margin finishing, on margin fracture was studied by a Dutch group on initially 480 restorations over several years. After 1 year, the influence of the CSA was significant, but finishing of the margin was not (Advokaat et al., 1979). Restorations with $CSA > 90^\circ$ showed more fracture than restorations with $CSA = 90^\circ$. These observations were also made after 2 years (Advokaat et al., 1980) and 3 years (Akerboom et al., 1981). However, the possible effects of the CSA and margin finishing on margin fracture were omitted when the study had progressed to 8 years (Akerboom et al., 1986).

Nadal et al. (1961) compared 237 restorations placed in deep and wide cavities with 64 high-mercury containing restorations placed in narrow and shallow cavities. After 1 year, margin fractures were seen in 40% of the restorations placed in the small cavities, compared to 60% in the large cavities.

Goldberg et al. (1980) studied initially 475 restorations over 1.5 years. Using ANOVA analyses, the investigators compared margin fracture scores among different subgroups, categorized by alloy, operator, tooth and number of restored surfaces. No differences in margin fracture scores were observed between MO/DO and MOD restorations.

The relationship between the quality of the finish of the cavity wall and marginal integrity was assessed by Leidal & Dahl (1980). In the proximal parts of 38 cavities the entry sides were finished with a marginal trimmer, and the exit sides were left unfinished. The investigators reported that after 4 years no differences in margin quality between the entry and exit sides of the restorations could be detected.

Observational design

Wilson & Ryge (1963) compared 1425 restorations after 1 year. Margin fracture occurred more frequently in class 2 compared to class 1 restorations, and when the cavity preparation had been categorized as inadequate. However, a description of how the cavities were evaluated was not included

in the paper.

Matsuda & Fusayama (1970) presented a photographic technic for recording margin fracture progression. After observing 32 restorations over 1 year, the investigators reported that margin fractures prevailed in the areas with intersections between restoration margins and fissures. The margin fractures were attributed to amalgam flash, which broke off during the first 6 months of the study.

Mahler & Marantz (1980) were the first to relate margin fracture to cavity width. Margin fracture scores of 255 class 1 and 2 restorations after 3 years clinical service were reassessed, and categorized by intra-oral tooth location, tooth type and restoration width. The investigators concluded that restoration size did not influence margin fracture behaviour.

Mjör & Espevik (1980) noted in a study over 3 years that of two clinicians, one prepared larger cavities for the restorations, and these restorations showed more margin fractures. However, no statistical data were presented to document if the relationship was due to different cavity widths, or to other factors such as differences in the amalgam handling.

Osborne & Gale (1981) reassessed the margin fracture scores of 429 restorations after 2 years clinical service. The restorations were categorized by alloy, tooth position and cavity width and statistical differences were calculated with ANOVA. Significantly less breakdown was reported for the conservative restorations. This was also reported when 193 of these restorations had become 13-14-years old (Osborne & Gale, 1990). Also Laswell et al. (1990) reported effects of the cavity width on 140 restorations from the same study material.

Berry et al. (1981) reported margin fracture scores of 138 restorations after 3 years. Less margin fracture was seen in 30 restorations placed in cavities with $< 1/4$ intercusp distance compared to the wider restorations.

Also Birtcil et al., (1981) reported less margin fracture in small restorations. In this study, probit analyses were used to assess the effects of alloy, surface finish and cavity size on margin fracture after 30 months. Unfortunately, the definitions for small, medium and large restorations were not included in the report.

Cross-sectional

Elderton (1975, 1977a) investigated the association between the presence of cavosurface margin irregularities and angle on the prevalence and morphologic appearance of margin defects. The cavosurface (CSA) and amalgam margin (AMA) angles were measured in the "best" and "worst" margins of old and new restorations. Elderton concluded that lower CSA angles were associated with improved restoration adaptation. Moreover, it was concluded that irregularities would be unlikely to cause more than small

amounts of margin fracture of the amalgam. The margin fracture scores varied also along the cavosurface margins, with more fracture present where fissures and cavosurface margins were connected.

Discussion

In the first experimentally designed studies related to margin fractures the restorations were equally distributed into tooth locations and cavity sizes (Mahler et al., 1970; Mahler et al., 1973), or contra-lateral teeth (Osborne & Gale, 1973). Although the stratifications of the restorations over the teeth and cavities are documented in the papers no information was presented on the rationale for this stratification. However, the relevance of balancing the study material by these factors was not questioned until later (Goldberg et al., 1980).

Several studies report on a possible association between the cavity width and margin fractures. However, although most of these studies were experimentally designed to compare different amalgam alloys, all analyses with respect to cavity design have been made retrospectively. The potential cause-effect relationship reported in these studies can therefore not be considered based on experimentally designed studies.

The reports by Berry et al. (1981) and Birtcil et al. (1981) lacked descriptions of the intra-oral location of the small and large restorations. Comparing large restorations in lower premolars with small restorations in first molars may give confounding results, since the extent of marginal fracture also varies with the intra-oral location of the restoration (Mahler & Marantz, 1980; Goldberg et al., 1980; Osborne & Gale, 1990; Smales et al., 1990). These two studies should therefore also be considered observational when relating the findings to effects of the cavity sizes on margin fracture.

Tooth fractures

There are few data in the literature that show a clear association between the cavity design and the prevalence of tooth fractures. Some studies report that tooth fractures occur most often in mandibular molars (Hiatt, 1973; Abou-Rass, 1983; Cavel et al., 1985), and primarily on the non-functional cusp side of the tooth (Ghera et al., 1987). Limited observational data indicate that the size of the restoration may be an etiological factor in tooth fractures (Snyder, 1976), and especially excessive depth in MOD restorations (Silvestri, 1976).

Discussion

The actual failure mechanism of tooth fractures remains unknown, although it is reasonable to assume that the restoration volume influence the risk for cusp fractures. It is equally probable that several other factors promote tooth fracturing (Rosen, 1981). The water content of the hard tissues is an important

variable, as shown by the high fracture rates in endodontically treated teeth (Hansen et al., 1990). The prevailing hypothesis is that cusp fractures is the end result of progressive fatigue of brittle tooth tissue (Bell, Smith & de Pont, 1982). However, this hypothesis has not been proven experimentally or clinically.

Adverse effects on the pulp

No definite conclusions have been made about pulp reactions as a function of specific cavity depths. On the other hand, it can be assumed that the more tubules exposed and the shorter the distance before deleterious substances reaches the pulp, the higher the risk for pulp reactions (Stanley, 1971; Mjör, 1983).

Discussion

The influence of the preparation procedures on the pulp has been studied with histologic techniques by several investigators (Langeland, 1967). The cavity depth is probably the most decisive factor when estimating the potential adverse effects of cavity design features on the pulp tissue (Stanley, 1971). However, it is methodologically difficult to distinguish between the effects of the cavity depth per se and other parameters (Langeland, 1960; Hamdt, 1982). Other parameters are direct effects of the components in the tooth filling material (Möller, 1979), possible remains of bacteria in the cavity (Bergenholtz et al., 1982), marginal leakage around the restoration (Brännström 1982), and temperature changes due to damaging finishing of the restoration (van Amerongen, 1990). Another uncontrolled variable is the individual reaction pattern of the dentin and pulp in different teeth and locations on the tooth (Mjör, 1983).

Moreover, there is presently a concensus among pulp biology researchers that much of the previous work on restorative dentistry and pulp biology has been flawed (Pashley et al., 1992).

Adverse effects on the supportive tissues

Experimental design

Fisher et al. compared the changes of alveolar bone height for 54 pairs of restorations. 50% of the restorations had gingival margins extended into the sulcus. After 4 years, the cumulative bone resorption was similar for the non-restored surfaces and the restored surfaces with minimal extension. The bone loss was significantly higher for the restorations with margins extended into the sulci (Fisher et al., 1984). The same conclusions were valid when the study was extended to 10 years observation (Markitziu, 1987).

Observational design

Longitudinal studies

In a Swiss study, 459 amalgam restorations, including 340 class 2 restorations, were placed in a dental school clinic. Gingivitis prevailed when the margins were placed subgingivally compared to supra-gingivally placed margins (Hammer & Hotz, 1979).

Cross-sectional studies

Two studies have reported that the prevalence of overhanging dental restorations (ODR) is higher when the gingival margin is located subgingivally (Leon, 1976; Arneberg et al., 1980). It is uncertain if the incidence of ODR is identical on both proximal surfaces (Gilmore & Sheiham, 1971; Pack et al., 1990) or higher on the distal compared to the other surfaces (Grasso et al., 1979).

Discussion

It is methodologically difficult to separate the effects of various local etiological factors, when assessing the association between periodontal disease and restorations (Ramfjord, 1974; Leon, 1977). Identified restoration parameters are the axiokingival location of the restoration margin (Løe, 1968), the location of the contact area and the axial contour of the restoration (Pilot, 1972; Hancock et al., 1980; Grasso et al., 1984), the plaque retentive ability (Skjørland, 1973; Wallman-Björklund, 1987; Svanberg et al., 1990), the chemical state (App, 1961), and roughness of the material (Wærhaug, 1956), the occurrence and size of overhangs or crevices (Biller-Karlsson & Sheaffer, 1988; Pack 1989; Brunsvold & Lane, 1990), and the possible contributing effects of a restoration on an adjacent tooth (Pack et al., 1990).

There is general consensus that all aspects which enhance the accumulation of plaque promote periodontal disease. Therefore, cavity designs that increase the prevalence of restoration discrepancies, cause supportive tissue breakdown indirectly. The prevalence of restoration margin discrepancies gingivally varies among different reports. One major reason is the lack of common assessment techniques and the use of a common terminology (Eichner & Voss, 1971; Holmes et al., 1989; Sorensen, 1990). Several reviews on overhanging dental restorations (ODR) have focussed on the relationship between ODR and gingival health, removal methods, and effect of removal on the gingival health (Biller-Karlsson & Sheaffer, 1988; Pack 1989; Brunsvold & Lane, 1990). Unfortunately, these papers make no references to the prevalence of ODR relative to aspects of the cavity design. Furthermore, there are no reports on the relationship between occlusal or proximal cavity widths and the external contour. However, from clinical experience it is known that an increase in the size of the proximal part of the cavity preparation hinders a

correct placement of the matrix, and thus the correct reproduction of the contour and the contact area (Bauer & Crispin, 1986; Kaplan & Schuman, 1986).

Epidemiological data show that the prevalence of ODR is lower today than previously (Gröndahl & Hollender, 1979; Hugoson et al., 1986; Lang et al., 1988). These investigators offer different explanations for their observations, such as increased concern for ODR, better techniques for placing fillings, and improved operative dental care. The last suggestion, however, is certainly not shared by the members of boards of dental examiners in USA (Smith et al., 1980). Other possible explanations are improved dental amalgams, and that cavities today are smaller, which facilitate control of a correct placement of the matrix. These factors leads further to improved condensation, carving and contouring of the restorations.

Evaluation of class 2 cavity preparations

The ideal class 2 cavity preparation

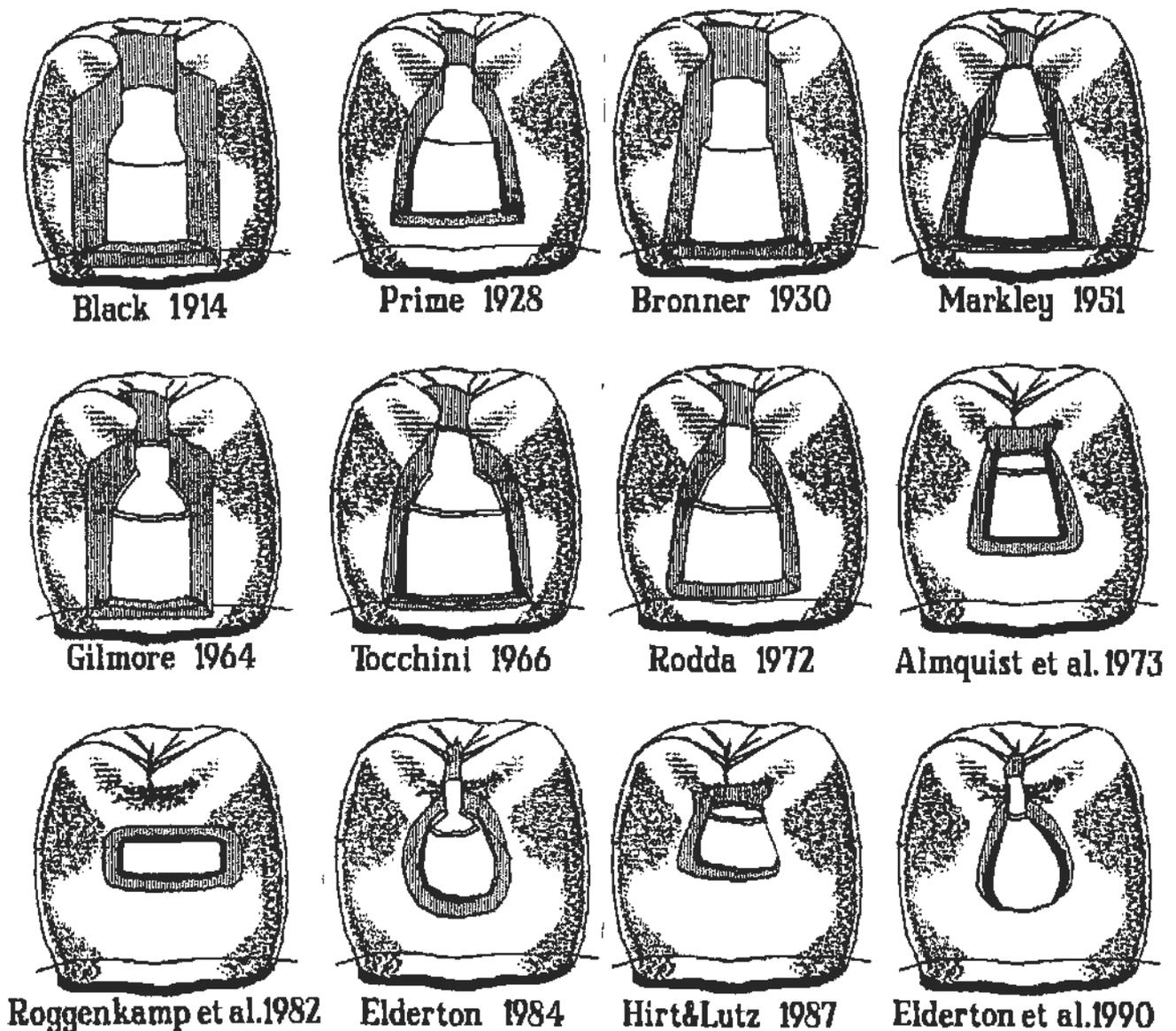
At the turn of the century Dr. G.V. Black described designs for cavity preparations on basis of studies on secondary caries of extracted teeth (Black, 1908). His conclusions were based on the current state of the oral health in the population and his own experiments on alloy compositions. G.V Black also described a classification system for cavities based on the location of the carious process, and formulated the operative steps for the preparation of cavities.

Black's classification system for cavities has since been in universal use, and the operative steps are still advocated in the modern textbooks on operative dentistry (Sturdevant et al., 1985; Marzouk et al., 1985; Charbeneau, 1988; Hørsted-Bindslev & Mjör, 1988). One advantage of the descriptive operative steps is their universal use to all types of preparations, irrespective of the caries lesion size, intra-oral location, or cavity class. Furthermore, the operative steps are a systematic approach to cavity preparations, which make the principles appear logical in teaching programs. However, some authors consider the teaching of cavity preparations based on these operative steps unfortunate, because of the mechanistic nature of the resulting cavities (Elderton, 1988; Leidal & Mjör, 1988; Elderton et al., 1990).

Different perceptions of optimal cavity designs have evolved, based on results from different dental research areas (Part I, sections 1&2). The changes in design have been motivated by the development of new improved

materials, traditional materials with better physical properties, better oral health in the population, the use of fluorides, assessments of biological effects on oral tissues and on improved equipment in the dental office. The literature show a wide variation of opinions on the ideal class 2 cavity, and several alternative preparation designs for caries lesions on the proximal surface have been presented (Fig. 1.1). However, there is lack of scientific proof that one or the other cavity design can be considered ideal. The lack of scientific proofs may explain the variation in teaching concepts of optimal class 2 designs for amalgam restorations in dental schools (O'Hara & Clark, 1984; Moore, 1992).

Fig. 1.1. Suggestions of ideal class 2 cavity designs for amalgam restorations presented in the dental literature.



Rationale for evaluating class 2 cavities

The objective of a cavity preparation is to stop the carious process and to remove soft, carious tissue. Any other removal of hard tissue is performed to obtain an adequate control of the operating field, or to ensure that the remaining tooth and the new restoration will withstand the physical forces and the long term influence of the oral environment. Consequently, the main factor governing the fundamental design of the preparation is the extent of the carious lesion and, in the case of secondary caries, the previous restoration. Besides the extent of the carious lesion, factors such as oral hygiene, bruxism and dental history of the patient are considered when a cavity is prepared (Sturdevant et al., 1985).

From these aspects, it seems difficult to differentiate between "good" and "bad" preparations. However, all operative procedures on teeth aim to maintain their integrity to ensure extended function in the mouth. By adapting this principle to operative cavity preparations, the optimal cavity preparation can be defined as the cavity with the design that will ensure the best prognosis of extended longevity of the restored tooth. Thus, the optimal cavity design maximizes the good, and minimizes the poor physical and mechanical properties of a tooth filling material (Mahler & Terkla, 1965). The concept can be applied to cavities prepared due to primary- (new preparations) or secondary caries (replacement preparations), and irrespective of the cavity size, extension, surface, or type of tooth involved.

Evaluation systems for class 2 cavities

Several systems for evaluating class 2 cavities for amalgam have been described in the dental literature (Table 1.20).

Table I.20. Evaluation systems of class 2 cavities for amalgam restorations presented in the dental literature.

<u>Nr</u>	<u>Investigators</u>	<u>University</u>	<u>Scoring Levels</u>	<u>Study aims</u>
(1)	Darby, Chen & Podshadley, 1965	Univ. Iowa	4	Assess the effect of an intensive course in operative dentistry
(2)	Fuller, 1972	Univ. Iowa	2	Determine the effect of training on inter- and intra-rater agreement
(3)	Haupt & Kress, 1973	U. N Jersey	2&5	Investigate influence of nature of scale and on rating reliability
(4)	Hinkelman & Long, 1973	U. Pittsburg	3	Evaluation preclinical course performance
(5)	Steures, 1975	U. Amsterdam	2	Evaluate the effect of audiovisually programmed instruction on performance
(6)	Forehand, Vann & Shugars, 1980	U. N. Carolina	2	Develop a method for self-evaluation
(7)	Goepferd & Kerber, 1980	Univ. Iowa	5	Compare intra- and interexaminer reliability using 2 evaluation methods
(8)	Charbeneau, 1981	U. Michigan	5	Guidelines to improve the self-evaluation
(9)	Vann, Machen & Hounshell, 1983	U. N. Carolina	5	Compare intra- and interexaminer reliability using 3 evaluation methods
(10)	King & Bedi, 1984	U. Hong Kong	2	Design an evaluation system based on pictorial criteria for self-assessment

Many of these evaluation systems reflect Black's principles for preparing cavities, by their design and the evaluating "steps". It is possible that the prevalent references to Blacks terminology may be explained by the fact that the majority of the evaluation systems were made in dental school environments to assess student performances. Furthermore, the evaluation systems differ markedly with respect to number of cavity design variables, scoring levels and the scoring criteria or wording of these.

Cavity design variables

The design of a prepared cavity in a tooth is complex and may be described by a combination of both qualitative and quantitative measurements. A compilation of cavity features suggested by various investigators as clinically important is presented in Table I.21.

Table I.21 Cavity design variables recorded and scored in evaluation systems presented in Table I.20 of class 2 cavities.

Variables:	Paper nr:	1	2	3	4	5	6	9&7	8	10
Specific to occlusal part										
Extension		*	*	*		*	*	*	*	*
Mesiodistal resistance form		*	*	*		*	*	*	*	*
Isthmus width			*			*	*	*		*
Smoothness of outline			X	(*)		*	*			*
>1 mm marginal ridges						*	*			*
Cavosurface angle			*	*						*
Converging proximal walls			*							*
Buccal/lingual wall convergence		*	*				*	*		*
Occlusal depth			*	*			*	*	*	*
Acuteness of internal angles			*					*		*
Margin ridge wall convergence										*
Flatness of pulpal floor										*
Thickness of remaining walls						*				
Enameloplasty							*			
Specific to proximal part										
Buccal/lingual wall convergence		*	*			*	*	*		*
Extension		*	*	*		*	*			*
Acuteness of internal angles			*	*		*	*	*		*
Beveled isthmus						*		*		*
Proximal depth		(*)	*	X			*	*	*	*
Gingival floor location	(*)	*	X				*	*		*
Cavosurface angle		(*)	*	X				*		*
Acuteness of external angles			*							(*)
Curvature axial wall			*							
Gingival floor curvature			*							
Gingival floor bevel			*							
Unspecific, both parts										
Caries removal	(*)	X				*	*	*		
Cavity washed						*			*	
Outline	(*)	X		*				*		
Depth	(*)	X		*				*		
Cavosurface angle						*		*		
Resistance form				*						
Retention form					*			*		
Enamel finish				*						
General appearance	(*)	X								

The number of evaluated cavity design features in the different evaluation systems vary between 4 (Hinkelmann & Long, 1973) and 20 (King & Bedi, 1984). The list of cavity design variables is fairly similar to the list that members of boards of dental examiners for licenses in USA examine when considering the cavity preparation performance of applicants (Smith et al., 1980). Most of the evaluation systems assess the occlusal and the proximal parts separately, while both parts were assessed simultaneously in 3 of the evaluation systems (Darby et al., 1965; Hinkelman & Long, 1974; Charbeneau, 1981).

It is difficult to assess the validity of including a certain number of design features in the evaluation systems, since this also depends on the number of scoring levels and wording of the scoring criteria presented to the examiner (Haupt & Kress, 1973). A clinically relevant system for evaluation of cavity preparations should include all aspects that are decisive for the longevity of restorations, but exclude all other variables. On the other hand, subdividing the cavity into separate cavity design variables makes the evaluation cumbersome, especially when each feature is scored on several levels (Patridge & Mast, 1978).

Scoring levels

Table I.20 shows that the number of scoring levels vary between 2 and 5. The variability in the number of scoring levels depends partly on the clinically identifiable levels of a particular design feature. For example, remaining fissures, caries or unsupported enamel be categorized as present/absent, while, e.g., cavity depth and width can be categorized into different levels. Other cavity design variables, such as undermined enamel can be assigned scores according to the intra-tooth location, e.g., 0 on the occlusal surfaces, 1 proximally, and 2 gingivally. It has been reported that the optimal number of scale points for maximized operational feedback instructions to students is from 3 to 5 points (Lindvall, 1967; Fernandez 1967; Haupt, 1971). However, increasing the number of scoring levels induces discrimination problems, and thus decreases the accuracy of scoring (Goepferd & Kerber, 1980).

Thus, no definite conclusions can be made with respect to the optimal number of scoring levels. It has been suggested that it is feasible to quantify multi-dimensional criteria into one unified index with the help of canonical correlation (Schiff et al., 1975). However, such evaluation indices may not be relevant clinically. The reason is that if a cavity preparation includes one single crucial error, even if excellent in all other aspects, a unified index will obscure this error. On the other hand, this can be taken into account by defining that the lowest registered code determines the overall code of each dimension as suggested by Charbeneau (1981).

Wording of the scoring criteria

The performance and objectivity of any evaluation system is primarily related to the descriptive precision of its performance criteria (Fuller, 1972). Even presumptive expert evaluators show little agreement if there are no performance criteria, or if the performance criteria are imprecise (Mackenzie, 1973). Maintaining a constant decision criteria is an important aspect for evaluation. A review of research on sensory discrimination indicates that decision criteria change with time and are influenced by a variety of factors such as verbal instructions on the degree of strictness to be used (Swets, 1973). The wording and base from which evaluations begins, also leads to different behaviour of the evaluators (Natkin & Guild, 1967). It has also been reported that illustrations, pictures or models improve the reliability of the scorings (Ryge & Snyder, 1973; King & Bedi, 1984). Unfortunately, the written criteria for the different scoring levels were not described in the different papers in Table 1.20.

Training of the evaluators

A study of the accuracy of measurement of clinical performance in dentistry showed that competence in practice does not automatically lead to competence in evaluation of clinical performance (Haupt, 1971). Some investigators placed great emphasis on prior training of the participants prior to evaluations (Ryge, 1980; Ryge & Mjör, 1988). However, the effect of training evaluators to improve the inter-and intra- reliability of scoring cavity preparations is uncertain, since such evaluations also includes qualitative judgements. Patridge & Mast (1978) found little or no effect of training the evaluators. The effect of training the evaluators on the scoring reliability is difficult to assess in the other papers in Table 1.20, since these did not include descriptions of the procedures used for training.

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4. A 5-year prospective clinical study on the relationship between margin fractures and patient, dentist, material, and cavity design variables

Amalgam restorations frequently exhibit margin fractures on the occlusal surfaces (Mahler, 1967). The clinical consequence of these margin fractures is uncertain. Today, more dentists than before replace restorations with margin discrepancies (Boyd, 1989). There is considerable controversy of the necessity of replacing restorations due to margin fractures on the occlusal surface (Goldberg, 1990; Maryniuk, 1991). The controversy is partly due to the uncertain etiology of margin fractures, and subsequent clinical performance of the restored tooth. The etiology of margin fractures is certainly multifactorial (Bryant 1981a, 1981b; Mahler, 1988). One important parameter influencing the rates of margin fractures is the operator, which may be related to the handling of the amalgam alloy (Mahler & Marantz, 1979), or aspects of the cavity preparations (Letzel et al., 1978; Letzel & Vrijhoef, 1984). Specific features of the cavity preparation design may in this context be important. In vitro experiments and observational clinical studies have shown that factors such as the buccolingual width, presence of proximal retention grooves, and the angle and quality of the cavosurface margin (Part I, sections 1 & 2) may influence margin fracture rates. There are no reports on prospective clinical studies focused on margin fractures rates as functions of the cavity morphology.

A prospective clinical study was initiated to assess margin fractures in class 2 amalgam restorations made under routine conditions by general practitioners. The aims of the study were to record the extent of margin fractures ("ditching") of class 2 amalgam restorations, and to assess a possible relationship between margin fractures and the quantitative and qualitative features of the cavity preparation, material properties and patient variables.

Materials & Methods

The study included several methodological investigations, including developing a system for assessing the various aspects the prepared cavities. Moreover, a method for recording the outer and inner outline of the restorations at the isthmus area, and a validation study of scoring margin fractures directly on impressions of the restored teeth.

Study protocol

All clinical procedures were described in a study protocol, issued to the participating dentists in 1979 (NIOM, 1979). The study and the protocol were designed according to the guidelines for clinical evaluation of dental materials endorsed by the American Dental Association (ADA, 1980) and Federation Dentaire Internationale (FDI, 1982). The protocol also gave instructions on the correct use of materials, condensation and finishing of the restorations. It was stressed that the dentists should maintain their daily clinical routines, but the handling of the material was to follow the manufacturers' instructions. The protocol included also suggestions for the types of bur, engine, hand and rotation instruments, and matrix techniques.

Special instructions were made for impression and photographic techniques, and procedures for direct clinical evaluation. In case of restoration failure a sample from the failed restoration, if available, was to be returned for laboratory analyses.

Dentists

The dentists were selected with the assistance of administrators in the national public health services and the national dental associations. The dentists were to be in general practice, and have patients available for follow-up for at least 5 years. Seven Scandinavian general practitioners participated in the study (Table II.1).

Table II.1. The participating dentists distributed by country and types of practices.

<u>Country</u>	<u>Dentists</u>	<u>Type of practice</u>
Denmark	1	Private practice
Norway	2	School dental service
Sweden	2	Public health service
Finland	2	Private practice

The participants had practiced as dentists varying between 15 and 30 years when the present study was initiated. No in-depth assessments were made to why the dentists had volunteered to participate in the study. Upon questioning, the prevailing answers were that the participation was considered as a continuing dental education, or that they wanted "to be involved" in clinical investigations.

Operator training

The dentists had at the beginning of the trial participated in a training course on the use of the USPHS scoring system (Cvar & Ryge, 1971). The inter- and intra-reliability of the USPHS scorings after the course were within the accepted range of 85% agreement.

The group met yearly during the first 4 years for 2-day discussions of problems, reviewing the USPHS criteria, and discuss preliminary data and techniques. The seminars also aimed to reinforce the necessity of following the instructions in the study protocol and the recommendations in the handling of the materials.

Patients

Two hundred and ten individuals were selected by the dentists among their regularly attending patients (Table II.2). The only information provided prior to patient selection was a preference for patients requiring at least 3 class 2 restorations. Table II.2 shows that less than 1/3 of the 211 patients received more than 2 restorations, although accounting for 55.5% of the restorations.

Table II.2. The number of patients per dentist and the number of restorations per patient.

Dentist	Number of restorations placed in each patient									Total			
	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>9</u>	<u>12</u>	Patients		Restorations	
										n	%	n	%
Dentist 1	34	15	2		1					52	24.6	75	16.0
Dentist 2		5	3	2	3	1	3	1		18	8.5	78	16.7
Dentist 3	3	4	2							9	4.3	17	3.6
Dentist 4	24	14	4	7	1	1				51	24.2	103	22.0
Dentist 5	16	13	4	3						36	17.1	66	14.2
Dentist 6	17	5	5	3		1				31	14.6	60	12.8
<u>Dentist 7</u>		<u>1</u>	<u>4</u>	<u>2</u>	<u>3</u>	<u>1</u>	<u>2</u>		<u>1</u>	<u>14</u>	<u>6.7</u>	<u>69</u>	<u>14.7</u>
Sum patients	94	57	24	17	8	4	5	1	1	211		468	
% of patients	44.5	27	11.4	8.1	3.8	1.9	2.4	.4	.4				
Cumulative %		71.5	82.9	91	94.8	96.7	99.2	99.6	100				
Sum restorations	94	114	72	68	40	24	35	9	12				
% of restorations	20.1	24.4	15.4	14.5	8.5	5.1	7.5	1.9	2.6				
Cumulative %		44.5	59.9	74.4	82.9	88	95.5	97.4	100				

The indications for placing the amalgam restoration could be primary caries or revision of a failed restoration. The age of the patients varied from 8 to 71 years, with a mean age of 28 years. For three dentists, the mean ages of the patients varied between 12 and 16 years. For the other dentists the mean ages of the patients were between 31 and 40 years. There was a slight majority of female patients (57%).

Recording of the cavities

No instructions on minimum requirements for the cavity preparation quality or morphology had been issued in advance. At the onset of the study, the dentists were aware that the primary objective was to study restoration performance. Furthermore, they knew that their preparations were to be evaluated, but they did not know any details regarding the measurements and assessments of the cavities.

Immediately before inserting the amalgam, an impression of the cavity was made with silicone impression materials (Xantopren blue and Optosil, Bayer, Leverkusen, FRG). It was stressed to the dentists, and described in the study protocol, that the impression was to be made after applying an optional base. If a base was employed, a hard setting type of cement should be used. Thus, the restoration bulk thickness could be determined, but not the total cavity depth of the preparation. The use of varnish and product was optional, but the dentists were instructed to avoid using varnish that flowed over the cavosurface margins.

Casts of the impressions were produced within 72 hours using an epoxy material (Durcupan, Fluka AG, Buchs, Switzerland).

Evaluation of the cavities

The evaluation of the cavities in the epoxy casts was made at 10 x magnification in a stereomicroscope (Spencer American Optical). One evaluator examined the models, unaware of the dentists' identities. All measurements were made with transparent plastic strips with millimeters engraved, and a periodontal probe with 2-mm markings (CBG, Hilming). The procedures for evaluating the cavities are outlined in Table II.3.

Table II.3. Procedures for recording the morphology and features of the cavity preparation on epoxy casts of teeth with class 2 cavity preparations.

External outline

Occlusal

1. Measure in mm the width of the intercusp distance and the width of preparation at the isthmus, the maximum and the minimum width of the preparation. Assess relative widths of preparation to the intercusp distance. Record the minimum and the maximum extension of the preparation.
2. Measure in mm the mesiodistal extension relative to the marginal ridge.
3. Assess the relative placement of the buccal and lingual margins on the cusp surfaces.
4. Measure in mm the width of enamel remaining adjacent to fissures, grooves or previous restorations.
5. Assess the continuation of fissures from the cavosurface margin. Differentiate between fissures and grooves. Adequate differentiation between the two structures is the tip of the periodontal probe.

Proximal

1. Apply a plane through the relevant buccal and lingual cusp tips. The part of the tooth circumference bisected by this plane is referred to as the interproximal circumference. Assess the buccolingual extension relative to the interproximal circumference. Measure the minimum and maximum extension width at the marginal ridge and at the gingival margin.
2. Measure in mm the maximum and minimum gingivoocclusal extension of the cavosurface margin relative to the marginal ridge.

Depth of preparation

Occlusal: Trace a periodontal probe parallel to the buccal and lingual walls. Measure the distance in mm from the occlusal surface to the pulpal wall. Measure the minimum and maximum depth of the preparation.

Proximal: Trace a periodontal probe parallel to all walls, perpendicular to the tooth surface. Measure the distance in mm from the tooth surface to the axial wall. Measure the minimum and maximum depth of the preparation.

External cavity definition

Cavosurface angle

Trace a periodontal probe parallel to all walls. Visually assess the angle between the probe and the tooth surface. Check the angle for continuity.

Definition of cavity walls and margins

Evaluate visually the **degree of continuity** of walls and margins. All points within a 1 mm² wall or a 1 mm margin must be part of the same spatial plane or line to be defined as continuous.

Margin roughness

Occlusal: The occlusal margins are not rated.

Proximal: At 20 x magnification rate all proximal margins according to the CMI index (Tronstad & Leidal, 1974) depicted on the photographs.

Internal cavity definition

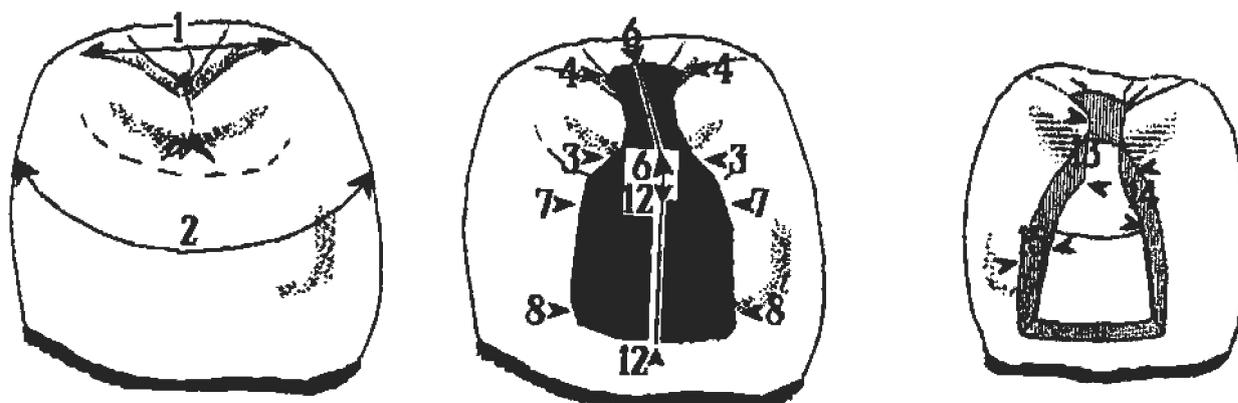
1. Assess the shape and continuity of the occlusal and proximal internal line angles,
2. Assess the form of the pulpoaxial line angle (isthmus).
3. Align the periodontal probe occlusogingivally. Compare the diameter tip of the probe with the size of eventual grooves in the buccoaxial, linguoaxial and gingivoaxial line angles.

Retention

Inspect tooth directly occlusally. Assess the degree and extent of discernable buccal, lingual and axial walls.

The different aspects of the cavities were described according to the following variables (Table II.4).

Table II.4. Description and codings of the variables of the cavity design recorded. Numbers on the diagram correspond to the numbered descriptions on the extreme left.



1. Intercusp width between buccal and lingual cusps, (ICW).
2. Proximal circumference width, (PCW)
Measured in mm.

Occlusal extension:

3. Buccolingually, over the axial wall
4. Buccolingually, at the dovetail (Only MO & DO restorations)
5. Buccolingually, average
Measured in mm and as proportions of ICW.
6. Mesiodistally, from proximal surface to medial axial wall

Proximal extension:

7. Buccolingually, at the ~~isthmus~~
8. Buccolingually, at the gingival margin
9. Buccolingually, average
Measured in mm and as proportions of PCW.
10. Minimum distance from marginal ridge to the gingival margin
11. Maximum distance from marginal ridge to the gingival margin
12. Distance from marginal ridge to the gingival margin, average
Measured in mm.

Occlusal & Proximal Depth:

13. Distance from the occlusal surface to the pulpal wall
14. Same as above, over the pulpoaxial angle
15. Distance from the axial wall to the proximal surface
Measured in mm.

Qualitative aspects:

16. Location of the buccal and lingual margins on the cusp inclines;
Codes: 1: Follow fissures; 2: Some cusp incline removed; 3: Cusp removed < 2/3; 4: Cusp removed > 2/3; 5: Cusp fracture imminent.
17. Parts of enamel with thickness < 1 mm next to grooves, fissures or previous restorations;
Codes: 1: Slices >1 mm or not present, 4: Slices < 1mm remain;
18. Continuation of deep fissures from the cavosurface angle;
Codes: 1: Fissures removed or not present; BO: Buccal fissure present; LO: Lingual fissure present; PO: Proximal fissure present.
19. Areas with cavosurface angles < 90°
Codes: 1: No areas; OB: Occlusobuccal; OP: Occlusoproximal; OL: Occlusolingual; PB: Proximobuccal; GP: Gingivoproximal; PL: Proximolingual.
20. Cavosurface definition (Facets)
Codes: 1: Walls smooth and well defined; 2: Ragged in isolated areas; 3: Ragged over larger areas; 4: Poor definition, facets/planes or sharp corners; 5: Form and walls impossible to detect
21. Bevel of the axiopulpal line angle;
Codes: 1: Smooth bevel; 4: Sharp line angle.
22. Morphology of the gingival floor.
Codes: 1: Distinctive groove; 2: Flat floor and no groove; 4: Deep groove undermined the enamel or chamfered floor, 5: Depth < 1 mm and marked sloping of the floor apically.
23. Location of acute internal line angles;
Codes: 1: Smooth internal angles; or sharp or indistinct in the areas: PF: Pulpofacial; PA: Pulpoproximal; PL: Pulpolingual; GL: Gingivolingual; GF: Gingivofacial.
24. Acuteness of external gingivoproximal line angle;
Codes: 0: 45°-60°; 1: 45° and 60°-90°; 2: 60°-70°; 3: 60° and 70°-90°; 4: 70°-80°; 5: 70°-80° and 80°-90°; 6: 70°-80° and 90°; 7: 80°-90°; 8: 80°-90° and 90°; 9: 90°
25. Degree of discernable walls in occlusal part.
26. Degree of discernable walls in proximal part.
Codes: 1: Retention conspicuous; 4: Retention absent in one or more areas; 5: Retention absent or result in gross loss of tissue.
27. CMI index scores along the proximal walls
28. CMI index scores in the external line angle
29. CMI index scores along the gingival margin
Code 0: All margins smooth and perfect; 1: Slight roughness. Acceptable margin. Few, isolated, small chips at the enamel edge; 2: Moderate roughness. Imperfect margin. Continuous row of small chips and/or a few larger chips at the enamel edge; 3: Wall or margin rough. Unacceptable margin. Many large chips and/or a continuous fracture of the enamel edge (Tronstad & Leidal, 1974).

Recording the outline of the restorations.

The cavities were overfilled with amalgam and carved, but not burnished. Rubber dam was not used. Finishing and polishing was performed within 2 weeks after the placement. At this stage, an impression was taken of the tooth with silicone impression materials (Xantopren blue and Optosil, Bayer, Leverkusen, FRG). It represented the base line (day 0) for subsequent evaluations.

The minimum bulk thickness of the restoration, the bulk thickness along the lingual and buccal walls, and the buccal and lingual amalgam margin angles at the isthmus were assessed on 150 restorations using a double impression method. The procedures of the recording method were to make buccolingual sections through the axiopulpal line angle in the impressions. Cuts in the same planes and locations were then made on the impressions of the cavities, using landmarks of the tooth morphology for orientation. The sectioning was made by hand using a scalpel with stainless steel razor blade. The cuts were placed in a Nikon silhouette projector with 10 x magnification. The enlarged silhouettes provided details of the axial cavity walls and the pulpal floor, and the periphery of the tooth and the restoration (Fig. II.1).



Fig. II.1. Composite tracings outlining the restoration and tooth contours. The two tracings on the right were made independently by two individuals.

The cuts of the pre- and post-restored impressions were aligned axial to the projector lens by making a parallel second cut about 1 mm. medial to the first cut, yielding a slice of the impression materials. One of the two silhouettes, regardless which one, was traced on an overhead plastic sheet. After tracing the silhouettes, the cut slices were repositioned on the glass slides and fixed to the remaining pieces. By aligning the silhouette of the other slice in the x- and y-direction, a composite tracing could be made. The dimensions of the restorations and the crowns were measured on the composite tracings. Distances between points in the tracings were measured with an ordinary ruler, to the nearest mm (Fig. II.2).

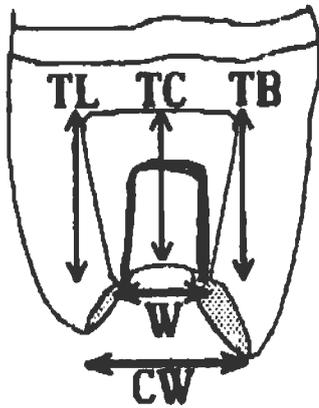


Fig. II.2. The dimensions measured on the tracings. TL= Distance between the pulpal floor and the restoration surface along the lingual wall, TC= Distance between the pulpal floor and the restoration surface at the minimum bulk thickness, TB= Distance between the pulpal floor and restoration surface along the buccal wall, W= Restoration buccolingual width at the isthmus, and CW= Cusp width.

Since the silhouettes were magnified 10 times, the dimensions were actually recorded to the nearest 0.1 mm. If the cavosurface or the internal line angle was rounded, two straight converging lines were drawn to meet beyond it. The angle formed by the two lines was bisected and the point at which the bisector met the rounded internal angle was used as the measuring point. At the buccal or lingual walls, the distance was measured between the cavosurface margin on the occlusal surface and the line angle, regardless of whether the restoration was over- or undercarved.

The minimum bulk thickness was for 95% of the restorations smaller than the bulk thickness at the buccal and lingual walls, with differences up to 1.4 mm. The measures of the bulk thickness of the restoration along the lingual and buccal cavity walls, using the double impression method were correlated to the cavity measures from the epoxy casts. The Pearson's correlation coefficient between these measures was $r=.95$. Relatively good correlations were also computed for the measures of the cavity width and cusp distances ($r = .94$ and $r = .97$). Therefore, only the measures of the minimum bulk thickness and the amalgam margin angle scorings were included as new variables in the subsequent statistical analyses (Table II.5).

Table II.5. Description of recorded variables of the restoration outline.

1. Minimum distance from the occlusal restoration surface to the pulpal wall
Measured in mm.

2. Acuteness of the amalgam margin angle (AMA) at the isthmus.
Measured in degrees. Code 1: $<40^\circ$, 2: $40-80^\circ$, 3 $> 80^\circ$

The restoration volume was calculated from cavity design and restoration variables:
(Occlusal depth+ Bulk thickness/2) x mean occlusal buccolingual width x mesiodistal extension
+ Mean proximal depth x mean proximal buccolingual width x axiocervial extension
Measured in mm^3 .

Restorations

The material consisted at base line of 468 restorations, comprising MO (35.9%), DO (32.7%) and MOD (31.4%) restorations, located in premolars and molars in both jaws as outlined in Table II.6.

Table II.6. Assignment of type of restorations by tooth type (n=468). Percentages presented for the rows.

<u>Restoration</u>	<u>Maxillary</u>		<u>Mandibular</u>		<u>Total</u>
	<u>Premolar</u>	<u>Molar</u>	<u>Premolar</u>	<u>Molar</u>	
MO	15(9%)	<u>87(52%)</u>	4(2%)	62(37%)	168
DO	<u>70(46%)</u>	12(8%)	45(29%)	26(17%)	153
MOD	<u>86(58%)</u>	17(12%)	19(13%)	25(17%)	147
Total	<u>171(36%)</u>	116(25%)	68(15%)	113(24%)	468

No teeth were restored more than once during the study, i.e., multiple restorations in the same tooth were not included in the study material. The majority of the restorations were placed between December 1979 and 1981. Thirty-two restorations were completed in 1982, and the last restoration was placed in January 1983.

Amalgam alloy

One amalgam alloy with a conventional composition and 4 high-Cu precapsulated amalgam alloys were used in the study. The amalgam alloys were randomly assigned to the teeth to be restored. The amalgam alloys and their batch numbers are presented in Table II.7.

Table II.7. Amalgam alloys used in the present study.

<u>Amalgam alloy</u>	<u>Producer</u>	<u>Batch no</u>
Revalloy	SS White Ltd., U.K.	5979 08
Amalcap Non-Gamma-2	Vivadent, W.Germany	300879 1270
Dispersalloy	Johnson & Johnson, U.S.A	021679 9B 809
Indiloy	Shofu Dental Corp., Japan	050378 27 7805
Tytin	SS White Ltd., U.K.	106 79 02022779

The materials were chosen to represent the latest in amalgam alloy technologies within their respective categories (NIOM, 1980). Revalloy and Amalcap Non-Gamma-2 have since been withdrawn from the Scandinavian market (NIOM, 1992).

Five dentists used the conventional amalgam alloy and two high-Cu amalgam alloys. One dentist used the conventional and one high-Cu amalgam alloy, while one dentist (#4) used 3 high-Cu amalgam alloys (Table II.8).

Table II.8. Amalgam alloys used in the present study and the distribution of restorations for the 7 dentists.

	Revalloy	Amalgam alloy			Tytin	Sum
		Amalcap Ng2	Dispersalloy	Indiloy		
Dentist 1	28			25	22	75
Dentist 2	28	26			24	78
Dentist 3	6		5	6		17
Dentist 4		34	34		35	103
Dentist 5	23		19	24		66
Dentist 6	36			24		60
Dentist 7	22	24	23			69
Sum	143	84	81	79	81	468
Percent (%)	30.5	17.9	17.3	16.9	17.3	

Recording of the restorations

The patients were recalled for polishing within 2 weeks after the restoration placements. After the polishing, recalls were made after 6 months, and after that yearly from the base time. At the recalls the restorations were recorded by two methods (Table II.9). One recording method, used by all the dentists, was to take impressions, using silicone impression materials (Xantopren blue and Optosil, Bayer, Leverkusen, FRG). The teeth were washed and dried before the impressions. An alternative was to make two impressions, and discard the first impression.

The other recording method was either to score the restorations according to the protocol of the USPHS system (Cvar & Ryge, 1971), or to photograph the restorations. Each dentist could initially choose their preferred recording method (Table II.9).

Table II.9. Recording method used by the 7 dentists (n=468 restorations).

Dentist	Recording method		
	Photo	Impression	USPHS
1		75	
2	78		
3		17	
4		103	
5	66		
6		60	
7	69		
Total	213	468	255

Three dentists recorded their restorations on photographs, using a 200 mm Medical Nikor lens (Nikon Inc, Garden City, USA) at 1.5 x magnification and black and white film. Each dentist was supplied with a copy of the first photograph taken at base time to help in the standardization of the later photographs.

Scoring margin fractures on the restorations

The direct scoring according to the protocol of the USPHS system was used by four dentists. The alternative scorings were: Alfa, crevice into which the explorer cannot penetrate; Beta, crevice that the explorer will penetrate; Charlie, margins with dentin or base exposed; and Delta, restoration mobile, fractured or missing in part or in toto (Cvar & Ryge, 1971).

The indirect scoring of margin fractures was made on the impressions at 10 x magnification in a stereomicroscope (Spencer American Optical). The assessments using photographs were made on prints at 6 x magnification.

The margin fractures on the photographs and the impressions were scored according to selected reference sets consisting of six groups. The six groups showed increasing extent of fracture, and equal intervals of perceptible difference in the extent of fracture. The reference sets are illustrated in Fig. II.3.

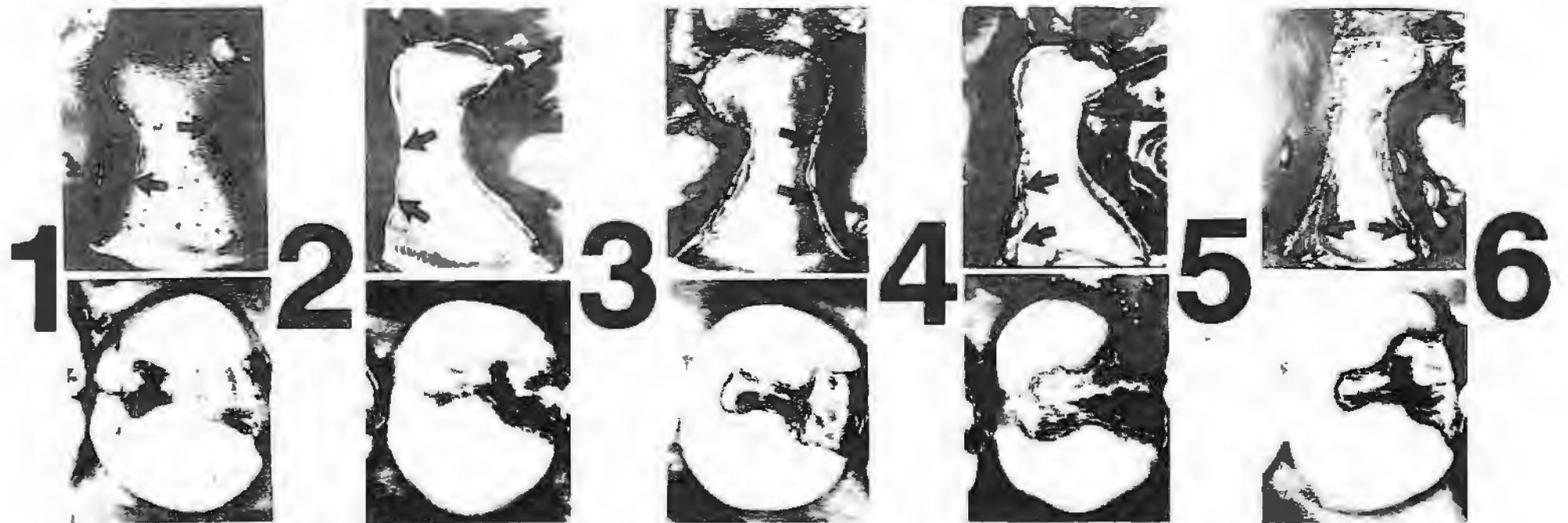


Fig. II.3. The scoring systems for margin fractures evaluated on impressions and on photographs of teeth with restorations. The numbers one to six indicate progressively larger fractures, 1 having margin relationships equal to or better than the photographs to the left, 2 having margin relationships between the next two adjacent photographs, and so forth; 6 denotes margin fractures equal to, or more than on the photographs to the right.

All scorings were made by a trained technician and a dentist. Any differences in the scorings between the two evaluators were solved by joint agreement to one value.

Statistics

Statistical analyses were computed by transforming the categorical values of the margin fractures to ridit scores (Bross, 1958), and according to the algorithms described by Fleiss (1981). Paired comparison tests using the Bonferroni correction factor at the 5% significance level, were used for comparisons of different subsets of the restorations. The subsets were made for the different patient, dentist, and material variables (Table II.10), and various aspects of the prepared cavities and restorations (Tables II.4, II.5).

Table II.10. Listing of clinical variables and coding of the variables in the statistics.

Margin fracture score	at baseline after 1/2 year after 1 year after 2 years after 3 years after 4 years after 5 years	Codes: (1): Good,(2),(3),(4),(5),(6): Poor
Dentist	(1),(2),(3),(4),(5),(6),(7)	
Type of amalgam alloy	(1): Revalloy, (2): Amalcap Non-Gamma-2, (3): Tytin, (4): Dispersalloy, (5): Indiloy	
Restoration location	(1): 14,24,15,25, (2): 16,26, (3): 17,27,18,28, (4): 34,44,35,45, (5): 36,46, (6): 37,47	
Restoration type	(1): MO, (2) DO, (3) MOD	
Patient gender	(1): Female, (2): Male	
Patient age	Age at the time of placement	

The mean ridit scores for the subsets were calculated relative to the categorical values of Revalloy after 3 years clinical service (Table II.11).

Table II.11. Distribution and calculation of ridit scores of Revalloy at 3 years (n=184).

	Categories					
	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>
Cumulative frequency	1	24	87	55	13	4
Ridit	.5	14.1	60.9	90.8	97.8	100
	.003	.071	.372	.758	.943	.989

The scoring of Revalloy after 3 years clinical service was selected as the standard reference, since the distribution of the values spanned the full range of the response variable, i.e, the 6 category scale, and because all participating dentist had used the amalgam alloy. The ridit scores for Revalloy for one dentist (#4) has been published previously (Mjör & Espevik, 1980).

Results

Detailed information related to the measurements and evaluations of the cavity preparations have been included as an Appendix. No systematic detailed patterns in cavity design could be distinguished. These results will only be used to statistically analyze effects on margin fractures and for analyses of reasons for failure (Part III)

After 5 years, 299 restorations remained for observation. The loss of restorations was primarily due to patient dropout, especially teenagers dismissed from the school dental services. The prevailing replacement reasons were secondary caries (n=25) and bulk fractures (n=18) (Table II.12).

Table II.12. Cumulative loss of restorations during the 5 year observation period.

	Year				
	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>
Observed	443	423	392	336	299
	(96%)	(91%)	(85%)	(73%)	(63%)
Drop-out of patients	17	27	47	93	120
	(3%)	(5%)	(9%)	(19%)	(26%)
Cumulated loss	8	18	29	39	49
	(1%)	(4%)	(6%)	(9%)	(11%)
Failure reasons					
Secondary caries	3	10	17	22	25
Bulk fractures	5	8	11	14	18
Tooth fractures				2	4
Margin fracture			1	1	2

Margin fractures as a function of clinical variables

The amalgam alloys displayed different ridit scores for the margin fractures. The four high-Cu amalgam alloys categorized into one group had significantly better ridit scores than Revalloy after 6 months, and subsequently up to 5 years ($p < .05$). Dispersalloy, Tytin and Indiloy, but not Amalcap Non-Gamma-2, showed significantly better ridit scores than Revalloy at different observation periods. In general, Indiloy and Dispersalloy had better ridit scores compared to the two other High-Cu amalgam alloys, but these differences were not statistically significant (Fig. II.4).

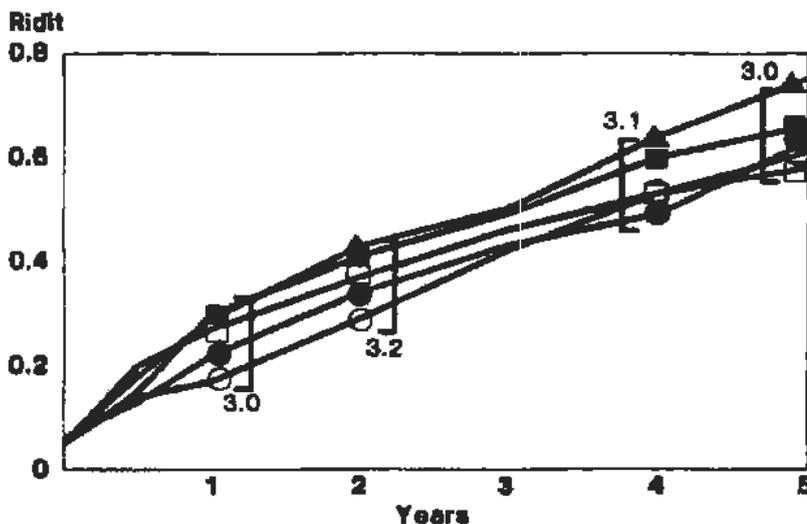


Fig. II.4. The ridit means for 5 amalgam alloys. The alloys are Revalloy (closed triangles, $n=143$), Amalcap Non-Gamma-2 (closed squares, $n=84$), Tytin (closed circles, $n=81$), Dispersalloy (open squares, $n=81$) and Indiloy (open circles, $n=79$). The numbers at the brackets indicate the critical ratios between the mean ridits. When 5 subgroups are compared, each individual paired comparison requires a critical normal curve value of 2.8 according to the Bonferroni criterion to be at a significance level of $\alpha = .05$.

The ridit scores differed among the dentists. The restorations placed by one of the dentist showed markedly better ridit scores compared to those made by the other dentists. A significant difference was observed between two dentists after 6 months (Fig. II.5).

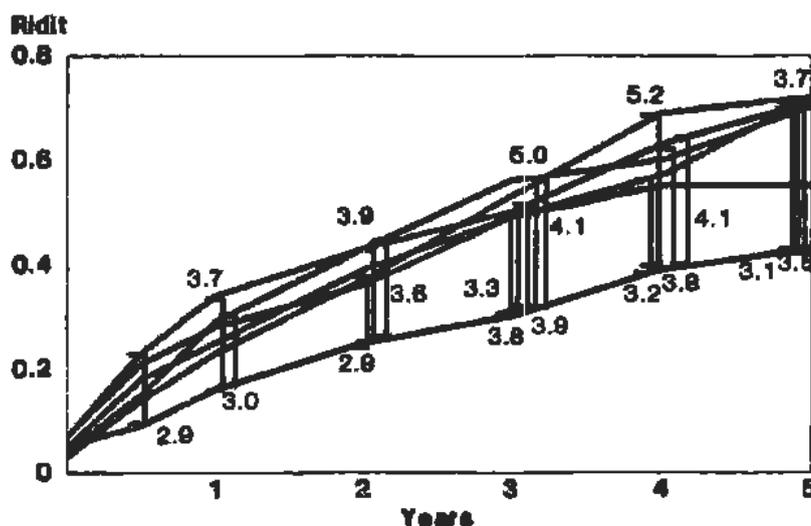


Fig. II.5. The ridit means for 6 different dentists. The ridit means for the last dentist is not shown due to the low number of submitted restorations. The numbers at the brackets indicate the critical ratios between the mean ridits. When 6 subgroups are compared, each individual paired comparison requires a critical normal curve value of 2.9 according to the Bonferroni criterion to be at a significance level of $\alpha = .05$, and 3.4 for $\alpha = .01$.

The ridit scores were practically identical for Revalloy, Amalcap Non-Gamma-2 and Tytin when these had been placed by one of the dentists (#2) (Fig. II.6), in contrast to the average ridit scorings of the amalgam alloys (Fig.II.4),

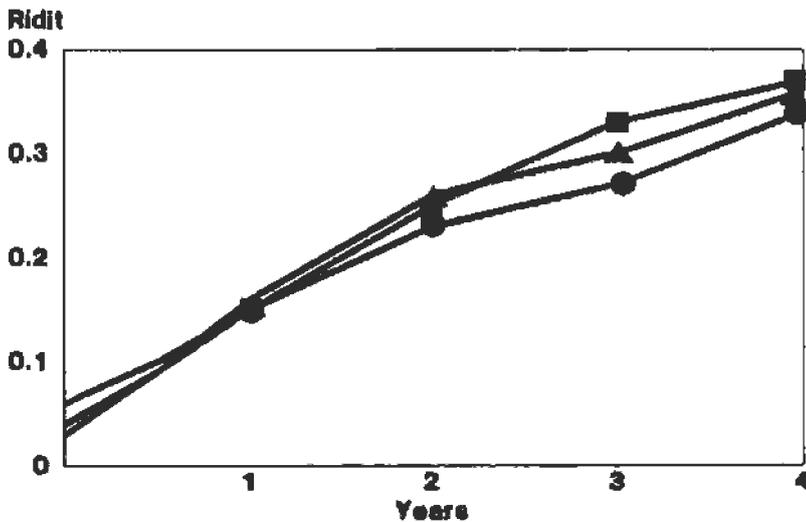


Fig. II.6. The ridit means for 3 amalgam alloys made by one dentist. The alloys are Revalloy (triangles, n=28), Amalcap Non-Gamma-2 (squares, n=26) and Tytin (circles, n= 24). When 3 subgroups are compared, each individual paired comparison requires a critical normal curve value of 2.4 according to the Bonferroni criterion to be at a significance level of $\alpha = .05$. No paired comparisons reached the required critical normal curve value.

The ridit scores of the restorations made by one dentist (#2) were better compared to the ridit scores of the other dentists, even when comparing the ridit scores for the Revalloy restorations made by this dentist to the restorations made from high-Cu amalgam alloys by the other dentists (Fig. II.7).

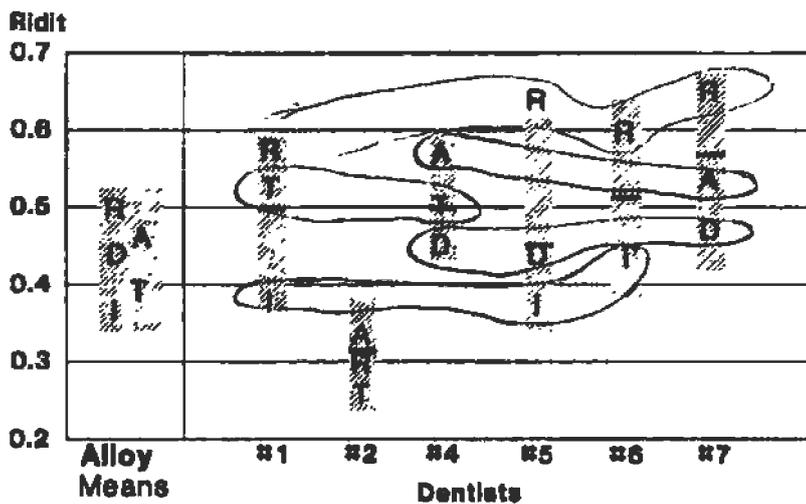


Fig. II.7. The ridit means at 3 years for 5 amalgam alloys placed by 6 dentists. (One dentist excluded due to the low number of submitted restorations). Each dentist used 3 amalgam alloys, except one dentist who used two amalgam alloys. The amalgam alloys are A (Amalcap Non-Gamma-2), D (Dispersalloy), I (Inditoy), R (Revalloy) and T (Tytin). The ridit means for each dentist are marked with horizontal lines. The shaded areas are the 95% confidence interval of the means.

The mean cavity sizes prepared by dentist #2 were compared to the cavities made by the other dentists. The only difference observed was that the single dentist had prepared insignificantly larger cavities (Fig. II.8).

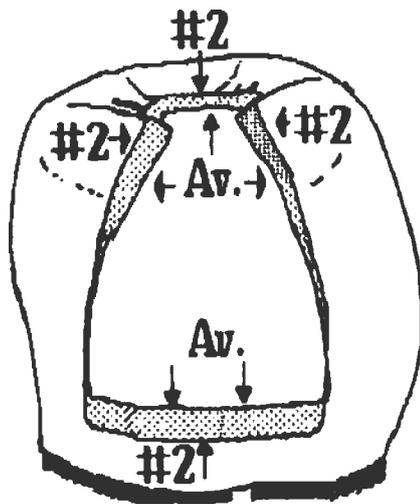


Fig. II.8. The average external cavity outline of the preparations made by six of the participating dentists (Blank areas, marked with arrows and "Av.", n=390), and by the dentist with the restorations with better ridit scores (Shaded areas, marked with arrows and "#2", n=78).

The incidence of discrepancies in the cavities prepared by the single dentist were compared to the other dentists'. Fairly similar incidences of cavity discrepancies were noted, except a lower frequency of preparations with diverging occlusal cavity walls and a higher frequency of preparations involving > 2/3 of the cusp inclines (Table II.13).

Table II.13. The prevalence of discrepancies of the cavity prepared by the dentist with less margin fractures (dentist #2) compared to the prevalence in the cavities made by the other dentists (Other).

	Dentist #2	Other
Continuous fissures from cavosurface angle	3%	5%
Rough and variable cavosurface angles	45%	45%
Diverging occlusal cavity walls	5%	25%
Occlusal unsupported enamel	3%	5%
Cusp reduction > 2/3	60%	27%
Remaining parts of enamel < 1mm	15%	20%

Also the amalgam margin angles were similar, in average 65° versus 63° for the single dentist. Moreover, comparisons of other potentially confounding variables, such as different patient ages and type and location of the restorations did not indicate any differences between the two groups.

The ridit scores for margin fractures varied with the intraoral location of the restorations. Poorer ridit scores were observed for the first molars of both the upper and lower jaw, compared to the other teeth. In general, the mandibular teeth had better ridit scores than the maxillary teeth. Ranking the ridit scores by the individual tooth showed the same pattern in both jaws, i.e., first molars > premolars > second molars. However, these differences of ridit scores between the subgroups were not statistically significant. An exception was a significant difference of ridit scores between the upper first molars and the lower premolars after 4 years (Fig. II.9).

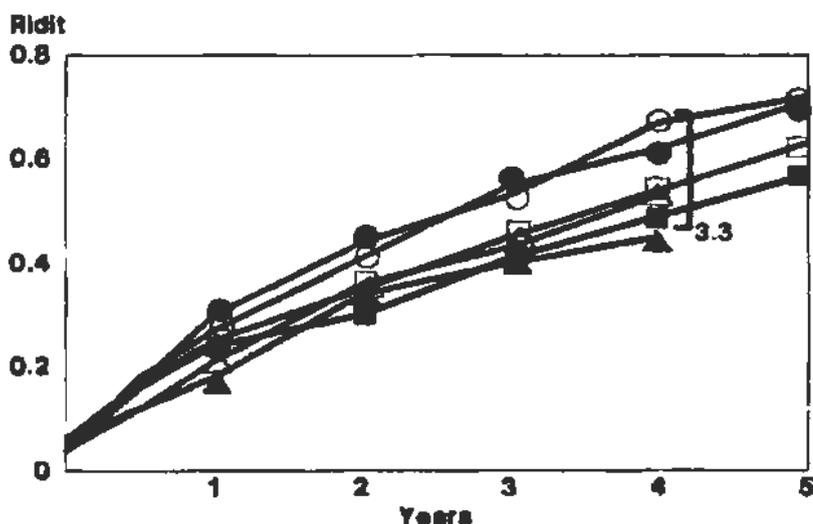


Fig. II.9. The ridit means for different tooth categories. 1. molars (circles, n=101 (upper) & n=87 (lower)), 2. molars (triangles, n=15 & n=26) and premolars (squares, n=68 & n=68). Open symbols depict maxillary teeth while closed symbols indicate the mandibular teeth. When 6 subgroups are compared, each individual paired comparison requires a critical normal curve value of 2.9 according to the Bonferroni criterion to be at a significance level of $\alpha = .05$, and 3.4 for $\alpha =$

The patients' age or gender did not seem to influence the ridit scores. No trends or statistical differences were noted ($p > .05$) (Figs. II.10-II.11).

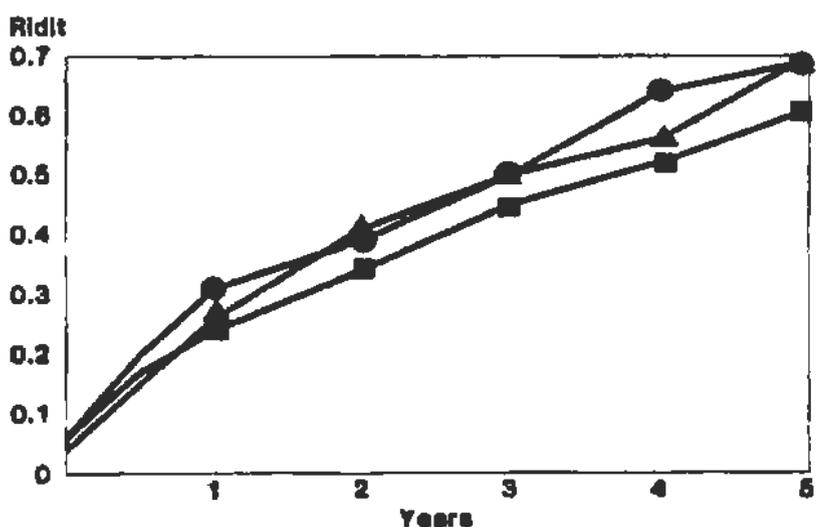


Fig. II.10. The ridit means for subgroups of patients categorized according to age at the time of restoration placement. Less than 18 years old (circles, n=181), 18-38 years old (squares, n=214) and more than 38 years old (triangles, n=73). When 3 subgroups are compared, each individual paired comparison requires a critical normal curve value of 2.4 according to the Bonferroni criterion to be at a significance level of $\alpha = .05$. No paired comparisons reached the required critical normal curve value.

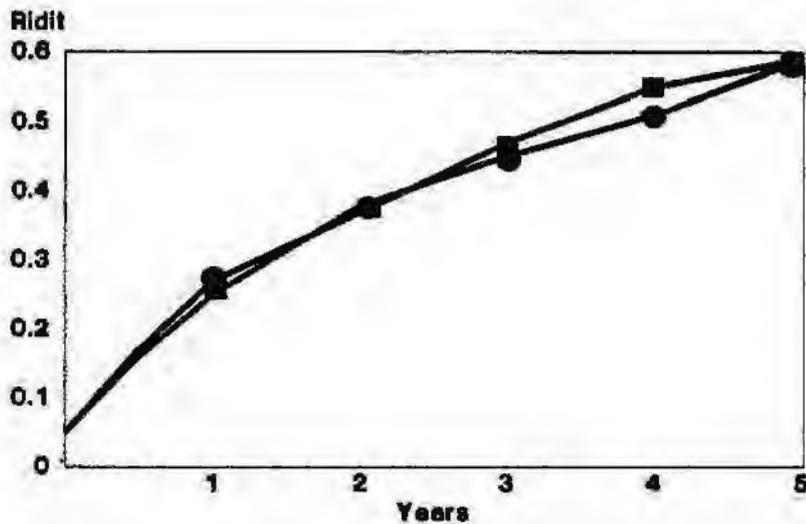


Fig. II.11. The rudit means for subgroups of patients categorized according to gender. Female (circles, n=267) and male (squares, n=201) patients.

When 2 subgroups are compared, each individual paired comparison requires a critical normal curve value of 2.2 according to the Bonferroni criterion to be at a significance level of $\alpha = .05$. No paired comparisons reached the required critical normal curve value.

Association with cavity morphology

A breakdown of the rudit scores according to the type of restoration showed no differences between the two- and three-surfaced restorations. However, better rudit scores were seen for the DO restorations, compared to the MO and MOD restorations after 2,3,4 and 5 years ($p < .01$) (Fig. II.12).

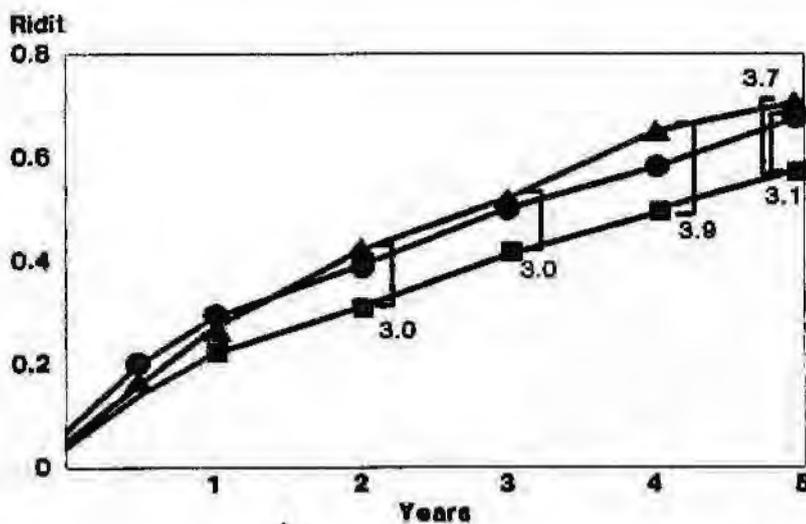


Fig. II.12. The rudit means for different restoration types. MOD (circles, n=147), MO (triangles, n=168) and DO (squares, n=153) restorations. The numbers at the brackets indicate the critical ratios between the mean ruidits. When 3 subgroups are compared, each individual paired comparison requires a critical normal curve value of 2.4 according to the Bonferroni criterion to be at a significance level of $\alpha = .05$, and 2.9 for $\alpha = .01$.

Only 3 variables of the cavity design showed significantly different rudit scores among the subgroups. These were the cavosurface smoothness, the presence of fissures along the cavosurface margins, and diverging axial walls.

The differences of ridit scores for the restorations placed in cavities with regular and irregular cavosurface margins were significantly different after 1 year up to 5 years (Fig. II.13).

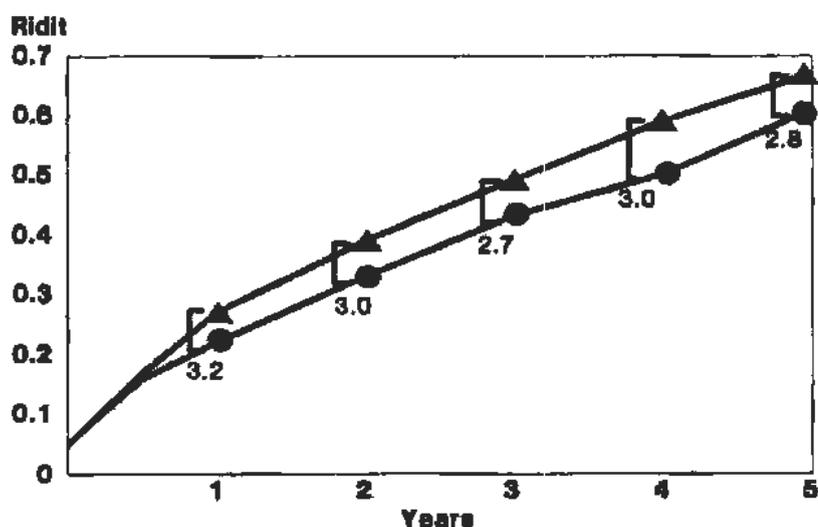


Fig. II.13. The ridit means for restorations placed in cavities with rough and variable cavosurface angles (triangles, n=112), and with smooth cavosurface angles (circles, n=326). The numbers at the brackets indicate the critical ratios between the mean ridits. When 2 subgroups are compared, each individual paired comparison requires a critical normal curve value of 2.2 according to the Bonferroni criterion to be at a significance level of $\alpha = .05$, and 2.8 for $\alpha = .01$.

The restorations with a presence of occlusal fissures in continuation with the cavity margin had significantly poorer ridit scores after 2, 3 and 4 years. Poorer ridit scores were also present at 6 months, 1 year and 5 years, but the differences were not statistically significant (Fig. II.14).

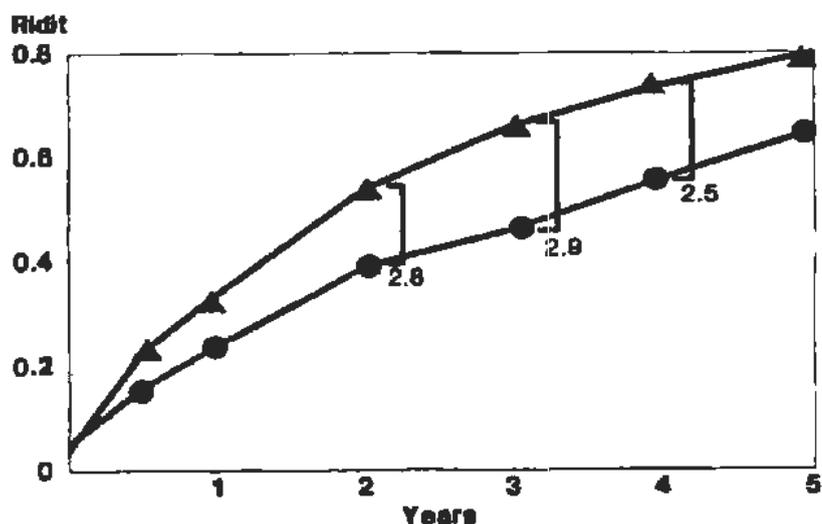


Fig. II.14. The ridit means for restorations placed in cavities with deep fissures perpendicular to the cavosurface angle (triangles, n= 23), and without (circles, n= 358). The numbers at the brackets indicate the critical ratios between the mean ridits. When 2 subgroups are compared, each individual paired comparison requires a critical normal curve value of 2.2 according to the Bonferroni criterion to be at a significance level of $\alpha = .05$, and 2.8 for $\alpha = .01$.

Restorations placed in cavities with diverging axial cavity walls displayed poorer ridit scores compared to those with converging walls. This differences was statistically significant at 3 years ($p < .01$), and 4 and 5 years ($p < .05$) (Fig. II.15).

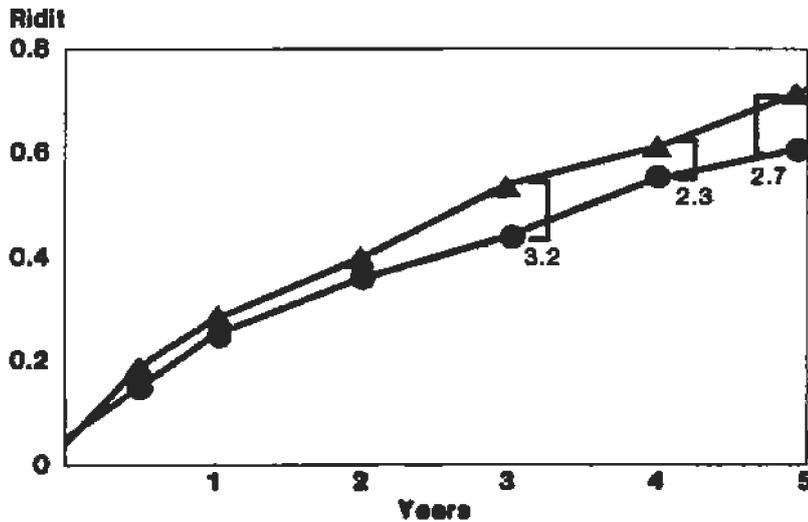


Fig. II.15. The ridit means for restorations placed in cavities with converging occlusal cavity walls (circles, $n=261$), and with diverging occlusal cavity walls (triangles, $n=177$). The numbers at the brackets indicate the critical ratios between the mean ridits. When 2 subgroups are compared, each individual paired comparison requires a critical normal curve value of 2.2 according to the Bonferroni criterion to be at a significance level of $\alpha = .05$, and 2.8 for $\alpha = .01$.

The association between margin fractures and other cavity design variables was relatively poor. No associations were observed to the different indices for the occlusal buccolingual width (Fig. II.16).

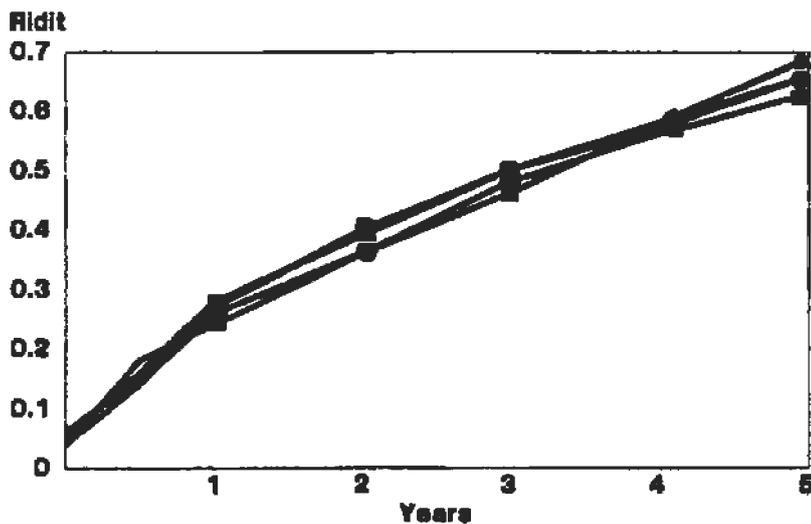


Fig. II.16. The ridit means for restorations placed in cavities of different widths. Less than 1/4 of the intercuspal width (ICW) (circles, $n=206$); more than 3/4 of the ICW (triangles, $n=44$); 1/4 to 3/4 of the ICW (squares, $n=187$). When 3 subgroups are compared, each individual paired comparison requires a critical normal curve value of 2.4 according to the Bonferroni criterion to be at a significance level of $\alpha = .05$. No paired comparisons reached the required critical normal curve value.

The ridit scores did not indicate a pattern between margin fractures and the location of the margins on the cuspal inclines (Fig. II.17).

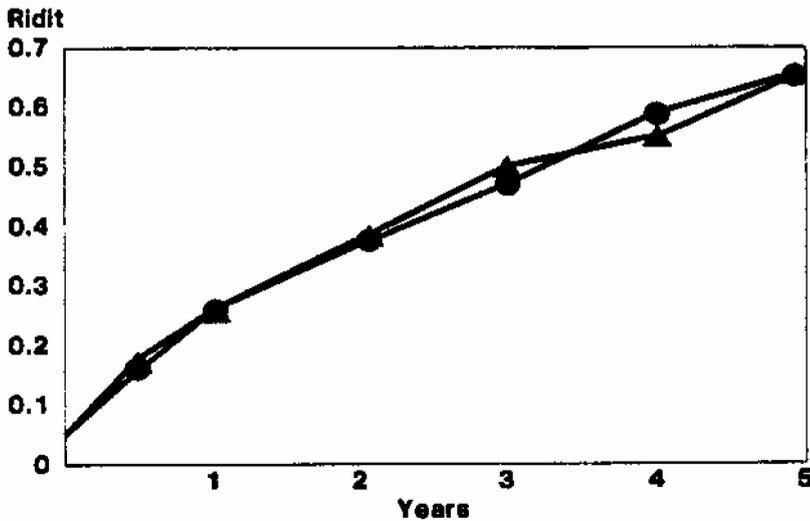


Fig. II.17. The ridit means for restorations placed in cavities with the cavosurface angle located occlusally to 2/3 of the cuspal incline (triangles, n=171), and apically to 2/3 of the cuspal incline (circles, n=271). When 2 subgroups are compared, each individual paired comparison requires a critical normal curve value of 2.2 according to the Bonferroni criterion to be at a significance level of $\alpha = .05$. No paired comparisons reached the required critical normal curve value.

A possible relationship between the buccolingual cavity width and margin fractures depending on amalgam alloy composition was assessed by subgrouping the cavity widths stratified by the amalgam alloys. Fig. II.8 shows that such a relationship may exist. However, further statistics were not computed due to the low number of observations. An inverse relationship was observed between the buccolingual cavity width and the ridit scores for Revalloy and Amalcap Non-Gamma-2, while Tytin, Indiloy and Dispersalloy showed a gradual increase of ridit scores with increased cavity widths (Fig. II.18).

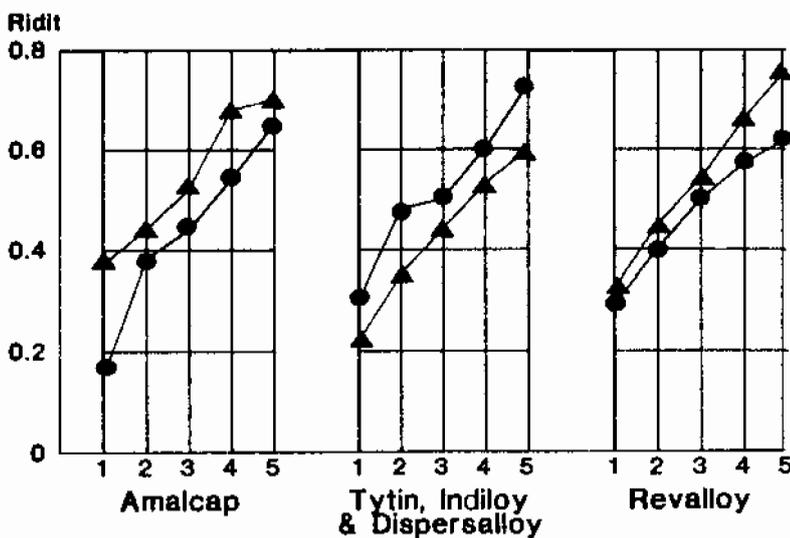


Fig. II.18. The ridit means for restorations during 5 years, made by different amalgam alloys and placed in cavities of different widths. The ridit scores are for the restorations made from Amalcap Non-Gamma-2, from Tytin, Dispersalloy and Indiloy, and from Revalloy. Triangles: less than 1/4 of the intercusp distance; Circles: more than 3/4 of the intercusp distance.

Subgrouping the restorations according to the cavity depth indicated more margin fractures on the restorations placed in the deepest cavities after 6 months, and subsequently the next 5 years. However, the differences in ridit scores were not statistically significant at any of the observation periods ($p > .05$) (Fig. II.19).

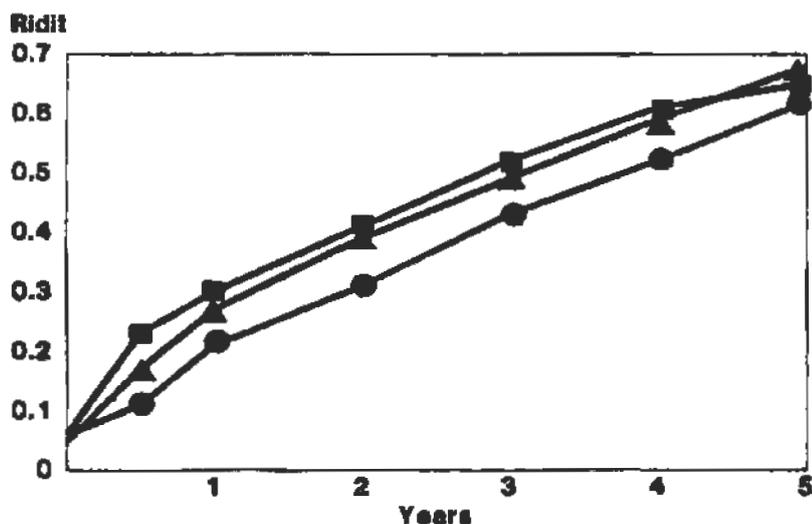


Fig. II.19. The ridit means for restorations placed in shallow cavities, less than 2 mm (circles, $n=91$), medium (triangles, $n=294$), or in deep cavities, i.e., more than 3 mm (squares, $n=56$). When 3 subgroups are compared, each individual paired comparison requires a critical normal curve value of 2.4 according to the Bonferroni criterion to be at a significance level of $\alpha = .05$. No paired comparisons reached the required critical normal curve value.

The relationship between cavity depth and the ridit scores for the margin fractures was studied further by stratifying the data from the different amalgam alloys. The analyses showed slightly different associations for the various amalgam alloys. The marked association between cavity depth and ridit scores was apparent for the restorations made from Dispersalloy, but was for the Revalloy restorations (Fig. II.20).

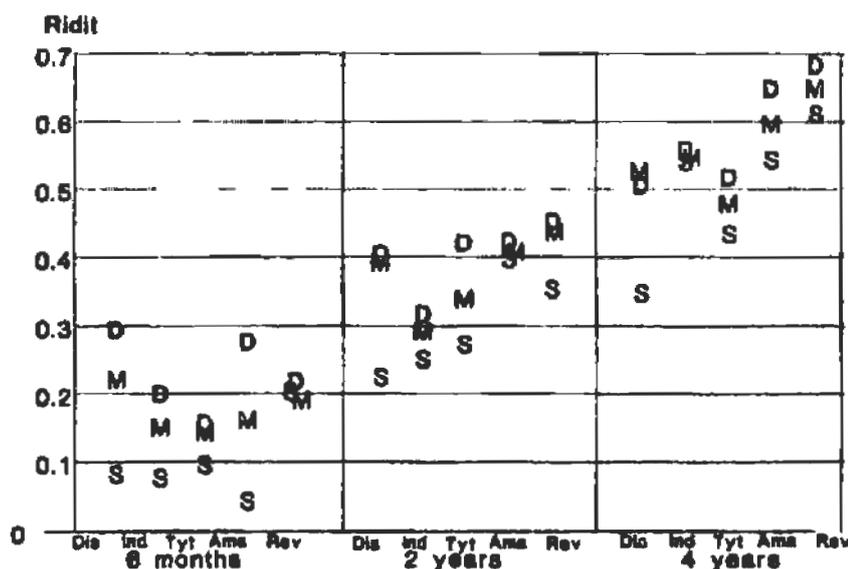


Fig. II.20. The ridit means for restorations placed in shallow cavities, less than 2 mm (S), medium (M), or in deep cavities, i.e., more than 3 mm (D) for 5 different amalgam alloys. Results after 6 months, 2 years and 4 years.

When the restorations were categorized according to their minimum bulk thickness, i.e., the restoration bulk and not the cavity depth, no differences among the subgroups were observed (Fig. II.21).

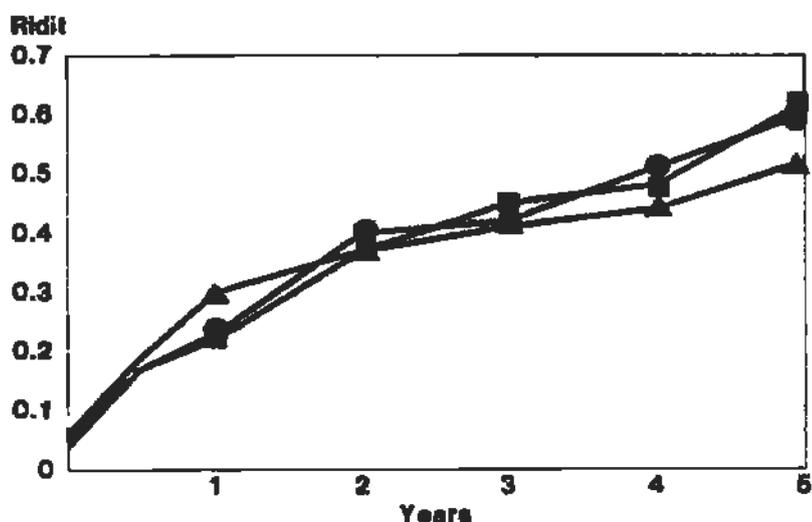


Fig. II.21. The ridit means for restorations with different minimum bulk thickness. Less than 1.5 mm (circles, n=56), between 1.5- 3 mm (triangles, n=54), or more than 3 mm (squares, n=40). When 3 subgroups are compared, each individual paired comparison requires a critical normal curve value of 2.4 according to the Bonferroni criterion to be at a significance level of $\alpha = .05$. No paired comparisons reached the required critical normal curve value.

The ridit scores were not influenced by differences in amalgam margin angles measured at the isthmus (Fig. II.22).

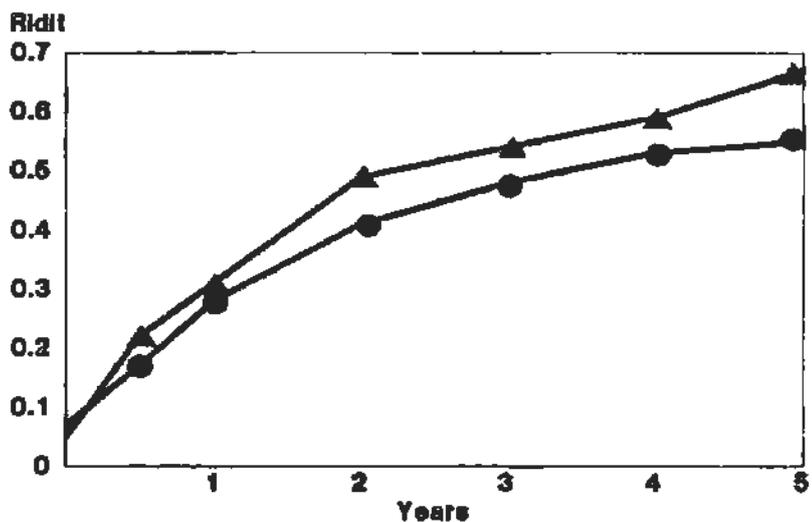


Fig. II.22. The ridit means for the restorations with amalgam margin angles at the isthmus less than 45° (circles, n=51) and more than 45° (triangles, n=99). When 2 subgroups are compared, each individual paired comparison requires a critical normal curve value of 2.2 according to the Bonferroni criterion to be at a significance level of $\alpha = .05$. No paired comparisons reached the required critical normal curve value.

The smallest restorations ($< 3 \text{ mm}^3$) had significantly better ridit scores than the voluminous restorations ($> 6 \text{ mm}^3$) at the half year, 1, and 3 years examinations (Fig. II.23).

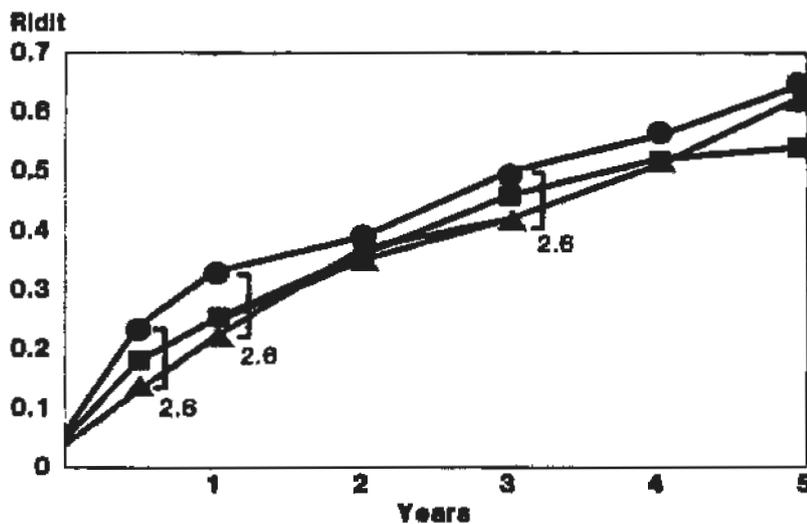


Fig. II.23. The ridit means for restorations with different volumes: $< 3 \text{ mm}^3$ (triangles, $n=102$), $3-6 \text{ mm}^3$ (squares, $n=111$) and $> 6 \text{ mm}^3$ (circles, $n=84$). When 3 subgroups are compared, each individual paired comparison requires a critical normal curve value of 2.4 according to the Bonferroni criterion to be at a significance level of $\alpha = .05$.

Unsupported enamel occlusally could not be related to the ridit scores (Fig. II.24).

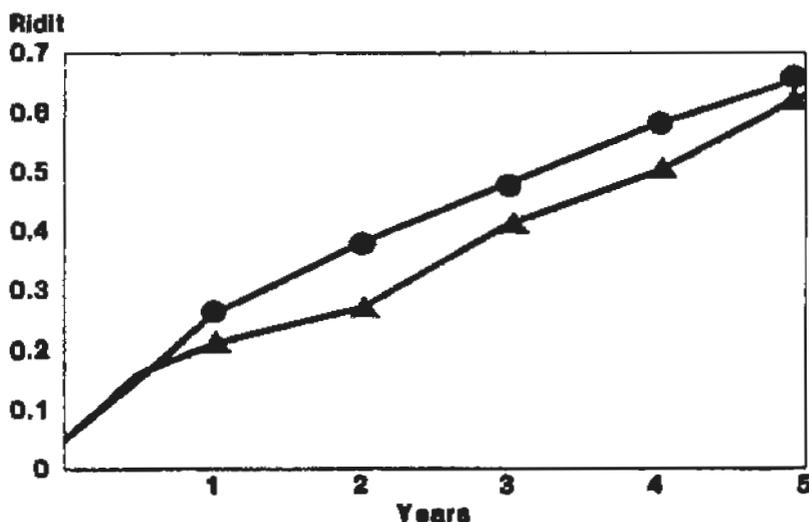


Fig. II.24. The ridit means for the restorations placed in cavities with unsupported enamel occlusally (Triangles, $n=25$), and in cavities without unsupported enamel occlusally (Circles, $n=415$). When 2 subgroups are compared, each individual paired comparison requires a critical normal curve value of 2.2 according to the Bonferroni criterion to be at a significance level of $\alpha = .05$. No paired comparisons reached the required critical normal curve value.

The restorations placed in cavities with segments < 1mm between the margin and previous restorations or fissures did not display more margin fractures than the restorations with no such segments (Fig. II.25).

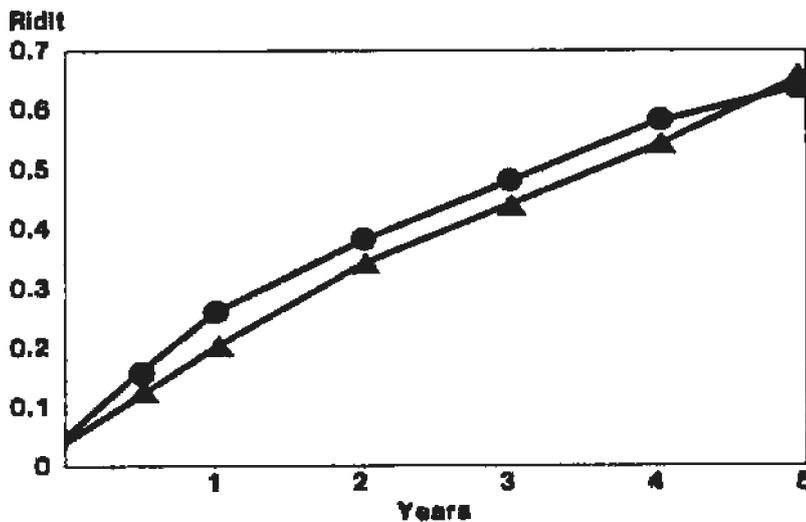


Fig. II.25. The riddt means for the restorations placed in cavities with less than 1 millimeter enamel remaining between the new preparation and former restorations (Triangles, n=65), and in cavities without remaining enamel (Circles, n=240). When 2 subgroups are compared, each individual paired comparison requires a critical normal curve value of 2.2 according to the Bonferroni criterion to be at a significance level of $\alpha = .05$. No paired comparisons reached the required critical normal curve value.

Discussion of methodology

Cavity preparations

In vitro evaluation

Evidently, limiting the evaluation of a cavity preparation to an in vitro examination of epoxy models is not optimal. One problem is that it is not possible to detect remaining demineralized areas along the cavity margins or in the fissures. It may be assumed that such lesions increase the risk for wall lesions, i.e., secondary caries, along the restorations, although this remains to be verified. A more important objection is the lack of a possible detection of remaining carious tissue. Recent studies, using caries detector dyes, have shown that dentists using the conventional optical and tactile criteria fail to detect caries at the enamel--dentine junction in over 50% of cavities (Anderson, Loesche & Charbeneau, 1985; Kidd et al., 1989). On the other hand, the clinical consequences of leaving remaining caries beneath a restoration are uncertain, and will probably be influenced by factors such as microleakage and the use of fluorides and dietary habits of the patient (Kidd, Joyston-Bechal & Smith, 1990).

Textbooks in operative dentistry suggest minimal penetration past the dentinoenamel junction. However, it is impossible to record the enamel thickness on models of teeth. Furthermore, it is difficult to exactly locate the cementsoenamel junction, as well as the axiocervical extension of the cavity on the proximal surface relative to the gingiva. Comparisons, e.g., secondary caries incidence, between clinical performance of restorations with sub- versus supragingivally located margins are, therefore, impossible using the in vitro method.

From a cariologic view, the buccolingual extension should ideally be measured relative to the adjacent tooth instead of as a fraction of the tooth circumference. In future studies, it should be possible to avoid this problem by using a double impression technique with elastomers or commercially available double impression systems, e.g., the EOS-system (Vivadent, Lichtenstein).

The advantage of using an indirect method is that examinations of the impressions and casts from different angles may show discrepancies that are undetected at the clinical examination. Impressions and casts may also be stored. They represent the detailed cavity design immediately before the restoration of the tooth; details that are lost once the cavities are filled with a restorative material.

The use of an ordinal scale for scoring cavity design features

Table II.4 shows that 15 cavity design features that were not measured on an interval scale were scored according to an ordinal scale. The discrimination of these scores were made according to an evaluation system originally described by Ryge & Snyder (1973), and developed further by Charbeneau (1981) (Table II.14).

Table II.14. Basis of the ordinal scores for quality evaluation of cavity design features based on rating systems developed by Ryge & Snyder (1973) and Charbeneau (1981).

-
1. A defined ideal preparation; The design will provide the best prognosis of extended longevity of the restored tooth.
 2. The preparation is satisfactorily, but exhibit features that might lead to premature failure; Deviates from the ideal to a small degree in a few areas.
 3. The preparation is satisfactorily, but exhibit features that might lead to premature failure; Deviates from the ideal to a small degree in large areas and/or to a marked degree in a few areas
 4. The preparation is not of acceptable quality. Future damage to the tooth and/or its surrounding tissues is likely to occur; Deviates from the ideal to such a degree that damage to the restoration or tissue is likely to occur in near future.
 5. The preparation is not of acceptable quality. Damage to the tooth and/or its surrounding tissues is now occurring; Preparation causes damage to the soft or hard tissue
-

For some of the cavity design features, only two clinically identifiable levels could be distinguished, and were scored accordingly.

The intra-examiner agreement was 85%, which indicated that the evaluation system could be used for assessment of cavities with good consistency.

Statistical considerations

The cavity design features rated by an ordinal scales (n=15) were in average categorized by 4 scores. Sixteen cavity design variables were measured on interval scales. Provided that the measurements of the 16 variables were categorized to 3 groups, the present evaluation system would, in theory, yield $4^{15} * 3^{16}$ possible "morphologic cavity preparation categories". Although the great majority of preparations would be limited to several hundreds of these categories, the total number of categories illustrate the complexity of a class 2 cavity design when described in detail. Of the 468 prepared cavities examined in the present study, none could be placed in the same morphologic categories. This was to be expected, since it can be assumed that even under strictly controlled clinical conditions, two cavities will never be identical, as long as the criteria for evaluating the cavities are detailed enough.

A consequence of the heterogenic nature of class 2 cavity preparations is that it is difficult, if not impossible, to conduct in vivo prospective experimental studies on cause-effects of cavity design features and replacement reasons or restoration survival. The reason is that it will be practically impossible to obtain enough identical samples, i.e., cavity preparations, to obtain meaningful data in long term clinical studies.

Cross-correlations of the cavity design variable values, with calculations of the Pearson's correlation coefficients, showed only interactions between the different indices of the buccolingual cavity widths ($p < .05$). The variables of the cavity designs were, therefore, treated as independent variables in the ridit analyses. However, Pearson's correlation measures only a linear relationship between variables. Multiple bi-variate plots of the categorized values were, therefore, made for all the variables. None of these plots suggested any non-linear correlation between the cavity design variables. On the other hand, this does not necessarily rule out any possible interaction effects of the cavity variables on the incidence of margin fractures.

Representativity

The cavities in the present study were of slightly poorer quality compared to cavities prepared by Danish dentists attending clinical courses in operative dentistry (Jokstad et al., 1989). However, a mere 400-500 restorations made by 7 dentists cannot be regarded as representative of either the approximately

30 000 Scandinavian dentists, nor to the tens of thousands class 2 restorations made daily in Scandinavia. It is thus not possible to infer any representability of the quality or the sizes of the cavities prepared in the present study.

Restorations

Recording of the restoration outlines

Taking an impression is a well-established technique in dentistry. Its use for recording two-dimensional silhouettes has been reported previously. Xhonga, Wolcott & Sognaes (1972) compared tracings of impression made by silicone rubber at 20x to study erosion. Terkla, Mahler & Van Eysden (1973) studied proximal extrusion of amalgam restorations, using a similar technique, while Leinfelder (1975) used composite tracings to measure loss of sealant material over time. Elderton (1977) described a method for measuring the cavosurface and amalgam margin angles. The recording method was adopted in the present study, with slight changes. One specific detail was the use of a traveling microscope to acquire a high accuracy of orientation of the impressions for cutting. It was considered that for measurements related to clinical assessments, such an elaborate procedure was not necessary. The cuts were, therefore, made freehand. Although this increased the risks for alignment errors, such errors were not experienced during the present study.

Table II.15 presents the mean measurements of different dimensions measured on tracings of the same teeth and made by two individuals independently, as well as duplicate tracings made by one individual (compare with Fig. II.2).

Table II.15. Mean bucco-lingual width, distances from the pulpal floor to the surface of the restoration, and cusp width (millimeters, mean \pm SD). Measured on tracings of pre- and post-restored impressions by two individuals (#1 and #2a) (n=20 x 2), and on replicate pairs of tracings made by the same individual (#2b) (n=10 x 2).

	#1	#2a	#2b
Width, buccolingual	2.10 (.45)	2.20 (.50)	2.20 (.60)
Distance, buccal wall	1.75 (.45)	1.75 (.50)	1.75 (.50)
Distance, lingual wall	1.70 (.55)	1.70 (.60)	1.70 (.65)
Minimum bulk	1.40 (.50)	1.55 (.50)	1.55 (.60)
Cusp width	5.45 (.70)	5.60 (.75)	5.40 (.95)

The error of the recording method was determined by comparing measurements from tracings made independently by two individuals of the same 20 impressions, and for duplicate tracings by the same individual of 10 impressions (Fig. II.1). The reproducibility of the measurements was tested by comparing the two sets of measurements made two weeks apart. Statistical analyses included inter- and intra-examiner correlations and computed standard deviations based on differences between measurements. Students T-tests for paired samples were applied to determine if there was any difference between the measurements. The standard deviations of the differences between tracings of the same teeth made by two individuals varied between .16 to .24 ($.02 < p < .90$), and for the duplicate tracings made by one individual between .08 and .53 ($0.11 < p < 0.85$). Thus, the inter-examiner standard deviations were higher than the intra-examiner standard deviations and no significant differences were found by the Students T-test for the different dimensions. The Pearson product moment correlation coefficients between the measurements varied between .91 and .99 for the different dimensions ($p < .001$). The lowest agreement (.91) was for the minimum restoration bulk thickness. The measurements of this dimension showed agreement on 15 of the 30 measurements within 0.1 mm, 28 of 30 within a margin of 0.2 mm, and the greatest difference was 0.3 mm.

The standard deviations of the differences between replicate measurements of the same tracings varied between .07 to .16. In general, the standard deviations of differences of measurement were lower for the replicate measurements than for the measurements of the replicate tracings.

The high Pearson correlation coefficients and low standard deviations indicated that the method was highly reproducible, and suitable for studies of the restoration and tooth dimensions in restored teeth, with a resolution of about 0.1 mm.

Scoring margin fractures on impressions

Various techniques for recording margin fractures have been described in the literature. The most common variant is the recording on black and white photographs (Osborne et al., 1976; Mahler, Terkla & van Eysden, 1973), or color slides (Smales, 1983; Kroeze, 1989). Other investigators have used impressions from which replicas are made. The replicas have been observed (Santucci, Racz & Norman, 1979), photographed (Mitchem, 1972; Richter & Mahler, 1973; Mjör & Ryge, 1981), assessed in a profile recorder (Smales & Creaven, 1979; Mahler & van Eysden, 1974), or in a scanning electron microscope (SEM) (Lutz et al., 1979), or measured quantitatively by other methods (Eick et al., 1973; Elderton, 1977; Miller et al., 1988).

In field trials, the recording is made by a non-specialized staff in their normal clinical practice. Field trials should, therefore, exclude technique sensitive recording methods and high caliber equipment (Møller, 1977). In addition, the clinical recording procedures should be fast and simple, to obtain continuous cooperation with the clinicians and the patients. Although scoring margin fractures on photographs is relatively simple for the evaluators, photographic recording of restorations is not optimal in field trials since it is time-consuming and require training of the clinical staff. An alternative indirect recording technique using impressions seems advantageous, since minimal training of the personnel would be required in the procedures for taking impressions. However, a disadvantage of this method is the extra work of making casts of the impressions, which increases the preparation time and possibly also introduce artifacts in the replicas (Pameijer, 1974).

It seemed advantageous to assess if the scoring of margin fractures could be made directly on the impressions. Evaluating margin fractures directly on impressions was described by Kusy & Leinfelder (1977), but only one paper have discussed the use of the method (Mjör & Ryge, 1981). In order to validate the procedure of scoring margin fractures directly on impressions, it was considered necessary that the method enabled an easy recognition of the fractures, and showed comparable fracture ratings with other validated indirect or direct methods.

The inter-examiner agreements on scoring impressions were assessed by Kappa statistics (Fleiss, 1981) for three examiners, using a subsample of 50 impressions. The inter-examiner agreements between the three examiners were $K = .41$ between examiner A and examiner B, $K = .49$ between examiner B and examiner C, and $K = .47$ between examiner A and examiner C. Examiner A and C were technicians trained to score margin fractures on photographs, while examiner B was a dentist. The examiners were not calibrated before the impressions were scored.

The scorings of the margin fractures on the impressions were compared to the scorings using photographs and to the clinical USPHS system ratings. The scores obtained when using impressions showed a fair correlation to the ratings obtained with the USPHS clinical evaluation (Kappa = .43), and to the scores with the photographic technique (Kappa = .43). The score and rating distributions using the three evaluations systems are depicted in Fig. II.26.

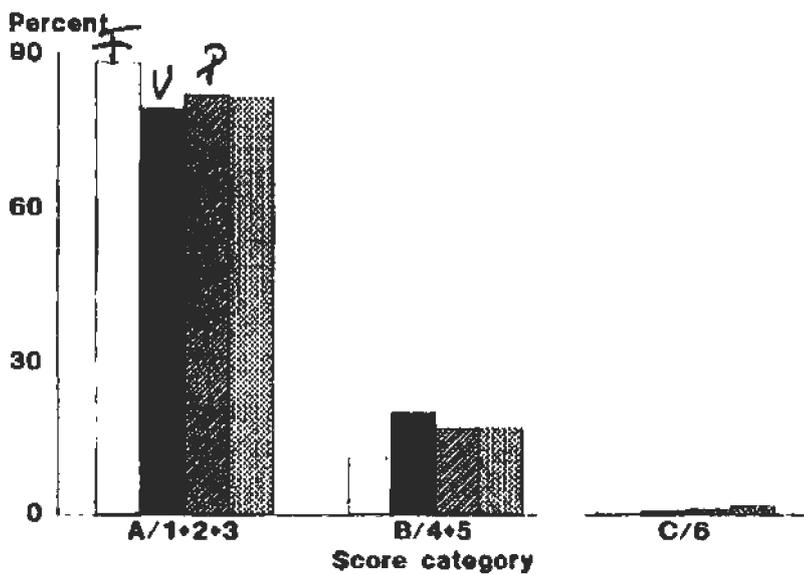


Fig. II.26. The rating distribution of the scores of margin fractures of 277 amalgam restorations using the USPHS clinical method (closed Bars) and photographs (open bars), compared with the score distribution of 192 restorations assessed by using impressions (bars with light shadow) and photographs (bars with dark shadow). The data are pooled as USPHS scorings Alfa, crevice along the margin into which the explorer cannot penetrate, A = ratings 1+2+3, Beta, crevice into which the explorer will penetrate, B=4+5, and Charlie, margins with dentin or base exposed, C=6.

The inter-examiner agreement of the scorings using impressions and a 6 point scale reference set could be considered satisfactory. Thus, margin fractures can be discriminated on impressions with relatively high accuracy. Furthermore, the rating distribution of the scorings using impressions showed good correlation to the rating distributions when using the clinical USPHS rating method and when using photographs for recording margin fractures.

Margin fracture scores and statistics

Several methods for scoring the extent of margin fractures have been presented in the literature. Statistic inferences from such scorings have been presented using parametric (Letzel, 1978, Mahler & Marantz, 1979), non-parametric (Osborne et al., 1976; Fukushima Setcos & Phillips, 1988), and ridit statistics (Mahler, Terkla & van Eysden, 1970). Assigning numerical values to several outcome categories and applying parametric statistics appropriate to quantitative scales may be inappropriate, as the results depend on the particular numbers employed and because the impression is given of greater precision than really exists (Jacobsen, 1988). The two other statistics, non-parametric and ridit analysis uses essentially the same approaches. While ridit analysis uses a probability relative to a reference distribution for identifying differences between subgroups, the Mann-Whitney test (also known as the Wilcoxon Rank Sum W-test) uses the sum of sets of ranks as a measure of the differences between samples (Kantor, Winkelstein & Ibrahim, 1968; Selvin, 1977). Ridit analyses of scorings of margin fractures were introduced by Mahler et al. (1970), and have since been used in many clinical studies

(Mahler, 1988). An assumption made in ridit analysis is that the discrete categories represent intervals of an underlying but un-observable continuous distribution (Bross, 1958; Fleiss, 1981). Provided the distribution of any other group over the same categories, the mean ridit for a group may be calculated. The resulting values are interpretable as probabilities. Possible tests for comparing ridits between $k+1$ subgroups are chi-square or multiple t-tests with the option of adding the Bonferroni correction procedure. The algorithms described by Fleiss (1979) were used in the present study, which were based on multiple Bonferroni-corrected t-tests. The reason was that although both chi-square and t-tests will identify differences among subgroups, only the latter will identify the subgroups that differ from each other (Fleiss, 1979). An advantage of ridit analysis is that the number of scoring groups can vary, and may not necessarily be of equal lengths. Furthermore, subjectivity in scoring margin fracture will not confound the results as it is applied both to the reference and the studied group. A disadvantage of ridit analysis is that the method is not multivariate, which limits the applicability of the method and the validity of the statistical inferences when the study is not properly controlled (Torp, 1982). Another disadvantage of ridit analysis is that the ridit values represent probabilities versus a reference standard, which in many studies is not defined. Ridit values are thus not fixed, making inter-study comparisons difficult and meta-analyses impossible (Thompson & Pocock, 1991; van 't Hof, 1991; Cohen, 1992).

Study design

Clinical research methods in restorative dentistry may be classified by the characteristic of the method, i.e., experimental or observational; by the nature of the data gathering, i.e., longitudinal or cross-sectional; and by the direction of the data gathering, i.e., retrospective or prospective (Hendriks, 1985). An alternative classification is either into explanatory clinical trials or pragmatic, which is synonymous with field, trials (Jacobsen, 1988). The prerequisite for categorizing a clinical study as an experimental study is that the research plan is designed to provide cause-effect-relationships, the presence of an experiment and control group, one or more variables allocated randomly in the experimental group, standardized evaluation criteria and observers, elimination of confounding by manipulation of the independent variables, valid statistical analysis and inferences and the possibility of generalization of the results. Also, a clearly formulated hypothesis should be formed (Jacobsen, 1988). The principal idea of the present study was to observe the performance of amalgam restorations placed on typical patients by dentists in their working environments. All clinical variables identified as potentially influential on margin fractures were controlled by explicit descriptions in the study protocol, and the pre-trial training courses. The group of dentists participating in this study was

heterogeneous and did not represent any particular segment of dentistry. Thus, no conclusions can be made regarding their representativity. It should also be considered that using different dentists and groups of patients can introduce uncontrolled variables and confounding (Jacobsen, 1984). Since the present study involved many variables, and relatively few restorations were followed for observation, the design of the study cannot be considered strictly experimental. The results in the present study should, therefore, be verified in more controlled studies, limited to only some of the variables, before valid extrapolations can be made.

Patient dropout

The dropout rate in this study was relatively small, with 63% of the patients remaining after 5 years observation. The largest dropout group was teenagers leaving the school dental services. It was considered necessary to assess if this group or the remaining dropout patients confounded the margin fracture ridit scores. The possible influence on the average ridit scores by a selective dropout of patients was assessed by comparing the ridit score for the restorations that could be followed during the full 5 year observation period to the ridit scores for each subset of patients with 2,3 and 4 year observation periods. The ridit scores for each subset of patients with 2,3,4 and 5 year observation periods are shown in Fig. II.27.

No statistical differences between the four subsets could be seen, except between the 0-2 years and 0-3 years groups at the 2-years observation. However, the difference was not reflected by a trend among the 4 subgroups. The ridit scores for the 0-2 years observation group were the highest, and lowest for the 0-3 years observation group, while the 0-4 and 0-5 years observation groups showed ridit scores in between ($p < .05$). The observed difference was, therefore, disregarded.

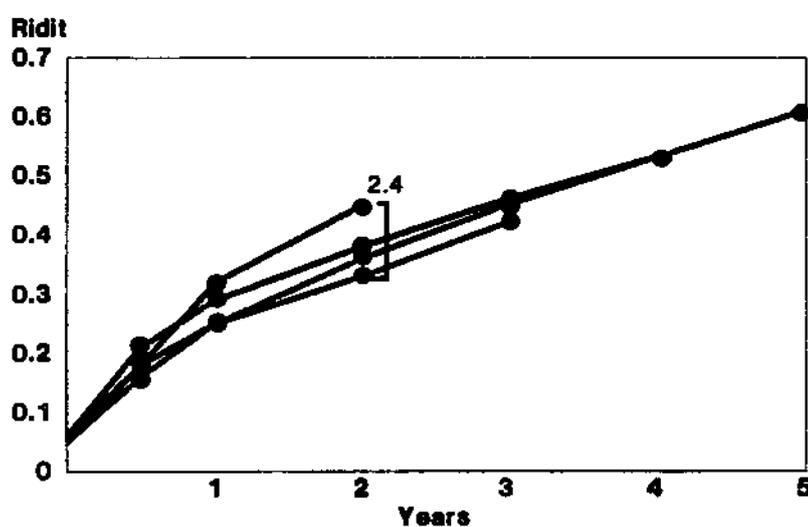


Fig. II.27. The ridit means for the restorations with 0-2 years ($n= 30$), 0-3 years ($n= 57$), 0-4 years ($n= 44$) and 0-5 years ($n= 296$) observation times, as a function of time. Forty-one restorations were lost during the first 2 years of the study. The numbers at the brackets at 2 years indicate the critical ratio between the mean ridits of the maximum and minimum values at this point (2-year and 3-year cohorts). When 4 subgroups are compared, each individual paired comparison requires a critical value of 2.6 according to the Bonferroni criterion to be at a significance level of $\alpha= .05$.

Discussion of results

Association with clinical variables

Amalgam alloy

The observation that less margin fractures were observed for the high-Cu amalgam alloys compared to the conventional amalgam alloy is according to previous observations (Mahler, 1988). However, the relatively poor ridit scores for Amalcap Non-Gamma-2 shows that more copper in the amalgam alloy does not necessarily lead to less margin fracture compared to conventional amalgam alloys. The ranking of the amalgam alloys is identical with the ranking of these amalgam alloys in other studies after 5 years (Osborne, 1990), 13 years (Osborne & Norman, 1990), and 14 years (Osborne, Norman & Gale, 1991). On the other hand, the data also shows that a conventional amalgam alloy in the hands of a proficient dentist may equal the behavior of the high-Cu amalgam alloys, when confining this to margin fractures.

Operators

An explanation for the superior clinical performance of the restorations placed by one of the dentists was not clear. The prepared cavities were fairly identical, as well as the amalgam margin angles. On the other hand, the amalgam margin angle was only measured at the isthmus, and was not necessarily representative of the whole restoration margin. Furthermore, this particular dentist had placed all 76 restorations in only 17 patients, while the other dentists had distributed their restorations in a larger number of patients. Although the demographic data of the patients were similar to the remaining patients, considered as one group, it is possible that these 17 patients had an oral environment different from the other patients, e.g., better oral hygiene, favorable saliva, lower masticatory forces, etc.

Clinical variables that were not assessed in the present study, which may have confounded the results are the frequency and location of overfilling along the margins, or steep amalgam margin angles. Also saliva contamination during placement or excessive use of varnish can explain the differences among the dentists. However, since only one dentist showed superior results versus the other dentists, and not vice versa, these factors are not probable explanations of the dentist differences.

Other parameters associated with the operator that may affect the incidence of margin fractures are possibly the trituration time (Osborne & Gale, 1974;

Mjör & Espevik, 1980), use of rubber dam (Letzel et al., 1979), the condensation techniques (Letzel, van 't Hof & Vrijhoef, 1987), and the technique for carving, burnishing and polishing (Jeffrey & Pitts, 1989).

The proportioning and trituration time was controlled by the dentists' adherence to the manufacturers' instructions. All cavities had been prepared and restored without the use of rubber dam. One study has shown that the type of condensation instrument is of little importance in margin fracture (Letzel et al., 1987). Wilson & Ryge (1963), on the other hand, reported that students using heavy condensation pressure produced restorations with less margin fractures. The effect of the technique for burnishing the restoration margins is difficult to estimate, and nearly impossible to record since the "surface treatment" is influenced by factors such as burnishing load, direction of the strokes, number of strokes, beginning time after trituration and the size of the burnisher (Kanai, 1966; Bauer, 1987; Jeffrey & Pitts, 1989).

The use of varnish was compulsory and not controlled. In vitro experiments have shown that margin leakage depend on the type of varnish (Ben-Amar, 1989). To what extent cavity varnish types and thicknesses induce margin fractures is unknown. It is conceivable that some varnish types may be incorporated into the amalgam along the margin, depending on the type used, and thereby reduce the strength in these areas (Staehele & Merker, 1989; Charlton, Murchison & Moore, 1991). Thus, there is a theoretical possibility that the type or amount of varnish may be related to margin fracture. However, the clinical data on such relationship is sparse, and the existing data are not conclusive (Advokaat et al. 1980; Borgmeyer et al., 1981; Advokaat, Akerboom & Borgmeyer, 1986).

Intra-oral location

The relationship between the intra-oral location and margin fractures is controversial, both concerning differences between teeth in separate dental arches and premolars versus molars. The differences in ridit scores observed in the present study may partly be attributed to the slightly greater cavity sizes in the first molars, and the smaller sizes in the mandibular premolars, compared to that in the other teeth (Jokstad & Mjör, 1989). On the other hand, some of the diverging conclusions may be due to the frequent lack of differentiation between 1 and 2 molars in the different studies. Mahler & Marantz (1980) found only slight differences between molars and premolars. However, they did not specify the intra-oral location beyond describing the teeth as cuspids and bicuspid. Goldberg et al. (1980) reported more fractures in the molars compared to the premolars after 1.5 years. Neither did these investigators differ between 1 and 2 molars. Mjör & Espevik (1980) concluded on the basis of 3 years observations that contralateral teeth showed similar

ridit scores, which contrast the findings of MacRae, Zacherl & Castaldi (1962). Osborne & Gale (1981) reported different margin fracture scores among the tooth groups, but only the lower premolars had statistically significant lower ridit scores than the other teeth. In a latter study, differences were noted between the molars and premolars and between the upper and the lower jaws (Osborne & Gale, 1990). Similar findings were reported by Laswell et al. (1990) using the same study material. Also Smales, Gerke & Hume (1990) observed less fracture in the premolars. However, in both latter studies, no differentiation was made between the first and second molars and premolars. Another explanation of the diverging conclusions is that the quality of the occlusal cavity margins may vary in different tooth categories (Jokstad, 1989). In addition, the bite force is probably also a significant etiological factor. Since the maximum bite force occurs in the first molar regions (Bates, Stafford & Harrison, 1975), one may expect more material deterioration and margin fractures in these regions. This hypothesis is supported by studies of wear of posterior composites (Leinfelder et al., 1986) and fissure sealants (Conry, Pintado & Douglas, 1990), which show increased wear in the first molar regions.

Association with cavity morphology

(^{over}Restoration) class

The ridit scores were similar for the two- and the three-surfaced restorations. One study has shown similar margin fracture scores for class 1 & 2 restorations (Mahler & Marantz, 1980), while another reported similar margin fracture scores for class 1, 2 & MOD restorations (Goldberg et al., 1980). Three-surfaced restorations have increased flexibility of the cusps compared to the two-surface restorations (Part I, section 2). For this reason, several investigators have suggested that margin fracture occurs more frequently in three- compared to two-surfaced restoration (de Vree, Peters & Plasschaert, 1984). However, this hypothesis was not supported by the present data. The observation that DO restorations had lower ridit scores than the other class 2 restorations is difficult to explain. Some differences may be due to a slightly higher frequency of DO restorations in the mandibular premolars than in the other teeth. This contrasts, however, with the observation that the average dimensions of the DO cavities were larger than the MO restorations, and the frequency of cavity discrepancies higher (Jokstad, 1989; Jokstad & Mjör, 1989). There are to the author's knowledge no previous reports where the margin fracture incidences of MO- and DO- restorations have been compared.

Cavity size

Different measures for the buccolingual widths were calculated, but correlations between any of these and margin fractures could be observed. Previous studies show no correlation (Mahler & Marantz, 1980; Osborne et al., 1989), poor correlation (Birtcil, Pelzner & Stark, 1981; Mjör & Espevik, 1980; Smales et al., 1990), or significant associations (Nadal, Philips & Swartz, 1961; Wilson & Ryge, 1963; Osborne & Gale, 1981 & 1990; Berry et al., 1981). It is difficult to compare the results in these reports, since the methodology for measuring the cavity size and quality of the cavosurface angle seldom is described. A detail that may remain undetected is the mutilated or large cavosurface angle on the contralateral surface, which frequently is present in narrow preparations unless specially shaped burs are used (Kinzer & Morris, 1976). It is also uncertain to what degree the higher amalgam margin angles routinely carved in narrow cavities may influence the clinical behaviour (Elderton, 1977; Elderton, 1984). Furthermore, the larger the restorations, the greater is the length of their margins, and the more likely changes from the ideal are found. Finally, the lack of consistency in the previous reports may also be explained by a variable effect of the cavity width for the different types of amalgam alloy (Fig. II.18). Interactive effects of the materials and the cavity width was also noted by Osborne & Gale (1981).

The margin fractures could be related to the depth of the cavity preparation and to the restoration volume, but not to the minimum bulk thickness of the restoration at the isthmus. The reduction of cusp stiffness as a function of the volume of removed tooth tissues has been documented (Hood, 1991). The association to margin fractures in the present study support the hypothesis that increased flexibility of the axial walls induce more fracture of the margins (Derand, 1977; de Vree et al., 1984; Laswell et al., 1990; Osborne & Gale, 1991).

An alternative hypothesis is that margin fracture is the result of a dimensional instability of amalgam over short or long time, which is accentuated in restorations with more bulk along the axial cavity walls. This hypothesis presumes that the margin fracturing will be influenced by the adaptation of the amalgam along the margin, i.e., good adaptation horizontally causes more expansion vertically. In this context, the amalgam alloy composition and condensation technique are important parameters. In theory, expansion and contraction may be induced by temperature changes (Wright & Yettram, 1978). Expansion may also develop due to corrosion and phase shifts in the material (Paffenbarger, Rupp & Patel, 1979). This mechanism would be different from the well known expansion in saliva-contaminated Zn-amalgams. The hypothesis can be supported by sporadic observations of margin extrusion in clinical studies (Sweeney, 1940; Vrijhoef, Spanauf &

Driessens, 1975; Osborne, Winchell & Phillips, 1978; Beech, 1982). A close relationship between margin fractures and extrusions of the proximal and the occlusal parts of the restorations were observed in two clinical studies with 3 different amalgam alloys (Mahler & van Eysden, 1974; Terkla et al., 1973). Extrusion of amalgam was also registered indirectly as an increased frequency of the score "Catch of explorer towards restoration" compared to the baseline evaluation in a 4 year clinical study (Leidal & Dahl, 1980). Furthermore, two studies of wear of dental materials in-vivo have reported a negative wear of amalgam restorations, i.e., extrusion of the restorations (Roulet, Mettler & Friedrich, 1980; Mettler, Friedrich & Roulet, 1978). Finally, one textbook on dental materials describes a continuous expansion of amalgam due to corrosion, which on the occlusal surface constantly is reduced by the abrasive forces (Leinfelder & Lemons, 1988). Unfortunately, the textbook authors did not present any references to support this statement.

Cavosurface margin

The association between cavosurface margin quality and ridit scores confirm the results of Leidal & Dahl (1980). The reason for the poorer ridit scores is probably due to an inadequate condensation along margins areas with poor cavosurface definitions (Geiger, Reller & Lutz, 1989), and lack of vertical support when subjected to occlusal forces (Granath & Hiltcher, 1970). On the other hand, Elderton (1977) found, based on an observational study, no support for the hypothesis that margin fractures are influenced by cavosurface irregularities.

The removal of enamel if less than 1 mm remain between the cavity preparation and fissures, remaining restorations or other defect is advocated in textbooks on operative dentistry (Marzouk, Simonton & Gross, 1985; Sturdevant et al., 1985; Charbeneau, 1988). However, the 65 restorations placed in cavities with less than 1 millimeter enamel remaining between the new preparation and former restorations did not show higher ridit scores than the other restorations. In other words, the enamel slices did not fracture and contribute to secondary caries or margin fracture. The present data, therefore, indicate that removing thin enamel slices as a preventive procedure against margin fractures occlusally is unnecessary.

Twenty-five restorations had been placed in cavities with cavosurface angles less than 90° occlusally. These sectors did not fracture and contribute to "marginal ditching". The observations are in accordance with Elderton (1977), who found no support that cavities with cavosurface angles < 90° significantly influenced fracturing of the restoration margins.

The observation indicates that it may be unnecessary to remove undermined enamel occlusally before restoring with amalgam. However, such a conclusion

may not be valid, since it is a well-established observation that unsupported enamel along margins shows microcracking and fractures upon stress, e.g., when using an amalgam matrix (Boyde & Knight, 1972). It is more probable that the use of a strictly geometrical definition of undermined enamel, i.e., 90°, is incorrect when describing a cavosurface margin on the occlusal surface.

The reason the occlusal cavosurface angles smaller than 90 degrees or thin enamel slices could not be associated with margin fractures is presumably because of the variation in the enamel prism directions on the cusp inclines (Boyde, 1976). Cavosurface angles smaller than 90 degrees or slices of enamel remaining between the preparation and former restorations should, therefore, not be removed unless the enamel easily can be cleaved and removed with hand instruments.

The ridit scores for the 23 restorations placed in cavities with deep fissures in continuation with the cavosurface angle were significantly higher than the ridit scores for the other restorations. All these fissures became obliterated with amalgam after insertion of the restoration. The material excess fractured after variable periods. Also, in some restorations, the size of the fractured surface gradually increased. The association between remaining deep fissures in continuation from the margin and extent of margin fractures is according to previous in vitro investigations (Jørgensen & Wakumoto, 1968), and observational results (Matsuda & Fusayama, 1970).

The higher ridit scores of the restorations placed in cavities with diverging occlusal walls support the data from other cross-sectional (Elderton, 1977 & 1984) and longitudinal (Akerboom et al., 1981) studies. The higher scores were especially seen on the restorations with thin remaining cusps, which support the hypothesis that margin fracturing is the result of a biomechanical mechanism between the restoration and the cusp (Derand, 1977). On the other hand, the increase could also be explained by the low amalgam margin angles frequently present in cavities with high cavosurface angles (Elderton, 1977; Elderton, 1984).

General results

In general, Figs. II.4- II.25 show that the differences in ridit scores among the independent variable subgroups often appeared at the 1 year observation, and sometimes after 6 months, while after that, the ridit scores were relatively parallel during the next 5 years. This has also been noted in other clinical trials, where the investigators report differences between amalgam alloys after a relatively short observation period, with no changes in the discrimination between the amalgam alloys later during the observation period (Larson et al.

1979; Ricker & Greener, 1988). Even after 13-14 years the ranking of amalgam alloys by their ridit scores is identical with the ridit scores after 1 year (Osborne & Norman, 1990; Osborne et al., 1991). This signifies that at least one process which causes margin fractures occurs during the first year after placement of the restoration. This hypothesis, however, does not identify or exclude etiological factors that may cause fractures, e.g., mercuroscopic expansion (Jørgensen, 1965), creep (Mahler et al., 1970), biomechanics (Derand, 1977), bulk corrosion (Sarkar, Osborne & Leinfelder, 1982), crevice corrosion (Sutow, Jones & Hall, 1989) or fatigue rupture (Williams & Cahoon, 1989).

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5. 10-Year observations on failures of class 2 amalgam restorations, and retrospective analyses of patient, material, and cavity design characteristics

A review of the dental literature shows that today's knowledge on the association between details of the class 2 cavity prepared for an amalgam restoration and the restoration performance is primarily based on empirical experience, in vitro experiments (Tables I.2-I.8), and clinical observational longitudinal and cross-sectional studies (Tables I.18-I.19). In addition, a few experimentally designed clinical studies have focused on selective aspects of the cavity preparation and short term restoration discrepancies (Table I.17). In general, the results from the different studies are not consistent, and the conclusions are often contradictory. Furthermore, there is a lack of clinical data on the relationship between cavity design and restoration failures.

Associations between cavity design and restoration performance should be clarified to minimize confounding when conducting clinical trials of new or alternative restorative materials. Studies have shown the markedly different clinical performance of new restorative materials when placed in wide versus narrow cavities (Forsten, 1989; Leinfelder, 1991), or depending on the amount of remaining enamel axially to the proximal gingival margin (Roulet & Noack, 1991; Mayer, 1991). The physical and mechanical properties of the new alternative materials enable observations of the direct effects of the cavity design on the incidence of restoration discrepancies and restoration performance. It is logical to assume that amalgam restorations are also subject to the same influences. However, the relationship is not as apparent due to different, and possibly superior, material properties, or because previous clinical research has not focused on the possible association.

There is also lack of data on the clinical performance of dental materials and on the quality of dental service provided by dentists in general practices, especially on the interaction between clinical performance of restorations and quality of service (NIDR, 1991).

Studies on potential relationships between cavity design or dentists and restoration performance should preferably be observational, before implementing more experimental studies and formulations of cause-and-effect hypotheses. One possible starting point is to assess clinical characteristics and

cavity preparations of restorations that fail clinically, e.g., in much the same way as done by Healey & Philips (1949), with the distinct difference that the baseline information should be available. The experimentally designed study described in Part II, elucidating the effects of different clinical variables on margin fractures, included recordings of many clinical variables that have been shown to influence the short term restoration performance. Furthermore, the cavity preparations used in Part II of this study frequently showed marked deviation from the textbook descriptions of the ideal class 2 cavity. It seemed feasible, therefore, that several restorations would fail after a relatively short service period due to inadequate cavity preparations. These data, therefore, provided an excellent opportunity to conduct such an observational retrospective study on the restorations that failed for any reasons, or remained in service. Consequently, the restorations were followed for a 10-year period.

The aims of the study were to record the service period and the replacement reasons of class 2 amalgam restorations made under routine conditions by general practitioners, and to relate the clinical performance of the restorations retrospectively to patient, dentist and material variables, and quantitative and qualitative features of the prepared cavity.

Materials and methods

The materials and methods have been described in Part II, section 1. The patients have since the placement of the restorations been recalled each year for an examination of their dental status. The quality of the restorations has been evaluated clinically by dentists who were trained in using the criteria of the USPHS system (Cvar & Ryge, 1971). The use of x-rays and other diagnostic aids to assess the status of the restorations were left to the dentists' decisions, depending on the clinical situation. In case of a restoration needing replacement, recordings were made of the date, the reason for failure and the exact location of the defect. The reasons for replacement are shown in Table III.1.

Table III.1. Restoration status after 10 years clinical service.

In situ
Lost due to patient dropout
Replaced due to secondary caries
Replaced due to bulk fractures
Replaced due to tooth fracture
Replaced due to margin fractures
Replaced due to other reasons

When secondary caries occurred, the original impressions of the cavities were examined for possible contacts between the cavosurface margins and the adjacent tooth. In case of restoration bulk fractures, the last photographs and impressions made before the fracture were examined for typical wear facets, cracks or deep sulci on the occlusal surface. All failed restorations were retrieved, if possible, for metallographic examinations (Johansson & Mjör, 1988).

A modified DFT increment score was recorded at each yearly examination. The modification from the conventional DMT increment index was that only increments due to manifest primary or secondary caries lesions that had required operative treatment were included in the present DFT increment score. Thus, the presence of secondary caries lesions, which ordinarily do not influence the DMFS or DMFT indices, increased the DFT score in the present study. On the basis of the DFT increment scores, the patients were categorized into three groups: low increment group: < .5 DFT increment/year; medium increment group: between .5 and 2 DFT increment/year and high increment group: > 2 DFT increment/year. In some cases, the patient changed DFT increment groups during the 10-year observation period.

The service period of the restoration was defined as the number of months between the placement of the restoration and the time of failure. In case of patient dropout, the date of the last observation in which the restoration functioned was recorded. The estimated survival of the whole observation sample was computed using Kaplan-Meier survival analyses. The survival functions were calculated using all the restorations, and on random samples with only one restoration from each patient.

Restorations grouped by failure reasons were related to different clinical variables by two statistical methods. Ridit analysis was used to relate retrospectively the failed restorations to the margin fracture scores before the failure, and compare the ridit scores of the groups distinguished on the bases of the restoration fates.

Linear discriminant analyses were also applied. Both forced and stepwise selection entry of classification variables were applied initially. Preliminary analyses showed that both algorithms produced similar results, and the stepwise selection entry was, therefore, used in the present study. The classification variables are presented in Tables II.4, II.5 and II.11. Separate analyses were calculated with all variables included, or with only the cavity design variables included. Linear discriminant functions include classification variables that minimize the within-group variability and maximize the between-group variability of a second group. The ratio between the between-group sum of squares and the within-group sum of squares were described the eigenvalues of the discriminant functions. The first group consisted in all the analyses of restorations remaining in situ after the observation period. The

second group consisted of either failed restorations due to secondary caries, or failed restorations due to restoration bulk fractures. The between-groups and within-groups variability calculations were based on Wilks' lambda (U-test). Discriminant analyses were not applied for the other failure reasons, due to the low number of replacements.

The importance of the different clinical variables for classifying the restorations into the separate groups was assessed by ranking the standardized coefficients in the discriminant functions. Also the correlation coefficient between the individual clinical variables and the discriminant function scores gave some indications of the contribution of the variables. The frequency of inclusions in the different calculated discriminant functions also gave an indication of the relative importance of the variables.

The sensitivity of each discriminant function was measured as the probability that a failed restoration had been classified as a failure restoration, while the specificity was measured as the probability that a restoration in situ had been classified to survive the observation period. The percentages of correct classification calculated by each discriminant function were assessed by comparing to the actual fate of the restorations after 10 years observation period. The equalities of the group covariance matrices were calculated with the Box's M test, and differences between the groups were shown by using a multivariate F-statistic.

During the 10 years observation period, a fairly high dropout rate was observed. After 10 years only 59 patients with 113 of the original restorations (24%) remained in the study, and 125 patients with 279 restorations had dropped out. The main part of the dropout patients were adolescents who ceased receiving dental care in the school dental services because of age. The dropout of these patients was especially high after 3-6 years. Table III.2 show the the number of patients and restorations examined, and the number of restoration failures after 5 and 10 years, categorized by the patients' age group.

Table III.2. Cross-tabulation of the number of restorations examined and the reasons for not being examined at each yearly examination, grouped according to the patients' age.

	Patients < 16 years (Dentists #3,#4,#6)			Patient > 16 years (Dentists #1,#2,#3,#5,#7)		
	Restorations			Restorations		
	<u>Present</u>	<u>Dropout</u>	<u>Failed</u>	<u>Present</u>	<u>Dropout</u>	<u>Failed</u>
Baseline	175			293		
1 year	161	8(5%)	6	282	9(3%)	2
2 years	150	12(7%)	13	273	15(5%)	5
3 years	135	19(11%)	21	257	28(10%)	8
4 years	106	42(24%)	27	230	51(17%)	12

5 years	81	60(34%)	34	218	60(20%)	15
6 years	40	101(58%)	35	182	91(31%)	20
7 years	21	115(66%)	39	142	127(43%)	24
8 years	15	119(67%)	41	112	152(52%)	29
9 years	13	120(68%)	42	107	156(53%)	30
10 years	11	121(69%)	43	102	158(54%)	33

Thus, the study material consisted of two patient subgroups. One patient group included adolescents and had a high dropout rate after 6 years (58%). The dropout rate in the second patient group consisting of adults only was 31% after 6 years. At the same time, the frequency of restoration failures was relatively high in the adolescent group compared to the adult group. Due to the heterogenic nature of the two patient subgroups, additional discriminant analyses were carried out for each group. In the analyses of the adolescents, the failed restorations and the restorations remaining in situ after 5 years were used, while the 10-year results were used for the adult patient group.

Results

A cross-tabulation of the 211 patients by the number of placed restorations per patient, varying from 1 to 12 restorations, and by the patient compliance in the study is presented in Table III.3.

Table III.3. Cross-tabulation of the number of restorations placed in each patient (n=211), by the compliance of the patients. The digits in parentheses indicate replacements (n=76) in the cross-tabulation groups.

Patient Replacements	Number of restorations placed in each patient									Sum	
	<u>1</u>	<u>2</u>	<u>3</u>	<u>4</u>	<u>5</u>	<u>6</u>	<u>7</u>	<u>9</u>	<u>12</u>	Pat.	Rest.
Dropped out No	48	26	14	6	3	1	3	1		102	
Dropped out Yes		6(6)	5(6)	6(10)	2(3)	2(3)	1(1)		1(1)	23	30
Dismissed Yes	22(22)	4(8)		1(4)						27	34
Remaining Yes		2(2)	2(2)	2(3)	2(3)	1(1)	1(1)			10	12
Remaining No	24	19	3	2	1					49	
Sum:	94(22)	57(16)	24(8)	17(17)	8(6)	4(4)	5(2)	1	1(1)	211	76

Table III.3 shows that 23 patients who later dropped out of the study accounted for 30 replacements. Twenty-seven patients had all their restorations replaced (n=34), and had been dismissed. Ten patients remaining in the study had replaced 12 restorations, while 49 patients had all their restorations intact at the end of the observation period.

The estimated survival pattern of all the restorations in the present study is shown in Table III.4.

Table III.4. Actuarial life table for 468 class 2 amalgam restorations.

Period Months	Restorations entering <u>time period</u>	Restorations withdrawn	Restorations not <u>surviving</u>	Estimate of cumulative proportion <u>surviving</u>	Std. error proportion <u>surviving</u>	
0-6	468	7	3	0.99	0.004	
6-12	458	10	5	0.98	0.006	
12-18	443	0	4	0.97	0.008	
18-24	439	10	6	0.96	0.009	
24-30	423	12	5	0.95	0.011	
30-36	406	8	6	0.94	0.013	
36-42	392	22	7	0.92	0.015	
42-48	363	24	3	0.91	0.016	
48-54	336	17	5	0.90	0.017	
54-60	314	10	5	0.89	0.018	5 years
60-66	299	30	2	0.88	0.019	
66-72	267	24	4	0.87	0.021	
72-78	239	20	4	0.86	0.022	
78-84	215	46	4	0.84	0.024	
84-90	165	24	4	0.82	0.027	
91-96	137	11	3	0.80	0.030	
96-102	123	3	2	0.79	0.032	
102-108	118	1	0	0.79	0.032	
108-114	117	0	1	0.78	0.033	
114-120	116	0	3	0.76	0.036	10 years

The survival analysis indicates an estimated 89% (Std. error = 1.9) survival after 5 years, and 76% (Std. error = 3.6) after 10 years. Three comparative survival analyses, using random samples with only one restoration from each patient, showed an estimated survival pattern similar to that of the whole material (Fig. III.1).

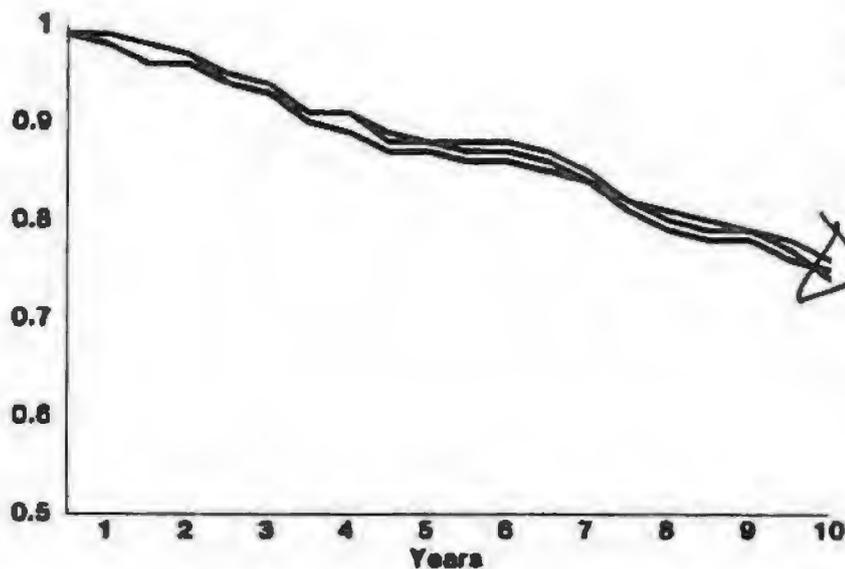


Fig. III.1. The estimated survival period of class 2 amalgam restorations up to 10 years based on one restoration from each patient. Three samples with one randomly chosen restoration from each patient, n=211.

Thus, no differences were noted between the survival statistics when using the individual patient or the individual restoration as the statistical unit. The fate of the restorations in the three samples and in the whole sample was 16% failures, 60% lost due to patient dropout, and 24% censored restorations.

After 10 years, 70 restorations had been replaced due to secondary caries and tooth or restoration bulk fractures. Three restorations failed due to margin fractures, while 3 restorations had been extended into larger restorations. The cumulative number of failed restorations during the observation period is shown in Fig. III.2.

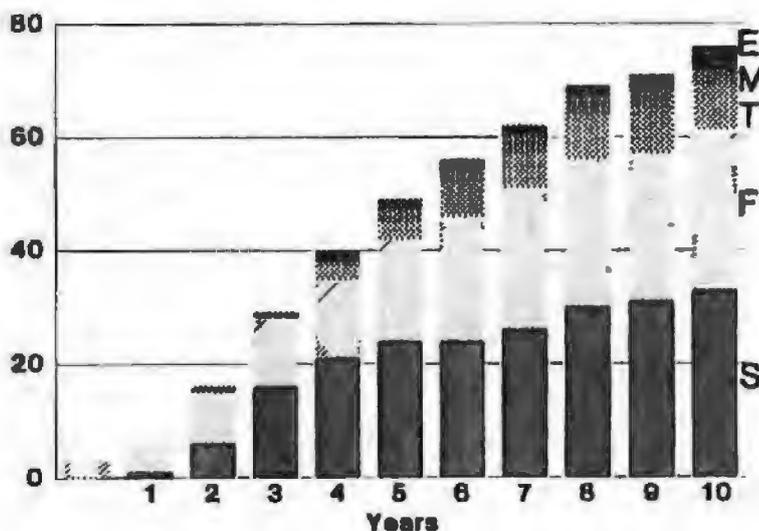


Fig. III.2. Cumulative relative frequencies of the replaced restorations (n=76) according to the criteria for replacement and in relation to the age of the restorations. The letters represent the criteria for replacement. S; Secondary caries, F; Restoration bulk fractures, T; tooth fractures, M; Restoration margin fractures, E; Extended into larger restoration.

All secondary caries had developed on the proximal surfaces. A retrospective control of the impressions of the cavities showed that the proximal cavosurface margins in these teeth had been placed without contact with the adjacent teeth. However, it was not possible on all the impressions to assess if the gingival margin had been in contact with the adjacent tooth. In 2 cavities, the gingival margins had probably been in contact with the adjacent tooth.

The restoration bulk fractures had occurred either along the buccoproximal margin (n=4) or occlusally in the isthmus areas (n=23). The retrospective control of the last photograph and impression made before the restoration bulk fractures showed that in 6 teeth, typical attrition facets on the occlusal surfaces were seen. The bulk fractured restorations did not include any restorations with deeply carved sulci on the occlusal surfaces.

The 76 failed restorations were distributed among 53 patients. Twelve patients had more than one failed restoration, accounting for 29/76 (38%) of the replacements. These patients were examined in detail for any patterns of replacement reasons (Table III.5)

Table. III.5. Replacement reasons for patients with more than one replaced restoration (4, 3 and 2). Each letter denotes one replacement. S; Secondary caries, F; Restoration bulk fractures, T; Tooth fractures, E; Extended into larger restorations.

<u>Patient</u>	<u>Restorations</u>		<u>Reasons</u>
	<u>Placed</u>	<u>Replaced</u>	
Patient #128	4	4	SSFF
Patient #175	4	3	SSS
Patient #111	2	2	SS
Patient #90	4	2	SS
Patient #129	4	2	SF
Patient #24	2	2	FF
Patient #176	3	2	SE
Patient #94	2	2	FF
Patient #69	4	2	FT
Patient #50	2	2	FT
Patient #198	6	2	TT
Patient #201	5	2	TT
Patient #58	5	2	TT
Sum:	47	29	11S, 9F, 8T, 1E

A weak relationship between the individual replacement criteria could be noted for the patients with multiple replacements, e.g., for the tooth fractures. The 8 tooth fractures observed in the study occurred among 5 patients, and three patients had two fractured teeth. However, statistics were not applied due to the low number of observations.

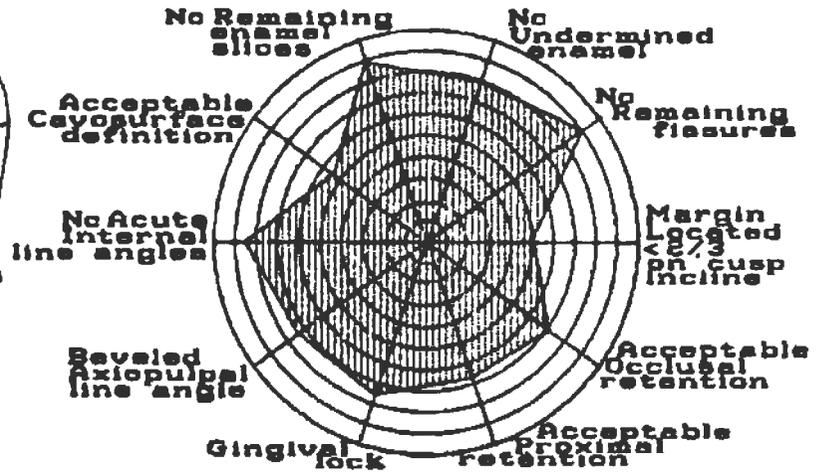
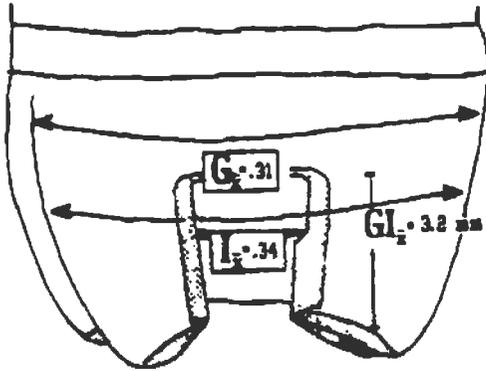
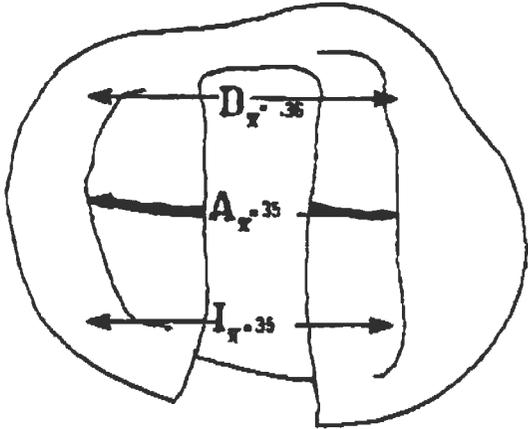
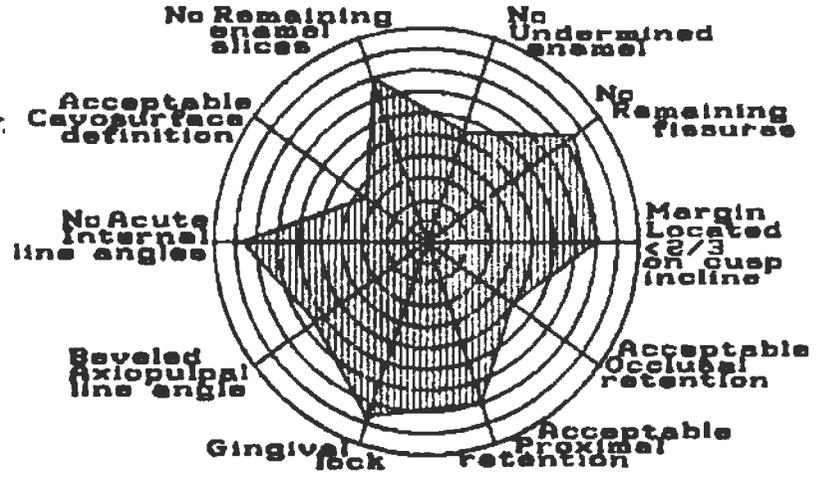
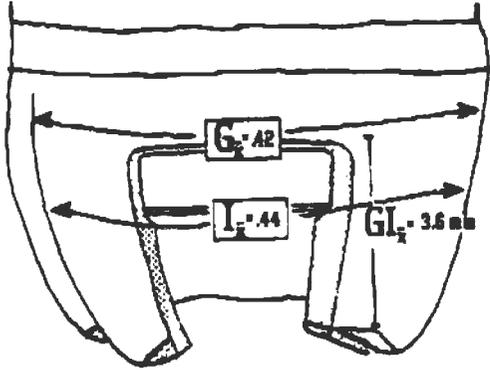
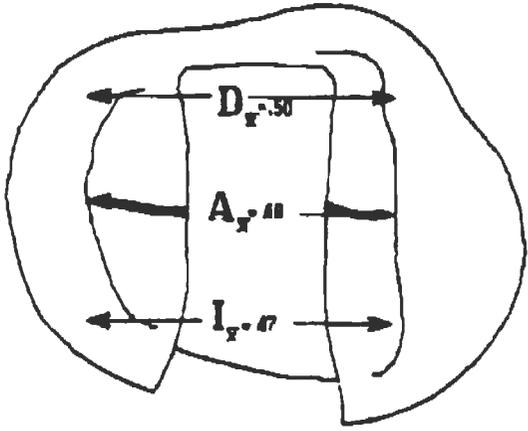
The incidence of replacements as well as the criteria for replacement varied among the dentists. Secondary caries was frequently diagnosed by two dentists (#4 and #6) compared to the other dentists. Two dentists (#1 and #4) had made 19 of the 27 bulk fractured restorations, as well as the 3 restorations replaced due to to margin fractures (Fig. III.3).

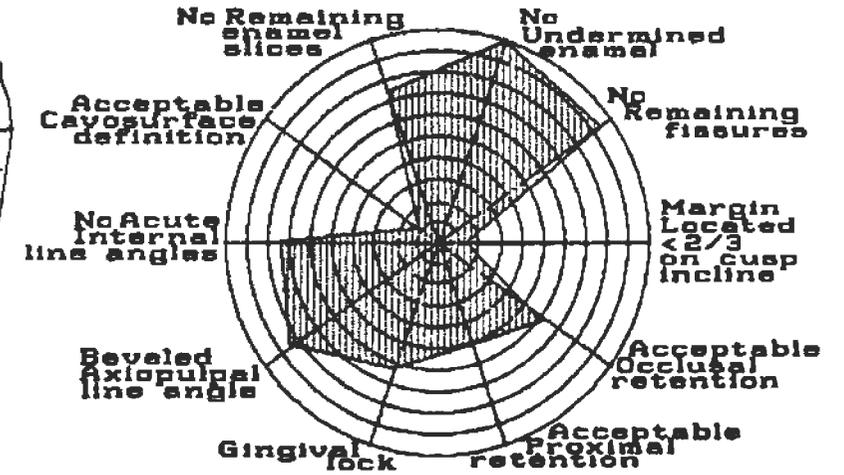
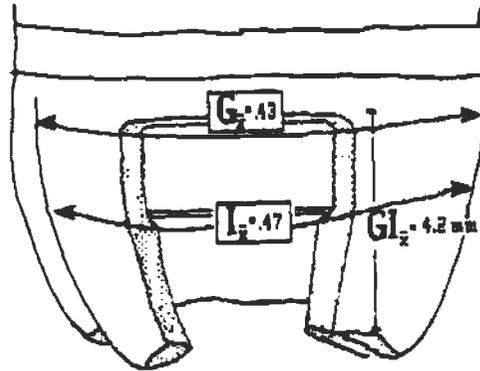
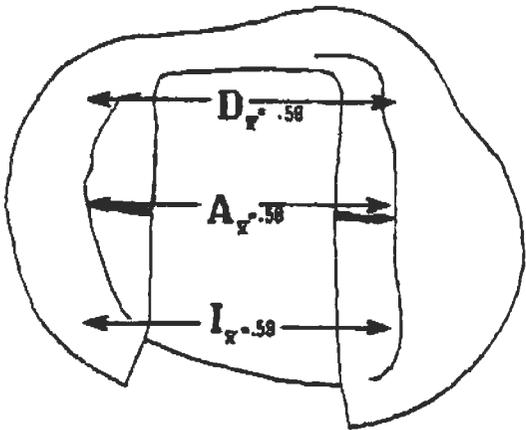
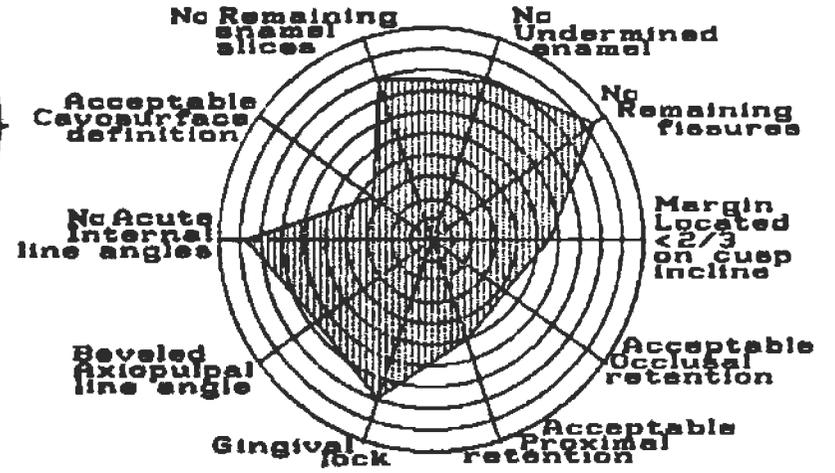
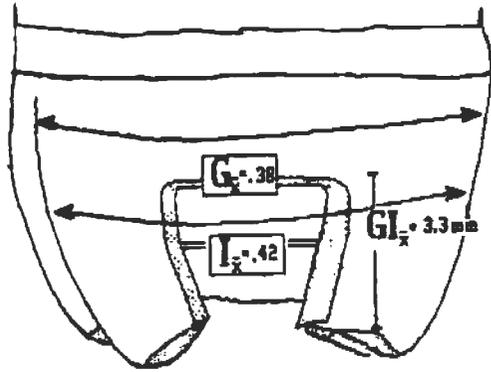
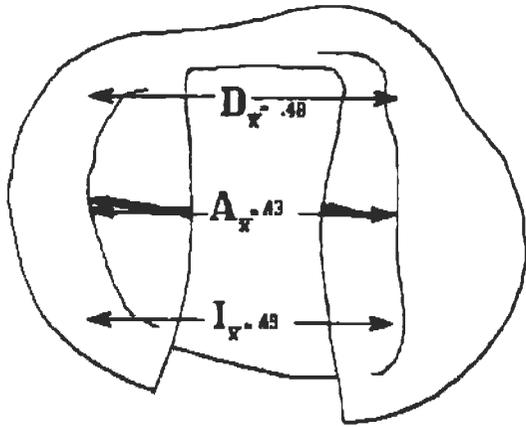
Operator:	Years									
	1	2	3	4	5	6	7	8	9	10
#7 (89/8)		FF		T	TT		T	ST		
#6 (80/10)		S	SSSS	S			E	FSS		
#5 (86/3)		F	F					S		
#4 (103/30)	F	SS	SS	SS	FF	FF	FF			
	F	SS	SS	SS	SS	SS	SS	F		
#3 (17/3)		F							F	S
#2 (78/8)				S	TF	T	F		S	
#1 (76/18)	F	F	F	M	M	FF	MFR	ST		FES
Functional:	443	423	392	336	299	239	165	123	117	113
Dropout:	17	10	20	48	27	54	66	36	4	0
Replaced:	6	10	11	10	10	6	8	7	2	4

Fig. III.3. Replacement incidence for each dentist. The numbers in brackets show the number of restorations placed by each dentist and the number of replacements. Each letter represents one replacement. S: secondary caries (n=35), F: restoration bulk fracture (n=27), T: tooth fracture (n=8), M: margin fractures (n=3), E: extended into larger restoration (n= 3). The 3 lines along the bottom show the number of functional restorations at the yearly observations, and lost restorations due to patient dropout and replacement within each yearly interval.

The average sizes of the cavity preparations and the prevalence of preparation discrepancies within each failure group is presented in Fig. III.4. The minimum restoration thicknesses (mm) and restoration volumes (mm³) are shown in Fig. III.5. It must be stressed that the preparation designs are shown for illustrative purposes. They do not represent "typical" preparation designs of the cavities classified according to the failure reason of the restorations, and the averaged data do not represent statistical units. Instead, each individual failure represents the unit used in the discriminant analyses. All data on the failed restorations and cavity morphologies are presented in the appendix.

Fig. III.4. Average sizes, and prevalence of preparation discrepancies of class 2 cavities prepared for amalgam restorations. The discrepancies are shown by the circles in the right column. Zero percent acceptable scorings is in the center and 100% is at the outer circle, i.e., the shadowed areas represent acceptable scorings. The first row shows the cavity data for the restorations that remain in situ after 10 years (R, n=113). Next row shows the data for the restorations replaced because of secondary caries (S, n=35), followed by the restorations replaced due to bulk fractures (F, n=27), and to tooth fractures (T, n=8).





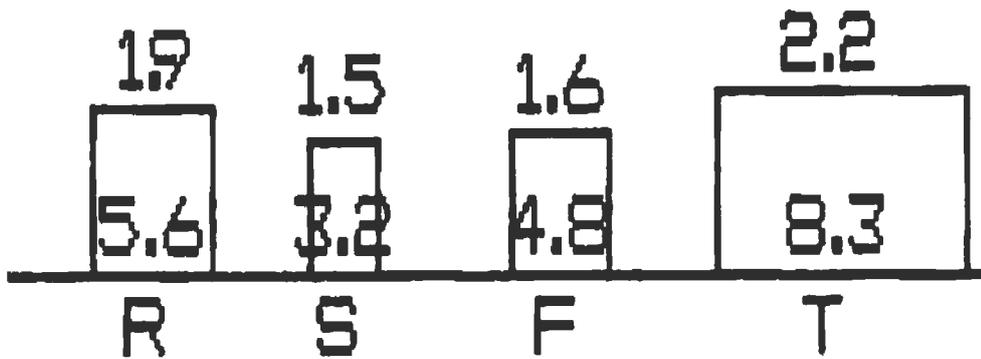


Fig. III.5. The minimum thickness measured at the isthmus, assessed on tracings of cross-sectioned teeth with restorations, vertical dimensions, and average restoration volumes within each failure group. R = restorations that remain in situ after 10 years (n=113), S= restorations replaced because of secondary caries (n=35), F= restorations replaced due to bulk fractures (F, n=27), and T= replaced because of tooth fractures (T, n=8).

Retrospective calculations of ridit scores for margin fractures within the different failure groups showed that the restorations failing due to bulk fracture had significantly poorer ridit scores throughout the first 5 years of the study, when compared to the other restorations (Fig. III.6).

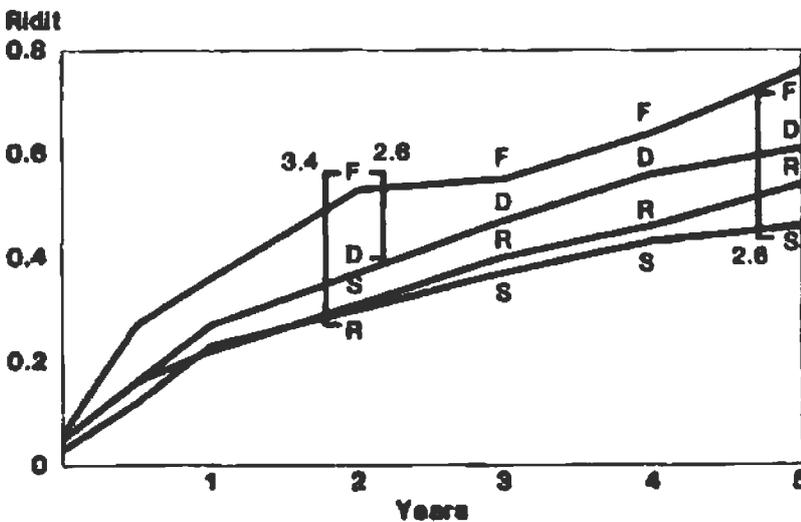


Fig. III.6. Retrospective calculations of the margin fracture scores throughout the first 5 years of the study of restorations grouped by the fate of the restoration. S: Secondary caries (n=35), F: Restoration bulk fractures (n=27), R: Restorations in situ after 10 years (n= 113), D: restorations lost to patient dropout (n= 279). When 4 subgroups are compared, each individual paired comparison requires a critical normal curve value of 2.6 according to the Bonferroni criterion to be at a significance level of $\alpha = .05$.

The low number of failures due to margin fractures (n=3) invalidated any attempts to associate the clinical variables to this reason for failure.

The number of tooth fractures was also low (n=8), and detailed analyses were, therefore, omitted. However, the general impression was that tooth fractures were mainly associated with voluminous cavity preparations (Appendix).

In the first discriminant analyses, the restorations remaining in situ formed one group, while the second group consisted of failed restorations due to secondary caries. Table III.6 shows the important classification variables in the discriminant function when the data from all the patients were included in the analysis, and the observation period was 10 years. Table III.7 includes the results using the data for the 16-year-old and younger patients and an observation period of 5 years. Table III.8 presents the results for the adult patient group and using the 10-year observation period.

Table III.6. Clinical variables included in the discriminant functions using the stepwise method. The selection of variables was based on multivariate F-statistics with a significance level $p < .05$. Restorations failing due to secondary caries (n=35) versus the remaining restorations (n=154). High values of the underlined variables increase the risk of classification into the failure group, while high values of the other variables are associated with survival.

Clinical variables:	All clinical variables included in analysis			Only cavity variables included in analysis		
	Inclusion	Coefficient	Correl.	Inclusion	Coefficient	Correl.
<u>Patient DFT increment</u>	1	.66	.74			
Margin score prior to failure	2	-.40	-.29			
Proximal buccolingual width, gingiva	3	-.70	-.48	1	-.99	-.72
Poor occlusal retention	4	-.26	-.36	2	-.54	-.54
Patient age	5	-.22	-.57			
Volume				3	-.31	-.57
Restoration bulk, isthmus				4	-.22	-.52
Eigenvalue:		.537			.243	

Table III.7. Clinical variables included in the discriminant functions using the stepwise method. The selection of variables was based on multivariate F-statistics with a significance level $p < .05$. Restorations failing due to secondary caries ($n=24$) versus the remaining restorations ($n=91$). High values of the underlined variables increase the risk of classification into the failure group, while high values of the other variables are associated with survival.

Clinical variables:	All clinical variables included in analysis			Only cavity variables included in analysis		
	Inclusion	Coefficient	Correl.	Inclusion	Coefficient	Correl.
<u>Margin score prior to failure</u>	1	-.63	-.39			
<u>Patient DFT increment</u>	2	1.17	.35			
<u>Dentist</u>	3	-.46	-.15			
<u>Patient age</u>	4	.78	.14			
Restoration bulk, isthmus				1	-.69	-.59
<u>Cavity depth, occlusal</u>				2	.92	.46
Proximal buccolingual width, gingiva				3	-.30	-.48
Eigenvalue:		.881			.152	

Table III.8. Clinical variables included in the discriminant functions using the stepwise method. The selection of variables was based on multivariate F-statistics with a significance level $p < .05$. Restorations failing due to secondary caries ($n=6$) versus the remaining restorations ($n=129$). High values of the underlined variables increase the risk of classification into the failure group, while high values of the other variables are associated with survival.

Clinical variables:	All clinical variables included in analysis			Only cavity variables included in analysis		
	Inclusion	Coefficient	Correl.	Inclusion	Coefficient	Correl.
<u>Mean occlusal cavity depth</u>	1	-1.17	-.43	1	-.95	-.59
<u>Patient age</u>	2	.54	.40			
<u>Restoration bulk, isthmus</u>	3	.40	.16	2	.62	.62
Eigenvalue:		.158			.088	

The best discriminant model was obtained when all clinical variables were available for inclusion, using only the data for the youngest patient group (Table III.7). The eigenvalues dropped markedly when the non-cavity design variables were not included in the analyses, e.g., from .537 to .243 (Table III.6) and from .881 to .152 (Table III.7). The discriminant model limited to the data from the adult patients and 10-year observation period showed a poor fit

to the data set, with eigenvalues less than .20. The low eigenvalues and the failure of identifying the same classification variables as in Table III.6 and Table III.7 was probably due to the low number of replacements among the adult patients (n=6) (Table III.8).

The discriminant functions showed that the clinical variables related to the failed restorations had different characteristics for the adult and the adolescent patients. Two classification variables were included in all the discriminant functions, i.e., the patient age and the restoration bulk at the isthmus. In both patient groups, secondary caries was associated with high patient age (Table III.7, III.8). However, when the whole patient material was considered (Table III.6) secondary caries was associated with low age.

The relationship to restoration bulk showed different patterns in the two patients subgroups. Secondary caries was associated with restorations with little occlusal bulk placed in deep cavities in the adolescent patient group (Table III.7), in contrast to restorations with much bulk placed in shallow occlusal preparations in the adult patient group (Table III.8). When the whole patient material was considered, shallow cavities were associated with secondary caries, due to the higher number of cases in the youngest patient group (24 versus 6 failures), (Table III.6).

Tables III.6 and III.7 showed that the restorations with narrow proximal buccolingual widths along the gingiva were more likely to be classified into the secondary caries group. Furthermore, high patient DFT increments and low incidence of margin fractures before failure were associated with the secondary caries restorations. The dentist was identified as a significant variable in the youngest patient group (Table III.7). When all the patients were analyzed, the secondary caries group was associated with restorations with small volumes (Table III.6).

In the next discriminant analyses, the restorations failing due to restoration bulk fractures formed the first group, while the remaining restorations formed the second group (Tables III.9, III.10, III.11). Table III.9 shows the clinical variables included in the discriminant function when all the patient data were considered, with a 10-year observation period. Table III.10 includes the data for the 16-year-old patients and younger, with a 5-year observation period. Table III.11 presents the results limited to the adult patients, and a 10-year observation period.

Table III.9. Clinical variables included in the discriminant functions using the stepwise method. The selection of variables was based on multivariate F-statistics with a significance level $p < .05$. Restorations failing due to restoration bulk fractures ($n=27$) versus the remaining restorations ($n=162$). High values of underlined variables increase the risk of classification into the failure group, while high values of the other variables are associated with survival.

Clinical variables:	All clinical variables included in analysis			Only cavity variables included in analysis		
	Inclusion	Coefficient	Correl.	Inclusion	Coefficient	Correl.
Poor occlusal retention	1	-.43	-.54	1	-.47	-.60
<u>Margin score prior to failure</u>	2	.46	.37			
Occlusal buccolingual width, isthmus	3	-.77	-.25	2	-.69	-.29
Poor proximal retention	4	-.26	-.34	3	-.37	-.37
Proximo-gingival external angle	5	-.28	-.25	4	-.32	-.28
Restoration bulk, isthmus				5	-.36	-.31
Eigenvalue:		.313			.253	

Only one non-cavity design variable was included in the function, i.e., the margin score before failure. A higher probability of classification into the restoration bulk fracture failure group was associated with a high incidence of margin fractures before failure. Little restoration thickness and narrow occlusal ~~buccolingual width at the isthmus~~ was also associated with bulk fractures. Moreover, poor occlusal and proximal retention and acute external proximogingival line angles was also identified as influential variables.

Table III.10. Clinical variables included in the discriminant functions using the stepwise method. The selection of variables was based on multivariate F-statistics with a significance level $p < .05$. Restorations failing due to restoration bulk fractures ($n=10$) versus the remaining restorations ($n=105$). High values of the underlined variables increase the risk of classification into the failure group, while high values of the other variables are associated with survival.

Clinical variables:	All clinical variables included in analysis			Only cavity variables included in analysis		
	Inclusion	Coefficient	Correl.	Inclusion	Coefficient	Correl.
Restoration bulk, isthmus	1	-.59	-.45	1	-.66	-.52
<u>Restoration volume</u>	2	.75	.25	2	.69	.29
Dentist	3	-.48	-.27			
Patient age	4	.50	.10			
Eigenvalue:		.503			.371	

The dentist was identified as an influential classification variable. Patient age was also included in the discriminant function, with more bulk fractures associated with the older patients. Two cavity design classification variables were identified, i.e., restoration volume and restoration bulk at the isthmus. The bulk fractured restorations were associated with large volumes and with little restoration thickness at the isthmus.

Table III.11. Clinical variables included in the discriminant functions using the stepwise method. The selection of variables was based on multivariate F-statistics with a significance level $p < .05$. Restorations failing due to restoration bulk fractures ($n=14$) versus the remaining restorations ($n=121$). High values of underlined variables increase the risk of classification into the failure group, while high values of the other variables are associated with survival.

Clinical variables:	All clinical variables included in analysis			Only cavity variables included in analysis		
	Inclusion	Coefficient	Correl.	Inclusion	Coefficient	Correl.
Poor proximal retention	1	-.46	-.49	1	-.36	-.50
Axio-cervical extension proximal	2	-.58	-.20	2	-.70	-.20
<u>Occlusal cavity depth, isthmus</u>	3	.58	.27	3	.47	.28
Occlusal buccolingual width	4	-.72	-.11	4	-.76	-.11
Eigenvalue:		.499			.475	

When the adult patients were considered using the 10 year data, the bulk fractured restorations were associated with deep occlusal cavities, limited axiocervical extension of the proximal part, poor proximal retention and narrow occlusal buccolingual width.

The study material in Table III.10 and Table III.11 should be considered separately, because of different patients and dentists. This is also shown by the markedly lower eigenvalues, i.e., less optimal model of the discriminant functions, when the whole patient material was included in the discriminant analyses (Table III.9). It is, therefore, interesting that the discriminant functions identified almost similar cavity design variables as influential, and with comparable eigenvalues.

The sensitivities and specificities of the discriminant functions are presented in Table III.12. The reasonably high levels indicate good discrimination of the different models, varying between 71% and 90% for classifying secondary caries, and between 76% and 90% for classifying restoration bulk fractures (Table III.12).

Table III.12. Concordance of calculated classifications to the actual classifications using discriminant analyses, with different definitions of the failure groups. The Box's M test measures the equality of the group covariance matrices.

	<u>Sensitivity</u>	<u>Correctly Specificity</u>	<u>Box's M classified</u>	<u>significance</u>
Failure group = Secondary caries				
Whole study material, 10 years observation				
All variables	.83	.77	.81	.218
Cavity variables	.78	.77	.78	.024
Adolescents, 5 years observation				
All variables	.91	.89	.90	.002
Cavity variables	.70	.75	.71	.001
Adults, 10 years observation				
All variables	.81	.83	.81	n.a. (to few)
Cavity variables	.78	.83	.78	n.a. (to few)
Failure group = Restorations bulk fractures				
Whole study material, 10 years observation				
All variables	.77	.70	.76	.091
Cavity variables	.77	.70	.76	.080
Adolescents, 5 years observation				
All variables	.91	.82	.90	n.a. (to few)
Cavity variables	.86	.82	.86	n.a. (to few)
Adults, 10 years observation				
All variables	.86	.79	.85	n.a. (to few)
Cavity variables	.84	.79	.84	n.a. (to few)

Discussion of methodology

Evaluating the restoration quality

Evaluation systems for amalgam restorations have usually been described in papers focused on restoration quality in cross-sectional or longitudinal clinical studies (Table III.12).

Table III.12. Criteria for the assessment of quality of amalgam restorations.

Author	Criteria										Scale	Other pts. criteria	
	<-----Contour----->					<Margin>		<Fracture>					
	Occl. Prox.	Marg. ridge	Cont. point	Occl.	Occl.	Excess Deficit	Surfac. Rough	Tooth Filling	Caries				
Gruebbel, 50						<----->			*	*		2	
Abramowitz, 66				*		<----->						2	
Lotzkar et al., 71				*	*	<----->						2	
Bailit et al., 74	*	*	*	*	*		*	*	*	*		2	
Mjör & Haugen, 76				*			*	*	*	*		2	
Anaise et al., 77		*	*	*	*	<----->		*		*		2	Gingiva,ii
Llewelyn, 77				*			*	*	*	*		2	
Dunston et al., 78			*	*	*		*	*	*	*		2	Gingiva
Dahl & Eriksen, 78						<----->	*	*	*	*		2	i
Skogedal et al., 79				*			*	*	*	*		2	
Gibson et al., 82						<----->		*	*	*		2	Margin stain
Kroeze et al., 88							*	*	*	*		2	
Hammons et al., 67	*	*	*	*	*	<----->		*				3	
Hammer et al., 79				*			*		*	*		3(2)	Gingiva,iii
Smales, 83				*			*	*				3	Margin stain
Rytömaa et al., 84						<----->		*		*		3	
Smales & Creaven, 85				*	*	<----->		*				3	Margin stain
Cvar & Ryge, 71							*		*	*		4(2)	
Ryge & Snyder, 73	*	*	*	*	*		*	*	*	*		4(2)	Pain
California DA, 77	*	*	*	*	*		*	*	*	*		4(2)	Pain
Pieper et al., 88			*	*	*		*	*		*		4	
Charbeneau, 81	*	*	*	*	*		*	*	*	*		5	Gingiva
Carpenter, 81	*	*	*	*	*		*	*	*	*		5	Gingiva

Include assessments of:

- i Occlusal extension
- ii Occlusal and proximal extension
- iii Gingival extension

The evaluation systems vary with respect to the number of criteria, the number of scale or scoring points, and descriptions of the criteria for evaluation. Also the training of the evaluators vary, or lack description in the reports. Furthermore, the procedures for recording, and the use of additional diagnostic aids such as X-rays or color photographs vary. All these parameters affect significantly the reliability and validity of the evaluation systems, and, therefore, make comparisons among the different systems difficult (Ryge, 1980; Patridge & Mast, 1978).

In the present study, the USPHS system was chosen due to its ease in learning and application (Cvar & Ryge, 1971). Furthermore, the universal use of the USPHS system is an indication of the validity and reliability of the evaluation system. However, in the present part of the study, only one, and not the prescribed two clinicians, recorded the characteristics of the restorations. Furthermore, the clinicians examined the restorations they had inserted themselves.

Survival statistics and estimation of the service period

The question of correctness of selecting the patient or the individual restoration as the experimental unit for statistical assessments has been raised in several survival studies (review: Osborn, 1987). In a study of restorations in primary molars, significantly lower survival estimates were calculated when the experimental unit was changed from the patient to restoration (Wong & Day, 1989). This was especially apparent when the study sample included a high ratio of highly caries active patients. In the present study, the survival estimates using three different samples with one restoration from each patient did not differ from that using all the restorations as the experimental unit. However, the standard errors of the survival estimates are calculated from the formula: $s.e. \text{ Survival} = \text{Survival} * \text{Square root of the sums of the proportion of failures during each interval, divided by the difference between the effective numbers exposed to risk of failure and the failures during each interval (Greenwoods formula) (Cutler \& Ederer, 1958)}$. The survival estimates when only one restoration from each patient was included in the survival statistics had, therefore, lower 95% confidence-intervals, due to the lower number of observations. Thus, the data in the present study show that the restoration can be used as the experimental unit in the survival statistics when the study samples do not include many restorations from patients with extremely high or low caries activity.

The estimated survival of the restorations was calculated on the basis of the dates for replacement and censored restorations. Censoring occurred either when the restoration was in situ after the 10 years observation period, or had

been lost due to patient dropout. To estimate restoration survival correctly, the censoring mechanism must be independent of the true service period of the restoration (Davies, 1987). The main reason for the dropout of patients in the present study (125 patients, 279 restorations) was because the school dental service only treats patients less than 18 years old. Seventy-five patients with 133 restorations belonged to this category, and the dropout was mainly during the first 4-6 years of the study. Thus, the censoring mechanism for these patients satisfied the criterion for correct survival estimation. Other dropout reasons were changes of residence, (16 patients, 54 restorations, 4 child and 12 adult patients), dissatisfaction or financial dispute with the dentist (2 patients, 10 restorations), or other unspecified reasons (9 patients, 15 restorations). A dependency between the survival and the censoring mechanism could theoretically have been possible for the two latter patient dropout groups. On the other hand, since these groups totaled only 11 patients with 25 restorations, the possible small bias may be disregarded.

Discriminant analysis and characteristics of failed and surviving restorations

Discriminant analysis is a statistical technique commonly used to identify variables that are important for distinguishing among groups, and predict group membership for cases whose group membership is undetermined (Lachenbruch, 1975). In linear discriminant analyses, scores from combinations of different predictor or classification variables are calculated, and related to a response variable. In the present study the specific reasons for restoration failures were the response variables. The coefficients in the discriminant function are chosen so the values of the functions differ as much as possible between two or more groups categorized by the response variable. In other words, the discriminant functions include the variables and their coefficients that maximize the between-group sum of squares relative to the within-group sum of squares (Lachenbruch, 1975). Thus, by categorizing according to the restoration's fate after 10 years, the clinical variables included in the functions with the highest coefficients and correlations would be related to the success or failure of the restorations.

The linear discriminant function requires that the classification or predictor variables have a multivariate normal distribution. This distribution was obviously not multivariate for many variables in the present study, which were coded dichotomously. However, discriminant analysis has been shown to perform fairly well in a variety of situations. In a comparative study of linear discriminant analysis versus logistic regression and classification and regression tree (CART), all three models approached general results that were

fairly similar (Stamm et al., 1991).

In the present study, the sensitivity and specificity levels differed among the discrimination functions. The most obvious reason is that since a replacement is a terminal event, only one reason for replacement can be recorded. Another explanation is that dentists do not necessarily discover or diagnose correctly the clinical state of the restorations (Elderton & Nuttall, 1983). Incorrect diagnosis will not only affect the classification rate of the discriminant analysis, but also the calculation of the discriminant function is confounded. The operators in the present study had been trained in assessing the restorations by the USPHS system (Cvar & Ryge, 1971). [It was, therefore, assumed that this source of error was controlled, although the clinicians independently recorded their own restorations.]

Another factor that probably influenced the sensitivity and specificity levels was the non-continuous nature of some of the discriminant variables. When combinations of continuous and discrete variables are included in a discriminant function, the probability of incorrect classification increases (Gilbert, 1968). Finally, the relatively low probability values of the Box-M tests indicate different covariance matrices for some of the discriminant functions. Better classification models could perhaps have been made using quadratic discriminant analysis. However, since the sample sizes were small and the covariance matrices rather similar, as measured with the Box-M statistics, it was assumed that the linear discriminant analysis performed satisfactorily.

Linear discriminant analysis has been used in biomedical and sociological research, but has only to a limited degree been used in dentistry (Table III.13).

Table III.13. Studies in dentistry using discriminant analysis.

Investigators	Study aims
Honkala et al., 1984	Identify clinical variables of caries prone children in a cross-sectional study
Tolo & Schenck, 1985	Test if the levels of antibodies to any bacteria can be used in diagnosis of periodontitis
Stecksén-Blics & Gustaffson, 1986	Report the accuracy of a model to predict 1 year caries increments in children
Bader et al., 1986	Assess the performance of potential predictors in identifying that proportion of a sample of children who would experience high increments of caries over 18 months
Tollefsen et al., 1986	Determine whether immunosuppressive therapy influences the systemic immune response to periodontal disease
Wastell & Gray, 1987	Analyze aspects of facial pain
Abernathy et al., 1987	Describe a caries prediction model based on multiple factors relating to a large number of children, and the results of an application of the model
Schroeder & Edwardsson, 1987	Report the predictive values of a model for identifying high

Maryniuk, 1990a	caries increments in 3-year old children Determine which information is responsible for explaining restoration replacement behavior
Russell et al., 1991	Predict 2 years caries increments in Scottish adolescents from salivary, clinical and microbiological variables
Stamm et al., 1991	Compare caries risk assessment models made from linear discriminant analysis, logistic regression and classification analysis and regression tree (CART).

Most of these studies have focused on using discriminant analysis for predicting the future caries activity of patients on the basis of a battery of clinical variables. A model that predicts the clinical prognosis of a patient, or in this study a restoration, should preferably be of a prospective nature in order to verify the predictive power of the model. However, the statistics have also been used for more descriptive purposes in observational studies (Honkala et al., 1984; Maryniuk, 1990a). In the present study, the discriminant analyses were retrospective, and thus observational. A formulation of the situation was: provided that the restoration is in situ after 10 years, or 5 years, which variables can best predict the failure patterns ? The discriminant functions in the present study can, therefore, not be used for prognostic purposes for new restorations in other populations.

Design of the study

The first part of this clinical study was based on an experimentally designed study of the effects of clinical variables on margin fractures. When several aspects of the observation material in the first study part were considered, it was apparent that this second part of the study could only be described as a retrospective observational study.

The dentists and the patients did not represent any specific segments. The aim was to obtain a study material from "everyday dental practices". They were selected by a representative on NIOM's board of directors and representatives of the national dental associations in collaboration. Thus, any generalization of the results to the general population of dentists or specific patients cannot be done. It must be regarded as an attempt to single out "everyday dentistry" as an area of research; a jungle of variables that have one feature in common: it is clinically relevant in the true sense of the term.

It is unknown if the patients and the treatment provided by the dentists can represent the dentists' "average" patients and treatment items. Furthermore, the number of restorations placed in each patient varied. This factor is of little importance when assessing margin fracture, but complicates statistical

analyses of restoration survival or replacement reasons. It is theoretically possible that a dependency exists between replacement reasons or restoration survival when multiple restorations from the same patients are included in the study sample. The problem is avoided by selecting only one restoration from each patient, but at the cost of loss of clinical data. Pairwise comparisons of restorations in individual patients could be justified, but this method also creates loss of clinical data. Furthermore, the effects of patient age, gender, caries activity etc. cannot be assessed using this method.

The cavities in the present study varied markedly in size and quality (Jokstad & Mjör, 1989; Jokstad, 1989). The cavities could be categorized into many "morphologic cavity groups", i.e., no systematic cavity design patterns could be distinguished. Furthermore, previous studies have suggested that differences in cavity morphology have only minor effects on the clinical performance of the restoration, indicating that large numbers of observations are needed before any statistically significant conclusions can be made. Thus, the heterogeneity of the cavity preparations and the relatively low number of restorations under observation, clearly made the second part of the study incompatible with an experimental study design.

Confounding factors

Potentially confounding factors of the present study are the lack of a qualitative evaluation of the proximal surfaces beyond the use of USPHS criteria and x-ray photographs at the yearly recalls. Ethical considerations prevent such routine exposure to radiation for research purposes. Furthermore, detailed examinations of the proximal adaptation, prevalence of porosities, subgingival surface roughness or size of potential margin overhangs were not carried out. It has also been suggested that displacement of cavity bases during the amalgam condensation is an important factor in the recurrence of caries near the proximal margin (Grajower, Bielak & Eidelman, 1984; Novickas, Fiocca & Grajower, 1989). Although a restoration morphology or lack of adaptation on the proximal surface was not used as a reason for replacement during the trial, it was realized that these aspects could have influenced the prognosis of the restoration. However, the proximal surfaces were not examined in detail for several reasons. The most important reason was that, since the main objective of this clinical trial was to collect clinical data that reflected the status of the dental treatment carried out in the general practices, any interference with the daily treatment carried out by the dentists should be avoided. Furthermore, the participating dentists were informed of the general guidelines for safeguarding of patients in clinical trials (ADA, 1980; FDI, 1982), and it was, therefore, assumed that they adapted to an acceptable

quality of dental care, and would correct and report any discrepancies of the restoration if detected. Another reason for not recording the proximal surface quality was the lack of a universally accepted and simple evaluation system for scoring discrepancies on the proximal surface. Finally, the cost and logistic factors must be considered, since it was believed that the potential gain of information obtained by, for example, a scanning electron microscope study of replicas could not justify the use of the extra time and laboratory personnel.

Generalization of the results

Due to the observational design and the retrospective nature of the analyses, the results from the 10-year study cannot be directly generalized to specific dentists, restorations or patient populations. The possible confounding of the results due to uncontrolled variables should also be acknowledged. Furthermore, it must be recognized that the statistical analyses per se cannot justify the clinical conclusions based on a limited material. However, the results from the present study may be of assistance in identifying the most relevant factors in future detailed studies.

Discussion of results

General results

The main reasons for failure of amalgam restorations were secondary caries (43%) and restoration bulk fractures (36%), followed by tooth fractures (11%). These observations are in general agreement with the observations in several cross-sectional and longitudinal studies of amalgam restorations (Table III.14).

The variable prevalences of the replacement criteria in the present study and among the other studies can partially be due to different patient ages and caries activity. Furthermore, it is likely that the variation in frequencies of secondary caries and restoration bulk fractures is influenced by the dental care situation and socioeconomic factors in the different study populations. This hypothesis may be supported by the observation that the prevalence of restoration bulk fractures in the population generally is underestimated (Lemmens et al., 1987).

Table III.14. Criteria for replacement of amalgam restorations reported in cross-sectional surveys.

Investigators	Country	Second. Margin		Fracture			Patient		Nr. of restorations			
		Caries	Integrity	Restoration	Tooth	Other	Clinic	Age	Class	Decid.	Permanent	
Healey & Phillips, 1948	USA	54	19	26		1	D.School			0	1521	
Moss, 1953	USA	54	<-----35----->			11	Military	19-27		0	1000	
Allan, 1969	UK	<-----68----->		4	6	22	D.School			<-----201----->		
Barnes et al. 1973	USA	58	<-----37----->			5	Military	17-66		0	625	
Richardson & Boyd, 1973	Canada	68	7	9	7	9	Gen.Prac	Av.26		131	1512	
Cheetham et al., 1975	Australia	66	7	9	5	13	Gen.Prac	Av.31	All	0	1965	
Lavelle, 1976	Canada	54	21	24		1	Gen.Prac	20-40		0	6000	
Dahl & Eriksen, 1978	Norway	53	<-----33----->			14	Student		2	<-----200----->		
Mjör, 1978	Sweden	54	10	13	12	11	Gen.Prac			<-----1443----->		
Mjör, 1979	Sweden	65	8	12	10	5	Gen.Prac			<-----1061----->		
Rytömaa et al., 1984	Finland	<-----23----->		38		39	Student	Av.20		0	73	
Klausner et al., 1985	USA	53	13	13	11	10	Gen.Prac		All	<-----2146----->		
"		56	12	20	9	3	"		2	<-----1234----->		
Allander et al., 1984	Sweden	39	8	18	12		Gen.Prac	> 20	2	0	2033	
Mjör, 1985	Norway	72	<-----28----->					Gen.Prac			50	587
Boyd & Richardson, 1985	Canada	50	23	9	8	10	Gen.Prac	Av.34		183	3479	
Akerboom et al., 1986	Holland	14	4	33	23	26	D.School		2	0	1544	
Mjör & Åsenden, 1986	Norway	46	28	14	7	15	Nat.H.S	6-18		0	236	
Qvist et al., 1986	Denmark	33	15	30	10	7	Gen.Prac	>16	2	<-----1064----->		
Klausner et al., 1987	USA	53	17	8	13	9	Gen.Prac		All	<-----2996----->		
"		54	18	13	10	6	Gen.Prac		2	<-----1137----->		
Welland et al., 1989	Germany	69	20	8	0	3	Gen.Prac		All	0	451	
Qvist et al., 1990	Denmark	35	11	33	10	11	Gen.Prac	>16	2	0	1142	
MacInnis et al., 1991	Canada	66	7	15	5	7	Gen.Prac	>18	2	0	2280	
Mjör & Toffenetti, 1992	Italy	59	11	13	7	10	Gen.Prac		All	0	787	
Present study, 1992	Scandinavia	43	4	36	11	5	Gen.Prac	8-71	2	0	468	

The relative frequency of restoration bulk fractures was slightly higher than reported in cross-sectional studies, but significantly lower than in a longitudinal study by Letzel et al. (1989). The proportions of high-Cu vs conventional amalgam alloys in the sample materials may account for some of the differences (Osborne, Norman & Gale, 1991). Another factor may be different methods for carving the occlusal surfaces. Detailed reproductions of the sulci and ridges on the occlusal surfaces (Childers, 1983) may cause lack of occlusal bulk and weaken the restoration. A third factor that may have caused the different frequencies of bulk fractures is the effect of different methods for placing base materials. Both the brands and the thickness influence the strength of the restoration (Luke, 1972; Hormati & Fuller, 1980).

Other investigators have focused on the poor inter-operator agreement on criteria for replacement (Mjör & Haugen 1976; Merrett & Elderton, 1984; Espelid & Tveit, 1991), and the intra-operator lack of consistency in using these criteria (Marken, 1962; Merrett, 1983). A further problem when comparing the results from different clinical investigations is that the variables in the study designs are often poorly described or omitted (Maryniuk, 1984). Therefore, the influence of factors like the intra-oral location of the restoration, the patients' dental status, the consumption of fluorides or the use of fluoridated toothpaste, the frequency of dental visits, and other clinical factors on the results prevent detailed comparisons of the results in the different reports.

The median survival time of amalgam restorations was reported to vary between 5 and 8 years in several studies in the mid 80-ties. This somewhat short life span had been estimated by using statistical techniques that possibly underestimated the correct survival time in longitudinal studies (Robinson, 1971; Crabb, 1981), or were based on survival analyses confounded with high proportions of censored data (Elderton 1983; Davies, 1987). The median age of failed amalgam restorations recorded in cross-sectional studies (Mjör, 1981; Qvist, Thylstrup & Mjör, 1986), was also misinterpreted by many as the median survival time of amalgam restorations. It is presently unknown how the median age of failed restorations compares to the median age of restorations in situ and to the survival time, but some preliminary data suggest that the time periods may be comparable (Jokstad, Mjör & Qvist, 1991). The more recent survival analyses indicate longer survival times (Smales, Gerke & Hume, 1990; Dawson & Smales, 1992). The data from the present study support the prevailing view that the median survival of class 2 amalgam restorations is more than 10 years (Mjör, Jokstad & Qvist, 1991). The slight variations among the more recent survival data are probably due to different study methodologies and inclusion or exclusion of clinical variables (Maryniuk, 1984; Jacobsen, 1988). It may also be assumed that the difference is explained by an effect of preventive measures on secondary caries and improved materials (Table III.15).

Table III.15. Estimated survival or actual remaining (%) amalgam restorations in permanent teeth reported in longitudinal and cross-sectional clinical studies.

First author	Country	Observation period	Years			Median (years)	Pat./Restor. No	Restoration Clinic	Type	Dentists	Method
			5	10	20						
Allan	UK	1952-67	38				7/887	Gen.Prac/Mil.	Cl. 1&2		
Allan	UK	1954-69	55	20		5	31/ 93	Gen. Practice			
Allan	UK	1951-71	73	36	15	8	47/ 148	Gen. Practice			
Robinson	UK	1948-71	83	55	23	11	43/ 145	Gen. Practice		1	*
Lavelle	Canada	1953-73	80	50	10	10	400/ 536	Gen. Practice		3	*
Walls	UK	1971-76	57	36		6	409/1031	Dental Hosp.		Students	* □
Hunter	UK	1949-76	70	48	30	10	113/5354	Gen. Practice		†	* □
"	"		74			28	113/3754	"		"	□
Gray	UK	-80				10	513/6731	Military		>10	□
Crabb	UK	1969-79	65	44		9	155/1018	Dental Hosp.	All		
Hamilton	USA	1969-79	53	30			77/ 209	Gen. Practice		1	* †
Elderton	UK	1978-83	46			<5	720/1206	Dent.Estim.Board	All		* □
Paterson	UK	1967-83	67	34		8	200/2344	Nat. Health Serv.	All	16	* □
Meeuwissen	Holland	1958-77	70	50		10	1000/8492	Military			* □
Milen	Finland	1975-85	71	50		10	217/ 933	Child Nat Dent S			* □
Bentley	USA	1970-85	88	72		15	70/ 433	Dental College		Students	* □
Arthur	USA	1965-87	92	83	70	>22	327/1198	Military	All		□
Robbins	USA	-88	80	54	19	11	171/ 171	Military	Complex		□
Arthur	USA	-88	91	77	52	>20	1211/6141	Military	Class 2		□
Moffa	USA	-88				13	/1727	Dental School	Class 2		□
Laswell	USA	1977-88	84			34	47/ 160	Dental School	2		
Letzel	Holland	1974-88	90				414/2660	Dental School	Cl. 1&2	5	
Roberson	USA	1983-88	98				/1200	Dental School			□
Roberts	UK	1978-88	82				9/163	Gen Practice	Cl 2	1	□
van Dijken	Sweden	1984-90	92				44/ 132	Dental School	Cl 2	1	□
Bjertness	Norway	1970-88	93	85	80		32/	Gen. Practice	All	6	□
Westerman	Germany	1980-89	70			7.5	636/1311	Gen. Prac	MOD	1	□
Smales	Australia	1966-80	92	78	74	>18	/1801	Dental School	All		□
Smales	Australia	1972-90	80	64	48	14	100/1345	Military	All		□
Present study	Scand.	1979-92	89	81		>10	210/ 468	Gen. Practice	Cl. 2	7	□

* converted restorations and extracted teeth included as failures

† patient drop out included as failures

□ Life table analysis

Failure reasons and clinical variables

The discriminant analyses of the characteristics of those restorations that failed provided no set pattern or single clinical variables that could be considered as predictive of failure (Table III.6-III.11). Also Drake (1988a) reported in a clinical study the difficulties of identifying one or several single variables to account for differences in failure rates among patients. The discussion will focus on the association between the failures and the operator, the amalgam alloys, the patients, margin fractures after 5 years, and the cavity design features.

Operators

The data showed slight variations among the dentists in the use of the different criteria for replacements. This finding may partly be due to variable diagnostic abilities of the dentists (Swallow et al., 1978; Nuckles et al., 1991). It is also known that the frequency of replacements of restorations vary among dentists (Bailitt et al., 1979). These observations have led to questions if restoration replacements are based on biological and scientific principles, or may be motivated by economic considerations (Committee of enquiry into unnecessary dental treatment, 1986; Grembowski Milgrom & Fiset, 1988). Secondary caries is especially difficult to diagnose correctly (Kidd, 1989), and several investigators have described the poor abilities of dentists to distinguish between recurrent caries and defective margins, or active and arrested caries (Elderton & Nuttall, 1983; Merrett & Elderton, 1984; Kidd, Toffenetti & Mjör, 1992). The correct diagnosis of gingival margin discrepancies is also influenced by the sharpness and quality of the explorer (Rappold, Ripps & Ireland, 1992) and the location of the restoration margin (Christensen, 1966). Dentists are less consistent and accept larger discrepancies of the margins when these are not visible (Dedmon, 1982 & 1985). It is uncertain to what extent these factors may have influenced the replacement incidence among the dentists in the present study.

The replacement incidence among the operators differed, which partly can be explained by different patients, i.e., age and DFT increments. Other explanations may be a difference in the operators' assessment of the restoration quality at the time of replacement, or inferior properties of the amalgam as a function of poor operator handling (Gjerdet & Hegdahl, 1985). The present study design allows no conclusions as to what extent the variation is the result of the patient sampling or other factors.

Amalgam alloys

It is interesting that the replacement rate of the conventional amalgam alloy was equal to the high-Cu amalgam alloys during the observation period, in spite of the higher margin fracture scores of the conventional amalgam during the first 5 years. Thus, the absence of the gamma-2 phase in the amalgam per se does not assure an increased clinical service period. There are limited data in the literature on the comparative performance of conventional and high-Cu amalgam alloys over 8-10 years. The lack of association between amalgam alloy type and clinical service period has been reported by Smales (1991) and Smales et al. (1991). Also Moffa et al. (1989) reported no differences in the survival of amalgam restorations made from conventional and high-Cu amalgam alloys over 19 years. Two opposite conclusions were made by Osborne et al. (1989a, 1989b) on the basis of two 13 year-old trials. On the other hand, Letzel et al. (1989, 1990) reported significantly better survival of high-Cu compared to conventional amalgam alloys after 12.5 years observation. However, these investigators based their conclusions on a study of a selected patient sample (dental students, dental hospital staff and dentists). Secondary caries was practically non-existent in this patient material, and the main reasons for replacing the restorations were bulk and margin fractures. Thus, at present there are no conclusive data in the dental literature to support the assumption that the use of high-Cu amalgam alloys guarantees a better survival behaviour than the use of conventional amalgam alloys. The present study also indicates that the survival of restorations is not a function of the amalgam alloys used. Further clinical studies should be initiated to determine the relationship between the amalgam alloy composition and the long term restoration survival.

Increasing the copper content of an amalgam alloy has one detrimental effect on amalgam and that is the fracture toughness (Lloyd, 1990). It was, therefore, interesting to observe that the present study showed no differences between the restoration bulk fracture rates among the amalgam alloys (Appendix).

Patients

All the adult patients were regular attenders, which reflects a good dental health consciousness. A further inference may be that the incidence of secondary caries is lower in this group, compared to the irregular attenders. At recall controls it is common that dentists correct minor discrepancies, which otherwise would jeopardize the prognosis of the restoration. It is, therefore, probable that on average, the restorations in regular attenders have longer service time than those in the irregular attenders. However, there are critical

opinions to this assumption (Holloway 1975; Sheiham, Maizels & Cushing, 1982). It has also been suggested that the need for operative restorative treatment is higher in regular attenders than in irregular attenders (Nuttall, 1984; Kroeze, 1989; MacInnis, Ismail & Brogan, 1991). However, there are no experimental investigations in the literature where the hypothesis has been tested.

One important variable identified by the discrimination statistics associated with the failures due to secondary caries was the DFT increments (Table III.6, Table II.7). This variable had the highest standardized coefficients in the discriminant functions (.70, Table III.6). The DFT increment score also correlated with the discriminant function scores ($r = .60$, Table III.6). Furthermore, when the variable was not included in the discriminant function with only cavity design variables, the eigenvalues dropped from .62 to .27 (Table III.7) and from 1.23 to .62 (Table III.7). $.88 \rightarrow .15$

To what extent the modified DFT increment index in the present study reflects the patients' caries incidence or increment during the observation period is uncertain. Several studies have categorized patients on the basis of the yearly DMFS increments, for use as dependent or independent variables in clinical caries trials. Söderholm & Birkhed (1988) defined a "highly caries active subgroup" as individuals with DMFS increments $> 3 / 2$ years. Stamm et al. (1988), Stewart & Stamm (1991) and Stamm et al. (1991) defined children with "high caries rates" as having DMFS increments $> 1/\text{year}$. Russell et al. (1991) categorized the patients into low (< 1 DMFS increment/2 years), medium (1-2.5) and high caries increment categories (> 5 DMFS increment/2 years).

There are objections against using DMFT or DMFS increments as an index of the patient caries activity (Demers et al., 1990). The first objection is that the DMFS increment may be influenced by other factors besides caries. The change of DFT was, therefore, in the present study only calculated for placements or replacements due to primary or secondary caries. Furthermore, manifest caries lesions requiring treatment is not synonymous with the caries activity and caries incidence, since these situations include both initial and cavitated lesions, factors that may be influenced by the operators' diagnostic abilities (Gröndahl, 1979). In addition, although caries is present, with or without cavitation, today this is not necessarily synonymous with operative treatment, i.e. the placement of a restoration. Recent studies have shown that the "treatment threshold" of primary and secondary caries is influenced by the individual dentist's treatment philosophy (Espelid 1987; Elderton, 1990; Maryniuk, 1990b; Tveit & Espelid, 1992). There are also problems associated with the differentiation between active and arrested secondary caries lesions (Kidd, 1990). An attempt was made to control these factors by arranging the yearly seminars with discussions and review of the USPHS system the first 5

years of the study. This was considered adequate calibration of the dentists diagnostic abilities and treatment intervention on restoration failures. However, no attempts were made to calibrate the dentists on the diagnosis of primary caries.

On the other hand, it has been suggested that in caries increment studies or clinical trials one has no alternative but to accept that fillings placed during the period of study were placed for the treatment of disease (Pitts, 1991). Therefore, many cariologic studies employ the difference between the final and baseline DMFS values as a practical measure of caries increments (Abernathy et al., 1987; Stamm et al., 1991; Rusell et al., 1991; Scheinin et al., 1992).

The effects of the patient caries activity for predicting failure of restorations due to secondary caries was shown by Bentley et al. (1990). In this study, the caries activity was classified by the numbers of specific cariogenic microorganisms. The investigators reported that the highly caries active patients showed significantly higher failure rates than the patients with low caries activity.

In another recent study, Barr-Agholme et al. (1991) reported that there were ". . . no reports in the literature concerning the influence of caries activity on the success rate of fillings . . ." The caries activity in this study was defined on the basis of the progression of a radiolucent zone into the dentin on radiographs. In contrast to Bentley et al. (1990), the investigators reported that neither the age nor the caries activity during a 2 years observation period significantly influenced the success rate of proximal light-cured composite and amalgam restorations in primary molars. A strong effect of patient age on primary caries (Demers et al., 1990) and secondary caries (Qvist et al., 1986; Qvist, Qvist & Mjör, 1990) has been reported previously. The identification of the relationship between low patient age and secondary caries in the present study (Table III.6) is in accordance with these results.

Cavity class and intraoral location

In two longitudinal studies of 140 and 36 bulk fractured restorations, it was suggested that amalgam restorations in the mandibular teeth and especially in the premolars were very susceptible to bulk fractures (Lemmens et al., 1987, 1988). This conclusion was supported by a subsequent meta-analysis of the same data, in addition to a larger data set on longitudinal studies at the University of Nijmegen, Holland, reporting that the amalgam restorations in lower premolars had a marked tendency to fail (Peters, Letzel & van 't Hof, 1990). These observations are in contrast to the present results, where only 1 of the 27 fractured restorations was located in the lower premolars. Furthermore, no patterns or effects of the intra-oral location on restoration bulk fractures were observed. Also Drake (1988b) found no differences in

restoration survival in the different tooth groups and jaws. It seems questionable on the basis of present clinical data that the risk of restoration bulk fracture varies with the intra-oral location.

Margin fractures as a predictor of longevity

Several studies have failed to identify significant correlations between margin fracture scores and specific reasons for replacement (Moffa et al., 1989; Osborne et al., 1989b), or find only weak correlations to restoration bulk fractures (Osborne, Binon & Gale, 1980; Lemmens et al., 1988; Laswell et al., 1989; Letzel et al., 1989).

The alleged correlation between margin fractures and recurrent caries is controversial. Two factors should be considered in this context, the relationship between the size of the defects and secondary caries, and the association between the location of the defect and location of secondary caries. A relationship between poor occlusal restoration adaptation in certain locations, e.g., in areas with incompletely removed fissures, and recurrent caries has been described in a study of extracted teeth (Jørgensen & Wakumoto, 1968). On the other hand, Merrett & Elderton (1984) found no associations between margin fracture and secondary caries in extracted teeth. Similar data have been reported by other investigators (Grajower & Novickas, 1988; Kidd & O'Hara, 1990). Other in vitro experiments show that a correlation does not seem to exist between the size of the crevice and secondary caries (Söderholm, Antonsson & Fischlschwiger, 1989), or describe only a correlation in extremely cariogenic environments (Derand, Birkhed & Edwardsson, 1991).

In a cross-sectional study, Goldberg et al. (1981) examined 1556 restorations in 87 patients. The prevalence of secondary caries was correlated to the margin fracture scores and indices of the patients' oral health. Using log-linear analyses, the investigators suggested that there was a significant relationship between these three factors. In another observational longitudinal study, an increased prevalence of secondary caries was recorded in the restorations with the poorest margin fracture scores, i.e., analog to score 5 or 6 in the present study (Eriksen, Bjertness & Hansen, 1986). On the other hand, the clinical significance of poor occlusal margin fracture scores was questioned after a longitudinal clinical study showing no differences in replacement frequencies due to secondary caries between a spherical amalgam alloy and a non-gamma-2 amalgam alloy (Hamilton, 1983). The significance of poor margin fracture scores on the occlusal surface for estimating the risk of secondary caries may also be questioned. There are no reports demonstrating a correlation to the margin adaptation on the proximal surfaces, which are the areas where secondary caries lesions prevail (Eide & Birkeland, 1982; Mjör, 1985).

The margin fracture scores were included in the functions that discriminated between the remaining restorations in situ and the failure groups consisting of secondary caries restorations (Table III.6, Table III.8), and bulk fractured restorations (Tables III.9-III.10). The coefficient and correlations were relatively high in the discriminant functions, indicating that the variable was important for the classifications into the different groups. High ridit values were associated with restoration bulk fractures; low values were associated with secondary caries. Another indication of the importance of the variable was the reduction of the eigenvalues of the discriminant functions when only the cavity design variables were included in the discriminant analyses. In the caries' discriminant functions the eigenvalue dropped from .82 to .27 (Table III.6) and from 1.23 to .62 (Table III.7), although this also was due to the removal of the DMT increment-variable. In the discriminant functions using the bulk fractured restorations as one of the response groups, the eigenvalues dropped from .31 to .25 when the margin fracture scores were omitted in the discriminant function (Table III.9).

The association between margin fracture and failure reason was also supported by the retrospective calculations of ridit scores of margin fractures for the different failure groups during the first five years of the study (Fig. III.6). Better ridit scores were seen for the failing restorations due to secondary caries, and poorer ridit scores were seen for the bulk fractured group compared to the other restorations.

The present study shows that restorations with more margin fractures after relatively short clinical service is associated with later restoration failures due to bulk fracture. Further experimental studies should elucidate if the common denominator for these discrepancies is high masticatory forces, or a progression in material corrosion.

Cavity design

In general, the majority of amalgam restorations functioned satisfactorily for 10 years, in spite of frequent marked deviations from textbook descriptions of ideal class 2 cavity preparations. The restorations that failed showed no set cavity design pattern or single cavity design feature that could be considered as predictive of failure. The association to cavity design will, therefore, be discussed in relation to the failure reasons.

Secondary caries

The restoration and cavity design features included in the discriminant function were narrow buccolingual widths gingivally on the proximal surface, poor occlusal retention, small cavity volumes and little restoration bulk at the isthmus. The identification of these variables reflects, at least to a certain

degree, the morphologies of the cavities and restoration contouring made by the two operators with the highest incidences of restorations with secondary caries (Fig. III.3). The restorations had mostly been placed because of primary caries, and the cavities were, therefore, on an average smaller compared to the other cavities. It is difficult, therefore, to make any conclusions on the possible association between restoration volume and the risk for failure due to secondary caries observed in Table III.6. The different cavity preparations and restoration contouring may also account for the identification of different cavity design variables for classification among the adolescent and adult patients. In the youngest patient group secondary caries was associated with restorations with little bulk placed in deep cavities (Table III.7), in contrast to restorations with much bulk placed in shallow occlusal preparations in the adult patient group (Table III.8).

The association between narrow extensions at the gingiva and secondary caries could signify that the operator in these cases had not extended the preparation beyond the areas of the caries lesions, or had placed the restoration margins in contact with the adjacent tooth. This was not possible to inspect on the epoxy casts. The observation draws attention to the problem that conservation of tooth tissue proximally may increase the risk of leaving sectors of demineralized enamel along the cavosurface angle, or not placing the gingival margins or the axiogingival line angles away from the adjacent teeth (Otto & Rule, 1988).

Another possible explanation of the observed relationship between small cavities in the proximal parts and high incidence of secondary caries is the recent hypothesis suggested by Duncalf & Wilson (1992) on the basis of an *in vitro* experiment. These investigators reported that restorations in the preparations of conservative design exhibited more adaptation defects, porosity; and voids than did the restorations in the preparations of conventional design. The defects were attributed to poor condensation in the proximal cavity parts due to inadequate instrument design or condensation techniques. Future studies should elucidate if this situation is valid in the clinic.

Previous investigators have suggested that the incidence of secondary caries is reduced when the restoration margins are placed subgingivally (Budtz-Jørgensen, 1971; Hammer & Hotz, 1978). The present study does not indicate that the prevalence of secondary caries can be related to the cervicoaxial location of the margin. However, the lack of relationship may be influenced by the study design in the present study, since the gingival extension of the prepared cavities was not assessed clinically, but relative to the occlusal marginal ridge on the epoxy casts (Jokstad & Mjör, 1989).

The assumption that remaining fissures in continuation from the restoration margins could be related to secondary caries (Jørgensen & Wakumoto, 1968; Sturdevant, 1985), was not supported by the present observations. None of

the secondary caries lesions were found on the occlusal surface.

The lack of association between the quality of the cavosurface angle and secondary caries was unexpected. It is possible that the criteria used in the present study for evaluating the quality of the cavosurface margin was too rough, and that the cavosurface margins considered acceptable were in effect, clinically unsatisfactory. The same cavity preparations had also been scored according to the CMI index (Tronstad & Leidal, 1974). However, since most of the cavosurface margins were considered unacceptable using the CMI index, we had suggested that the CMI index was too finely graded (Jokstad & Mjör, 1989). The present data indicate that this conclusion could have been premature, and that the CMI index indeed could have been more clinically relevant than the one used in the present study.

many

Restoration fractures

When the whole study material was included in the discriminant analyses, the variables associated with bulk fractures were narrow buccolingual widths at the isthmus, poor occlusal and proximal retention, acute axiokingival line angles and shallow restorations at the isthmus. This varied slightly from the variables identified when the data for the two separate patient groups, i.e., adolescent and adults, were used in separate discriminant statistics. It is possible that the discriminant function using the whole study material could have been confounded. On the other hand, the identification of different variables may indicate a different bulk fracture etiology for the adolescent and the adult patients. This may also explain the lower eigenvalue of the discriminant function using the whole study material (Table III.9), compared to the discriminant functions using the separate patient groups (Tables III.10-III.11).

In the adolescent patients bulk fractures prevailed among the voluminous restorations with shallow occlusal depths. Since restoration volume normally correlates to strength, the increased fracture rate may indicate that the bulk fractures in this patient group occurred primarily by trauma. The restoration bulk fractures that occurred during the first 6 months of the study were probably also the result of supracontact. In contrast, in the adult patients the fractures were associated with restorations placed in cavities with deep occlusal parts, limited axiocervical extension in the proximal part, poor proximal retention and narrow buccolingual extension occlusally (Table III.11).

It is generally presumed that an adequate occlusal restoration bulk is needed in a class 2 cavity, especially in the isthmus region to avoid restoration bulk fractures (O'Hara & Clark, 1984). However, the definition of "adequate depth" is primarily based on *in vitro* experiments, and empirical data. A literature search has not identified any clinical studies reporting that restorations with large occlusal bulk give longer clinical service than those with less bulk (Part I, section 2). Additionally, the presumption that a deepening of the preparation

decreases the risk of bulk fractures is based on the idea that the compressive forces during masticatory function produce only vertical force vectors in the restorations, which is not correct (Gibbs et al., 1986; Krejci et al. 1990). The data in the present study show that among the adolescent patients the cavity depth had no influence on the bulk fracture risk. Furthermore, the data showed that in the adult patients the bulk fractures prevailed for the restorations with higher occlusal cavity depths. Thus, the data suggests that the etiological mechanism in bulk fracturing is influenced by additional factors besides resistance towards vertical forces during chewing.

The observation that limited occlusal buccolingual width is associated with restoration bulk fractures is in accordance with in vitro experiments, reporting that wide restorations tolerate higher stresses than narrow restorations before isthmus fracture (Table I.9) (Mondelli & Vieira, 1972).

Tooth fractures

Many restorations performed well for 10 years in large cavities. The data, therefore, show that it may be justified to attempt placing amalgam restorations in teeth, which otherwise would require crowns.

The in vitro experiments which have shown that teeth with wide restorations are more prone to cusp fractures (Blaser et al., 1983; Mondelli et al., 1980) were partly confirmed in the present study. However, the low number of tooth fractures (n=8) during the observation period prevent any statistical inferences to the cavity design. It was thus impossible to assess if the cavity depth had a greater influence than the width on the fracture strength of the tooth (Blaser, 1983; El-Sherif et al., 1988).

For the same reason, the present results could not be used to assess the association between internal features of the cavity and the clinical performance of the restorations.

Margin fractures

The prevalence of replacements due to margin fractures was low in the present study. This observation contrasts some reports suggesting that many amalgam restorations are replaced because of defective margins (Boyd & Richardson, 1985). Several hypotheses have been suggested to explain the frequent use of the criterion for replacements in USA and Canada. One hypothesis is that lack of patients due to a general decrease of the caries prevalence in the population induces more and possibly unnecessary replacements (Drake, Maryniuk & Bentley, 1990). However, so far there is lack of research to substantiate this theory. On the other hand, this specific discrepancy of amalgam restorations has been extensively focused upon in the dental literature, and in the aggressive marketing of new amalgam alloys and alternative restorative materials. A plausible explanation for the increased

use of the replacement criterion is that dentists have been led to believe that margin fracture is a serious clinical problem (Maryniuk & Brunson, 1989).

The low frequency of replacements due to gross margin fracture in the present study is also interesting, since the dentists did not use rubber dam when the restorations were placed. One previous study have reported that the use of rubber dam does not influence the incidence of margin fractures (Letzel et al., 1979). On the other hand, Bouschor & Martin (1976) have stated that the moist breath of the patient is enough to moisture-contaminate amalgam, cause delayed expansion and margin fractures, despite the use of cotton rolls. The present results do not support this hypothesis.

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6. Conclusions

A review of the literature on in vitro and in vivo studies of class 2 cavity designs shows that the present day concepts of optimal cavity preparations for amalgam restorations are primarily based on in vitro results and observational in vivo studies. There is a lack of experimental investigations that have elucidated the effects of cavity design features on restoration performance.

The literature shows a wide variation of opinions on the ideal class 2 cavity preparation for amalgam restorations. Evaluation systems described in the literature on class 2 cavity designs often reflect the authors' views on the "ideal" cavity, rather than objective characteristics of the quantitative and qualitative features. The evaluations systems vary greatly with respect to the number of cavity design features examined and the scoring levels. Several of the systems lack written criteria, and descriptions for training the evaluators.

An evaluation system was designed for recording cavity preparations. It described procedures for recording cavity design variables and included variables that reflected the morphologies of cavity preparations. Characteristics of the cavity preparations that could be potentially influential on the short and long term performance of the restorations could be scored on an interval scale. The intra-examiner reliability of the scoring, measured on one examiner, was 85% agreement on two scorings.

A method using composite silhouette tracings of sectioned elastomere impressions could be used for measuring the amalgam margin angles and the occlusal thickness of the restoration at the isthmus with a resolution of about 0.1 mm. High Pearson's correlation coefficients and low standard deviations indicated that the method was highly reproducible, and suitable for studies of dimensions of the restoration and the tooth in situ.

The scoring of margin fractures on impressions using a 6 point scale references set, showed satisfactory inter-examiner agreement on scoring, as evaluated by Kappa statistics, indicating that margin fractures can be discriminated on impressions with relatively high accuracy. The rating distribution of scorings using impressions showed good correlation to rating distributions using the clinical USPHS evaluation method or photographs for recording margin fractures.

Margin fractures of amalgam restorations are influenced by the dentist, the alloy, and the intra-oral location of the restoration. The cavosurface margin quality, fissures in continuation with the margins, and convergence of cavity walls are cavity design factors that are associated with margin fractures.

The reasons for the replacement of amalgam restorations recorded in 7 Scandinavian general practices over 10 years were secondary caries (43%), bulk fractures (36%), tooth fractures (11%), margin fractures (4%) and conversion into larger restorations (5%). The estimated survival periods were 89% after 5 years, and 75% after 10 years. These results were comparable to data from other longitudinal and cross-sectional clinical studies.

Discriminant analyses were applied on groups of restorations remaining in situ and on those that failed after 10 years, to identify which clinical variables that exerted the strongest influence on the calculation of discriminant scores for classifying the restorations. Restorations failing due to secondary caries were associated with high patient DFT increments and narrow preparations along the gingiva on the proximal surface. Bulk fracturing of the restorations were associated with the dentist, lack of occlusal and proximal retention, and narrow occlusal parts of the restoration. Alloy composition and restoration type had no influence on the bulk fracture incidence. Low margin fracture scores prior to failure were associated with secondary caries, while high scores were associated with bulk fractured restorations.

APPENDIX

Appendix. Characteristics of the clinical variables and photographs of the cavity for the failed restorations, listed by the length of the clinical service period (Months, first column). The next column lists the dentist, followed by the patient data, i.e., age, gender and DFT increment group. The next column lists the restoration type, tooth and material used. Thereafter, the last margin fracture score prior to failure, and the assessment methods used, i.e., clinical (USPH), impressions (Imp) or photographs (Pho). The following columns delineate characteristics of the restoration (Volume and Bulk (mm)), and the prepared cavity (Width, Depths). Discrepancies of the prepared cavity are marked on the diagrams. The following markings indicate: ○: undermined enamel, ■: rough cavosurface, ▴: fissures or thin enamel slices along margin, ▶: sharp angles.

I. Secondary caries

Dentist Months	Patient: Age Gender DFTinc.	Restoration: Type Tooth Material	Last margin score before failure (Method)	Restoration Volume (mm ³) Bulk (mm)	Cavity		Quality	Photograph
					Width	Depths		
11 #4	6807 Male Medium	26 MO Tytin	Beta-2 (USPH-Imp) 32 21	25 33 33 33 33	3.5 2.5	3.0 3.0	○	
12 #6	6812 Male High	16 MO Tytin	Alfa (USPH) 23 18	20 25 25 25 60	3.0 2.0	1.5 2.0	■	
12 #4	6605 Female High	15 DO Dispensalloy	Charlie-2 (USPH-Imp) 19 16	33 33 33 25 25	2.5 1.5	2.5 3.5	○	
13 #4	6703 Male High	25 DO Tytin	Beta-1 (USPH-Imp) 18 13	33 40 40 25 25	2.0 1.0	2.0 3.0	○	
15 #4	7008 Male High	25 DO Amalcap	Alfa-3 (USPH-Imp) 19 16	20 25 25 25 25	2.5 1.5	2.0 3.5	■	
22 #4	7008 Male High	15 DO Dispensalloy	Alfa-2 (USPH-Imp) 16 12	20 20 20 20 20	2.0 2.0	0.5 3.0	▴	
24 #4	6705 Female High	25 DO Amalcap	Alfa-3 (USPH-Imp) 17 10	20 20 25 25 25	2.0 1.5	1.0 3.0	■	

Dentist Months	Patient Age Gender DFTinc	Restoration Type Tooth Material	Last margin score before failure (Method)	Restoration Volume (mm ³) Bulk (mm)	Widths		Depths		Quality	Image
					—	—	—	—		
24 #6	6912 Female High	16 MO Indloy	Charlie-2 (USPH-Imp)	31 10	33 40 40 40 75	3.0	2.0 2.0	2.0		
24 #4	7106 Female High	16 MO Dispervalloy	Charlie-4 (USPH-Imp)	39 16	40 40 40 50 50	3.5	2.0 2.5	1.5		
24 #4	7106 Female High	36 MO Amalgap	Beta-3 (USPH-Imp)	45 14	40 50 33 33 99	4.0	2.0 2.0	2.0		
25 #4	6903 Male High	15 MOD Amalgap	Alfa-3 (USPH-Imp)	36 16	20 20 33 25 33 20 20	3.0	2.0 2.0 2.0 2.0	1.5 3.0 2.0		
25 #4	6710 Female High	36 MO Dispervalloy	Beta-5 (USPH-Imp)	42 18	40 40 50 60 99	3.5	2.5 3.0	2.0		
28 #6	6711 Male High	36 DO Indloy	Alfa-2 (USPH-Imp)	36 11	60 50 50 33 33	4.0	2.0 1.5	1.5		
34 #6	6711 Male High	46 DO Revalloy	Alfa-2 (USPH-Imp)	31 15	60 33 33 40 40	3.0	2.0 2.0	1.5 3.0		
34 #6	6711 Male High	15 MOD Indloy	Beta-3 (USPH-Imp)	38 8	25 25 33 33 33 25 25	3.5	2.0 2.0 2.5 2.5	1.0 3.5 1.5		
35 #4	6801 Female High	46 MO Amalgap	Alfa-3 (USPH-Imp)	23 9	33 40 33 40 50	2.5	1.5 1.5	2.0		

Dentist Months	Patient: Age Gender DFTinc.	Restoration: Type Tooth Material	Last margin score before failure (Method)	Restoration Volume (mm ³)	Widths		Depths		Quality
					Bulk (mm)				
36 #4	6910 Female High	15 DO Tytin	Beta-2 (USPH-Imp)	18 11	25 25 25 25 25	2.0 1.5	3.0 2.0		
38 #2	4907 Male Low	45 MOD Amalcap	2-3 (Imp-Pho)	45 9	33 33 33 33 40 40 40	1.5 1.5 1.5 1.5	3.0 2.0		
38 #4	6603 Male High	25 DO Dispensalloy	Alfa-2 (USPH-Imp)	24 13	25 20 25 25 25	2.5 2.0	3.5 1.5		
38 #4	6603 Male High	24 DO Tytin	Alfa-3 (USPH-Imp)	17 10	25 25 20 25 20	2.0 1.5	2.5 1.5		
40 #6	7207 Male High	16 MO Indiloy	Alfa-3 (USPH-Imp)	29 16	40 50 40 40 50	2.5 3.0	4.0 1.0		
42 #4	6712 Male High	26 MO Amalcap	Alfa-4 (USPH-Imp)	29 15	25 25 25 25 33	3.0 2.5	3.5 2.5		
50 #4	6804 Male High	35 DO Amalcap	Alfa-4 (USPH-Imp)	15 8	66 66 66 20 25	1.5 1.0	2.5 1.5		
52 #4	7006 Female High	26 MO Amalcap	Beta-4 (USPH-Imp)	28 19	25 25 40 33 50	3.0 3.0	3.0 1.5		
59 #4	6807 Male High	44 DO Amalcap	Alfa-2 (USPH-Imp)	13 8	25 33 33 33 25	1.5 1.0	2.0 1.5		

Dentist Months	Patient Age	Restoration Type	Last margin score before failure (Method)	Restoration Volume (mm ³)	Restoration		Quality
					Bulk (mm)	—Widths—	
72 #4	7111 Female Medium	26 MO Titan	Alfa-4 (USPH-Imp) 24 13	25 33 25 25 33	3.0 2.0	2.0 1.5	
75 #4	7107 Male High	26 MO Amalcap	Alfa-5 (USPH-Imp) 27 19	33 33 33 33 60	2.5 2.0	2.5 3.0	
84 #6	6812 Female High	25 DO Revalloy	Alfa-2 (USPH-Imp) 26 11	33 33 33 25 20	2.0 2.0	1.5 3.5	
86 #6	7208 Female High	46 MO Revalloy	Alfa-4 (USPH-Imp) 49 14	40 50 33 33 99	4.0 2.0	2.0 2.0	
86 #5	5302 Female Medium	44 DO Dispersalloy	4-3 (Imp-Pho) 24 8	50 40 50 40 50	1.5 1.5	2.0 3.0	
87 #7	4909 Male Low	24 DO Revalloy	3-3 (Imp-Pho) 27 15	40 33 25 33 33	1.5 1.5	2.0 3.0	
94 #1	1308 Male High	34 DO Titan	Alfa-2 (USPH-Imp) 87 17	50 50 50 75 60	2.0 2.0	2.0 5.5	
99 #2	4802 Male Low	16 DO Revalloy	3-3 (Imp-Pho) 51 14	84 66 60 60 50	2.0 2.0	2.0 3.5	
109 #3	6404 Female Low	37 MO Indiloy	Alfa-4 (USPH-Imp) 12 12	25 25 80	3.0 1.0	2.0 1.5	

Dentist Months	Patient:		Restoration:		Last margin score before failure (Method)	Restoration Volume (mm ³)	---Widths---			---Depths---			Quality
	Age	Gender	Type	Tooth			Bulk (mm)						
120 #1	1901	47	Female	MOD	Alfa-3 (USPH-imp)	124 18	40 40 40 75 40 40 40	2.5 2.5 2.5 2.5	4.0	1.5	2.0	3.5	

II. Restoration bulk fractures

Dentist Months	Patient:		Restoration:		Last margin score before failure (Method)	Restoration Volume (mm ³)	---Widths---			---Depths---			Quality
	Age	Gender	Type	Tooth			Bulk (mm)						
4 #1	5009	14	Female	DO	Alfa (USPH)	26 12	50 40 40 40 40	2.0 2.0	2.0	1.5			
6 #4	7105	16	Male	MO	Alfa (USPH)	26 9	33 33 25 25 33	2.0 2.5	3.0	2.0			
6 #4	7010	36	Male	DO	Alfa (USPH)	27 12	75 50 40 25 25	2.0 2.0	3.5	1.5			
12 #7	4809	26	Male	MOD	3-2 (Imp-Pbo)	101 23	40 50 60 66 60 50 50	3.5 3.0 2.5 2.5	4.0	1.0	2.0	4.0	
12 #3	6402	46	Male	MOD	Alfa-3 (USPH-imp)	122 15	40 50 50 99 66 50 40	1.5 2.0 2.5 2.5	4.0	3.0	2.0	3.5	
15 #5	5707	35	Male	DO	4-5 (Imp-Pbo)	28 17	50 50 50 60 50	2.5 2.0	2.5	1.0			

Dentist Months	Patient Age Gender DFTinc.	Restoration: Type Tooth Material	Last margin score before failure (Method)	Restoration Volume (mm ³) Bulk (mm)	—Widths—			—Depths—			Quality
18 #1	4112 Male Low	47 MOD Titan	Charlie-5 (USPH-Imp)	112 19	40 50 40 80 50 60 50	2.5	3.0 2.0 2.5 3.0	2.0	4.5		
19 #7	3904 Male Medium	26 MOD Dispersalloy	5-6 (Imp-Pho)	191 11	50 66 60 70 80 84 84	4.0	2.5 2.5 2.5 2.0	1.5	5.5		
25 #1	4609 Female Medium	17 MO Revalloy	Delta-5 (USPH-Imp)	26 12	40 40 40 33 50	3.5	2.5 2.0	1.0			
26 #5	5105 Female Low	15 MOD Dispersalloy	3-3 (Imp-Pho)	96 18	40 40 40 40 40 50 50	4.0	2.5 2.5 2.5 2.5	2.0	4.0		
28 #4	7003 Male Medium	26 MO Titan	Beta-3 (USPH-Imp)	20 9	20 25 25 25 40	3.0	2.0 2.0	2.0			
39 #4	6908 Male Medium	36 MO Amalcap	Alfa-4 (USPH-Imp)	37 14	40 40 33 33 50	3.0	2.0 1.5	2.0			
46 #4	7106 Female High	46 MO Dispersalloy	Beta-5 (USPH-Imp)	27 11	40 40 33 33 99	5.0	2.0 2.0	2.0			
48 #2	5610 Male Medium	47 MO Titan	3-3 (Imp-Pho)	71 27	40 40 60 50 99	3.5	3.0 4.0	2.0			
49 #4	7107 Female Medium	36 DO Amalcap	Beta-4 (USPH-Imp)	47 14	60 33 33 33 33		2.5 2.0	2.5	1.0		

Dentist Months	Patient: Age Gender DPTinc.	Restoration: Type Tooth Material	Last margin score before failure (Method)	Restoration Volume (mm ³)	—Widths—			—Depths—		Quality	
					Bulk (mm)	—Quality—		—Quality—			
50 #4	7107 Female Medium	16 MO Dispensalloy	Alfa-2 (USPH-Imp)	26 13	25 25 25 25 33	3.5	2.0 2.0	2.0			
59 #4	7106 Female High	26 MO Tytin	Beta-4 (USPH-Imp)	35 15	33 40 33 33 50	3.5	2.0 1.5	2.0			
60 #4	6710 Female High	15 DO Tytin	Alfa-4 (USPH-Imp)	22 19	33 33 33 25 25	3.0	2.0 2.0	3.0 1.5			
64 #1	4606 Female Low	46 MO Revalloy	Beta-5 (USPH-Imp)	67 8	50 50 40 50 99	3.0	2.0 2.5	2.0			
67 #1	4609 Female Medium	14 DO Tytin	Alfa-3 (USPH-Imp)	32 15	33 33 33 40 40	3.0	2.0 2.0	2.5 2.0			
68 #2	4607 Male Low	25 MOD Amalcap	2-2 (Imp-Pho)	89 19	40 40 33 33 33 40 50	3.0	3.0 3.0 4.0 4.0	1.5 1.5			
79 #1	4906 Female Low	46 MOD Revalloy	Beta-3 (USPH-Imp)	133 22	50 60 40 84 80 40 40	4.0	2.0 2.0 2.0 2.0	2.0 2.0			
81 #6	7004 Male Medium	16 MO Indilloy	Alfa-3 (USPH-Imp)	29 12	33 33 25 25 50	3.0	2.0 2.5	1.5			
82 #1	4312 Female Low	25 MOD Revalloy	Beta-5 (USPH-Imp)	119 22	50 60 50 50 50 40 40	5.5	3.0 3.0 3.0 3.0	3.0 2.0			

Dentist Months	Patient:		Restoration:	Last margin score before failure (Method)	Restoration Volume (mm ³)	Widths	Depth	Quality	
	Age Gender DFTinc.	Tooth Material	Type						
85 #4	7107 Female Medium	26 MO Amalgap	Alpha-4 (USPH-Imp)	26 14	25 33 25 20 33	3.0 2.0 2.0 2.0			
102 #3	6508 Male Low	46 MOD Revalloy	Beta-5 (USPH-Imp)	62 9	33 33 40 66 40 40 40	1.5 1.5 2.0 2.0 3.0 1.5 1.5			
117 #1	3910 Female Medium	15 DO Indicoy	Charlie-3 (USPH-Imp)	37 17	33 25 20 40 40	2.5 2.0 3.5 2.0			

III. Tooth fractures

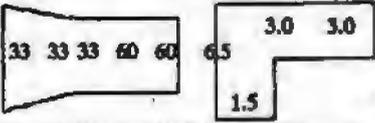
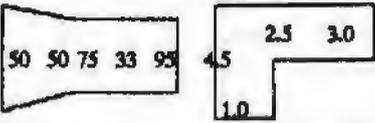
Dentist Months	Patient:		Restoration:	Last margin score before failure (Method)	Restoration Volume (mm ³)	Widths	Depth	Quality	
	Age Gender DFTinc.	Tooth Material	Type						
38 #2	4611 Female Low	36 DO Amalgap	4-5 (Imp-Pho)	34 22	95 50 50 25 25	3.0 2.0 4.0 2.0			
43 #7	4106 Female Low	46 MOD Amalgap	4-3 (Imp-Pho)	120 23	60 66 80 50 60 50 40	2.0 2.0 1.5 2.0 3.5 2.0 1.5			
57 #7	3806 Male Medium	34 DO Amalgap	3-3 (Imp-Pho)	39 21	50 50 60 66 60	2.5 1.5 5.0 1.0			
60 #2	5610 Male Medium	15 MOD Amalgap	3-3 (Imp-Pho)	107 34	25 33 50 60 60 50 50	4.0 4.0 4.0 4.0 4.5 2.0 2.0			

Dentist Months	Age Gender	Type Tooth DFT Inc. Material	score before failure (Method)	Restoration Volume (mm ³) Bulk (mm)	—Widths—				—Depths—				Quality
63	#7 Female Low	4106 24 MOD Dispervalloy	3-2 (Imp-Pho)	107 15	40 50 60 70 80 50 50	3.5	2.0 2.0 2.0 2.0	2.0 2.0					
84	#7 Male Medium	3806 17 DO Revalloy	4-3 (Imp-Pho)	69 19	33 40 75 60 60	5.5	2.0 2.0	2.0					
94	#1 Female Medium	3910 26 MO Revalloy	Alfa-5 (USPH-Imp)	50 23	40 40 40 99 99	3.5	3.0 4.0	1.5					
96	#7 Male Medium	3806 25 MOD Revalloy	4-3 (Imp-Pho)	74 22	33 33 50 55 50 33 40	4.0	3.0 2.5 2.5 2.0	1.5 1.5					

IV. Margin fractures

Dentist Months	Age Gender	Type Tooth DFT Inc. Material	Last margin score before failure (Method)	Restoration Volume (mm ³) Bulk (mm)	—Widths—				—Depths—				Quality
36	#1 Female Low	5305 26 MOD Indiloy	Beta-4 (USPH-Imp)	137 22	50 60 60 66 66 60 50	3.5	3.0 3.0 3.0 4.0	2.0 2.0					
50	#1 Male Low	4905 15 MO Revalloy	Charlie-5 (USPH-Imp)	52 14	40 50 40 33 50	4.0	2.0 2.0	2.5					
78	#1 Male Med.	4911 15 MOD Revalloy	Beta-4 (USPH-Imp)	85 17	40 40 50 40 50 40 40	3.0	2.0 2.0 2.0 2.0	1.5 1.5					

IV. Extended

Dentist Months	Patient:		Restoration: Type Tooth DFTinc. Material	Last margin score before failure (Method)	Restoration Volume (mm ³) Bulk (mm)	Widths		Depths		Quality	
	Age	Gender				—	—	—	—		
70 #1	2508	26 Female Med.	MO Indiloy	Alpha-1 (USPH-Imp) 63 24	33 33 33 60 60 65	3.0 3.0	1.5				
74 #6	6912	36 Female High	MO Revalloy	Beta-5 (USPH-Imp) 35 17	50 50 75 33 95	2.5 3.0	1.0				
120 #1	1211	25 Male Low	MO Revalloy	Beta-5 (USPH-Imp) 36 14	40 50 66 33 40	2.0 2.0	1.5	