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Research Article

Clinical evaluation of Dyract in primary molars: 1-year results

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ABSTRACT: <u>Purpose</u>: To evaluate the 1-year clinical performance of Dyract in primary molars. <u>Materials and</u> <u>Methods</u>: 55 children (aged 4-9 years) received 1-3 restorations (n=91) utilizing Dyract, a new restorative material combining properties of both glass ionomers and composites. <u>Results</u>: The so-called compomer material showed good handling characteristics and a survival rate of 97% after 1 year. Nevertheless, the material demonstrated an average wear of 190 μ m during 1 year, with 67% of the restorations having occlusal wear of less than 200 μ m. The combination of a low failure rate and the ease of application makes the compomer material very suitable for

application in the primary dentition. (Am J Dent 1996;9:83-87).

CLINICAL SIGNIFICANCE: Dyract showed excellent handling characteristics and a low failure rate after 1 year of service in primary molars.

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Introduction

For a long time, dental amalgam has been the standard restorative material for Class I and II carious lesions in the primary dentition. The use of amalgam in dentistry has become more controversial. In Germany, as well as the Scandinavian countries, governmental directives have issued more restrictions for the indication of dental amalgam. Reasons for these directives are alleged health hazards as well as environmental concerns. In the light of this discussion on the risks of mercury to health and environment, there is a growing interest in amalgam alternatives. Resin composites and glass ionomer cements are frequent alternatives for dental amalgam. The glass ionomer cements in particular are considered to be suitable for restoring primary teeth in young children due to their ease of application and fluoride release.' However, in several clinical studies in the primary dentition, both the glass ionomers and composites showed a relatively poor performance.² Adhesive materials provide a means of restoring primary molars with minimal amount of destruction of healthy tooth tissue and reduced treatment time, while local fluoride release is a potential advantage.

Posterior Restorations (1989) as applicable for the assessment of primary teeth.

For the clinical trial, 55 children [27 male (49%) and 28 female (51%)], either attending the Department of Cariology and Endodontology of the Dental School in Nijmegen or a local pediatric dental clinic near Nijmegen, were selected. At the beginning of the study the mean age of the children was 7 years (range 3.6 - 9.3). All children were of good general health with no history of medical complications. The teeth selected were diagnosed as vital but having primary carious lesions needing Class I or II restorations. Nine carious lesions were diagnosed by pre-operative radiographs and 82 by visual inspection in combination with transillumination. The restorations included 11 Class I (12%) and 80 Class II (88%) restorations. No more than three restorations of the experimental material were inserted per patient. Restorations were placed by three experienced clinicians according to a strict protocol. The design of the preparation was determined by the extent of the decay. A major area of infected dentin resulted in a conventional preparation according to Black. The average bucco-lingual width of the conventional restoration was greater than one third of the intercuspal distance.

Recently a new light-curing, fluoride-releasing material of high strength and with adhesive properties, so-called "compomer" (Dyract^a), was introduced. This material combines the technology of glass ionomer cements and light-curing composites. According to the manufacturer, the characteristics of this new material are: good biocompatibility, fluoride release, adhesion to enamel and dentin, light-cured, easy to handle and superior strength compared to conventional glass ionomer. This clinical study evaluated the performance of Dyract used in Class I and II restorations in primary molars.

In case of the treatment of initial caries, a conservative preparation was chosen. For the conservative preparation, caries was removed and the preparation was not extended. In the Class II preparations, at the margins of the box a short bevel was prepared. Finally, of the 11 Class I preparations, four showed a conservative design (36%) and seven preparations were made according to the principles of Black (64%). For the 80 Class II restorations, a conservative preparation design was chosen in 19 teeth (24%) and a preparation according to Black in 61 teeth (76%). The average bucco-lingual width of the restorations according to Black was more than 1/3 of the distance between the cusps. A metal matrix was used in combination with wooden wedges. Isolation was performed with cotton rolls and a saliva ejector. After drying the cavity preparation with air, the primer (Dyract-PSA Prime/Adhesive^a) was applied according to the

Materials and Methods

The complete study involves a longitudinal trial over a period of 3 years, taking into consideration the ADA Guidelines for Submission of Composite Resin Materials for

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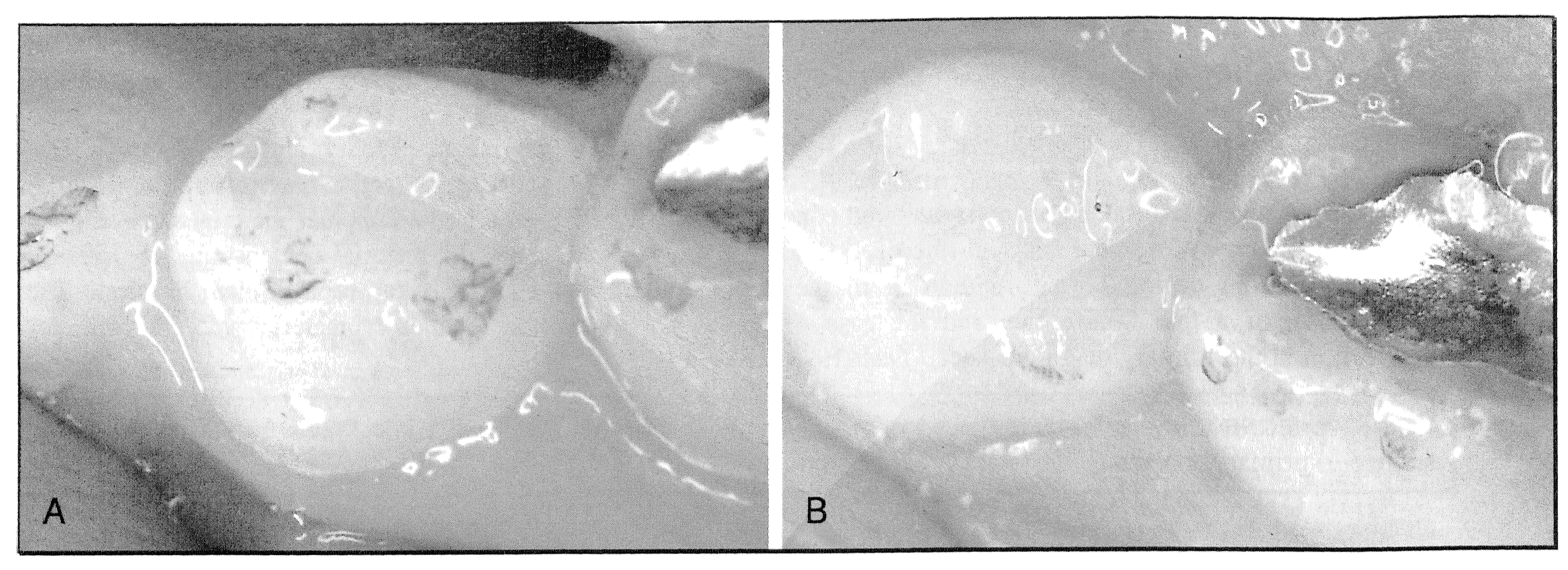


Fig. 1. Representative restoration (84 DO). A. Baseline; B. 1 year showing minimal wear.

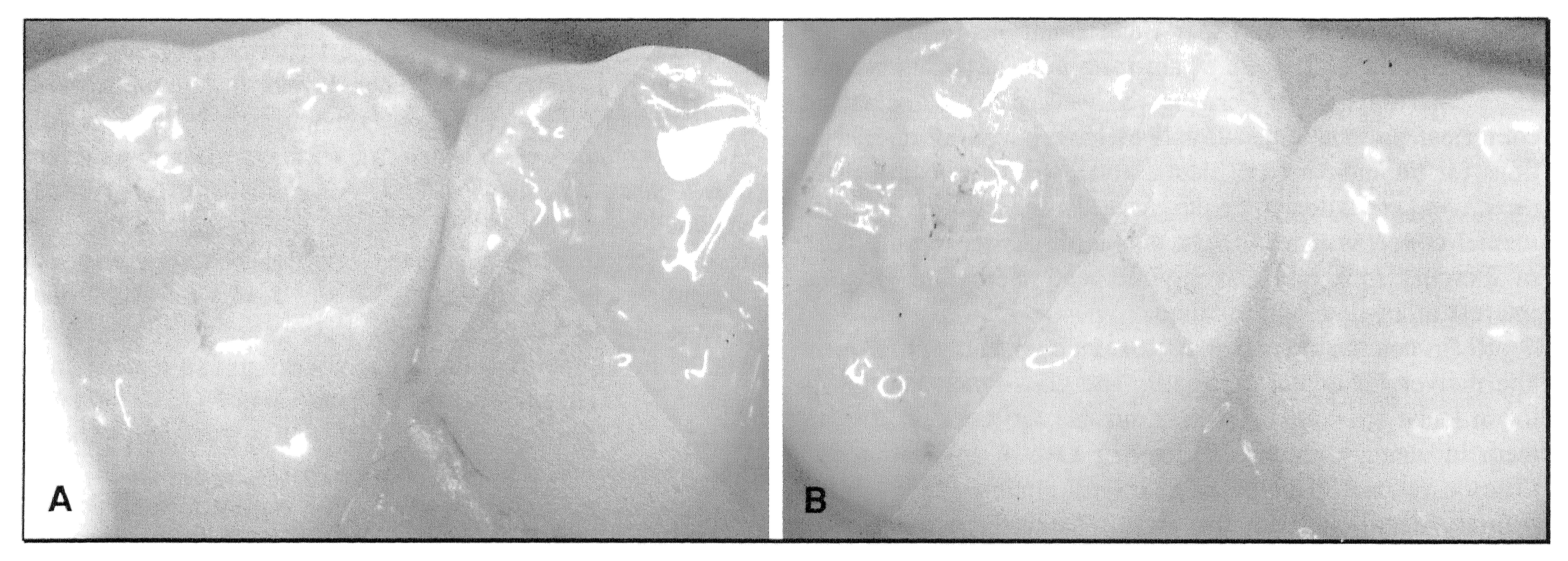


Fig. 2. Representative restoration (65 MO). A. Baseline; B. 1 year showing generalized wear.

manufacturer's instructions. The first layer of primer was applied and left for 30 seconds before gently drying and curing for 10 seconds. The second layer of primer was applied, immediately air-dried and cured for 10 seconds. The compomer (Dyract Compomer Restorative^a) is delivered in a compule, and was injected directly into the cavity preparation. The compomer was never applied in layers exceeding a thickness of 2 mm in order to allow a proper cure after a polymerization time of at least 30 seconds and to compensate for polymerization shrinkage. The intensity of the light-source (Euromax^a) was checked at weekly intervals and the light output was never below 450 mW/cm². Restorations were finished with composite finishing stones or multi-fluted burs. The baseline evaluation took place 1-3 weeks after placement of each restoration. The number of restorations that could be evaluated were 91 at baseline, 89 at 6-month recall and 86 at 1-year recall. At each evaluation, color slides and impressions with an addition silicone material were taken. The impressions were poured in an epoxy die (EpoxyDie^b). Finally, the performance of these restorations was assessed by two calibrated evaluators using a direct and indirect evaluation technique.

All restorations were scored independently by each investigator. When scores were not in agreement, this was

discussed by the evaluators at chairside until mutual agreement was achieved. The direct clinical evaluation consisted of a slightly modified version of the Ryge system.³ The Alfa (A) value indicates a clinically ideal condition. The Bravo value (B) indicates a clinically acceptable situation. The Charlie (C) value indicates a clinically unacceptable characteristic which might necessitate a replacement of the restoration. The Delta (D) value indicates a clinically unacceptable situation due to fracture, mobility or loss of the restoration and a replacement of the restoration is required. The Oscar (O) value indicates the absence of an adjacent approximal surface. Furthermore, the patients were interviewed and asked if they had experienced any post-operative sensitivity. The condition of the gingiva adjacent to the resAmerican Journal of Dentistry, Vol. 9, No. 2, April, 1996

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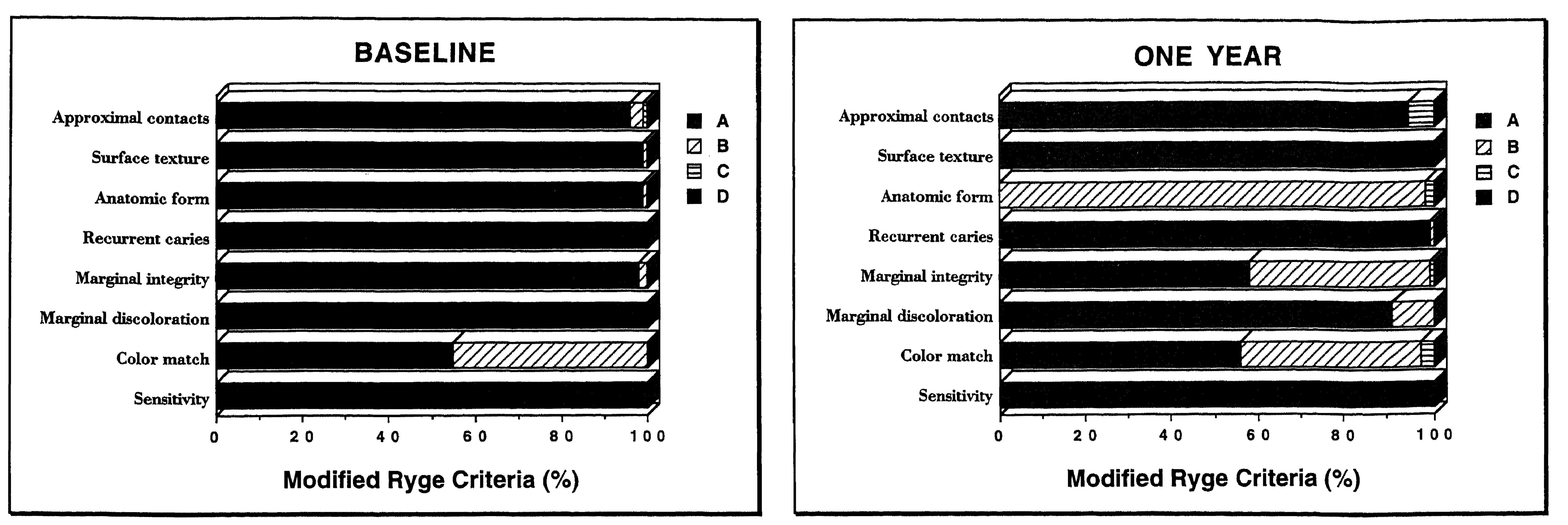


Fig. 3. Clinical assessment of restorations at baseline (Ryge criteria).

Fig. 4. Clinical assessment of restorations at 1 year (Ryge criteria).

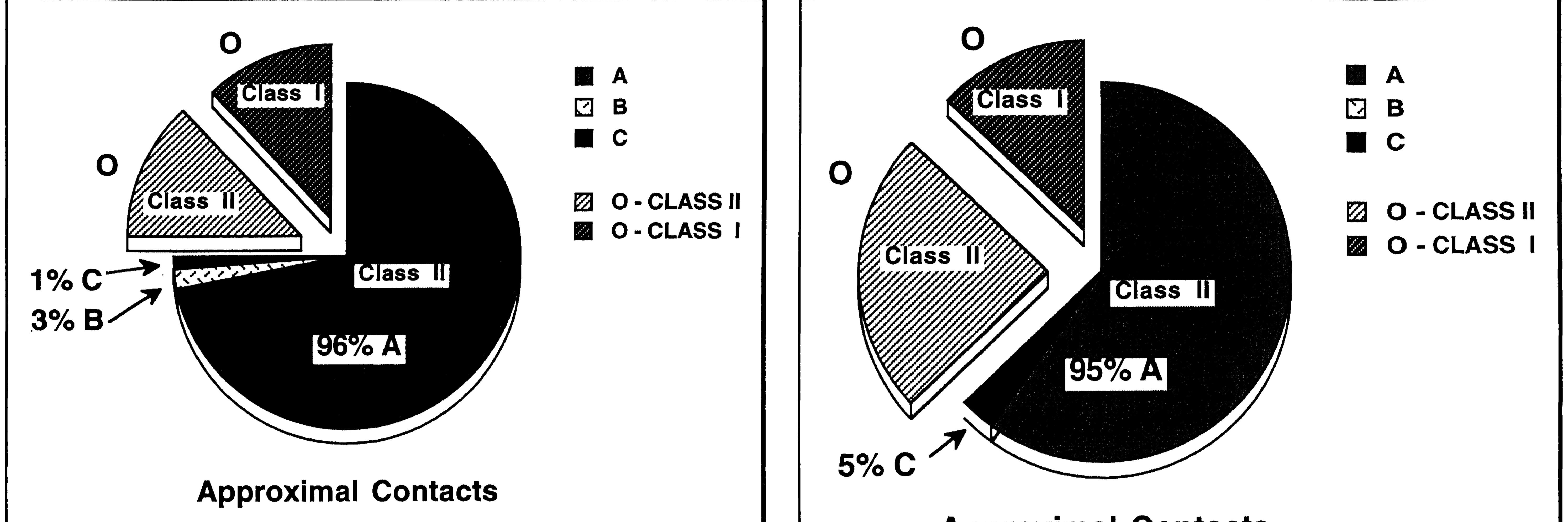


Fig. 5. Clinical assessment and distribution of approximal contacts at baseline (Ryge criteria).

torations was registered pre-operatively and at every recall using the Sulcus Bleeding Index.⁴ The following values can be attributed to the scores: (0) Healthy appearance, no bleeding on sulcus probing, (1) Apparently healthy, no change of color, no swelling, but bleeding from probing, (2) Bleeding on probing and change of color due to inflammation, no swelling, (3) Bleeding on probing and change of color and slight edematous swelling, (4) Bleeding on probing and change in color and obvious swelling, (5) Bleeding on probing

Approximal Contacts

Fig. 6. Clinical assessment and distribution of approximal contacts at 1 year (Ryge criteria).

the restorations according to the Ryge criteria at baseline, 6month and 1-year recalls. To compare baseline and 1-year results, the change in the various criteria (%) are shown in Figs. 3 and 4. In these bar graphs of criteria, the number of approximal contacts which could be present within the mixed dentition of the children was set at 100%. The actual distribution of approximal contacts in the entire population is depicted in Figs. 5 and 6.

and spontaneous bleeding and change in color, marked swelling with or without ulceration.

The indirect evaluation was performed on the epoxy casts to assess wear, maintenance of interproximal embrasure form and fracture. Wear was recorded according to the Moffa-Lugassy M-L Scale.^{5,6}

Results

The number of restorations subjected to direct clinical evaluation were 91 at baseline, 89 after 6 months and 86 after 1 year. Two examples of representative restorations at baseline and 1 year are shown, depicting minimal anatomic change (Fig. 1) and generalized wear and loss of anatomical contour (Fig. 2). Table 1 shows the results of the scores on

No post-operative sensitivity or other adverse reactions related to the restorative material could be recorded during the 1-year follow-up.

The scores for the condition of the gingiva adjacent to the restorations are shown in Table 2.

The results of wear measured on the epoxy casts according to the Moffa-Lugassy method are presented in Table 3. Epoxy casts were obtained of 91 restorations at baseline, 89 restorations after 6 months and 83 restorations after 1 year. The frequency distribution of restorations with respect to the actual wear after 1 year is presented in Fig. 7. The average loss of material at 1 year was 190 μ m. It appeared that 67% of the restorations showed a wear of 200 μ m or less. Due to an extreme generalized wear of the enamel in two cases, the

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Table 1. Evaluation of restorations at the different periods.

Category	Restorations (Number)											
	Score A		Score B			Score C			Score D/O			
	B	6 m	1 yr	B	6 m	1 yr	B	6 m	1 yr	B	6 m	1 yr
Sensitivity	91	89	86	0	0	0	0	0	0			
Color match	50	44	48	41	45	35	0	0	3			
Marginal discoloration	91	84	78	0	5	8	0	0	0			
Marginal integrity	89	64	50	2	24	35	0	1	1	0	0	0
Recurrent caries	91	89	85	0	0	1						
Anatomic form	90	79	0	1	9	85	0	1	1			
Surface texture	90	88	86	1	1	0	0	0	0			
Approximal contacts	65	61	51	2	0	0	1	4	3	23	24	32

(Class I)111111(no adjacent tooth - Class II)121321

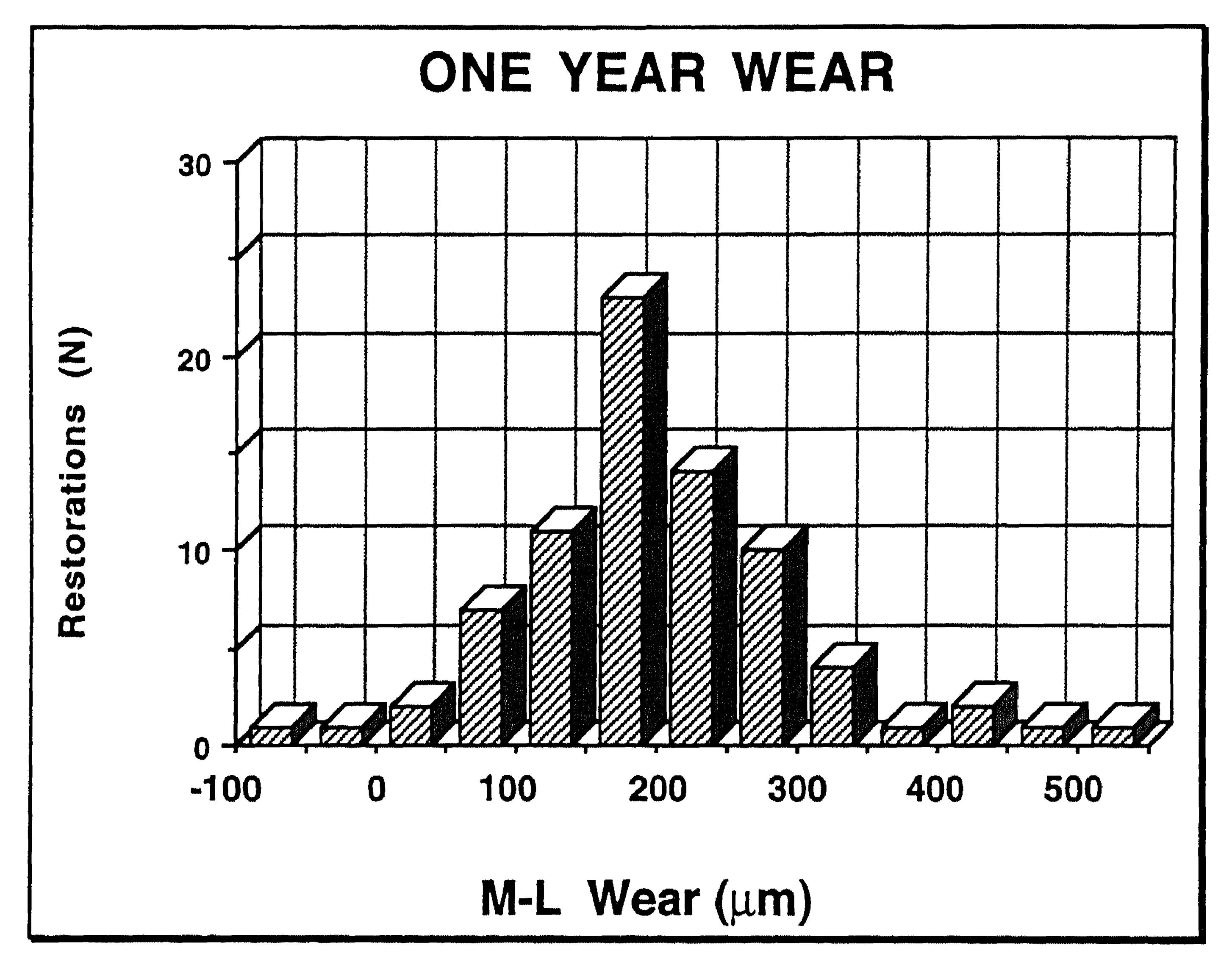


Table 2. Gingival health score.

	0	1	2	3	4	5	Score
B	47	16	14	3	0	0	11 (Class I)
6 months	49	28	1	0	0	0	11 (Class I)
1 year	54	13	8	0	0	0	11 (Class I)

Table 3. Loss of material (μ m).

Mean wearum

Fig. 7. Frequency distribution of the actual wear of the restorations after 1 year of service (Moffa-Lugassy method).

total amount of wear decreased after 1 year with 50 and 100 μm , compared to the 6-month evaluation. While none of the restorations demonstrated extensive wear at 6 months, four restorations (6%) showed a wear of 400 μ m or more at 1 year. The condition of the interproximal embrasures, as well as the presence of fractures as recorded on the epoxy casts, are presented in Table 4.

	wearpin		
Baseline	0μm		
6 months	100 μm		
1 year	190 µm		

it necessary to replace cotton rolls. As for the primer, the cotton rolls can stay in place, resulting in a lower risk for contamination and a more comfortable procedure for the child. As the compomer is delivered in a compule, the material can be injected directly into the cavity preparation. Immediately after light-curing is completed, the restoration can be finished.

Clinical evaluation of the compomer revealed that most of the restorations performed very well. None of the children had experienced any post-operative sensitivity directly after the restorations were inserted or at the 6-month or 1-year evaluations. Only two of the 86 restorations (2%) available for evaluation needed to be replaced due to fracture or recurrent caries. These were all Class II restorations with an adhesive preparation design. The presence of secondary caries after 1 year is most likely due to leakage and a subsequent caries process. By adding fluoride to restorative materials, the development of new caries lesions should be prevented. However, in order to prove the effect of the fluoride release from the restorative material on recurrent caries, a 1-year study is too short.' The first restoration combined a fracture with recurrent caries, the second restoration only demonstrated a fracture, while the third restoration showed secondary caries. A complete loss of retention was not observed at all. The clinical behavior of the compomer restorations is better than that of glass ionomer cement restorations in com-

Discussion

As stated by Kilpatrick,² the demands for a restoration in the primary dentition are somewhat different from those for the permanent dentition. This is due to the limited life span of the teeth themselves, the variations in levels of cooperation achieved by children and the different morphology of the teeth. The ideal restorative material for primary teeth should be easy to apply and have adhesive properties as this will limit the need for extensive preparation. The compomer material used in this study fulfils these demands. Adhesion is achieved by application of a special primer which only has to be air dried and cured. All other conditioners like phosphoric or poly-acrylic acid, require rinsing and drying which makes

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Table 4. Restorations at 6 months and 1 year.

Category	Score A		Sco	ore B	Score C		Score D/O	
	6 m	1 yr	6 m	1 yr	6 m	1 yr	6 m	1 yr
Embrasure where applicable (6 m: N=60; 1 yr: N=44)	40 67 <i>%</i>	9 20%	20 33%	35 80%	0	0	29 [33%	39 46%]
Fracture (6 m: $N = 89$; 1 yr: $N = 83$)	77 87%	72 86%	12 13%	10 12%	0 0%	0 0%	0 0%	0 0%

parable studies. Glass ionomer cement restorations appear to be very susceptible to fracture. In a 1-year study of Class II restorations in primary molars restored with the cermet Ketac-Silver, 7% of the restorations had to be replaced due to fractures.° A 5-14 month evaluation of Class II restorations in primary molars demonstrated 16% failure for the glass ionomer cement Ketac-Fil, and 23% failure for the cermet Ketac-Silver. After 1 year, 40% of the Ketac-Silver restorations in Class I and Class II restorations in primary molars had to be replaced due to fractures.¹⁰ Fracture of the glass ionomer cement was also the major reason for failure in Class II restorations in primary molars after 3 years.¹¹ The color match of the restorations with the adjacent tooth tissue demonstrates some variation. One of the operators deliberately selected non-matching shades for ease of finishing and detection of the restorations. This explains the mismatch in color at baseline. Furthermore, the translucent character of the compomer makes the material very sensitive

to 190 μm after 1 year. The measurement of wear is assessed as a relative change of the level of the restorations to the surrounding enamel. As excessive wear of enamel was frequently observed, the actual wear may be even higher in some patients. The compomer material demonstrates a different wear behavior than composites. In clinical studies on resin composites, wear rate is high during the first 6 months but decreases over time.^{12,13} The wear curve for the compomer material only tends to flatten very slightly from 100 μ m during the first 6 months, to 90 μ m from 6 months up to 1 year. Whether the wear rate will continue to decrease can not be predicted but is subject to further investigation. The importance of a prolonged study is evident from the studies of Walls et al^{14} and Welbury et al^{15} comparing the suitability of dental amalgam and a glass ionomer cement as a restorative material in the primary dentition. The 2-year results suggested that the glass ionomer cement was not worse than the amalgam.¹⁴ However, the 5-year results of the same trial demonstrated a higher survival rate for the amalgam than for the glass ionomer cement.¹⁵ Obviously, it would be difficult for the compomer material to meet the new guidelines for submission of resin composite for unrestricted use as a posterior restorative material. However, as also stated by other authors,^{1,2} further important requirements for a restorative material for the primary dentition are ease of application and efficiency in filling. The compomer material combines these requirements with a good survival rate at 1 year. If the loss of retention remains low and the wear does not result in a need to replace the restoration within the limited life span of the primary tooth, the compomer may prove to be an ideal material for restorations in the primary dentition.

to influences of ambient light on the color match.

Marginal discoloration was mostly related to the presence of a crevice and increased from 6% after 6 months to 10% after 1 year. Marginal defects like crevices or chipping were increasingly detected during the study.

The surface texture of the restorations was very smooth and comparable to the surrounding enamel.

No evidence was found for a negative effect of the compomer material on the condition of the gingiva.

A firm approximal contact was found for most of the Class II restorations. This was also evident on the epoxy casts. Evaluation of the casts demonstrated a slight broadening of the interproximal embrasure in 80% of the Class II restorations with an adjacent approximal tooth surface. However, in case of an approximal contact, usually the enamel of the primary molars at the contact will undergo

a. DeTrey/Dentsply, Konstanz, Germany.b. Vivadent, Schaan, Liechtenstein.

wear as well. There is no need to expect that the slight broadening of the interproximal embrasure will affect the eruption of the permanent successors.

The anatomic form demonstrated pronounced changes during the study. After 1 year, none of the restorations was free of changes in the anatomic form. If this change in anatomical contour increases over time and the primary tooth may be retained for an excessive period of time, the loss of anatomical contour may become a problem. If the successive tooth never develops, veneering with composite at a later stage may be considered.

A considerable wear was also scored indirectly on the epoxy casts. After correction for baseline under-contour, the average actual wear at 6 months was 100 μ m but increased

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clinical trial comparing a glass polyalkenoate (ionomer) cement restoration with amalgam restoration. Br Dent J 1991;170:177-181.

Press Notes

WOULD YOU DRINK WATER FROM YOUR DENTAL UNIT?

Contamination of dental unit water lines is not new to dentistry, but takes on a new dimension when considering immuno-deficient patients and existing infection control measures. Prevost et al (NYS Dent J 1995;61:22-7) evaluated the quality of water coming out of dental units, as it ends up in the mouths of the patients and in the ambient air as a result of aerosols generated by the handpieces. The results of the study demonstrated that all the dental units sampled were highly contaminated with microorganisms, some of which were opportunistic pathogens. No dental unit was free of this phenomenon.

RISK OF FLUOROSIS IN A FLUORIDATED POPULATION

The prevalence of fluorosis has increased in optimally fluoridated areas in recent years. Pendrys (JADA 1995;126:1617-24) estimated the potential direct impact that dental practitioners could have on reducing the amount of dental fluorosis in U.S. children by guiding the public toward the most appropriate use of fluoride products. An estimated 71% of the fluorosis cases can be explained by a history of having brushed more than twice a day with more than a pea-sized amount of toothpaste (greater than the recommended amount) through the first 8 years of life.

BACTERIAL AEROSOL REDUCTION WITH MOUTHRINSES

EFFICACY OF AN ANTI-GINGIVITIS CHEWING GUM

Smith et al (J Clin Periodontol 1996;23:19-23) studied the clinical effectiveness and stain-forming potential of chlorhexidine in a chewing gum base. After 8 weeks, stain extent was significantly lower in the chewing gum group than in the chlorhexidine rinse group. The results demonstrated that the chlorhexidine chewing gum used with normal tooth cleaning provided similar adjunctive benefits to oral hygiene and gingival health as a 0.2% chlorhexidine rinse.

GLOBAL CLIMATE CHANGE AND INFECTIOUS DISEASES

Climatic factors influence the emergence and reemergence of infectious diseases, in addition to multiple human, biological, end ecological determinants. Climatologists have identified upward trends in global temperatures and now estimate an unprecedented rise of 2°C by the year 2100. Many serious infectious diseases are disseminated with these climatic changes. Patz et al (JAMA 1996;275:217-23) summarized these interactions and suggested to further analyze the role of climate in the emergence of human infectious diseases.

Logothetis & Martínez-Welles (JADA 1995;126:1634-9) compared bacterial aerosol contamination generated by an air polishing device following two consecutive 30-second rinses with chlorhexidine gluconate (Peridex), an antiseptic mouthwash with essential oils (Listerine), or water. The results showed that Peridex significantly reduced colony-forming units at all eight operatory locations where samples where taken compared to Listerine and water. The latter two had no significant difference from each other.

PLAQUE FORMATION AFTER RINSING WITH DARJEELING TEA

Attin et al (Eur J Oral Sci 1995;103:416-8) evaluated the plaque surface area after rinsing with a Darjeeling tea containing low levels of fluoride. The effects were compared to those obtained with an amine fluoride/stannous fluoride rinse (Meridol), and tap water rinse used as a control. After 3 days, the results showed that a marked decrease in plaque surface area was only observed with the Meridol rinse.

REDUCTION OF AEROSOLS PRODUCED BY ULTRASONIC SCALERS Decreased air quality and potential aerosol contamination in

the dental operatory has been addressed by the Centers for Disease Control and Prevention which recommends that all sources of blood-contaminated splatter and aerosols be minimized. Harrel et al (J Periodontol 1996;67:28-32) concluded that the use of the high volume evacuator attachment for the ultrasonic scaler handpiece significantly reduced the aerosol contamination without increasing heat transfer to teeth.

EFFECT OF ANTIMICROBIAL RINSES ON PLAQUE FORMATION

Ramberg et al (J Clin Periodontol 1996;23:7-11) evaluated to what extent mouthrinses containing triclosan and chlorhexidine may modify the amount of new plaque formation on tooth surfaces adjacent to healthy and inflamed gingiva. The results demonstrated that significantly more plaque formed at sites with gingivitis than at surfaces adjacent to healthy gingiva, and pre-existing gingivitis significantly increased the amount of new plaque formed in subjects who rinsed with chlorhexidine or triclosan mouthwash preparations.