TITLE: A systematic review on marginal discoloration of adhesively vs. non-adhesively cemented all ceramic restorations.

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ABSTRACT

Background

The purpose of this systematic review was to correlate the clinical incidence of marginal discoloration of all ceramic restorations with the mode of cementation (adhesive vs. non-adhesive).

Types of studies reviewed

A literature search was conducted using electronic databases, relevant references, citations and journal hand searching for clinical studies reporting on marginal discoloration of all-ceramic restorations with a mean follow-up time of at least 5 years. The search period spanned from January 1990 up to February 2011. Summary estimates and 5-year event rates were reported and compared.

Results

16 studies were selected for final analysis over an initial yield of 346 titles. The mean observation time ranged between 5 and 10 years. The majority of studies used adhesive luting procedures for definitive cementation. Only 1 study directly reported on the incidence of marginal discoloration of both adhesively and non-adhesively cemented all-ceramic restorations and the difference was not statistically significant (P=0.5).

Clinical implications

The results of this systematic review showed that there is a lack of studies reporting on marginal discoloration rates of non-adhesively luted all-ceramic restorations. Unacceptable marginal discoloration rates of adhesively luted all-ceramic prostheses were relatively low even at 10 years of service.

Key-words: Meta-analysis, Systematic Review, All-ceramic restorations, Marginal discoloration, Adhesive, Luting

INTRODUCTION

All-ceramic restorations were introduced as a replacement of metal-ceramic restorations due to their potential for improved biocompatibility and esthetics.[1] Many all-ceramic materials have evolved through the years differing in various properties such as mechanical strength, optical behavior and luting requirements.[2,3] Ceramic materials may be classified into 2 broad categories based on the mode of cementation: ceramics that require an adhesive cementation (bonded) and ceramics that can be cemented with non-adhesive cements.[4] The first category includes etchable materials that require an adhesive cementation in order to attain their mechanical strength such as feldspathic and glass-ceramics. The second category includes ceramics based on high-strength, non-etchable cores, like alumina or zirconia.[5] Although efforts have been made to enhance the chemical bonding to these ceramics, these materials may be cemented with conventional non-adhesive techniques.[6,7]

Fracture or cement breakdown can result in microleakage, marginal discoloration, pulpal irritation, secondary caries, debonding, and decreased fracture load capacity.[8] Marginal microleakage and discoloration of all-ceramic restorations are important complications, especially in the anterior region where a discoloration that is not superficial and cannot be polished away may be a reason for prostheses replacement.[9] All prosthetic restorations are subject to microleakage at their margin. Causes of microleakage include lack of adhesion of the luting cement to tooth structure, shrinkage of the cement on setting, and mechanical failure or solubility of the cement.[10,11] Adhesive cementation has been shown to reduce marginal microleakage.[12-14] Nevertheless, resin luting agents may be more prone to water sorption and discoloration.[15-16]

The purpose of this systematic review was to correlate the clinical incidence of marginal discoloration of all-ceramic restorations with the mode of cementation (adhesive vs. non adhesive).

MATERIALS AND METHODS

Search strategy

The literature search was conducted by 2 reviewers (MD, IP), using different electronic databases (Medline - PubMed, The Scopus, The Cochrane Register of RCTs) for clinical studies reporting on marginal discoloration of all ceramic restorations.

The search terms that were used, alone or in conjunction were: ‘marginal discoloration’, ‘allceramic’, ‘cavosurface discoloration’, ‘marginal integrity’, ‘marginal color’, and ‘clinical trial’ . The search period spanned from January 1990 up to February 2011. The option of "related articles" was also used. Review articles as well as references from different studies were also used to identify relevant articles .Hand searching for the time period between January 1990 and February 2011 was conducted for the following journals: Journal of Prosthetic Dentistry, International Journal of Prosthodontics.

Selection of Studies

The review process consisted of two phases. During the first phase, the review was conducted by the 2 reviewers together. Any disagreement was resolved by discussion and in case of doubt, the full text of the article was obtained. Initially titles and/or abstracts were screened for relevance according to the following inclusion criterion: prospective or retrospective studies with clinical follow-up reporting on all-

ceramic restorations. Laboratory studies, studies in a language other than English or without an English abstract, technical articles, and case reports were excluded.

The full text of all relevant articles that passed the first review phase was obtained. Hand searching of the selected journals, as well as searching of the references of the selected studies, was also implemented at this point.

The relevant articles obtained were further screened during a second review phase using the following exclusion and inclusion criteria:

1. Type of all-ceramic system and material mentioned
2. Type of luting agent and luting technique mentioned
3. Mean follow-up time of at least 5 years
4. Marginal discoloration reported as outcome. Marginal discoloration was defined as clinically unacceptable staining that could not be polished away or was penetrating towards the pulp (Charlie rating according to the United States Dental Health Service-USPHS[17] or the California Dental Association-CDA[18] criteria).

The selection process during the second phase was conducted independently by 2 reviewers. Inter-reviewer agreement was determined using Cohen's kappa coefficients.

The final included studies that passed the second phase in the review process were classified according to the strength of evidence into 4 categories according to Jökstad et al[19]:

1. A1, controlled clinical trial with patient randomization (RCT).
2. A2, controlled clinical trial with split-mouth randomization (split-RCT).

3. B, prospective controlled trial without randomization (CCT).
4. C, clinical studies with different designs than categories A and B. (retrospective, case series, etc)

Data extraction

Data of the final studies were tabulated for marginal discoloration associated with all-ceramic restorations. The incidence of marginal discoloration was finally calculated in relation to time. In studies where only the minimum follow up time was mentioned, that interval was used to measure the total exposure time of the restorations. In cases of multiple publications following the same cohort of patients, the study with the longest follow-up was taken into account. The luting procedure was considered as adhesive if both the tooth and ceramic were etched and a silane/bonding agent or bonding monomers/primers were utilized for cementation.

Statistical analysis

The impact of statistical heterogeneity was assessed using Cochran's Q value[20] and the I^2 statistic[21] with I^2 values over 50% indicating a substantial level of heterogeneity. Marginal discoloration rates for all-ceramic restorations were calculated by dividing the total number of events (marginal discoloration) by the total all-ceramic restorations exposure time in years. The total number of events was extracted directly from the publication. The exposure time for a given study was calculated by multiplying the mean follow-up time by the number of restorations available for statistical analysis. The mean follow-up was directly extracted from the articles. Direct analysis between adhesive and non-adhesive luting groups was done whenever study design permitted. The Risk Ratio (RR) for marginal discoloration was calculated for the direct comparisons, with values below 1.0 favoring the

adhesive cementation group. Fisher's exact test was utilized for calculating the significance. For indirect comparisons, marginal discoloration rates / 100 prosthesis years were reported along with summary estimates size and 95% intervals based on random effects model. Poisson distribution was considered for the number of events per variable under examination in order to report 5 and 10 year discoloration rates. Comparison between subgroups of different luting agents as well as statistical significance was calculated using a mixed effects model. All *P* values were 2-sided with significance set at $P \leq 0.05$, except for $P < 0.10$ for the heterogeneity tests. Statistical analysis was performed using appropriate software (Comprehensive Meta-analysis Version 2, Biostat, Englewood NJ).

RESULTS

Figure 1 shows the process of identifying the studies finally included from an initial yield of 346 titles. 110 titles were common in databases. Initial screening of titles led to 236 titles from which 236 abstracts were obtained and screened for inclusion/exclusion criteria of first phase. 77 abstracts met the criteria of first phase from which 77 full texts were obtained. 48 studies were retrieved from journal hand searching and 52 from references and, therefore, 177 full texts were screened for inclusion/exclusion criteria of second phase. One hundred fifty nine studies were excluded during the second review phase. A significant number of these studies[22-83] were excluded for having a mean follow-up time of less than 5 years. Eighteen studies[84-101] met the criteria of the second review phase. By exclusion of studies of same cohorts[100,101], 16 studies[84-99] were finally selected for analysis. The inter-reviewer agreement for the 4 inclusion criteria was excellent (kappa: 0,951-0.963).

Eleven studies[84-93,99] had been were published in last ten years. The publication dates ranged from 1995 to 2010. Most of the studies were classified as category C

according to the strength of evidence, only one[85] as A1, and two[84,88] as A2. Most studies were implemented in a university setting. The studies included a total of 454 patients with an age range of 18 to 84 years. The demographics of the included studies are depicted in Table 1.

Six of the included studies [84, 90, 93, 94, 97, 98] reported on marginal discoloration of ceramic prostheses made out of feldspathic ceramics, 5 studies [86-88,91,92] on leucite reinforced glass-ceramic prostheses (Empress I, Ivoclar Vivadent, Schaan, Liechtenstein), 1 study[85] on lithium disilicate-reinforced ceramic (Empress II, Ivoclar Vivadent, Schaan, Liechtenstein) whereas 2 studies[89,95] included prostheses fabricated from both materials (feldspathic and leucite-reinforced), and 1 study[96] included prostheses fabricated from both feldspathic and a glass-ceramic (Dicor, Corning Glass Works, NY, USA). Only 1 study[99] reported on zirconia-based fixed partial denture prostheses, and in this study the abutments were considered as a unit.

A total of 1446 units of prostheses were placed and observed over a minimum period of 4 years up to a maximum period of 12 years. Most of the prostheses studied were inlays, onlays, or veneers. The mean observation time ranged between 5 and 10 years. The majority of studies used adhesive luting procedures for definitive cementation. Only 2 studies[97,99] employed non-adhesive cementation. Clinical information of the all-ceramic prostheses is presented in Table 2.

All of the studies reported on marginal discoloration rates either as absolute numbers or percentages. Most of the studies used either the USPHS or CDA criteria for marginal discoloration. Four studies[86,90,93,98] used a non-specific reporting method. Two studies[95,99] from the same group of investigators used the CDA criteria for prostheses evaluation but only reported the percentage with “deviation from

excellent", therefore the data from these studies was not analyzed quantitatively. Only 1 study[97] reported on marginal discoloration of all-ceramic inlays luted both adhesively and non-adhesively. The direct analysis of the data of this study[97] showed that the RR for marginal discoloration at 6 years of follow-up was 0.49 (95% CI: 0.09 to 2.67) with $P = 0.5$. Indirect comparison of the 2 luting techniques was not possible due to the lack of other studies reporting on non-adhesive cementation. High heterogeneity was identified in all the included studies (Q=8316, P<0.001, and $I^2 > 97\%$). Despite the high heterogeneity, indirect pooling of the studies reporting on adhesive luting was performed as a point of clinical interest. The indirect pooling of data from the studies reporting on adhesively luted restorations resulted in cumulative 5 and 10 year discoloration rates of 2.8% and 5.4% respectively (Table 3, Fig. 2). A sensitivity analysis was executed by excluding studies[94,98] characterized as outliers, but event rates and heterogeneity were not significantly affected.

DISCUSSION

Systematic reviews are often useful in the evaluation of various materials and interventions. They differ from other types of reviews in that they adhere to a strict scientific protocol to make them more comprehensive, to eliminate the likelihood of bias, and to provide more reliable results upon which to draw conclusions and make clinical decisions.[102] Rather than reflecting the views of the authors or being based on only a (possibly biased) selection of the published literature, they represent a comprehensive summary of the available evidence, with strict inclusion and exclusion criteria. The exclusion of papers in languages other than English may have resulted in the loss of some papers. On the other hand, it is difficult to gain access to non–English-language journals all over the world, and it is difficult to define the features of the peer-review processes of these journals. Moreover, when non-English papers

are selected, based on their abstracts, the contents must be translated, with the risk of interpretation problems.

The gold standard for systematic reviews is to include randomized controlled clinical trials which directly compare various interventions. The majority of the studies included in this review were prospective uncontrolled clinical trials. The studies presented with high clinical and statistical heterogeneity. This was an expected finding due to differences in study design, materials, clinical settings, operator experience, techniques, and patient allocation.[11] The included studies' design did not permit any analysis of the aforementioned factors. The heterogeneity persisted even after running a sensitivity analysis by excluding 2 studies[94,98] with outlier rates. One of these studies[98] reported on the outcomes of extended ceramic veneers. A recent systematic review[103] showed that extended ceramic veneers presented with increased complication event rates.

Only 1 study[97] allowed for a direct comparison between adhesive and non-adhesive luting, and the results showed no statistical significance. More prospective studies with a direct comparison are needed in order to draw robust conclusions. This systematic review showed a lack of documentation regarding marginal discoloration of all-ceramic restorations luted with non-adhesive techniques. Marginal discoloration rates for adhesively luted restorations were reported, as a point of clinical interest, after pooling the results of the studies using an indirect analysis. The results showed that the 5 and 10 year unacceptable marginal discoloration rates were relatively low. Due to the reported high heterogeneity, the summary rates should be viewed with caution. It is important to note that the studies also reported that a significant percentage of restorations presented with marginal discoloration that was superficial and could be polished off. Most of the authors correlated discoloration

with a time-dependant marginal disintegration due to wear and chipping of either the luting agent or the ceramic restorations. Therefore, it is important to inform patients, especially those who are esthetically demanding, of this complication. Marginal discoloration rates may also be influenced by the material, the type of prosthesis and the substrate upon which the prostheses are luted, and possibly reduced by locating the preparation margins on enamel.[85,104,105] The reporting of results of the final included studies did not permit an analysis on the influence of the above factors on marginal discoloration.

It was interesting to note that only one specific leucite-reinforced glass-ceramic material brand was included in the final group of studies. Although other commercial brands may possess similar chemistry and properties[106], the lack of clinical documentation in an issue of concern.[107]

Many factors influence the quality of dental restorations and various evaluation indices and criteria have been developed.[108] The final included studies did not use a uniform way of reporting marginal discoloration. Differences even existed between studies that utilized the same quality control criteria, in respect to the interpretation and reporting of different rating grades. Future studies should clearly define and follow standardized quality evaluation methods. In terms of marginal discoloration a clinically significant differentiation should be made between discoloration that can be amended and permanent discoloration.

Conclusion

The results of this systematic review showed that there is a lack of studies reporting on marginal discoloration rates of non-adhesively luted all-ceramic restorations. This scarcity of evidence does not permit any conclusions to be drawn

on the effect of the use of an adhesive technique during luting of all-ceramic restorations on the incidence of marginal discoloration.

Clinical Relevance

Unacceptable marginal discoloration rates of adhesively luted all-ceramic prostheses were relatively low even at 10 years of service.

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Table 1. Study design and demographics of included studies.

Study	Year	Category of evidence	Planned no. of patients	Actual no. of Patients	Drop out	Drop out %	Age range(y)	Mean age(y)	Setting
Federlin et al[84]	2010	A2	29	22	7/29	24	32-44	37	University
Aykor & Ozel[85]	2009	A1	30	30	0/30	0	28-54	NR	NR
Galiatsatos &Bergou[86]	2008	C(P)	29(8m,21f)	29	0/29	0	21-70	NR	Private
Guess & Stappert[87]	2008	C(P)	25(12f,13m)	9	16/25	64	19-64 f, 20-45m	43 f,45 m	University
Kramer et al[88]	2008	A2	31 (9m, 22f)	23	8/31	25.8	24-54	31	University
Molin et al [99]	2008	C(P)	18(12f,6m)	18	0/18	0	48-84 f, 55-69 m	58 f, 60 m	University
Fradeani et al[89]	2005	C(P)	46(17m,29f)	46	0/46	0	19-65 f, 20-66 m	38.3f, 36.8m	Private
Peumans et al[90]	2004	C(P)	25	22	3/25	12	19-69	NR	NR
van Dijken et al [91]	2003	C(P)	29(9m,20f)	26	3/29	10.3	22-68	45.5	University
Fradeani et al[92]	2002	C(R)	54(30f,24m)	49	5/54	9.2	20-66 f, 18-68 m	41 f, 40 m	Private
Galiatsatos & Bergou[93]	2002	C(P)	61(38f,23m)	61	0/61	0	18-70	NR	NR
Hayashi et al[94]	2000	C(P)	25	25	0/25	0	NR	NR	University
Molin & Karlsson [95]	2000	A2	20(11f,9m)	20	0/20	0	23-48 f, 23-56 m	33 f, 41 m	University
Pallesen & van Dijken[96]	2000	C(P)	16(11f,5m)	16	0/16	0	24-58	40	NR
van Dijken [97]	1998	C(P)	50(17m,33f)	49	1/50	2	19-70	34 f, 30.5 m	University
Walls[98]	1995	C(P)	12	9	3/12	25	NR	NR	University

NR: not reported, P: prospective, R: retrospective, f:female, m:male

Table 2. Clinical information of all-ceramic prostheses in included studies.

Study	Year	Type of prosthesis	Allceramic material	Planned no. of units	Actual no. of units	Drop out	Drop out %	Follow-up range(y)	Mean Follow-up(y)	Evaluation method	Luting (Adhesive, Non-adhesive)	Luting agent
Federlin et al [84]	2010	Onlays	Feldspathic	29	22	7/29	24.1	5.3-5.8	5.5	USPHS	Ahesive	Composite resin
Aykor and Ozel[85]	2009	Veneers	Lithium disilicate-reinforced	300	300	0/300	0	NA	5	USPHS	Adhesive	Composite resin
Galiatsatos and Bergou [86]	2008	Inlays & onlays	Leucite reinforced	64(20 onlays & 44 inlays)	64	0/64	0	NA	6	Other	Adhesive	Composite resin
Guess & Stappert [87]	2008	Veneers	Leucite reinforced	66	23	43/66	65.1	5-6	5	USPHS	Adhesive	Composite resin
Kramer et al [88]	2008	Inlays & onlays	Leucite reinforced	94 (85 inlays & 9 onlays)	68	26/94	27.6	NA	8	USPHS mod	Adhesive	Composite resin
Molin et al [99]	2008	3-unit Zirconia FPDs	Zirconia	38	38	0	0	NA	5	CDA	Non-Adhesive	Zinc phosphate or composite resin
Fradeani et al [89]	2005	Veneers	Feldspathic & Leucite reinforced	182	182	0/182	0	NR-12	5.7	CDA	Adhesive	Composite resin
Peumans et al[90]	2004	Veneers	Feldspathic	87	81	6/87	7	NA	10	Other	Adhesive	Composite resin
van Dijken et al [91]	2003	Inlays	Leucite reinforced	79	71	8/79	10.1	NA	5	USPHS	Adhesive	Resin-modified glass-ionomer or composite resin
Fradeani et al [92]	2002	Crowns	Leucite reinforced	125	119	6/125	4.8	4-11	7.3	CDA	Adhesive	Composite resin
Galiatsatos and Bergou [93]	2002	Veneers	Feldspathic	186	186	0/186	0	NA	5	Other	Adhesive	Composite resin
Hayashi et al [94]	2000	Inlays	Feldspathic	45	45	0/45	0	NA	8	USPHS mod	Adhesive	Composite resin
Molin & Karlsson [95]	2000	Inlays	Feldspathic & Leucite reinforced	60	60	0/60	0	NA	5	CDA	Adhesive	Composite resin
Pallesen & van Dijken[96]	2000	Inlays	Feldspathic & Glass-ceramic	32	29	3/32	9.4	NA	8	USPHS	Adhesive	Composite resin

van Dijken [97]	1998	Inlays	Feldsparthic	118	115	3/118	2.54	NA	6	USPHS mod	Adhesive & Non-adhesive	Composite resin & Glass ionomer
Walls [98]	1995	Veneers	Feldspathic	54	43	11/54	20.3	4.2-5.4	5	Other	Adhesive	Composite resin

NR: not reported, NA: not applicable, CDA: California Dental Association, USPHS: United States Public Health Service, mod: modified

Table 3. Estimated event rates and cumulative 5 & 10 years marginal discoloration rates

Study	Year	Type of prosthesis	Allceramic material	Actual no. of prostheses	Mean Follow-up (y)	Total exposure time (y)	# of discoloration events	Estimated rate (per 100 prostheses years)	Luting (Adhesive, Non-adhesive)
Federlin et al [84]	2010	Onlays	Feldspathic	22	5.5	121	0	0	Ahesive
Aykor and Ozel[85]	2009	Veneers	Lithium disilicate	300	5	1500	0	0	Adhesive
Galiatsatos and Bergou [86]	2008	Inlays & onlays	Leucite reinforced	64	6	384	2	0.5	Adhesive
Guess & Stappert [87]	2008	Veneers	Leucite reinforced	23	5	115	0	0	Adhesive
Kramer et al [88]	2008	Inlays & onlays	Leucite reinforced	68	8	544	8	1.5	Adhesive
Fradeani et al [89]	2005	Veneers	Feldspathic & Leucite reinforced	182	5.7	1037.4	0	0	Adhesive
Peumans et al[90]	2004	Veneers	Feldspathic	81	10	810	15	1.9	Adhesive
van Dijken et al [91]	2003	Inlays	Leucite reinforced	71	5	355	7	2	Adhesive
Fradeani et al [92]	2002	Crowns	Leucite reinforced	119	7.3	868.7	17	2	Adhesive
Galiatsatos and Bergou [93]	2002	Veneers	Feldspathic	186	5	930	0	0	Adhesive
Hayashi et al [94]	2000	Inlays	Feldspathic	45	8	360	14	3.9	Adhesive
Molin & Karlsson[95]	2000	Inlays	Feldspathic & Leucite reinforced	60	5	300	24*	NA	Adhesive
Pallesen & van Dijken[96]	2000	Inlays	Feldspathic & Glass-ceramic	29	8	232	5	2.2	Adhesive
van Dijken [97]	1998	Inlays	Feldsparthic	58	6	348	2	0.6	Adhesive
Walls [98]	1995	Veneers	Feldspathic	43	5	215	12	5.6	Adhesive
				Summary estimate (95% CI)				**0.56 (0.53-0.6))**	
				Cumulative 5y rates (95% CI)				**2.8 (2.6-3.0)**	
				Cumulative 10y rates (95% CI)				**5.4 (5.2-5.8)**	
Molin et al [99]	2008	3-unit FPDs	Zirconia	38	5	190	4*	NA	Non-adhesive
van Dijken [97]	1998	Inlays	Feldsparthic	57	6	342	4	1.2	Non-adhesive

CI: Confidence interval, NA: Non-applicable, *data excluded from analysis

Fig 1. Search strategy and results

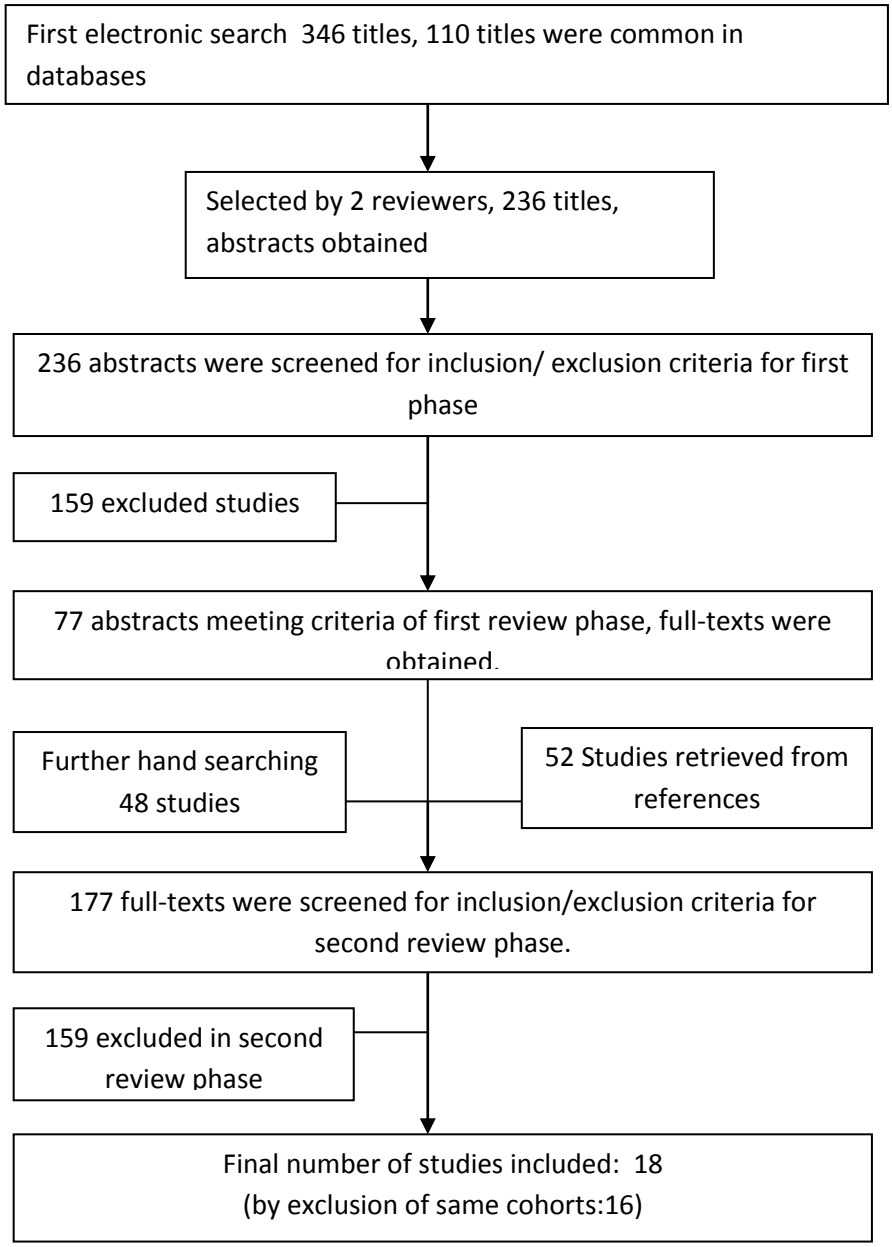
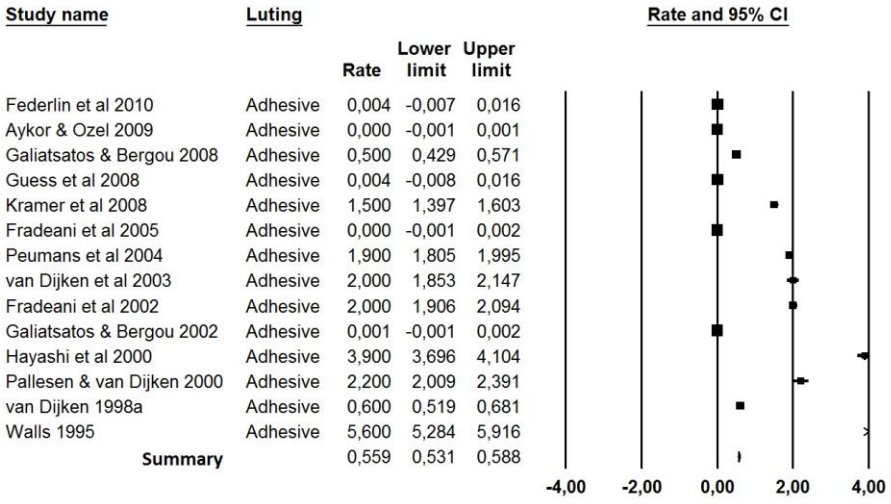


Fig 2. Forest plot of marginal discoloration rates in studies with adhesive luting



Legends:

Fig 1. Search strategy and results

Fig 2. Forest plot of marginal discoloration rates in studies with adhesive luting