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Clinical effectiveness of contemporary adhesives: A systematic review of current clinical trials

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Summary *Objectives*. The purpose of this paper was to review current literature on the clinical effectiveness of contemporary adhesives when used to restore cervical non-carious class-V lesions. Restoration retention in function of time was recorded in order to find out if adhesives with a simplified application procedure are as clinically effective as conventional three-step adhesives.

Data sources. Literature published from January 1998 up to May 2004 was reviewed for university-centred clinical trials that tested the clinical effectiveness of adhesives in non-carious class-V lesions. Restoration–retention rates per adhesive reported in peer-reviewed papers as well as IADR–AADR abstracts and ConsEuro abstracts were included and depicted as a function of time in graphs for each of the five adhesive classes (three- and two-step etch-and-rinse adhesives, two- and one-step self-etch adhesives, and glass–ionomers). The guidelines for dentin and enamel adhesive materials advanced by the American Dental Association were used as a reference. Per class, the annual failure rate (%) was calculated. Kruskal–Wallis analysis and Dwass–Steel–Chritchlow–Fligner pairwise comparisons were used to determine statistical differences between the annual failure percentages of the five adhesive categories.

Results. Comparison of retention of class-V adhesive restorations as a measure to determine clinical bonding effectiveness of adhesives revealed that glass–ionomers most effectively and durably bond to tooth tissue. Three-step etch-and-rinse adhesives and two-step self-etch adhesives showed a clinically reliable and predictably good clinical performance. The clinical effectiveness of two-step etch-and-rinse adhesives was less favourable, while an inefficient clinical performance was noted for the one-step self-etch adhesives.

Significance. Although there is a tendency towards adhesives with simplified application procedures, simplification so far appears to induce loss of effectiveness.

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Clinical performance can be correlated with, and predicted by, appropriate types of laboratory study.

Introduction

The major shortcoming of today's adhesive restoratives is their limited durability in the mouth [1]. Adhesive restorations only remain in optimum condition for 3–5 years [2]. The most cited reasons for failure of adhesive restorations placed with earlier adhesives are loss of retention and deficient marginal adaptation [3,4]. An improved retention of adhesive restorations was recorded with the introduction of the 'total-etch' (now referred to as 'etch-and-rinse') technique in the early 1990s, by which phosphoric acid is applied simultaneously to enamel and dentin [1,5–7]. Nowadays, there is an obvious trend in the development of adhesives with a simplified and thus more user-friendly application procedure.

The basic mechanism of bonding to enamel and dentin is essentially an exchange process involving replacement of minerals removed from the hard dental tissue by resin monomers that upon setting become micro-mechanically interlocked in the created porosities. Based upon the underlying adhesion strategy, three mechanisms of adhesion are currently in use with modern adhesives [8,9].

Following an 'etch-and-rinse' approach, the tooth is first etched (mostly 30–40% phosphoric acid) and rinsed off. This conditioning step is followed by a priming step and application of the adhesive resin, resulting in a conventional three-step application procedure. This etch-and-rinse technique is definitely still the most effective approach to achieve efficient and stable bonding to enamel. Tags are formed through in situ polymerization of resin within the created etch pits, thereby enveloping individually exposed hydroxyapatite crystals. At dentin, the primary bonding mechanism of etch-and-rinse adhesives is primarily diffusion-based and depends upon hybridization or micro-mechanical interlocking of resin within the exposed collagen fibril scaffold. Simplified two-step etch-and-rinse adhesives combine the primer and the adhesive into one application (often referred to as 'one-bottle' adhesives).

'Self-etch' adhesives use non-rinse acidic monomers that simultaneously condition and prime dentin. The tooth is no longer rinsed, which not only lessens the clinical application time, but also significantly reduces technique-sensitivity. In addition to a two- and one-step application procedure-depending upon the use of a separate solvent-free bonding agent or not-, a further distinction should be made between 'mild' and 'strong' self-etch adhesives. 'Strong' self-etch adhesives have a rather low pH (<1) and have been documented with a bonding mechanism and interfacial ultra-morphology resembling that produced by etch-and-rinse adhesives. Consequently, the underlying bonding mechanism of 'strong' self-etch adhesives is primarily diffusion-based, similar to the etch-and-rinse approach. 'Mild' self-etch adhesives (pH ± 2) only partially dissolve the dentin surface, so that a substantial amount of hydroxyapatite remains available within a submicron hybrid layer. Adhesion is consequently obtained micro-mechanically through shallow hybridization and by additional chemical interaction of specific carboxyl/phosphate groups of functional monomers with residual hydroxyapatite [10].

Glass-ionomers are still considered the only materials that are self-adhering to tooth tissue [11]. Nevertheless, a short polyalkenoic acid pre-treatment is recommended, resulting in a two-step approach. The polyalkenoic acid conditioner cleans the tooth surface; it removes the smear layer and exposes collagen fibrils up to about 0.5–1 μm depth [12]; herein, glass-ionomer components interdiffuse, establishing a micro-mechanical bond following the principle of hybridization [8,13]. Chemical bonding is additionally obtained by ionic interaction of the carboxyl groups of the polyalkenoic acid with calcium of hydroxyapatite that remains attached to the collagen fibrils [11].

Because adhesives have evolved so rapidly during the last few years, the time is right to prepare a status report on the clinical effectiveness of contemporary adhesives. Although laboratory testing of contemporary adhesives bonded to sound tooth substrate under optimal laboratory conditions has been shown to predict clinical effectiveness [9,14], the ultimate test method to assess bonding effectiveness remains a clinical trial. When investigating clinical effectiveness of adhesives, only studies involving non-carious class-V adhesive restorations should be considered, for which there are many reasons [1]: (1) cervical lesions do not provide any macro-mechanical retention; (2) they require for at least 50% bonding

Table 1 List of IADR, AADR and ConsEuro meeting abstracts that were screened for class-V clinical trials testing adhesives.

Meeting	Meeting site	Literature source
AADR/CADR	Minneapolis, MN, USA	J Dent Res 1998;77(Spec Iss A)
IADR	Nice, France	J Dent Res 1998;77(Spec Iss B)
IADR/AADR/CADR	Vancouver, Canada	J Dent Res 1999;78(Spec Iss/IADR Abstracts)
IADR/AADR/CADR	Washington, DC, USA	J Dent Res 2000;79(Spec Iss/IADR Abstracts)
IADR-CED	Montpellier, France	J Dent Res 2001;80(4)
IADR-CED/ScADR	Warsaw, Poland	J Dent Res 2001;80(4)
AADR/CADR	Chicago, IL, USA	J Dent Res 2001;80(Spec Iss/AADR Abstracts)
IADR	Chiba, Japan	J Dent Res 2001;80(Spec Iss/IADR Abstracts)
IADR/AADR/CADR	San Diego, CA, USA	J Dent Res 2002;81(Spec Iss A)
IADR-CED	Rome, Italy	J Dent Res 2002;81(Spec Iss B)
IADR-PEF	Cardiff, Wales, UK	J Dent Res 2003;82(Spec Iss C)
AADR/CADR	San Antonio, TX, USA	J Dent Res 2003;82(Spec Iss A)
IADR	Göteborg, Sweden	J Dent Res 2003;82(Spec Iss B)
IADR/AADR	Honolulu, Hawai, USA	J Dent Res 2004;83(Spec Iss A/CDrom)
ConsEuro	Munich, Germany	ConsEuro Abstracts

AADR, American Association for Dental Research; CADR, Canadian Association for Dental Research; CED, Continental European Division; IADR, International Association for Dental Research; PEF, Pan-European Federation; ScADR, Scandinavian Association for Dental Research; ConsEuro, Triannual Meeting of the European Federation of Conservative Dentistry.

to dentin; (3) when restored, they result in an enamel as well as dentin margin; (4) they are widely available; (5) they are usually found in anterior teeth or premolars with good access; (6) preparation and restoration of class-V lesions is minimal and relatively easy, reducing somewhat practitioner variability; (7) despite varying cavity-configuration factors of class-V lesions [15,16], and thus resultant interfacial stress, the mechanical properties of the composite used are relatively unimportant [17–19]; and (8) ineffective bonding commonly results in restoration loss, which is the most objective evaluation parameter.

The purpose of this paper was to review current literature on the clinical effectiveness of contemporary adhesives when used to restore cervical non-carious class-V lesions. Restoration retention as a function of time was recorded in order to find out if adhesives with a simplified application procedure are as clinically effective as conventional three-step adhesives.

Materials and methods

Literature published from January 1998 up to May 2004 was reviewed for university-centred clinical trials that tested the clinical effectiveness of adhesives in non-carious class-V lesions. Clinical trials of which the data of successive recalls were reported in more than one paper/abstract were combined and counted as one study. Restoration–retention rates per adhesive reported in peer-reviewed papers as well as IADR–AADR abstracts and ConsEuro abstracts were included (Table 1) and depicted as a function of time in graphs for each of the five adhesive classes (three- and two-step etch-and-rinse adhesives, two- and one-step self-etch adhesives, and glass–ionomers). Per class, the annual failure rate (%) was calculated by dividing the final retention rate by the number of recall years, multiplied with 100. Kruskal–Wallis analysis and Dwass–Steel–Chritchlow–Fligner pairwise comparisons were used to determine statistical differences between the annual failure percentages of the five adhesive categories (at a significance level of 0.05). The guidelines for dentin and enamel adhesive materials advanced by the American Dental Association [20] were used as reference. As per ADA guidelines, to obtain 'provisional acceptance' retention rates at 6 months must be at least 95%, whereas for 'full acceptance' retention rates must be at least 90% after 18 months of clinical use. When no 6- and/or 18-month recall data were provided, but the linear curve connecting the restoration-retention rates crossed the ADA reference rectangles (see graphs), the adhesive was considered to have failed to meet the respective ADA guideline.

Results

A list of published class-V clinical trials selected from the literature (January 1998–May 2004) is shown in Table 2. The adhesives tested in the selected class-V clinical trials are listed per adhesive class in Table 3. The retention rates

Table 2 List of published class-V clinical trials selected from the literature (January 1998–May 2004).

Study number[a]	Author	Journal
1.	Akimoto et al.	J Dent Res 2001;80(Spec Iss/AADR Abstracts):64, Abstr. No. 232
2.	Akimoto et al.	J Dent Res 2004;83(Spec Iss A/CDrom): Abstr. No. 249
3.	Baratieri et al.	Oper Dent 2003;28:482–7
4.	Benz et al.	J Dent Res 1999;78(Spec Iss/IADR Abstracts):310, Abstr. No. 1633
5.	Boghosian et al.	J Dent Res 1998;77(Spec Iss B):1022, Abstr. No. 3123
6.	Boghosian et al.	J Dent Res 1999;78(Spec Iss/IADR Abstracts):285, Abstr. No. 1436
7.	Boghosian	J Dent Res 2002;81(Spec Iss A):52, Abstr. No. 192
8.	Brackett et al.	Oper Dent 1999;24:9–13
9.	Brackett et al.	J Dent Res 2001;80(Spec Iss/AADR Abstracts):65, Abstr. No. 233
10.	Brackett et al.	Oper Dent 200126:12–6
11.	Brackett et al.	Oper Dent 2002;27:218–22
12.	Brackett et al.	Oper Dent 2002;27:112–6
13.	Brackett et al.	Oper Dent 2003;28:477–81
14.	Browning et al.	Oper Dent 2000;25:46–50
15.	Brunton et al.	J Adhes Dent 1999;1:333–41
16.	Burrow and Tyas	Oper Dent 1998;23:290–3
17.	Burrow and Tyas	Am J Dent 1999;12:283–5
18.	Burrow and Tyas	J Dent Res 1999;78(Spec Iss/IADR Abstracts):368, Abstr. No. 2102
19.	Burrow and Tyas	J Dent Res 2001;80(Spec Iss/IADR Abstracts):740, Abstr. No. 1708
20.	Burrow and Tyas	J Dent Res 2003;82(Spec Iss B):125, Abstr. No. 904
21.	Burrow and Tyas	Austr Dent J 2003;48:180–2
22.	Chinelatti et al.	J Oral Rehabil 2004;31:251–7
23.	Di Lenarda et al.	Oper Dent 2000;25:382–7
24.	Dondi Dall'Orologio and Lorenzi	J Dent Res 2004;83(Spec Iss A/CDrom): Abstr. No. 1375
25.	ElMahdy et al.	J Dent Res 1999;78(Spec Iss/IADR Abstracts):368, Abstr. No. 2099
26.	Ermis	Quint Int 2002;33:542–8
27.	Folwaczny et al.	Oper Dent 2000;25:251–8
28.	Folwaczny et al.	Clin Oral Investig 2001;5:31–9
29.	Folwaczny et al.	Am J Dent 2001;14:153–6
30.	Friedl et al.	J Dent Res 2004;83(Spec Iss A/CDrom), Abstr. No. 535
31.	Gaglianh et al.	J Dent Res 2002;81(Spec Iss A):79, Abstr. No. 428
32.	Gladys et al.	J Dent Res 2001;80(4):1203, Abstr. No. 20
33.	Helbig et al.	J Dent Res 2004;83(Spec Iss A/CDrom), Abstr. No. 537
34.	Klimm et al.	J Dent Res 2002;81(Spec Iss A):80, Abstr. No. 438
35.	Kubo et al.	J Dent Res 2004;83(Spec Iss A/CDrom), Abstr. No. 539
36.	Latta et al.	J Dent Res 1998;77(Spec Iss B):954, Abstr. No. 2582
37.	Latta et al.	J Dent Res 2000;79(Spec Iss/IADR Abstracts):272, Abstr. No. 1030
38.	Latta et al.	J Dent Res 2000;79(Spec Iss/IADR Abstracts):272, Abstr. No. 1027
39.	Latta et al.	J Dent Res 2002;81(Spec Iss A):52, Abstr. No. 193
40.	Loguercio et al.	J Adhes Dent 2003;5:323–32
41.	Martin et al.	J Dent Res 2002;81(Spec Iss A):52, Abstr. No. 195
42.	McCoy et al.	J Am Dent Assoc 1998;129:593–9
43.	Morigami et al.	J Dent Res 2003;82(Spec Iss B):306, Abstr. No. 2363
44.	Munoz et al.	J Dent Res 2001;80(Spec Iss/AADR Abstracts):65, Abstr. No. 237
45.	Munoz et al.	J Dent Res 2004;83(Spec Iss A/CDrom): Abstr. No. 541
46.	Ngo et al.	J Dent Res 2001;80(Spec Iss/IADR Abstracts):709, Abstr. No. 1460
47.	Özer et al.	J Dent Res 2004;83(Spec Iss A/CDrom): Abstr. No. 2841
48.	Özgünaltay and Önen	J Oral Rehabil 2002;29:1037–41
49.	Papathanasiou et al.	J Dent Res 2004;83(Spec Iss A/CDrom): Abstr. No. 538
50.	Perdigão et al.	J Adhes Dent 2001;3:343–52
51.	Peters et al.	J Dent Res 1999;78(Spec Iss/IADR Abstracts):368, Abstr. No. 2103
52.	Peters et al.	J Dent Res 2001;80(Spec Iss/AADR Abstracts):64, Abstr. No. 230
53.	Peumans et al.	J Dent Res 2001;80(4):1203, Abstr. No. 17
54.	Peumans et al.	Am J Dent 2003;16:363–8

(*continued on next page*)

Table 2 (*continued*)

Study number[a]	Author	Journal
55.	Platt et al.	J Dent Res 1998;77(Spec Iss A):236, Abstr. No. 1044
56.	Pollington and Van Noort	J Dent Res 2002;81(Spec Iss A):81, Abstr. No. 448
57.	Pollington and Van Noort	J Dent Res 2003;82(Spec Iss C):469, Abstr. No. 11
58.	Prati et al.	Clin Oral Investigat 1998;2:168–73
59.	Ripps et al.	J Dent Res 2000;79(Spec Iss/IADR Abstracts):273, Abstr. No. 1035
60.	Ripps et al.	J Dent Res 2001;80(Spec Iss/AADR Abstracts):64, Abstr. No. 231
61.	Ripps et al.	J Dent Res 2002;81(Spec Iss A):81, Abstr. No. 446
62.	Rose et al.	J Dent Res 2002;81(Spec Iss A):79, Abstr. No. 429
63.	Schwartz et al.	J Dent Res 1998;77(Spec Iss A):297, Abstr. No. 1534
64.	Siegel et al.	J Dent Res 1998;77(Spec Iss B):954, Abstr. No. 2581
65.	Swift et al.	J Dent 2001;29:1–6
66.	Swift et al.	J Am Dent Assoc 2001;132:1117–23
67.	Türkün	J Dent 2003;31:527–34
68.	Tyas	Oper Dent 1998;23:77–90
69.	Tyas and Burrow	Aust Dent J 2000;45:115–7
70.	Tyas	Oper Dent 2000;25:152–4
71.	Tyas and Burrow	Oper Dent 2001;26:17–20
72.	Tyas and Burrow	J Dent Res 2001;80(Spec Iss/IADR Abstracts):740, Abstr. No. 1707
73.	Tyas and Burrow	Am J Dent 2002;15:309–11
74.	Tyas and Burrow	Oper Dent 2002;27:438–41
75.	Ünlü et al.	J Dent Res 2002;81(Spec Iss B):236, Abstr. No. 27
76.	Van Dijken	Dent Mater 2000;16:285–91
77.	Van Dijken	J Dent Res 2001;80(4):1272, Abstr. No. 42
78.	Van Dijken	J Dent Res 2003;82(Spec Iss C):469, Abstr. No. 8
79.	Van Dijken	J Dent Res 2004;83(Spec Iss A/CDrom): Abstr. No. 2840
80.	Van Dijken	Am J Dent 2004;17:27–32
81.	Van Meerbeek et al.	ConsEuro, 2003: 60 Abstr. No. S21
82.	Van Meerbeek et al.	Oper Dent (accepted)
83.	De Munck et al.	J Dent Res 2003;82(Spec Iss B):126, Abstr. No. 907
84.	Wicht et al.	J Dent Res 1998;77(Spec Iss A):189, Abstr. No. 672
85.	Wilder et al.	J Dent Res 2001;80(Spec Iss/AADR Abstracts):65, Abstr. No. 234

[a] Study numbers as indicated in Figs. 1–5.

(in %) of all adhesives are schematically presented as a function of time and per adhesive class in Figs. 1–5. The average annual failure rates (in %) are schematically presented for each adhesive category in Fig. 6.

In general, in the 6.5 years of literature review only 35 peer-reviewed papers reported on the clinical effectiveness of adhesives in class-V clinical trials. Fifty abstracts were presented at the dental research meetings (Table 1). More publications reported on the clinical findings of simplified adhesives than of conventional adhesive systems. A lack of details of study methodology was noticed in some papers and in almost all abstracts.

With regard to three-step etch-and-rinse adhesives (Fig. 1; Tables 4 and 5), 14 clinical trials investigated the clinical effectiveness of 11 different adhesives, having lead to five publications in papers and 11 in abstracts, and resulting in 23 restoration–retention curves. Most of the three-step etch-and-rinse adhesives fulfilled the provisional (91%) and full (81%) acceptance ADA guidelines. The highest drop in restoration retention was recorded for Denthesive (Hereaus–Kulzer) that however used EDTA instead of common phosphoric acid as conditioning agent. The annual failure rate varied from 0 to 16%, with an average annual failure rate of 4.8% (Fig. 6).

With regard to two-step etch-and-rinse adhesives (Fig. 2; Tables 4 and 5), 25 clinical trials investigated the clinical effectiveness of 13 different adhesives, having lead to 15 publications in papers and 17 in abstracts, and resulting in 43 restoration–retention curves. In general, two-step etch-and-rinse adhesives performed clinically less favourable than conventional three-step etch-and-rinse adhesives. While 79% of the two-step etch-and-rinse adhesives fulfilled the provisional

Table 3 List of adhesives tested in the selected class-V clinical trials.

Brand name	Manufacturer
Three-step etch-and-rinse adhesives	
All-bond 2	Bisco, Schaumburg, IL, USA
Clearfil liner bond	Kuraray, Kurashiki, Japan
Denthesive[a]	Hereaus-Kulzer, Wehrheim, Germany
EBS	ESPE, Seefeld, Germany (now 3M ESPE)
Gluma CPS	Bayer, Leverkusen, Germany (now Hereaus-Kulzer)
Optibond DC	Kerr, Orange, CA, USA
Optibond FL	Kerr
Permagen	Ultradent, Salt-Lake City, UT, USA
Permaquik	Ultradent
Scotchbond multi-purpose	3M, St Paul, MN, USA (now 3M ESPE)
Two-step etch-and-rinse adhesives	
C36 Prime&Bond NT	Dentsply-Detrey, Konstanz, Germany
Gluma 2000	Bayer
One-coat bond	Coltène Whaledent, Altstätten, Switzerland
One-step	Bisco
Optibond Solo	Kerr
Prime&Bond 2.0	Dentsply-Detrey
Prime&Bond 2.1	Dentsply-Detrey
Prime&Bond NT	Dentsply-Detrey
Scotchbond 1 (single bond)	3M ESPE
Solobond M	Voco, Cuxhaven, Germany
Stae	Southern Dental Industries, Victoria, Australia
Syntac single-component	Ivoclar Vivadent, Schaan, Liechtenstein
Two-step self-etch adhesives	
AdheSE	Ivoclar Vivadent
ART Bond[b]	Coltène Whaledent
Clearfil liner bond 2	Kuraray
Clearfil SE	Kuraray
Denthesive 2[b]	Hereaus-Kulzer
NRC Prime&Bond NT	Dentsply-Detrey
Prisma Universal Bond 3[b]	Dentsply
Pro Bond[b]	Dentsply
Syntac[b]	Ivoclar Vivadent
One-step self-etch adhesives	
Admira Bond	Voco
AQ Bond	Sun Medical, Shiga, Japan
Sustel/F2000 primer-adhesive	3M
Futurabond	Voco
Hytac OSB	ESPE
Ibond	Hereaus-Kulzer
One-up bond F	Tokuyama, Tokyo, Japan
Prime&Bond 2.1 (without etching)	Dentsply-Detrey
Prime&Bond NT (without etching)	Dentsply-Detrey
Prompt-L-Pop	3M
Prompt-L-Pop (LP2)	3M
PSA	Dentsply-Detrey
Reactmer Bond	Shofu, Kyoto, Japan
Xeno III	Dentsply-Detrey
Glass-ionomers[c]	
Exp. Vitremer [*Primer*]	3M
Fuji Cap II[d]	GC, Tokyo, Japan
Fuji 2 LC [*GC Dentin conditioner*]	GC
Fuji bond LC [*GC Cavity conditioner*]	GC
Fuji Bond LL[d]	GC
HIFI Master Palette [*HI Tooth cleanser*]	Shofu
Ketac-fil [*Ketac Conditioner*]	ESPE
Photac-fil [*Ketac Conditioner*]	ESPE
Vitremer [*Vitremer Primer*]	3M

[a] EDTA as conditioning agent.
[b] Includes selective etching of enamel with phosphoric acid.
[c] Conditioning agent is indicated between squares.
[d] Insufficient information was provided regarding the use of a polyalkenoic acid conditioning agent or not.

acceptance ADA guidelines, only 51% fulfilled the full acceptance ADA guidelines. The annual failure rate varied from 0 to 19.5%, with an average annual failure rate of 6.2% (Fig. 6). The results reported for this group of adhesives varied more among the different research centres.

With regard to two-step self-etch adhesives (Fig. 3; Tables 4 and 5), 14 clinical trials investigated the clinical effectiveness of nine different adhesives, having lead to seven publications in papers and 10 in abstracts, and resulting in 17 restoration-retention curves. Eighty-two percent of the two-step self-etch adhesives fulfilled the provisional acceptance ADA guidelines, and 71% fulfilled the full acceptance ADA guidelines. The annual failure rate varied from 0 to 19.3%, with an average annual failure rate of 4.7% (Fig. 6). Among the nine adhesives reported on, only four adhesives are 'true' two-step self-etch adhesives, as the other adhesives were applied

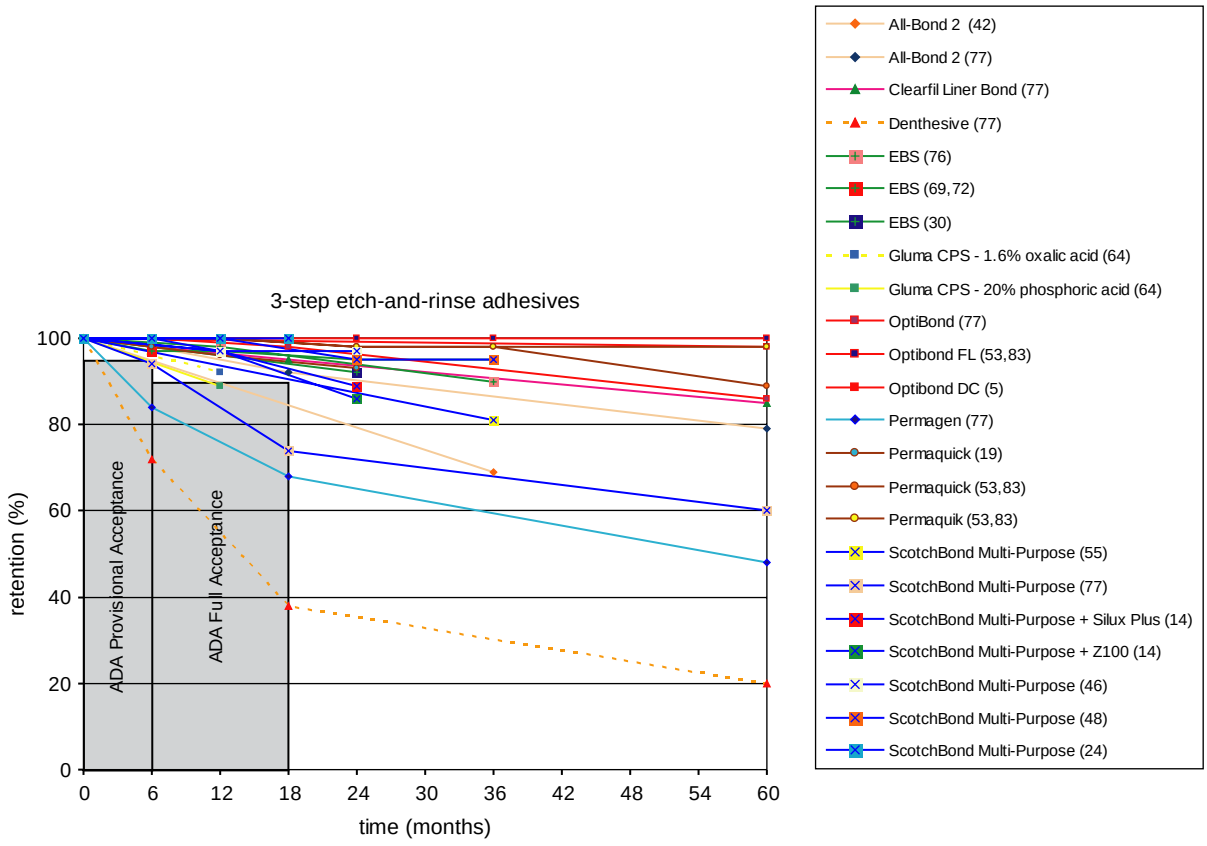

Figure 1 Schematic presentation of restoration retention rates of three-step etch-and-rinse adhesives in class-V clinical trials. The dashed line represents the retention rates of Denthesive that does not use phosphoric acid, but EDTA as conditioning agent.

including additional selective etching of enamel with phosphoric acid.

One-step self-etch adhesives have been tested most frequently (Fig. 4; Tables 4 and 5). Thirty-two clinical trials investigated the clinical effectiveness of 17 different adhesives, having lead to 11 publications in papers and 30 in abstracts, and resulting in 38 restoration-retention curves. Only 68% of the one-step self-etch adhesives fulfilled the provisional acceptance ADA guidelines, and 70% fulfilled the full acceptance ADA guidelines. The average annual failure rate was the highest recorded (8.1%; Fig. 6), with the annual failure rate varying strongly between the different adhesives (0–48%). Of the 38 restoration-retention curves, 14 represent the application of a compomer adhesive applied without separate acid-etching.

With regard to glass-ionomers (Fig. 5; Tables 4 and 5), 18 clinical trials investigated the clinical effectiveness of two different adhesives and of seven restorative glass-ionomers, having lead to 16 publications in papers and seven in abstracts, and resulting in 26 restoration-retention curves. Glass-ionomers presented by far with the highest retention rates. All glass-ionomers fulfilled the provisional (100%) and almost all the full (96%) acceptance ADA guidelines. The annual failure rate varied from 0 to 7.6%, with an average annual failure rate of 1.9% (Fig. 6).

The results of the statistical analysis comparing the average annual failure rates of the five adhesive categories are shown in Table 6. The average annual failure rate of glass-ionomers was significantly lower than that of the two-step etch-and-rinse adhesives ($p=0.0176$) and of the one-step self-etch adhesives ($p=0.0033$). An almost significant difference ($p=0.0578$) was found between the average annual failure rate of the three-step etch-and-rinse adhesives and that of the glass-ionomers.

Discussion

We reviewed current literature published between January 1998 and May 2004 with regard to class-V clinical trials in order to draw up the current status of clinical effectiveness of contemporary adhesives. Until now, this has never been done before. In total, 85 clinical trials have been

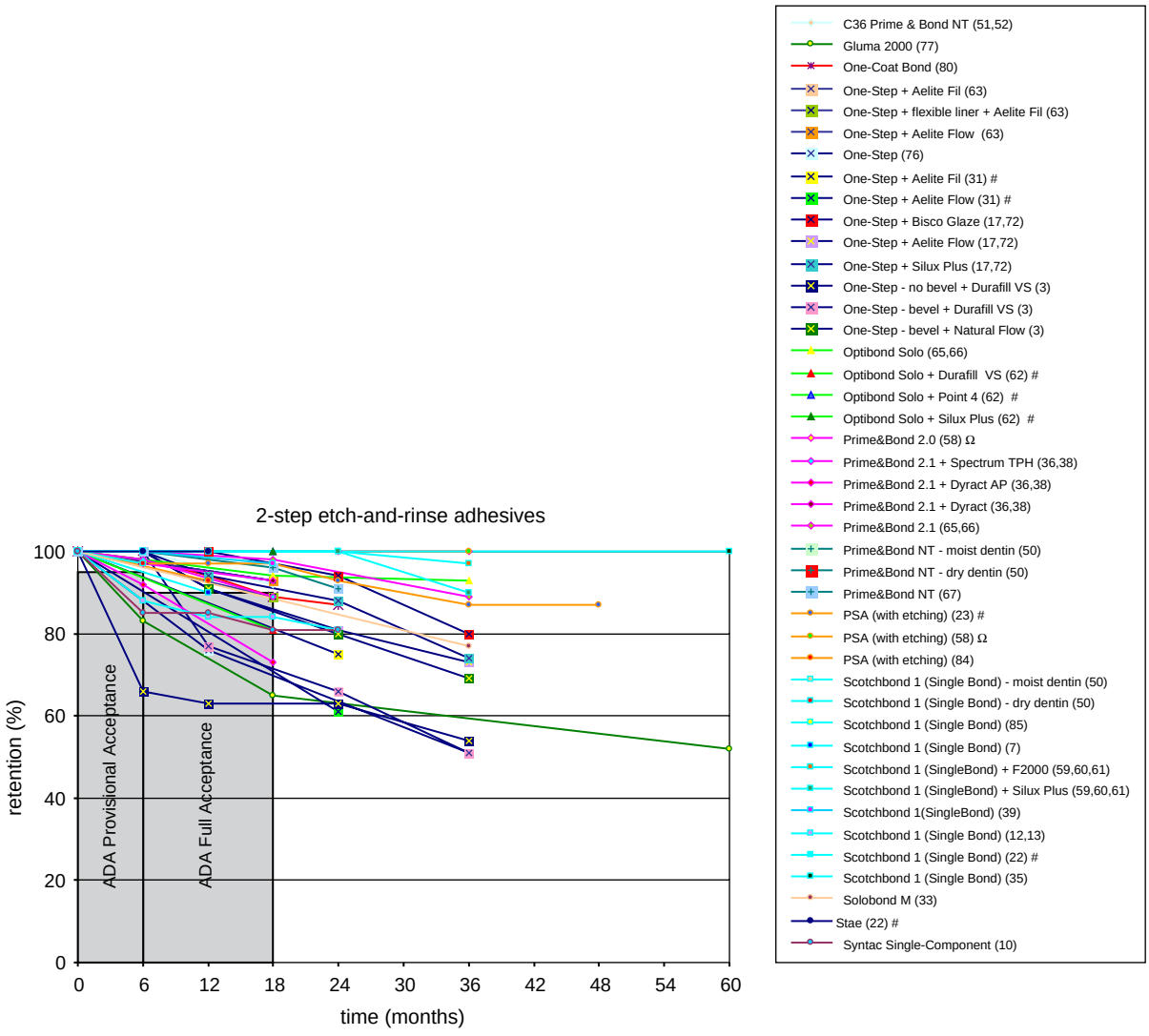

Figure 2 Schematic presentation of restoration retention rates of two-step etch-and-rinse adhesives in class-V clinical trials. # refers to a study, in which a limited number of carious lesions were included; Ω refers to a study, in which a limited number of class-III lesions were included.

published in peer-reviewed journals, IADR–AADR abstracts and ConsEuro abstracts during the last 6.5 years. Unfortunately, almost 60% of the clinical trials were published in abstracts. This must be ascribed in part to the rapid evolution that dental adhesive technology undergoes and the resultant high turnover of adhesives, which often leads manufacturers to introduce a successor product on the market even before a clinical trial on a precursor product has been completed. This has encouraged rapid publication of clinical trial data in abstract form, while publication in a peer-reviewed paper lasts much longer and therefore must have been regarded as much less rewarding.

Publication in a short abstract means that description of study methodology is often incomplete. In most abstracts, but also some papers, the materials and methods were poorly described (insufficient information provided regarding patient selection and in-/exclusive criteria, randomization methodology, the actual clinical procedure, recall rates, reasons of patient-drop out, etc.). In addition, a large variety in study design (not uncommonly without a proper control or 'gold standard', a 'paired-tooth' design, adequate randomization, a sufficiently high restoration/patient number, a sufficiently long follow-up, appropriate statistics, etc.), was noticed in these clinical trials, which makes it difficult to compare the overall clinical performance of adhesives. Retention, marginal integrity and clinical micro-leakage are usually the key parameters used to judge upon clinical effectiveness of adhesives. As retention is the most objective parameter available (i.e.

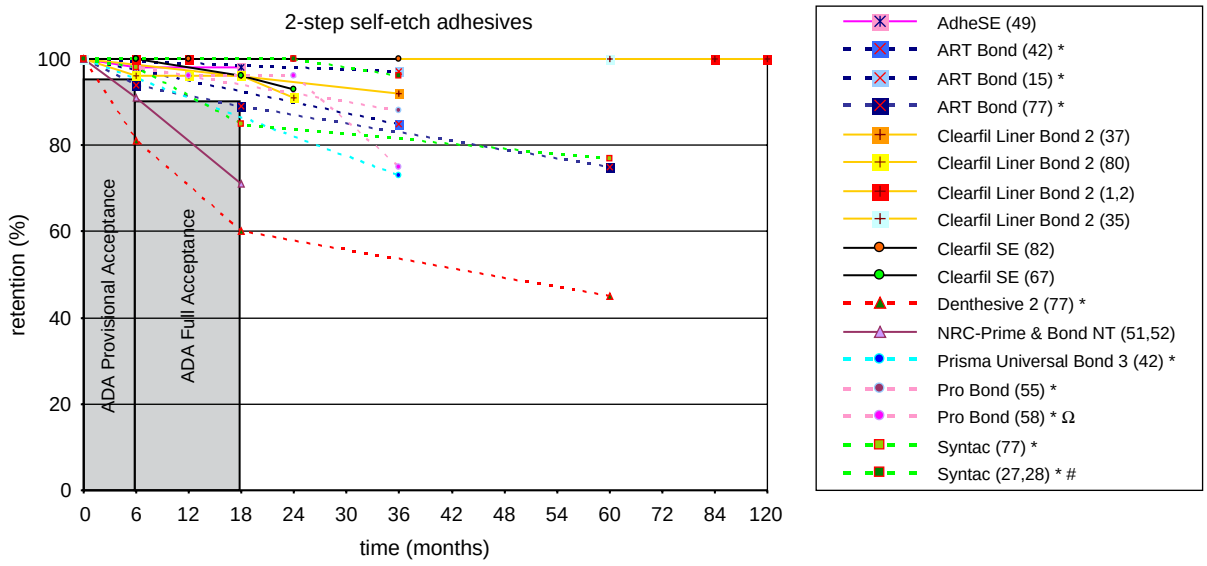

Figure 3 Schematic presentation of restoration retention rates of two-step self-etch adhesives in class-V clinical trials. * refers to an adhesive that is applied including selective etching of enamel with phosphoric acid; # refers to a study, in which a limited number of carious lesions were included; Ω refers to a study, in which a limited number of class-III lesions were included.

evaluating if the restoration is still present or not), retention rates were collected from the trial reports and mutually compared per adhesive category.

In some studies, a number of cervical carious lesions (seven studies indicated by # in Figs. 2–5) and class-III lesions (three studies indicated by Ω in Figs. 2–4) were included. In particular, the latter may have positively influenced the final retention rate, as some macro-mechanical retention might have been involved. Overall, the number of these restorations is limited, and consequently must not have had a significant effect on the general findings. Such lesion variables should however be excluded in future clinical trials testing adhesives. To increase the power of a class-V clinical trial, the study methodology must also be standardized better in the future. In many studies, patient-related factors, such as age, oral hygiene, occlusal loading and dentin sclerosis are more determining than any material property [1,21]. This patient factor can be ruled out by applying a balanced study design. In such a set-up, pairs of equal teeth (for instance, first and second premolar at the same side, left and corresponding right incisor, canine and premolar, respectively) with similar lesions are chosen in each patient and each tooth is assigned to one of the experimental treatments in a randomized way [1]. Such a 'paired-tooth' design also enables the use of more sensitive paired statistics, such as the McNemar test. Also an adequate number of patients, rather than restorations, is paramount to extend the results from the statistical sample to the population; statistical power analysis can help to determine the number of patients required. In addition, recall periods must be standardized more, evaluation criteria must be assessed by calibrated independent examiners following a standard index system, and recall rates and reasons for patient drop-out must be reported as well.

Besides adequate study design, also longer observation times, up to 5 years and longer, are needed to be able to provide data on the expected longevity of adhesive restorations. In this review, long-term clinical data with observation times of 5 years and longer are more available for the three-step etch-and-rinse adhesives, two-step self-etch adhesives and glass-ionomers than for the adhesives with simplified application procedures (two-step etch-and-rinse and one-step self-etch adhesives). The latter, however, are probably currently used most often in routine clinical practice. Of course, conventional adhesives remain longer on the dental market and their good short-term bonding performance has already been proven before [1]. For these adhesives, evaluating their clinical effectiveness over a longer term is most interesting. Simplified adhesives were introduced later. Several of these adhesives presented with a less optimal clinical effectiveness in the short term (Figs. 2 and 4), and are actually not worth evaluating over a longer term. Disagreeing with commonly made public statements, clinical effectiveness can be predicted in the laboratory [9,14]. Whereas conventional

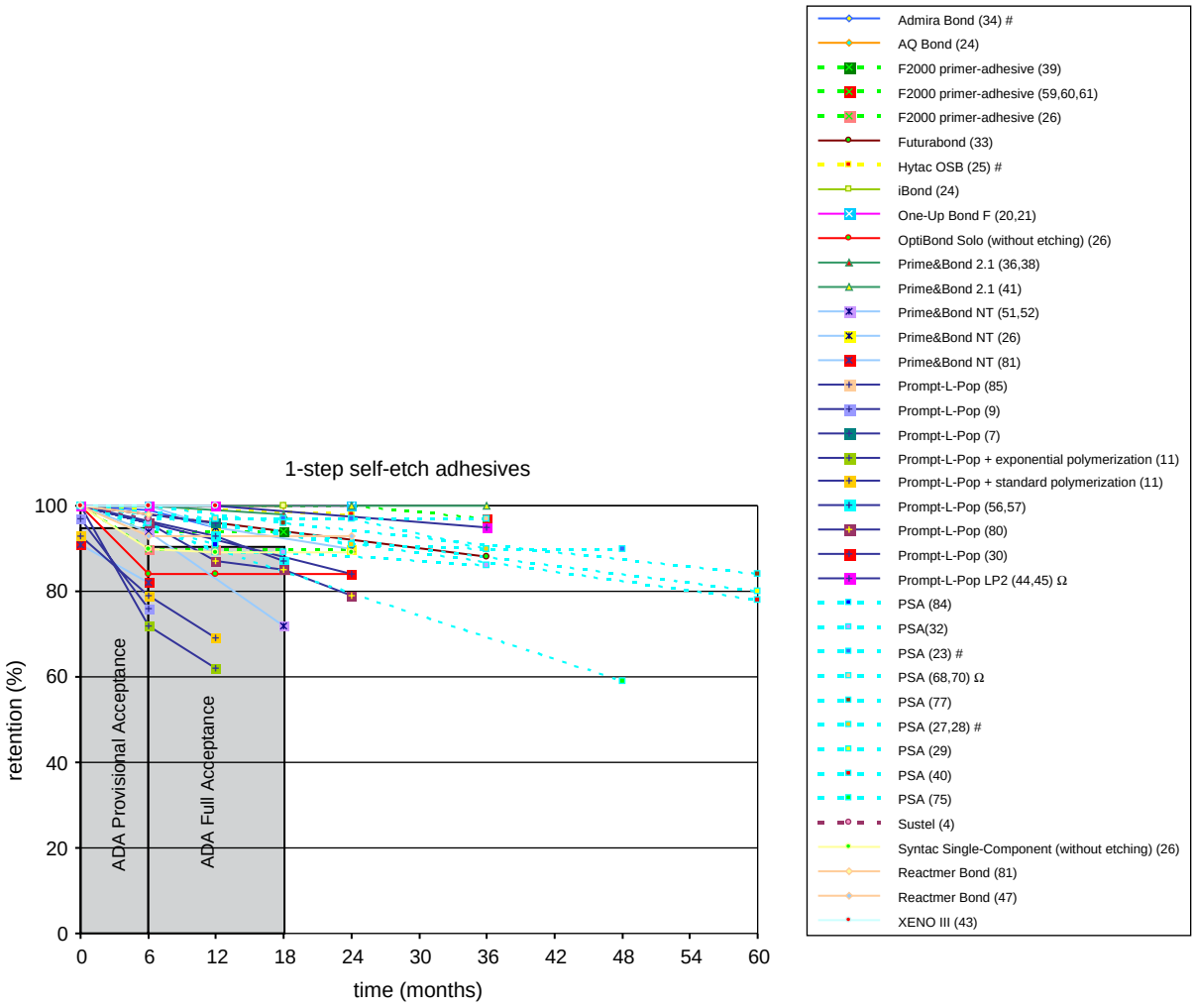

Figure 4 Schematic presentation of restoration retention rates of one-step self-etch adhesives in class-V clinical trials. # refers to a study, in which a limited number of carious lesions were included; Ω refers to a study, in which a limited number of class-III lesions were included. The dashed lines represent the retention rates of a compomer adhesive applied without separate acid-etching.

three-step adhesives commonly perform well in laboratory tests [22–26], simplified adhesives do not, and are less reliable and predictive. The latter adhesives should be subjected more to durability testing, during which the adhesive interface is aged mechanically (fatigue) and/or thermally (thermo-cycling). Once an adhesive survives in vitro durability testing, a clinical trial with a controlled and standardized study design remains needed to evaluate the clinical effectiveness on a long-term.

Comparing the clinical effectiveness of the five adhesive categories, the best clinical performance was recorded for the glass-ionomers. Their average annual failure percentage was significantly lower than that of the simplified adhesive systems (one-step self-etch and two-step etch-and-rinse adhesives), and almost significantly lower than that of the three-step etch-and-rinse adhesives. Furthermore, glass-ionomers are the only category, of which all fulfilled the ADA requirements. In most clinical trials selected, resin-modified glass-ionomers were tested. Most of them are actually restorative materials (Fuji 2 LC, GC; Photac Fil, 3M-ESPE; Vitremer, 3M-ESPE). Fuji Bond LC (GC) is the only commercially available resin-modified glass-ionomer adhesive, which can be used to bond resin composites to enamel and dentin. The excellent clinical data definitely confirm the unique self-adhesive property glass-ionomers possess. This self-adhesiveness must be ascribed to combined micro-mechanical interlocking and chemical interaction [9,10]. The micro-mechanical bonding component has been suggested to provide in particular resistance to abrupt de-bonding stress, while the chemical interaction may result in bonds that better resist hydrolytic break-down [9]. This two-fold bonding mechanism has therefore been

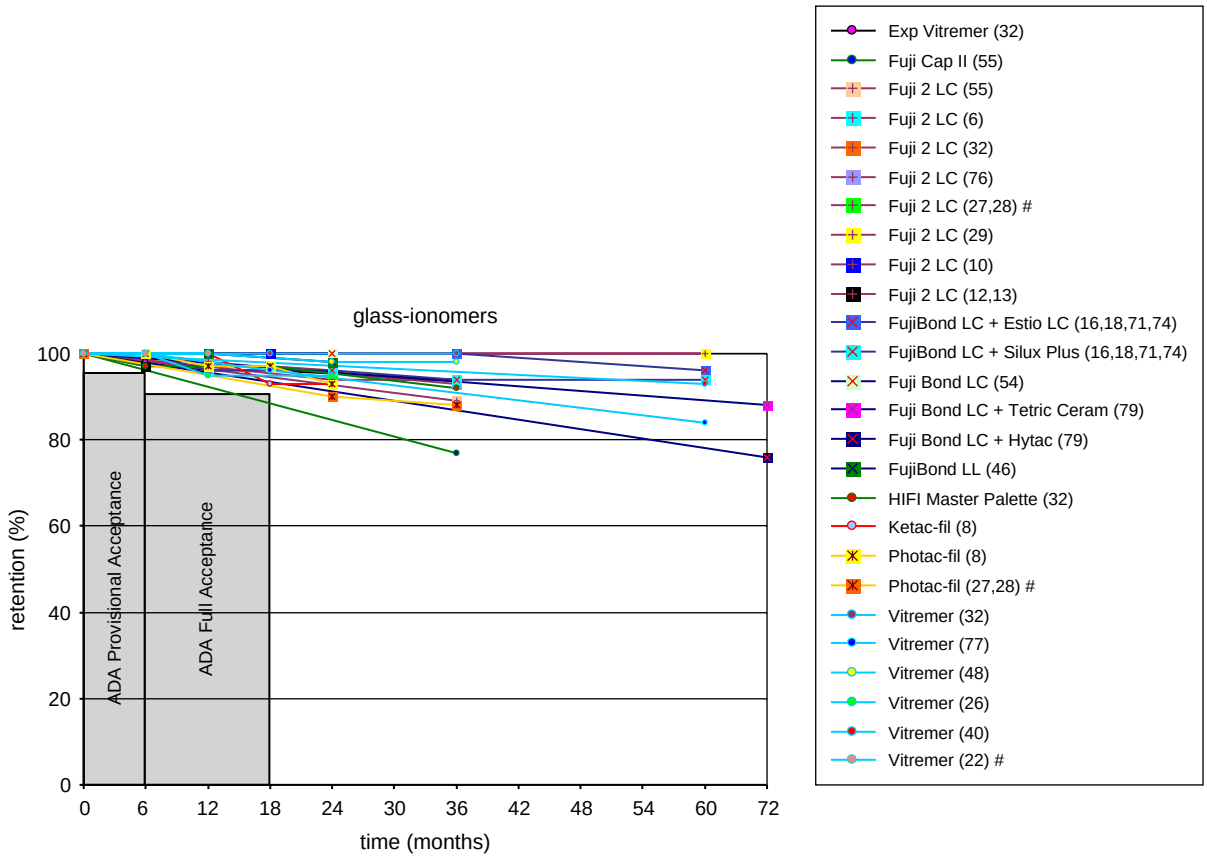

Figure 5 Schematic presentation of restoration retention rates of glass-ionomers in class-V clinical trials. # refers to a study, in which a limited number of carious lesions were included.

expected to be advantageous in terms of restoration durability, as was confirmed in this review.

The retention rate of resin-modified glass-ionomers was favourable for nearly all materials tested. The retention rates at 3 years varied between 88 and 100% (Fig. 5). Even after 5 years, the retention rates were high, varying between 84 and 100%. In a 6-year clinical trial, Van Dijken [27] mentioned a 12% loss of restorations using Fuji Bond LC (GC) in combination with a restorative

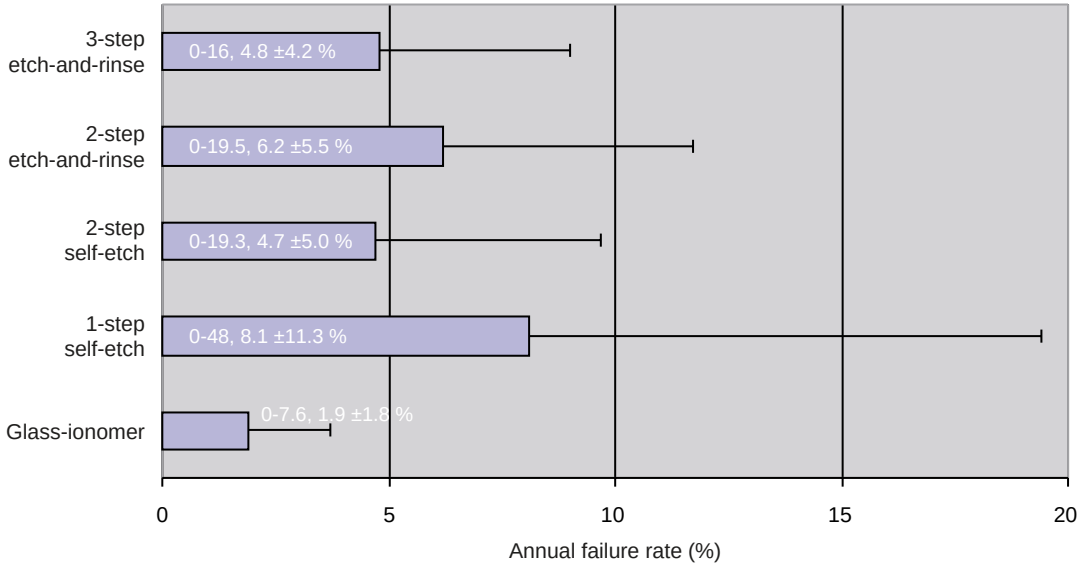

Figure 6 Schematic presentation of the average annual failure rates per adhesive category.

Table 4 List of the number of class-V clinical studies, total number of publications of class-V clinical studies, number of clinical study reports in peer-reviewed papers, number of clinical study reports in abstracts, total number of adhesives tested clinically, and the number of restoration retention curves acquired from the clinical trial data.

Adhesives class	Studies	Publi-cations	Papers	Abstracts	Adhesives	Retention curves
Three-step etch-and-rinse	14	16	5	11	11	23
Two-step etch-and-rinse	25	32	15	17	13	43
Two-step self-etch	14	17	7	10	9	17
One-step self-etch	33	41	11	30	17	38
Glass-ionomer	18	23	16	7	2/7[a]	26

[a] Number of glass-ionomer adhesives tested/number of glass-ionomer restoratives tested.

composite, and 24% when this adhesive was combined with a compomer. Despite the excellent clinical performance of the glass-ionomer adhesive, glass-ionomers commonly give lower scores than resin-based adhesives in bond strength tests [8,9,28]. This finding is mostly attributed to the low cohesive strength of the glass-ionomer itself, by which the material fails internally rather than that it debonds from the tooth surface [12]. In a laboratory durability study, the micro-tensile bond strength (μTBS) to dentin decreased significantly after 4-years of water storage [29]. Again, this reduced bond strength was ascribed more to degraded material properties rather than to decreased bonding potential.

In three clinical trials, conventional glass-ionomers were tested. A somewhat lower retention rate of 77% was noted for Fuji Cap II (GC) at 3 years [30], while HIFI Master Palette (Shofu) showed a retention rate of 92% after 3 years in a study of Gladys et al. [31]. Although conventional glass-ionomers have a high retention rate, their use in thin layers (feather edge) should be avoided, because of their low fracture strength; they are brittle and will break easily, in particular when stressed in tensile mode [32].

Besides glass-ionomers, three-step etch-and-rinse adhesives exhibited a reasonably good clinical effectiveness, with an average annual failure rate of 4.8%. Some frequently tested adhesives in this group were EBS (3M ESPE), Optibond (Kerr), Permaquick (Ultradent) and Scotchbond Multi-Purpose (3M ESPE). The retention rate recorded for a particular three-step etch-and-rinse adhesive in different studies was relatively uniform, indicating their low technique-sensitivity. An excellent clinical performance of the three-step etch-and-rinse adhesive Optibond FL (Kerr) with a 98 and 100% retention rate at 5 years was reported by, respectively, Boghosion et al. [33] and De Munck et al. [19]. A somewhat lower retention rate of 86% was recorded by van Dijken [34] after 5 years. Likewise, 96% of the restorations were still in place at 5 years when Permaquick was used [19]. For Clearfil Liner Bond, a retention rate of 85% at 5 years was recorded by Van Dijken [34]. This durable clinical effectiveness confirms laboratory research, in which three-step etch-and-rinse adhesives are considered as the 'gold standard' to compare the performance of new-generation adhesives with [23]. This superior performance in laboratory and clinical research must probably to a great extent be attributed to optimal enamel interlocking and dentin hybridization, as was demonstrated in several ultra-morphologic interface analyses [1,9,35,36]. In addition, all these abovementioned adhesive systems use a filled adhesive, which might have contributed to the superior clinical results as well. The intermediary layer of filled adhesive has been suggested to act as shock absorber during polymerization of the composite resin and during occlusal loading [37].

For All-Bond 2 (Bisco), somewhat lower and more varying retention rates were recorded. After 3 years, a 31% loss rate was recorded by McCoy et al. [38], while Van Dijken [34] mentioned a somewhat better retention score of 79% at 5 years. This greater variability in clinical performance may result from the presence of acetone as solvent in the primer, which seems to be a major factor

Table 5 Number of restoration retention curves fulfilling the ADA guidelines.

ADA guidelines	Provisional acceptance (6 months)	Full acceptance (18 months)
Three-step etch-and-rinse	91	81
Two-step etch-and-rinse	79	51
Two-step self-etch	82	71
One-step self-etch	68	70
Glass-ionomer	100	96

Table 6 Results of Kruskal–Wallis and Dwass–Steel–Chritchlow–Fligner statistics.

p-Values	Two-step etch-and-rinse	Two-step self-etch	One-step self-etch	Glass-ionomer
Three-step etch-and-rinse	0.9424	0.9998	0.9953	0.0578[a]
Two-step etch-and-rinse		0.8658	0.9871	0.0176[b]
Two-step self-etch			0.997	0.1112
One-step self-etch				0.0033[b]

[a] *p*-values indicate nearly statistically significant difference.
[b] *p*-values indicate statistically significant difference.

affecting handling [39] as well as performance [40]. Acetone-based adhesives require the use of the 'wet bonding' technique with a relatively small window of opportunity (high technique-sensitivity) to achieve optimal hybridization [39].

Only a few three-step etch-and-rinse adhesives did not (in all studies) fulfill the ADA guidelines for provisional and full acceptance (Denthesive, Hereaus-Kulzer; Permagen, Ultradent; Scotchbond Multi-Purpose, 3M ESPE). All these adhesives were tested in the same clinical trial [34], where they show very low retention rates (varying between 20 and 60%) after 5 years (Fig. 1). Scotchbond Multi-Purpose (3M ESPE), however, performed well with a retention rate of 95% after 3 years according to Özgünaltay et al. [41], while Platt et al. [30] recorded a lower retention rate of 81% after 3 years. A compromised bonding effectiveness in the long-term was also noticed in vitro for Scotchbond Multi-Purpose [22,23,25,42,43]. It has been hypothesized that this reduced durability is related to the incorporation of a high molecular-weight polyalkenoic-acid copolymer (also present in Scotchbond 1 and Prompt L-Pop) [23]. Phase separation was shown to occur, with the co-polymer being filtered out by the collagen network and deposited as a distinct gel on the exposed collagen network [35,44]. In the extreme case, the gel may hinder adequate resin-interdiffusion, by which the hybrid layer would be constituted of collagen mainly infiltrated by the low-MW 2-hydroxyethylmethacrylate (HEMA) that was polymerized to linear poly-HEMA chains, and of residual water (solvent) that was insufficiently removed (and/or kept in situ by HEMA). This rather poorly infiltrated and polymerized hybrid layer must then be more susceptible to degradation and can explain the less positive retention rates for this adhesive in the long-term.

In this review, two-step self-etch adhesives approach the gold standard (three-step etch-and-rinse) regarding clinical effectiveness. Their annual failure percentages show a somewhat larger variation (0–19.3%), which can be explained by the greater variety of adhesives in this adhesive category. In fact, two groups of adhesives must be distinguished. First, the actual precursors of two-step self-etch adhesives require enamel to be etched selectively with phosphoric acid before application of the self-etching primer and adhesive to both enamel and dentin (i.e. ART Bond, Coltène-Whaledent; Denthesive 2, Hereaus Kulzer; Pro Bond, Dentsply-Detrey; Prisma Universal Bond 3, Dentsply-Detrey; Syntac, Ivoclar-Vivadent). In total, six out of the 14 clinical trials testing two-step self-etch adhesives reported on the clinical effectiveness of such adhesives (indicated by * in Fig. 3). Several of them did not fulfil the ADA full acceptance guidelines. Furthermore, the retention rates after 5 years were not so favourable: a retention rate of 77 and 75%, respectively, was reported for Syntac (Ivoclar-Vivadent) and ART Bond (Coltène-Whaledent) by Van Dijken [34]. The higher drop-out of restorations using these adhesives may indicate that despite enamel etching the very superficial interaction of the adhesive with the dentinal surface deteriorates with time and insufficiently resists restoration de-bonding in the long-term [1].

Regarding the 'true' two-step self-etch adhesive approach (also self-etching enamel), 10 publications reported on the clinical performance of four adhesives. Only one of them did not fulfil the ADA guidelines for full acceptance, nml. NRC (abbreviation for Non-Rinse Conditioner, Dentsply-Detrey) when combined with Prime&Bond NT (Dentsply-Detrey). This adhesive belongs to the group of so-called 'strong' self-etch adhesives that also in the laboratory showed inconsistent bonding performance, as for instance when tested following a micro-tensile bond strength approach [8,45]. This is most likely caused by the high acidity of unpolymerized monomers remaining after light curing in a relatively high concentration at the oxygen-inhibited layer [46,47]. Lack of a sufficiently thick and uniform resin layer that stabilizes

the hybrid layer may also have contributed to the lower bond strength values.

The three other 'true' two-step self-etch adhesives fulfilled the ADA guidelines. Most frequently tested were Clearfil Liner Bond 2 (Kuraray) and its successor Clearfil SE Bond (Kuraray), both belonging to the group of 'mild' self-etch adhesives. The variability in retention rates between the different studies was low for both adhesives, again indicating their rather low technique-sensitivity. Clearfil Liner Bond 2 (Kuraray) presented with an excellent retention of 100% after 5 years [48], but also after 10 years [49], the longest evaluation period ever reported for a class-V clinical trial. A 91% 2-year and a 92% 3-year retention rate was reported, respectively, by van Dijken [50] and Latta et al. [51]. Likewise, an excellent clinical performance of Clearfil SE (Kuraray), with a 93 and 100% retention rate, respectively, at 3 years was reported by Türkün [52] and Van Meerbeek et al. [53]. The excellent clinical effectiveness of these two-step self-etch adhesives may in part result from simultaneous demineralization and infiltration of dentin, having lead to a shallow, but uniform resin-infiltrated dentin layer [54,55]. Furthermore, within the shallow hybrid layer residual hydroxyapatite around the exposed collagen fibrils remains available for additional chemical interaction with the functional monomers [9,10]. This chemical adhesion must be beneficial in terms of resistance to long-term hydrolytic degradation. These 'mild' two-step self-etch adhesives are the only simplified adhesives in this review that exhibit a good clinical effectiveness in combination with some clinical benefits such as ease of manipulation and reduced technique-sensitivity.

In general, two-step etch-and-rinse adhesives perform clinically less favourably than conventional three-step etch-and-rinse adhesives. The average annual failure rate was 6.2%, and the annual failure rates varied from 0 to 19.5%. These results were only significantly different from that recorded for the glass-ionomers ($p=0.0176$). The number of adhesives that did not meet the ADA full acceptance guidelines was obviously higher than for the three-step etch-and-rinse adhesives. Some frequently tested adhesives in this group were One-step (Bisco), Optibond Solo (Kerr), Prime&Bond 2.1 (Dentsply-Detrey), Prime&Bond NT (Dentsply-Detrey) and Scotchbond 1 (3M ESPE). For each of these particular adhesives, the results from the different research centers varied more than for the three-step etch-and-rinse adhesives, which points to a higher technique-sensitivity. In vitro studies also revealed that two-step etch-and-rinse adhesives bond less effectively/durably because of their reduced infiltration/hybridization potential [23]. Such sub-optimal hybridization might explain to a large extent why the hybrid layer produced by the two-step version is more prone to hydrolytic degradation than that produced by the three-step etch-and-rinse version. Simplified two-step adhesives have more difficulty in fully infiltrating the demineralized collagen mesh and in removing all residual solvent.

One-step (Bisco), an acetone-based two-step etch-and-rinse adhesive, did for instance not meet the ADA guidelines in most clinical trials. Almost 50% of class-V restorations restored with One-step debonded during 3 years of clinical function [18,56,57]. The already mentioned high technique-sensitivity of acetone-based adhesives can explain these compromised long-term results. Also another acetone-based etch-and-rinse adhesive, Prime&Bond 2.1 (Dentsply-Detrey) performed rather inconsistently in different clinical trials. A reasonably good clinical effectiveness was reported with a retention rate of 89% at 3 years by Swift et al. [58,59], while in another clinical study this adhesive did not fulfill the ADA requirements [60,61].

The large variability in retention rates collected from different clinical trials was most obvious for Scotchbond 1 (3M ESPE). This two-step etch-and-rinse adhesive performed excellent with a retention rate of 100% in a class-V clinical trial after 5 years of service [48], while in another study the adhesive did not even fulfill the ADA requirements [62,63]. In a study by Ripps et al. [64], 3% of the restorations were lost after 3 years when the adhesive was used in combination with a compomer (F2000, 3M ESPE), and 10% in case when micro-filled composite (Silux Plus, 3M ESPE) was used as restorative material. Such a widely varying bonding effectiveness is probably due to an operator dependent technique-sensitivity. Over- or under-drying of acid-etched dentin, a very technique-sensitive step [65–67], cannot only explain this varying clinical effectiveness, as this particular adhesive appeared relatively insensitive to the amount of drying [1,68]. In vitro research indicated conversely that with increasing thickness of the bonding layer [69] bond strengths decrease, probably because of incomplete solvent evaporation when thick layers of this water-based adhesive are applied. In the clinical study where Scotchbond 1 performed rather poorly, each layer was only lightly air-dried [62,63]. This may have resulted in poor solvent evaporation and thick adhesive layers. The presence of solvent in the hybrid layer weakens this layer and makes it more susceptible to hydrolytic degradation. In conclusion, two-step etch-and-rinse adhesives perform clinically not as well as conventional three-step

etch-and-rinse adhesives, and they have a higher technique-sensitivity.

An inefficient clinical performance was noted for the most commonly tested one-step self-etch adhesives. They show the highest average annual failure rate (8.1%) and the largest variability in annual failure rates (0–48%). Most adhesives failed to meet the ADA requirements. The most frequently tested one-step self-etch adhesives were Prompt L-Pop (3M ESPE) and PSA (Denstply-Detrey). Widely varying retention scores were recorded for both adhesives, which again indicates their high technique-sensitivity.

Indeed, for PSA (applied in combination with Dyract without etching) a 20% loss rate at 5 years was reported by Folwaczny et al. [70], Loguercio et al. [71], and by van Dijken [56], whereas even 41% of the restorations using PSA debonded within a 4-year period, as reported by Ünlü et al. [72]. In a few clinical studies, where enamel was etched selectively with phosphoric acid before PSA was applied, higher retention scores of 100% [73] and 87% [74] were recorded after, respectively, 3 and 4 years of clinical function. The less favourable results gathered when enamel was not etched, must be explained by the fact that the pretreatment with PSA did not produce any visible etching pattern on enamel and lead to a lower bonding potential as compared to when enamel was etched with phosphoric acid [75].

Likewise, several studies reported on the clinical performance of the 'strong' one-step self-etch adhesive Prompt L-Pop (3M ESPE). Rather favourable retention rates of 95% at 3 years were recorded by Munoz et al. [76] and 96% after 1 year by Boghosian et al. [77]. In the study of Munoz, however, class-III restorations were included as well, which may have positively influenced the retention rate (see above). A relatively high loss rate of 21% at 2 years was reported by Van Dijken [50]. Brackett et al. [78] noticed a loss rate of 31% after 1 year when the resin composite (Pertac II) was cured using soft start polymerization, while 38% of the restorations were lost when the resin composite was polymerized with high-intensity halogen light. A disappointing short-term bonding effectiveness was also recorded when Prompt L-Pop (3M ESPE) was tested in vitro [79,80]. Several explanations such as inhibition of polymerization of the restorative composite on top due to the high acidity of Prompt L-Pop, incomplete wetting and an insufficiently thick adhesive layer, phase separation between hydrophylic and hydrophobic ingredients, and resultant sensitivity to hydrolysis have been advanced to explain this lower bonding performance to dentin as compared to more conventional etch-and-rinse and self-etch adhesives. In conclusion, these simplified one-step adhesives are not as effective as conventional adhesives. Moreover, these simplified adhesives, though faster and easier to use, clinically have a high technique-sensitivity.

Conclusions

Comparison of retention of class-V adhesive restorations as a measure to determine clinical bonding effectiveness of adhesives revealed that glass-ionomers bond most effectively and durably to tooth tissue. Three-step etch-and-rinse adhesives and two-step self-etch adhesives showed a clinically reliable and predictably good clinical performance. The clinical effectiveness of two-step etch-and-rinse adhesives was less favourable, while an inefficient clinical performance was noted for the one-step self-etch adhesives. Although there is a tendency towards adhesives with simplified application procedures, simplification so far appears to induce loss of effectiveness. In addition, the simplified adhesives might be faster and easier to use clinically, but the resultant technique-sensitivity rises rapidly. Only two-step self-etch adhesives showed a good clinical performance in combination with a user-friendly and less technique-sensitive application procedure.

It was also clear from this review that there remains a definite need to standardize the study design of class-V clinical trials in order to evaluate the clinical performance of adhesives, so that comparison of results between different clinical studies for several parameters will be more reliable in the future.

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