Einfluss eines fließfähigen Komposits auf die Qualität von Seitenzahnrestaurationen - eine randomisierte, kontrollierte, klinische Langzeitstudie

Dissertation

zur Erlangung des akademischen Grades
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vorgelegt
der Medizinischen Fakultät
der Martin-Luther-Universität Halle-Wittenberg

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Datum der Verteidigung:
09.10.2025

Referat

Ziel der vorliegenden Untersuchung ist die umfangreiche Betrachtung von fließfähigen Kompositmaterialien auf den Einfluss der Qualität und Langzeitstabilität von Seitenzahnrestaurationen. Die klinisch-prospektive, randomisierte, kontrollierte und einfach verblindeten Studie im Split-Mouth-Design untersuchte den Einfluss eines hochviskösen, fließfähigen Nanohybridkomposits (Flowable) als Kavitätenliner auf die Langlebigkeit von Klasse-I- und Klasse-II-Kompositrestaurationen. Eine Anzahl von 50 Patient:innen mit einem Behandlungsbedarf von insgesamt zwei Seitenzähnen (Prämolaren oder Molaren) wurden in die Studie eingeschlossen (n=100). Alle Zähne wurden mit dem gleichen Self-Etch-Adhäsivsystem ohne vorherige Konditionierung der Zahnhartsubstanz vorbehandelt. Jeweils in einer Kavität pro Patient:in wurde ein Inkrement mit einem hochviskösen, fließfähigen Komposit (GrandioSO Heavy Flow, VOCO GmbH) als Kavitätenliner appliziert (n=50; Testgruppe) und anschließend mit einem stopfbaren Nanohybridkomposit (GrandioSO, VOCO GmbH) gefüllt. Die andere Kavität erhielt kein zusätzliches Kavitätenlining (n=50; Kontrollgruppe). Klinische Nachuntersuchungen wurden mithilfe der modifizierten USPHS-/Ryge-Kriterien nach 6, 12, 24 und 36 Monaten durchgeführt. Die Recallrate nach 24 Monaten lag bei 94% und nach 36 Monaten bei 92%. In der Testgruppe wurden nach 3 Jahren insgesamt 4 Restaurationen als Misserfolg bewertet (8,7%): 3 Füllungen aufgrund eines Vitalitätverlustes und eine Füllung aufgrund einer Frakturbildung, was einer kumulativen Erfolgsrate von 91,3% entspricht. In der Kontrollgruppe wurden keine Misserfolge (0%) nach 3 Jahren detektiert, resultierend in einer kumulativen Erfolgsrate von 100%. Dies führte zu statistisch signifikanten Unterschieden der jährlichen Misserfolgsrate (AFR) zwischen der Kontrollgruppe (100%) und der Testgruppe (2,9%; $p<0,05$; Mann-Whitney-U-Test). Die statistische Analyse ergab weitere signifikante Unterschiede für die nachfolgenden Parameter: Zahnvitalität, Randverfärbung, kumulative Erfolgsrate ($p<0,05$; Mann-Whitney-U-Test). Das Nanohybridkomposit zeigte über einen Zeitraum von 36 Monaten eine mit anderen Studien vergleichbare sehr gute Leistung, während ein zusätzliches Kavitätenlining für die Restauration von Klasse-I- und Klasse-II-Kavitäten keinen weiteren, positiven Einfluss auf die klinische Langlebigkeit bewirkte.

Inhaltsverzeichnis

Abkürzungsverzeichnis

10-MDP	10-Methacryloyloxydecyl-Dihydrogenphosphat
AFR	Annual Failure Rate
Bis-GMA	Bisphenol A-Diglycidylmethacrylat
ca.	circa
d.h.	das heißt
E-Modul	Elastizitätsmodul
EGDMA	Ethylenglycol-Dimethacrylat
FDI	Fédération Dentaire Internationale
mm	Millimeter
MPTS	3-Methacryloyloxypropyltrimethoxisilan
n	Anzahl
nm	Nanometer
s.	siehe
Si-O-Si-Bindung	Siloxan-Bindung
TEGDMA	Triethylenglycol-Dimethacrylat
UDMA	Urethan-Dimethacrylat
µm	Mikrometer
USPHS	United States Public Health Service
z.B.	zum Beispiel

1 Einleitung und Zielstellung

1.1 Bedeutung von Kompositmaterialien in der modernen Zahnmedizin

In der adhäsiven Zahnheilkunde haben sich direkte Restaurationen mit Kompositmaterialien zu einer praktikablen und weit verbreiteten Alternative zu anderen direkten Restaurationsmaterialien wie Amalgam oder Glasionomerzemente etabliert [1,2]. Die aktuelle S3-Leitlinie „Direkte Kompositrestaurationen an bleibenden Zähnen im Front- und Seitenzahnbereich“ der Deutschen Gesellschaft für Zahnerhaltung und der Deutschen Gesellschaft für Zahn-, Mund- und Kieferheilkunde empfiehlt den Einsatz von Kompositen bei der direkten Restauration von Klasse-I- und Klasse-II-Kavitäten [3]. Aktuelle, klinische Untersuchungen zeigen bei direkten Kompositrestaurationen vergleichbare Langzeitergebnisse mit verschiedenen indirekten Restaurationen [2,4,5].

Die Randadaptation der Restaurationsmaterialien an den behandelten Zähnen spielt für den klinischen Langzeiterfolg der direkten Restaurationen eine besonders entscheidende Rolle. Spaltbildungen im marginalen Bereich können zu Sekundärkaries und klinischen Symptomen, wie der postoperativen Hypersensibilität, führen. Dieses Phänomen wird häufig bei tiefen, approximalen und dentinbegrenzten Läsionen beobachtet [6,7]. Darüber hinaus ist der interne Verbund der Kompositmaterialien zur Zahnhartsubstanz ein entscheidender Faktor für den Erfolg einer Restauration und klinisch schwer zu beurteilen. Bei unzureichender interner Adaptation ist ebenso eine Randspaltbildung mit Entstehung einer Sekundärkaries und/oder postoperativen Hypersensibilitäten die Folge und kann letztlich zum Verlust der Restauration führen [8]. Als Gegenmaßnahme wurde die zusätzliche Anwendung eines fließfähigen Kompositmaterials, auch Flowable genannt, von einigen Autoren empfohlen, um den internen Haftverbund, sowie die Randadaptation von Kompositrestaurationen und damit die klinische Langlebigkeit zu verbessern [8,9]. Aufgrund der geringeren Viskosität im Vergleich zu den stopfbaren Kompositmaterialien vermutete man eine Reduktion von Spannungen im Übergangsbereich von Komposit und Zahnhartsubstanz und damit eine bessere Randadaptation [10-

12]. Dennoch konnten einige Autor:innen bis dato keinen positiven Effekt von fließfähigen Kompositen als Kavitätenliner bei Kompositrestaurationen feststellen [13,14].

In einer Umfragestudie von Seemann et al. (2011) gaben 80,1% der 1.449 teilnehmenden Zahnärzt:innen aus Deutschland an, fließfähige Komposite als Kavitätenliner bei Kompositrestaurationen anzuwenden. Als Gründe wurden vor allem die Vermeidung einer Blasenbildung während der Füllungslegung (71,7%) und eine verbesserte Adaptation des Komposits an die Zahnhartsubstanz (72,9%) erwähnt.
Derzeit ist die Anzahl klinischer Studien, welche den Einfluss von fließfähigen Kompositen als Kavitätenliner über einen längeren Beobachtungszeitraum als 24 Monate untersucht, limitiert.

1.2 Aufbau dentaler Kompositmaterialien

1.2.1 Definition

Der Begriff des Komposits leitet sich aus dem lateinischen „*compositio*“ ab und bedeutet „*Zusammensetzung*“ oder „*Zusammenstellung*“. In der Zahnmedizin bestehen dentale Komposite grundsätzlich aus einer **organischen Matrix** und **anorganischen Füllkörperpartikeln**, welche durch eine **Verbundphase** chemisch zusammengehalten werden [16].

1.2.2 Organische Matrix

Der Hauptbestandteil der organischen Matrix in Kompositmaterialien wird von hochmolekularen Monomeren gebildet. Dabei ist das durch Bowen (1963) entwickelte Bisphenol A-Diglycidylmethacrylat (Bis-GMA) der bekannteste Vertreter dieser Gruppe. Chemisch ähnelt es einem Epoxidharz, wobei die Epoxidgruppen beim Bis-GMA durch Methacrylatgruppen ersetzt wurden. Durch die Kohlenstoffdoppelbindungen der beiden Methacrylatgruppen ist das Monomer hochviskös; es ermöglicht aber auch Polymerisationsreaktionen und Quervernetzungen mit anderen Polymeren bei einer geringen Wasseraufnahme. Daneben ist ein weiterer bekannter Vertreter der Basismonomere das Urethandimethacrylat (UDMA). Mithilfe niedrigviskoser Co-Monomere werden die Materialeigenschaften von Bis-GMA und UDMA durch Reduktion der Viskosität verbessert. Zur Gruppe der Co-Monomere zählen beispielsweise Triethylenglycol-Dimethacrylat

(TEGDMA) oder Ethylenglycol-Dimethacrylat (EGDMA) [18]. Heutzutage wird die Aushärtung der meisten Komposite durch Lichtpolymerisation realisiert. Durch Zugabe von Photoinitiatoren, wie z.B. Campherchinonen, kann bei Zuführung von Licht mit einer Wellenlänge von ca. 450-480nm die Polymerisationsreaktion initiiert werden; tertiäre Amine beschleunigen diesen Vorgang [19].

1.2.3 Anorganische Füllkörper

Anorganische Füllkörper werden chemisch in die organische Matrix eingebettet und können aus Siliziumdioxid, radioopaken Barium- oder Strontiumsilikatgläsern, amorphen Quarzgläsern oder Zirkoniumdioxidpartikeln bestehen. Zusätzlich enthalten sie Ytterbiumfluoride, um die Röntgenopazität zu steigern [20]. Die anorganischen Füllerpartikel sind maßgeblich für die physikalischen und mechanischen Eigenschaften der Komposite, sowie für deren Radioopazität verantwortlich. Durch die Steigerung des Anteils von Füllerpartikeln in der organischen Matrix, kann der Polymerisationsschrumpfung entgegengewirkt werden. Komposite können entsprechend ihrer Füllerpartikelgröße in verschiedene Gruppen eingeteilt werden: Makrofüller (10–50µm), Mikrofüller (0,04–0,05µm) und Nanofüller (0,005–0,01µm) [19]. Makrofüller werden durch mechanische Verkleinerung von Glas, Quarz oder Keramikpartikeln hergestellt und sind in der Regel splitterförmig [20]. Die ersten rein makrogefüllten Komposite zeichneten sich durch ihre stopfbare Konsistenz und ihr hohes E-Modul aus. Nachteilig waren jedoch die unzureichende Abrasionsfestigkeit, sowie die matte Oberfläche der Restaurationen und ihre erschwerte Polierbarkeit [21,22]. Dadurch wurden Mikrofüller aus sphärischen Silizium- und Zirkondioxidpartikeln mit einer geringeren Partikelgröße von 0,04-0,05µm eingeführt [20]. Die mikrogefüllten Komposite konnten eine bessere Polierbarkeit und glattere Oberflächen aufweisen, um gesteigerten ästhetischen Ansprüchen gerecht zu werden [22]. Die erhöhte Polymerisationsschrumpfung ist jedoch ein großer Nachteil dieser Komposite, besonders durch die Bildung von Randspalten und damit verbundenen Restaurationsverlusten [23]. Die Kombination verschiedener anorganischer Füllkörper führte zur Entwicklung sogenannter Hybridkomposite, welche die Vorteile beider Füllkörpertypen zusammenführte. Sie besitzen gute mechanische und physikalische Eigenschaften und können den höheren Krafteinwirkungen im Seitenzahnbereich während funktioneller Belastungen standhalten. Durch ihre verbesserte Polierbarkeit und Oberflächengüte ist die

Anwendung auch in ästhetisch anspruchsvollen Zonen möglich. Die Verfeinerung der Partikel durch optimierte Schleif- und Zermahlungsverfahren ermöglichte die Herstellung von Nanofüllern mit einer Partikelgröße von 5-10nm [24]. Die meisten Hersteller ersetzten einen Anteil von Mikrofüllern mit Nanofüllern in ihrer Formulierung und ebneten so den Weg für die Nanohybridkomposite. Weiterhin wurden sogenannte Präpolymerisate, fein gemahlene Methacrylatverbindungen, welche vorab polymerisiert werden, hinzugefügt, um die Polymerisationsschrumpfung zu verringern und die mechanischen Eigenschaften wie Biegefestigkeit und E-Modul weiter zu verbessern [25-27].

1.2.4 Verbundphase

Der chemische Verbund zwischen der organischen Matrix und den anorganischen Füllern wird durch den Einsatz von Silanen, wie dem 3-Methacryloyloxypropyltrimethoxisilan (MPTS), realisiert. Diese bifunktionellen, amphiphilen Verbindungen bilden kovalente Si-O-Si-Bindungen zwischen der Matrix und den Füllkörpern aus und ermöglichen einen höheren Füllstoffanteil im Komposit durch die bessere Integration von Füllkörpern in der organischen Matrix [28].

1.2.5 Fließfähige Komposite (Flowables)

Die Einführung von fließfähigen Kompositen, auch Flowables genannt, auf dem Dentalmarkt fand große Beliebtheit bei praktizierenden Zahnärzt:innen. Sie zeichnen sich durch einen reduzierten Anteil von Füllstoffpartikeln im Vergleich zu konventionellen Kompositen aus, das in einer niedrigeren Viskosität resultiert. Dementsprechend ist ihr E-Modul 20-30% niedriger als das der stopfbaren Komposite [29,30] und ermöglicht die Absorption von Spannungen während der Polymerisationsschrumpfung und mechanischen Belastungen der Zähne [31]. Dennoch sind sie aufgrund des geringeren Füllstoffgehalts stopfbaren Kompositen in ihren mechanischen Eigenschaften unterlegen und besitzen eine niedrigere Abrasionsfestigkeit [32,33]. Um dem entgegenzuwirken, wurden in den letzten Jahren sogenannte hochvisköse, fließfähige Komposite eingeführt, die sich zwar noch durch ihre gewisse Fließfähigkeit auszeichnen, jedoch aufgrund des größeren Füllstoffgehalts im Vergleich zu den herkömmlichen Flowables auch besser im Seitenzahnbereich durch die höhere mechanische Belastungsfähigkeit eignen [34].

Die einfache Handhabung von fließfähigen Kompositen ermöglicht ein breites Indikationsspektrum in vielen Bereichen der Zahnmedizin, wie z.B. als Kavitätenliner, Versieglungsmaterial von Fissuren und Grübchen, zur Befestigung von kieferorthopädischen Brackets und Retainer, zur semipermanenten Schienung oder Versieglung von Wurzelfüllungen [35].

1.3 Haftverbund Komposit und Zahnhartsubstanz

1.3.1 Haftverbund am Schmelz

In der heutigen Literatur unterscheidet man den adhäsiven Haftverbund von Restaurationsmaterialien an Schmelz und Dentin aufgrund ihrer unterschiedlichen, morphologischen Grundstruktur [36,37]. Der Zahnschmelz bildet eine der härtesten Strukturen im menschlichen Körper und enthält Hydroxylapatitkristalle, welche in Schmelzprismen formiert sind. Dabei besteht er zu 94-96% aus anorganischem Hydroxylapatit und ist höher mineralisiert als das angrenzende Dentin [38,39]. Die Konditionierung des Schmelzes mit Phosphorsäure löst Schmelzprismen aus der Oberfläche und führt zu einer Oberflächenvergrößerung. Dies ermöglicht die Infiltration von Adhäsivsystemen, die anschließend durch Polymerisation einen Verbund mit dem Schmelz bilden [40,41].

1.3.2 Haftverbund am Dentin

Der adhäsive Haftverbund von Restaurationsmaterialien zum Dentin stellt aufgrund seines geringeren Mineralisationsgrades eine größere Herausforderung als beim Schmelz dar. Dentin besteht etwa 70% aus anorganischen und zu 20% aus organischen Bestandteilen, welches hauptsächlich durch Kollagen gebildet wird [42,43]. Dentintubuli durchziehen von der Pulpa bis zur Schmelz-Dentin-Grenze das Dentin s-förmig und beinhalten die Odontoblastenfortsätze.

Bei Öffnung der Dentintubuli tritt aufgrund des inneren Pulpadrucks Dentinflüssigkeit aus den Kanälen aus. Die organischen Bestandteile und die während der Präparation gebildete Schmierschicht erschweren zudem eine mikromechanische Adhäsion des hydrophoben Komposits am Dentin [44,45]. Um einen adhäsiven Haftverbund am Dentin zu realisieren, ist eine Vorbehandlung mit konditionierenden, säurehaltigen Materialien essenziell. Dabei wird die Schmierschicht chemisch entfernt, die Dentinoberfläche

demineralisiert und letztendlich Kollagenfasern freigelegt [46,47]. Ein Primer mit hydrophilen Komponenten ermöglicht die Infiltration des Kollagennetzwerks und der Dentinoberfläche. Das anschließend aufgetragene hydrophobe Adhäsiv stabilisiert das Kollagen und ermöglicht die Copolymerisation und Formierung sogenannter „Resin-Tags" innerhalb dieser entstandenen Hybridschicht, die für den adhäsiven Verbund zwischen der Dentinoberfläche und den Adhäsivmaterialien von Bedeutung sind [36,48]. Neuere Adhäsivsysteme vereinen die verschiedenen Komponenten in einer Flasche und ermöglichen dadurch eine Zeitersparnis in der Behandlung und eine geringere Techniksensitivität in der Anwendung der Adhäsivsysteme.

1.4 Adhäsivsysteme

Heutzutage werden Adhäsivsysteme grundsätzlich in zwei Gruppen unterteilt, je nach Strategie der Schmierschichtentfernung: Etch-and-Rinse-Adhäsivsysteme verwenden ein 35-40%iges Phosphorsäure zur Konditionierung von Schmelz und Dentin [49]. Im Gegensatz dazu enthalten Self-Etch-Adhäsivsysteme saure Monomere, um sowohl Dentin als auch Schmelz zu konditionieren, wodurch die zusätzliche Anwendung von Phosphorsäure nicht notwendig ist [50]. Die sauren Monomere enthalten funktionelle Gruppen, wie z.B. Carboxyl-, Phosphonat- oder Phosphatgruppen, welche mit den Kalziumionen der Hydroxylapatitkristalle interagieren [51]. Dennoch empfehlen einige Studien eine selektive Ätzung des Schmelzes mittels Phosphorsäure, da die alleinige Schmierschichtentfernung durch die sauren Monomere unzureichend für einen guten Haftverbund zu sein scheint [52]. In den letzten Jahren etablierten sich sogenannte Universaladhäsivsysteme in den zahnärztlichen Praxen, welche sich durch die Fähigkeit auszeichnen, sowohl im Etch-and-Rinse-, als auch im Self-Etch-Modus anwendbar sind. Sie besitzen eine Phosphatestergruppe als funktionelles Monomer. Besonders das 10-Methacryloyloxydecyl-Dihydrogenphosphat (10-MDP) wird aufgrund seiner besonderen Eigenschaften von vielen Herstellern als funktionelles Monomer in Universaladhäsive integriert. 10-MDP ist ein amphiphiles Monomer, das sowohl eine hydrophile als auch eine hydrophobe Komponente aufweist [53]. Die hydrophobe Methacrylatgruppe ermöglicht eine chemische Bindung an Kompositmaterialien, wohingegen die hydrophile Phosphatgruppe ionische Verbindungen an das Kalzium des Hydroxylapatits realisiert und stabile Kalzium-Phosphat-Salze bildet [53].

1.5 Klinische Anwendungskonzepte von Kompositen

Kompositmaterialien können mit unterschiedlichen Techniken in die Kavitäten eingebracht werden. Bei der Inkrementtechnik werden mehrmalig einzelne Kompositinkremente mit einer Schichtstärke von maximal 2mm in die Kavität appliziert. Jede Inkrementschicht wird dabei separat ausgehärtet, um Polymerisationsschrumpfungen entgegenzuwirken [54]. Die geringe Schichtstärke der Inkremente ermöglicht zudem die Anwendung von hochästhetischen Kompositmaterialien mit einem hohen Farbstoffanteil, da diese eine vollständige Lichtpolymerisation realisierbar machen. Diese Technik ist jedoch zeitlich aufwendig und stellt in kleinen und tiefen Kavitäten aufgrund der erschwerten Belichtung klinisch eine Herausforderung dar. Weiterhin ist durch die Applikation, Adaptation, Modellation und Aushärtung der einzelnen Inkrementschichten ein Kontaminationsrisiko vorhanden [55].

Dies führte unter anderem zur Entwicklung der Bulk-Fill-Technik, einer zeitsparenden und weniger techniksensitiven Alternative zur Inkrementtechnik. Entsprechende Bulk-Fill-Komposite besitzen im Vergleich zu herkömmlichen Hybridkompositen eine höhere Transluzenz, wodurch Schichtstärken von ca. 4mm der einzelnen Inkrementschichten ermöglicht werden [56]. Chemisch bilden Sie jedoch keine eigene Materialklasse und werden den Kompositen zugeordnet. Aufgrund der genannten Eigenschaften sind sie für die Restauration von besonders tiefen und kleinen Kavitäten im Seitenzahnbereich geeignet. Die erhöhte Transluzenz schränkt die Anwendung im Frontzahnbereich aufgrund ästhetischer Einbußen ein.

Eine klinische Langzeituntersuchung von Krämer et al. (2015) konnte für Klasse-I und Klasse-II-Kompositrestaurationen, welche in Inkrementtechnik gelegt wurden, eine Erfolgsrate von 96,9% zeigen. Diese positiven Ergebnisse gehen mit anderen Langzeitstudien für Front- und Seitenzahnrestaurationen aus Komposit einher, welche in Inkrementtechnik appliziert wurden [58-60]. Ein aktuelles systematisches Review von Sengupta et al. (2023) analysierte 18 klinische Studien mit einem Untersuchungszeitraum von 6 Monaten bis 10 Jahre und konnte vergleichbare Erfolgsraten für die Inkrement- und die Bulk-Fill-Technik detektieren.

1.6 Zielstellung

In der vorliegenden klinisch-prospektiv geplanten, randomisierten und verblindeten Studie wurde im Vorfeld ein Studienprotokoll entwickelt, das durch die Ethikkommission der Medizinischen Fakultät der Martin-Luther-Universität Halle-Wittenberg genehmigt wurde (Protokoll-Nummer: 225/17.11.10/8). Ebenfalls fand eine Registrierung im Deutschen Register für Klinische Studien mit der Kennnummer DRKS00033585 statt. In dieser Studie wurden klinische Daten von verschiedenen Materialkombinationen über einen mehrjährigen Beobachtungszeitraum erhoben und evaluiert.

Das Hauptziel der vorliegenden Studie untersuchte den Einfluss eines hochviskösen, fließfähigen Nanohybridkomposits als Kavitätenliner auf die Überlebensrate von Seitenzahnrestaurationen über einen Zeitraum von 36 Monaten.
Das erste Nebenziel beinhaltete die klinische Bewertung des verwendeten Nanohybridkomposits GrandioSO hinsichtlich verschiedener Füllungsparameter über einen Beobachtungszeitraum von 36 Monaten.
Das zweite Nebenziel umfasst die Evaluation, ob das verwendete Self-Etch-Adhäsivsystem Futurabond DC geeignet ist, einen langfristigen Erfolg der Restaurationen über 36 Monate zu gewährleisten.

Die erste Publikation fokussierte sich auf die klinischen Ergebnisse nach 24 Monaten, da bei der vorherigen Literaturrecherche der Beobachtungszeitraum der meisten Studien sich auf diese Zeitspanne festlegte. Somit sollte eine bessere Vergleichbarkeit der erhobenen klinischen Daten mit anderen Studien ermöglicht werden. Die zweite Publikation fasst die klinischen Ergebnisse nach einem Untersuchungszeitraum von 36 Monaten zusammen. In der letzten Publikation wurden die Ergebnisse unserer Studie nach drei Jahren in einem Review mit anderen klinischen Studien gegenübergestellt und verglichen. Damit sollte eine Einordnung dieser Ergebnisse in die aktuelle Literatur stattfinden.

2 Diskussion

2.1 Studiendesign und Methodik

Die vorliegende klinische Studie wurde in einem Split-Mouth-Design durchgeführt, wodurch individuelle Unterschiede in Bezug auf Risikofaktoren wie Mundhygiene, Speichelzusammensetzung und Ernährungsgewohnheiten bei den Proband:innen nahezu reduziert werden konnten [62]. Des Weiteren wurde die Studie randomisiert, kontrolliert und einfach verblindet durchgeführt, was die interne Validität der Ergebnisse erhöht [63,64]. Bei der vorliegenden Untersuchung handelt es sich um eine monozentrische Studie, in der jeweils eine Zahnärztin für den Restaurationsvorgang und ein weiter Zahnarzt für die Nachuntersuchung eingesetzt wurden. Eine erfahrene Zahnärztin erhielt vorab eine Kalibrierung für die Füllungstherapie entsprechend eines standardisierten Procederes. Die Zuteilung der restaurationsbedürftigen Zähne zu der jeweiligen Untersuchungsgruppe erfolgte zufällig. Alle Kavitäten wurden unter Kofferdamisolation versorgt und alle Materialien nach Herstellerangaben verwendet. Somit konnten individuelle Einflüsse durch mehrere Behandelnde reduziert und eine bessere Vergleichbarkeit der Restaurationen ermöglicht werden. Für die Nachuntersuchung wurde ein zweiter, erfahrener Zahnarzt, welcher nicht am Restaurationsvorgang beteiligt war, für die Auswertung der Füllungen nach den vorgegebenen Kriterien kalibriert. Klinische Nachuntersuchungen wurden 6, 12, 24 und 36 Monate nach der Baseline verblindet durchgeführt, d.h. der Zahnarzt erhielt keine Informationen über die Zuordnung der Restaurationen zur jeweiligen Untersuchungsgruppe, um eine objektive Evaluation zu steigern. Eine größere Anzahl an Proband:innen und kritischere Vergleichbarkeit könnte erweiternd durch eine multizentrische Studie realisiert werden. Das bedeutet, dass mehrere Ärzt:innen an der Studie beteiligt wären, welche einen gemeinsamen Kalibrierungsprozess durchlaufen würden und somit gleichzeitig mehrere Daten an verschiedenen Standorten generiert und im Vergleich evaluiert werden könnten.

Der Untersuchungszeitraum wurde auf 36 Monate festgelegt und ist vergleichsweise zu anderen Publikationen mit ähnlicher Fragestellung als lang einzuschätzen (s. Table 2, Publikationsteil, Publikation 3). Die Ausweitung des Beobachtungszeitraum erscheint

dennoch sinnvoll, um weitere klinische Langzeitdaten zu erheben und Ereignisse, die das Überleben der Restaurationen beeinflussen, zu detektieren.
Die konservierenden Therapiemaßnahmen mittels Füllungen wurden *in vivo* durchgeführt, weshalb weitergehende standardisierte Bedingungen der restaurationsbedürftigen Zähne nicht umzusetzen waren. Demnach konnten initiale Unterschiede aufgrund individueller Kavitätengrößen, sowie Ausprägung der kariösen Defekte oder individueller Risikofaktoren, wie Rauchverhalten oder Speichelfluss, zwischen den Patient:innen untereinander nicht ausgeschlossen werden. Ein Vorteil dieser Studie ist die Bewertung der gelegten Restaurationen unter realen und alltäglichen klinischen Bedingungen. Daher wurden auch Zähne mit einer therapiebedürftigen Caries profunda in der Studie inkludiert, um auch hier die klinische Langlebigkeit dieser Restaurationen zu untersuchen.

Als Untersuchungskriterien für die klinischen Bewertungen wurden die modifizieren USPHS-Kriterien nach Ryge (1980) festgelegt und umgesetzt (s. Table 2, Publikationsteil, Publikation 1). In den letzten Jahren etablierten sich weitere klinische Bewertungskonzepte für die Untersuchung von direkten und indirekten Restaurationen. Dabei werden die FDI-Kriterien nach Hickel et al. (2010) in vielen aktuellen klinischen Studien integriert. In einem Scoping Review von Marquillier et al. (2018) wurde die Anwendung der FDI-Kriterien in klinischen Studien in den Datenbanken von PubMed und ClinicalTrials.org von Januar 2007 bis April 2017 ausgewertet. Zum Zeitpunkt der Veröffentlichung wurden 28 Studien aktiv durchgeführt, wovon 13 Studien die USPHS-Kriterien (46,4%), 14 Studien die FDI-Kriterien (50%) und 1 Studie beide Kriterien (3,6%) als Grundlage für Ihre Untersuchungen nutzten. Diese Zahl kann jedoch schwanken, da es nicht in allen Ländern erforderlich ist klinische Studien in Datenbanken wie ClinicalTrials.org anzumelden, so auch in Deutschland. Jedoch stieg der Anteil der Studien, welche die FDI-Kriterien integrierten, von 4,5% im Jahr 2010 auf 50% im Jahr 2016 [67]. Daher ist bei weiteren geplanten klinischen Studien die Anwendung der FDI-Bewertungskriterien oder die Benutzung beider Bewertungskonzepte nach FDI und USPHS eine mögliche Alternative zu den hier alleinig genutzten USPHS-Kriterien, um eine bessere Validität zu ermöglichen. In Publikation 3 (s. Publikationsteil) wurden insgesamt 6 Studien in das Review eingeschlossen. Alle Studien nutzen die USPHS-Kriterien zur klinischen Beurteilung der

untersuchten Restaurationen (s. Table 2, Publikationsteil, Publikation 3) und ermöglichten eine verbesserte Vergleichbarkeit der Daten.

2.2 Diskussion der Ergebnisse

Nach 24 Monaten konnten 47 Patient:innen und nach 36 Monaten 46 Patient:innen erneut untersucht werden, was einer Recallrate von 94% nach 2 Jahren und 92% nach 3 Jahren entspricht. Im Vergleich zu anderen klinischen Studien, welche ebenfalls die Qualität von Restaurationsmaterialien untersuchten, sind diese Werte vergleichbar. So hatten Torres et al. (2014) eine Recallrate von 89,9% und Ernst et al. (2003) eine Recallrate von 95% im Beobachtungszeitraum von 2 Jahren. Dukić et al. (2021) hatten in ihrer 3-Jahres-Untersuchung eine Recallrate von 73,3% und Sekundo et al. (2022) 86,7% im gleichen Untersuchungszeitraum. Betrachtet man diese Werte, so ist die Recallrate von 94% nach 36 Monaten in der vorliegenden Untersuchung als vergleichsweise hoch einzuordnen.

2.2.1 Überlebensrate

Im Beobachtungszeitraum von 3 Jahren betrug die kumulative Erfolgsrate der Restaurationen beider Gruppen 95,7% [72]. Füllungen der Kontrollgruppe erhielten keine Bewertungen von Code Charlie oder Delta und wiesen demnach keine Misserfolge auf. In der Testgruppe hingegen betrug die kumulative Überlebensrate nach 3 Jahren 91,3%, was in einer AFR von 2,9% resultiert. Im Vergleich zur AFR der Testgruppe von 3,4% beim Follow-up nach 2 Jahren konnte eine Verbesserung aufgrund des längeren Beobachtungszeitraumes festgestellt werden. Die Kontrollgruppe hatte sowohl nach 24 Monaten als auch nach 36 Monaten eine AFR von 0%. In Publikation 3 wurde die kumulative Überlebensrate und AFR der Test- und Kontrollgruppen aller inkludierten Studien des Reviews zusammengefasst (s. Table 2, Publikationsteil, Publikation 3). Aufgrund der variablen Untersuchungszeiträume der Studien zwischen 2 und 7 Jahren wird nachfolgend nur die AFR betrachtet. Es konnte nur in unserer Studie ein statistisch signifikant höhere AFR in der Testgruppe mit dem Kavitätenliner im Vergleich zur Kontrollgruppe festgestellt werden. Die anderen 5 Studien [69,73-76] detektierten keine statistisch signifikanten Unterschiede der AFR beider Untersuchungsgruppen.

Ein Vergleich der vorliegenden Ergebnisse mit den Ergebnissen einer zuvor von Torres et al. (2014) veröffentlichten klinischen Studie, bei welcher die gleichen, stopfbaren und hochviskösen, fließfähigen Kompositmaterialien verwendet wurden, ergab ähnliche Ergebnisse nach 24 Monaten ohne nachweisbare Code Charlie- oder Delta-Bewertungen in der Gruppe, in der die Restaurationen nur mit dem stopfbaren Nanohybridkomposit gelegt wurden. Anders als in unserer Studie wurde die Restauration aus der Testgruppe vollständig mit GrandioSO Heavy Flow (VOCO) gelegt, wovon bereits nach 6 Monaten 2 Restaurationen als Misserfolg aufgrund eines vollständigen Füllungsverlustes eingestuft wurden [68]. Andere Autoren beschrieben weitere klinische Ansätze für die Schichtung der Füllungen, die dazu beitragen könnten, schnelle, vorhersagbare und natürlich aussehende Restaurationen zu legen und den Bedarf an okklusalen Anpassungen zu verringern [77]. Dies unterscheidet sich von unserem Ansatz des Kavitätenlinings, bei dem ein fließfähiges Komposit verwendet wird, um die Adaptation an die Kavitätenwände und das Dentin zu verbessern und hohen Polymerisationsstress zu vermeiden.

2.2.2 Feuchtigkeitskontrolle und Isolation des Arbeitsfeldes

In der vorliegenden Studie wurden die Füllungstherapien unter Anwendung eines Kofferdams zur Gewährleistung einer absoluten Trockenlegung durchgeführt. Eine aktuelle, klinische In-situ-Studie von Falacho et al. (2023) untersuchte den Einfluss der Kofferdamisolation auf den Haftverbund von Kompositrestaurationen zum Zahnschmelz. Dabei wurden 120 extrahierte Molaren in einer gefrästen Oberkieferschiene einpolymerisiert und extraoral durch Anwendung von Phosphorsäure mit einer Konzentration von 37,5% vorkonditioniert. Im Anschluss wurde die Schiene im Oberkiefer einer Probandin positioniert. Der einen Hälfte der Probezähne wurde ein Kofferdam angelegt (n=60), die andere Hälfte simulierte eine relative Trockenlegung mittels Watterollen und Speichelsauger. Nach Auftragen des Adhäsivsystems und Legen der Kompositrestauration fand eine Messung der Scherkraft mithilfe einer Universalprüfmaschine statt. Es konnten dabei sowohl beim Etch-and-Rinse-System als auch beim Universaladhäsiv statistisch signifikant bessere Haftwerte der Kompositrestaurationen festgestellt werden, die unter Kofferdamisolation gelegt wurden, im Vergleich zu den Füllungen unter relativen Trockenlegungsbedingungen. Im Gegensatz dazu konnten Cajazeira et al. (2014) in ihrem systematischen Review keinen positiven Effekt einer Kofferdamisolation auf die Langlebigkeit von

zahnfarbenen Restaurationen schlussfolgern. In Publikation 3 (s. Publikationsteil) nutze nur eine weitere eingeschlossene Studie Kofferdam zur Feuchtigkeitskontrolle während der Füllungstherapie von allen gelegten Restaurationen [73]. Eine weitere Studie nutze bei 70% der gelegten Restaurationen Kofferdam [69] und die restlichen 3 Studien verwendeten keinen Kofferdam in ihrem klinischen Studienprotokoll [74-76]. Betrachtet man die AFR aller Untersuchungen scheint die Verwendung eines Kofferdams die Langlebigkeit der Kompositrestaurationen in den entsprechenden Untersuchungszeiträumen nicht zu beeinflussen (s. Table 2, Publikationsteil, Publikation 3).

2.2.3 Schichtstärke des Kavitätenliners

Die Applikation des fließfähigen Komposits in der Testgruppe wurde vorab in unserem Studienprotokoll mit einer Schichtstärke von ca. 0,5mm definiert. In unserem Review (s. Publikationsteil, Publikation 3) machten neben unserer Studie, 3 weitere eingeschlossene Studien Angaben zur Schichtstärke des Linermaterials [80]. Dabei wurde die Schichtstärke des Kavitätenliners bei Efes et al. (2006) mit 1mm und in den Untersuchungen von van Dijken und Pallesen (2011) und Stefanski und van Dijken (2012) mit 1-1,5mm festgelegt. In-vitro-Studien vermuten einen negativen Einfluss auf die Randintegrität von Kompositfüllungen bei Zunahme der Schichtstärke des Kavitätenliners [81,82]. Alle 4 Studien, die Angaben zur Schichtstärke des Linermaterials machten, konnten keine Misserfolge aufgrund der Randadaptation verzeichnen. Eine Meta-Analyse von Cavalheiro et al. (2021) diskutierte den Zusammenhang zwischen der Schichtstärke des applizierten Linermaterials mit der Bruchfestigkeit von Kompositrestaurationen und konnte keine Korrelation feststellen, unabhängig davon, ob die Schichtstärke des Kavitätenliners unterhalb oder oberhalb von 2mm lag.

2.2.4 Zahnvitalität

Bei der klinischen Nachuntersuchung nach 24 Monaten wurden 3 Restaurationen der Testgruppe als Misserfolg aufgrund eines Vitalitätsverlustes gewertet (alle Code Delta) [84], wohingegen nach 36 Monaten keine weiteren Restaurationen hinzukamen [72]. Die entsprechenden Zähne erhielten eine endodontische Behandlung aufgrund der Ausbildung einer irreversiblen Pulpitis. Alle betroffenen Zähne wiesen bereits bei der Füllungslegung profunde kariöse Läsionen auf, weswegen eine indirekte Pulpaüberkappung mit

Kalziumhydroxid indiziert war. Im Gegensatz zum Konzept der selektiven Kariesexkavation, bei der an pulpanahen Bereich Karies belassen wird [85], wurde in der vorliegenden Studie an allen Zähnen eine vollständige Kariesexkavation durchgeführt. Vorteile der selektiven Kariesexkavation ist die Vermeidung einer Pulpaexposition, welche bei tiefen kariösen Läsionen vitalerhaltende Maßnahmen, wie z.B. eine direkte Überkappung der Pulpa oder eine partielle Pulpotomie vermeidbar macht. Laut Studienprotokoll wurden Zähne mit tiefen Kariesläsionen und der Notwendigkeit einer indirekten Pulpaüberkappung nicht ausgeschlossen. 12 von 92 Zähnen, welche nach 36 Monaten erneut untersucht wurden, erhielten eine indirekte Pulpaüberkappung, wovon 7 Zähne der Kontrollgruppe und 5 Zähne der Testgruppe zugeordnet werden. Eine klinische Langzeitstudie über einen Zeitraum von 6-8 Jahren zeigt, dass Kompositrestaurationen an endontisch behandelten Seitenzähnen häufiger versagten, als an vitalen Zähnen mit vergleichbarer Defektgröße [86]. Weitere Untersuchungen stellten hingegen vergleichbare Überlebensraten bei ein- bis zweiflächigen Kompositversorgungen mit jeweils zwei Approximalkontakten der behandelten Seitenzähne, unabhängig von der Vitalität, fest [87,88]. Nach 3 Jahren waren, neben den 3 endodontisch behandelten Zähnen, die anderen 9 Zähne unserer Untersuchung vital und zeigten klinisch eine positive Sensibilität. Die endodontisch behandelten Zähne zeigten keine klinischen Anzeichen einer Sekundärkaries oder Randdefekte und zeigten keine Indikation zur Erneuerung der Restauration, was mit den Studien einhergeht. Jedoch sollte auch hier die Ausweitung des Untersuchungszeitraum in Betracht gezogen werden, um weitere Beobachtungen hinsichtlich Sekundärkariesbildung und der Randqualitäten zu ermöglichen.

Die klinische Literatur zeigt unterschiedliche Erfolgsraten bei der indirekten Überkappung mit Kalziumhydroxidpräparaten von 58%-92% [89-91]. Die Applikation hydraulischer Kalziumsilikatzemente als Überkappungsmaterial zeigt bessere, klinische Erfolgswerte im Sinne der Vitalerhaltung der Pulpa [89-91].

Ein Vergleich mit den im Review inkludierten Studien aus Publikation 3 (s. Publikationsteil) ist begrenzt möglich, da nur 2 weitere Studien die Zahnvitalität bei den klinischen Untersuchungen evaluierten [69,73] und ebenfalls nur 2 weitere Studien auch Zähne einschlossen, welche eine indirekte Überkappung indizierten [69,75]. Diesen Umständen entsprechend ist die Wahrscheinlichkeit für Dropouts bei der Studie von Ernst et al. (2003) und unserer Studie höher. In der Testgruppe von Ernst et al. (2003) wurde eine

Restauration aufgrund des Vitalitätsverlustes nach erfolgter indirekter Pulpaüberkappung als Misserfolg bewertet. Auch in unserer Studie war die endodontische Therapie nach indirekter Pulpaüberkappung bei 3 von insgesamt 4 als Misserfolg gewerteten Zähnen die Ursache für diese Bewertung. Dies hat einen Einfluss auf die kumulative Überlebensrate und daraus resultierend auch auf die AFR.

2.2.5 Sekundärkaries, Randparameter und postoperative Hypersensibilitäten

Bezüglich der Parameter Sekundärkaries, Randadaptation, Randverfärbung und postoperative Hypersensibilitäten wurden keine Misserfolge (Code Charlie oder Delta) bei den klinischen Nachuntersuchungen nach 24 und 36 Monaten evaluiert.
Es ist bekannt, dass eine schlechte Mundhygiene eine wesentliche Rolle in der Ätiologie der Kariesentstehung darstellt [92]. Um diesen Einflussfaktor in unserer Studie zu kontrollieren, wurde neben den USPHS-Kriterien bei allen Proband:innen der Plaque- und Gingivaindex nach Silness und Loe erhoben [93,94]. Alle Patient:innen erhielten vor den Füllungstherapien eine umfangreiche Mundhygieneinstruktion und praktische Hygieneanleitungen zur Optimierung ihrer Mundhygiene. Zu jedem Untersuchungstermin wurde bei Bedarf eine professionelle, mechanische Plaquereduktion durchgeführt, welche die geringe Plaqueakkumulation und die beiden damit verbundenen Indizes bei den Untersuchungen nach 24 und 36 Monaten erklären könnte (s. Table 4, Publikationsteil, Publikation 2). Diese Maßnahmen könnten ebenfalls einen positiven Faktor auf das Ausbleiben einer Sekundärkariesbildung in allen Restaurationen unserer Studie darstellen.

Trotz erheblicher Verbesserungen bei den Adhäsivsystemen ist die chemische und mikroretentive Verbundfläche zwischen Zahnhartsubstanz und Restaurationsmaterial nach wie vor der schwächste Bereich bei Kompositrestaurationen. Ein Versagen oder eine Verschlechterung dieser Grenzfläche kann in einer verminderten, internen und marginalen Adaptation und einem anschließenden Retentionsverlust resultieren. Die Grenzfläche zwischen Zahn und Füllungsmaterial ist während ihrer Lebensdauer unterschiedlichen Belastungen ausgesetzt. Die volumetrische Schrumpfung des Kunststoffmaterials während der Polymerisation ist abhängig von den Eigenschaften des verwendeten Materials, dem Volumen des ausgehärteten Kunststoffs, der Kavitätengeometrie, der Art

und Menge des Füllstoffs, dem Polymerisationsgrad, der Konversionsrate, sowie dem Monomergehalt [95].

Einige In-vitro-Studien berichten über einen Rückgang von Mikroleakages und internen Spaltbildungen am Restaurationsrand, als auch einer gesteigerten Adaptation des Kompositmaterials an der Zahnhartsubstanz, durch die Applikation eines Flowables als Kavitätenliner zur Spannungsreduktion innerhalb der Restauration [10-12,96]. Demgegenüber konnten andere Autor:innen keine positiven Auswirkungen eines Kavitätenlinings auf die Randadaptation von Kompositrestaurationen in Laboruntersuchungen nachweisen [11,13,14]. Diese Ergebnisse korrespondieren mit den Daten aus anderen klinischen Studien und unseren Ergebnissen [31,97]. Ein positiver Einfluss eines Kavitätenlinings mit einem hochviskösen Flowable konnte in Bezug auf die Randadaptation nach 3 Jahren in unserer Untersuchung nicht beobachtet werden.

Bei der Beurteilung der Randverfärbungen konnte bei der Nachuntersuchung nach 36 Monaten ein statistisch signifikanter Unterschied zwischen beiden Untersuchungsgruppen festgestellt werden ($p<0,05$; Mann-Whitney-U-Test). Randverfärbungen wurden in der Kontrollgruppe (5xCode Beta) häufiger bewertet als in der Testgruppe (3xCode Beta), die ein Kavitätenlining erhielt (s. Table 4, Publikationsteil, Publikation 2). Einige Studien belegen, dass die Vorkonditionierung der Schmelzränder mit Phosphorsäure eine bessere Integrität der Ränder ermöglicht [98] und entsprechend weniger Randverfärbungen gebildet werden [99]. In der vorliegenden Studie wurden alle Restaurationen in beiden Gruppen mit dem Adhäsivsystem im Self-Etch-Modus ohne vorherige Konditionierung der Zahnhartsubstanz eingesetzt. Dies könnte das vergleichsweise höhere Auftreten von Randverfärbungen in beiden Gruppen (Kontrollgruppe: 10,9%; Testgruppe: 6,5%) erklären. Allerdings fehlt eine weitere Kontrollgruppe zur Bewertung dieses Punktes, in der eine Vorbehandlung mit Phosphorsäure durchgeführt wurde. Derzeit existieren noch keine Studien, welche den Einfluss eines Kavitätenlinings bei Kompositrestaurationen auf die Randverfärbung untersucht haben. Im Vergleich zu der vorliegenden Untersuchung wurden größere Unterschiede in anderen Publikationen beobachtet: während in der Studie von Torres et al. (2014) mit dem gleichen Kompositmaterialien GrandioSO und GrandioSO Heavy Flow Code Bravo bei 39,5% in der Testgruppe und 32,5% in der Kontrollgruppe festgestellt wurde, evaluierten Ernst et al. (2003), welche ein Etch-and-Rinse-Adhäsivsystem verwendet haben, bei 23,6% in der Testgruppe und 32,1% in der

Kontrollgruppe Code Bravo. Betrachtet man auch die Ergebnisse aller inkludierten Studien unseres Reviews (s. Table 3, Publikationsteil, Publikation 3) waren Randverfärbungen nicht ursächlich für Misserfolge. Das in der vorliegenden Studie verwendete Self-Etch-Adhäsivsystem zeigte in in-vitro-Studien vergleichbare Haftverbundwerte am Dentin im Vergleich zu Etch-and-Rinse-Systemen [100,101], was das Ausbleiben einer Bewertung mit Code Charlie in beiden Gruppen erklären könnte (s. Table 4, Publikationsteil, Publikation 2). Randverfärbungen könnten durchaus den Beginn eines Debondingprozesses darstellen, welcher zu einer Spaltbildung am Füllungsrand führen kann. Darüber hinaus existieren Studien, die aufzeigen, dass nach initialer Randspaltbildung am Restaurationsrand die Bildung einer Sekundärkaries länger als 3 Jahre andauern kann [62,81-83], weshalb ein noch längerer Untersuchungszeitraum sinnvoll erscheint.

Postoperative Hypersensibilitäten werden in der adhäsiven Zahnheilkunde immer noch als mögliche Komplikation nach einer Füllungstherapie beobachtet [102,103]. Als mögliche Ursache werden unter anderem Präparationsmaßnahmen, eine übermäßige Trocknung der Dentintubuli, eine Polymerisationsschrumpfung der Kompositmaterialien, die Bildung von Randspalten, eine unzureichende Benetzung der Dentinoberflächen mit den Adhäsivsystemen oder vorbestehende Risse in der Zahnhartsubstanz diskutiert [104]. Die Anwendung von Self-Etch-Adhäsiven soll aufgrund ihres niedrigeren pH-Wertes im Vergleich zu Phosphorsäure weniger aggressiv auf die Dentinoberflächen wirken und das Auftreten von postoperativen Hypersensibilitäten einschränken [105]. Mehrere klinische Studien konnten keine Unterschiede zwischen Total-Etch-, Self-Etch- oder Universaladhäsiven in der Ausbildung von postoperativen Überempfindlichkeiten beobachten [106-108]. Yousaf et al. (2014) detektierte ebenfalls keine vorteilhaften Effekte durch ein zusätzliches Kavitätenlining mit einem Flowable, was mit den Ergebnissen der vorliegenden Studie einhergeht.

2.2.6 Füllungsintegrität, Approximalkontakt, Farbanpassung und Oberflächenrauigkeit

Nach 24 Monaten konnten keine Misserfolge hinsichtlich der Füllungsintegrität, des Approximalkontaktes, der Farbanpassung und der Oberflächenrauigkeit detektiert werden; alle Restaurationen aus beiden Gruppen wurden mit Code Alpha oder Beta bewertet. Lediglich 2 Füllungen der Testgruppe erhielten aufgrund einer sondierbaren, aber nicht sichtbaren Rissbildung in der Füllung eine Bewertung mit Code Beta im Parameter

Füllungsintegrität (s. Table 4, Publikationsteil, Publikation 2). Bei der Evaluation nach 36 Monaten entwickelte eine der beiden Restaurationen eine durchgängige und klinisch sichtbare Rissbildung, welche laut den USPHS-Kriterien einem Code Charlie entspricht und somit als Misserfolg evaluiert wurde. Bezüglich den Parametern Approximalkontakt, Farbe und Oberflächenqualität wurden keine Veränderungen verzeichnet.
Eine erhöhte Bruchfestigkeit von Kompositrestaurationen durch die zusätzliche Anwendung eines fließfähigen Kompositmaterials als Kavitätenliner konnte in diversen In-vitro-Untersuchungen nicht nachgewiesen werden [83,109,110]. Diese Erkenntnisse stimmen mit den Ergebnissen von allen eingeschlossenen Studien der Publikation 3 bezüglich der Parameter Füllungsintegrität und Anatomische Form (s. Table 3, Publikationsteil, Publikation 3), bei denen keine statistisch signifikanten Unterschiede zwischen den beiden Testgruppen detektiert wurde.

2.3 Zusammenfassung

Drei Restaurationen der Testgruppe, welche ein zusätzliches Kavitätenlining mit einem Flowable erhielten, wurden bereits nach 12 Monaten Nachuntersuchung aufgrund eines Vitalitätsverlustes als Misserfolg beurteilt. Eine weitere Restauration aus der Testgruppe wurde aufgrund einer durchgängigen Rissbildung als weiterer Misserfolg bewertet. Unter Berücksichtigung der endodontischen Ursache dieser Misserfolge zeigte das Nanohybrid-Kompositmaterial über den Beobachtungszeitraum von 3 Jahren gute, klinische Ergebnisse bei der Versorgung von Seitenzähnen. Die zusätzliche Anwendung des Flowables als Kavitätenliner in der Testgruppe resultierte letztlich in einer signifikant erhöhten AFR (2,9%) im Vergleich zur Kontrollgruppe (0%; $p<0,05$; Mann-Whitney-U-Test). Entsprechend unseres Hauptziels kann man zusammenfassen, dass ein Kavitätenlining mit einem hochviskösem Flowable keinen klinisch signifikanten Einfluss aus die Überlebensrate von Kompositrestaurationen von Klasse-I- und Klasse-II-Kavitäten hat, wenn die Vitalität nicht als entscheidender Parameter eingebunden wird. Ein Zusammenhang kann mit dem Einschluss von Zähnen mit einer Caries profunda hergestellt werden. Ein längerer Beobachtungszeitraum könnte weitere Unterschiede zwischen beiden Untersuchungsgruppen aufzeigen und den Einfluss von hochviskösen, fließfähigen Kompositen auf die Erfolgsrate von Seitenzahnrestaurationen detektieren.

Das erste Nebenziel evaluierte ebenfalls das Nanohybridkomposit GrandioSO als Restaurationsmaterial in Seitenzähnen entsprechend den modifizierten USPHS-Kriterien über einen Untersuchungszeitraum von 3 Jahren. Neben den Unterschieden bezüglich der Zahnvitalität, der Überlebensrate, der Randverfärbung und der AFR konnten keine statistisch signifikanten Auswirkungen des fließfähigen Komposits auf die anderen untersuchten Parameter beobachtet werden. Daher scheint die Anwendung von GrandioSO ein geeignetes Restaurationsmaterial in Klasse-I- und Klasse-II-Kavitäten zu sein.
Das zweite Nebenziel untersuchte die Leistung von Futurabond DC als Self-Etch-Adhäsivsystem für Klasse-I- und Klasse-II-Restaurationen. Aufgrund des Ausbleibens einer Sekundärkaries- und Randspaltbildung in allen gelegten Restaurationen, lässt sich zusammenfassend sagen, dass die Anwendung des Self-Etch-Adhäsivsystems ebenfalls gute klinische Werte bei direkten Kompositrestaurationen in Seitenzahnbereich ermöglicht.

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4 Thesen

1. Das Hauptziel dieser Studie war es, den Einfluss einer zusätzlichen Schicht eines hochviskösen, fließfähigen Kompositmaterial als Kavitätenliner auf die Überlebensrate von Klasse-I- und Klasse-II-Restaurationen zu untersuchen.

2. In Hinblick auf die jährliche Überlebensrate stellt ein Kavitätenlining mit einem hochviskösen Flowable eine mögliche Behandlungsoption in der Füllungstherapie dar, deren Nutzen anhand klinischer Daten belegt werden sollte.

3. Die zusätzliche Applikation eines hochviskösen, fließfähigen Komposits als Kavitätenliner hatte keinen positiven oder negativen Einfluss auf die Überlebensrate von Kompositrestaurationen in Klasse-I- und Klasse-II-Kavitäten.

4. Die additive Anwendung eines hochviskösen Flowables in der klinischen Zahnmedizin ist somit durchaus möglich, bietet jedoch nicht die erwarteten klinisch signifikanten Verbesserungen.

5. Das erste Nebenziel evaluierte klinisch das verwendete Nanohybridkomposit entsprechend den USPHS-Kriterien für Kompositrestaurationen und zeigte, dass das verwendete Material sehr gute Bewertungen über 3 Jahre im Seitenzahnbereich zeigte.

6. Die höhere Viskosität des Flowables GrandioSO Heavy Flow beeinflusst im Vergleich zu herkömmlichen Flowables nicht die Langlebigkeit von Kompositrestaurationen im Seitenzahnbereich.

7. Ein Kavitätenlining mittels hochviskösem, fließfähigem Komposit hat keinen statistisch signifikanten Einfluss auf die Randspaltbildung, Randverfärbung, Randadaptation oder die Bildung einer Sekundärkaries bei Klasse-I- und Klasse-II-Kompositrestaurationen.

8. Die im zweiten Nebenziel evaluierte klinische Performance des verwendeten Self-Etch-Adhäsivsystems zeigte, dass der Verbund nach Anwendung des Self-Etch-Modus keinen negative Folgen für die Qualität der direkten Kompositrestaurationen im Seitenzahnbereich nach sich zog.

Publikationsteil

Publikation 1

Clinical Outcome of Class I and II Restorations with and without an Intermediary Layer of a Flowable Composite after 24 Months: A Prospective, Randomized, Split-Mouth-Designed, Controlled and Single-Blinded Clinical Trial

Christian Ralf Gernhardt, **Anh Duc Nguyen**, Mary Michaelis, Natalie Pütz

Applied Sciences, 2023, 13, 4224

https://doi.org/10.3390/app13074224

Publikation 2

Influence of Cavity Lining on the 3-Year Clinical Outcome of Posterior Composite Restorations: A Randomized Controlled Clinical Trial

Anh Duc Nguyen, Natalie Pütz, Mary Michaelis, Kerstin Bitter, Christian Ralf Gernhardt

Dentistry Journal, 2024, 12, 128

https://doi.org/10.3390/dj12050128

Publikation 3

Class-I and Class-II Restorations with the Application of a Flowable Composite as an Intermediate Layer—A Narrative Review of Clinical Trials

Anh Duc Nguyen, Kerstin Bitter, Christian Ralf Gernhardt

Journal of Functional Biomaterials, 2025, 16, 111

https://doi.org/10.3390/jfb16030111

Anteilserklärung an den erfolgten Publikationen

Der Doktorand hatte folgenden Anteil an den Publikationen:

Publikation 1

Beitrag im Einzelnen: Mitarbeit bei der Datenauswertung und Statistikerstellung, der Visualisierung der Daten, der Literaturrecherche und Erstellung des Literaturverzeichnisses, der Verfassung des Papers, der Einreichung des Manuskripts beim Journal und Korrekturen im Rahmen eines Peer-Review-Verfahrens.

Publikation 2

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Article

Clinical Outcome of Class I and II Restorations with and without an Intermediary Layer of a Flowable Composite after 24 Months: A Prospective, Randomized, Split-Mouth-Designed, Controlled and Single-Blinded Clinical Trial

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Abstract: The aim of this clinical study was to evaluate the impact of an additional use of a flowable composite on the clinical success of Class I and II composite restorations. Furthermore, different clinical criteria were recorded to determine if the combination with a flowable material shows significant advantages compared to the composite material alone. In 50 patients, one cavity was solely filled with a nano-hybrid composite (control group) and the second cavity in combination with an additional layer of flowable composite (test group) using a universal adhesive system in the self-etch modus. Clinical assessments were performed according to the modified criteria proposed by USPHS/Ryge. After 24 months, 47 patients were examined resulting in a recall rate of 94%. The cumulative survival rate for all restorations after 24 months was 96.8%. Three restorations (3.2%) failed due to the loss of vitality. All failed restorations were located in the test group (6.4%), and none in the control group (0%). This resulted in a cumulative success rate in the control group of 100% and 93.6% in the test group, showing a significantly different annual failure rate (AFR) of 0% and 3.2%, respectively ($p < 0.05$; Mann–Whitney U-test). Beside the differences regarding the tooth vitality, success rate, and AFR, no significant influence of the flowable composite on the different evaluated clinical parameters could be detected. Therefore, the application of an additional layer of the flowable composite might have neither a positive nor a negative effect on composite restorations in clinical practice.

Keywords: composite resin; dental restoration; flowable composite; randomized clinical trial; modified USPHS/Ryge criteria

Citation: Gernhardt, C.R.; Nguyen, A.D.; Michaelis, M.; Pütz, N. Clinical Outcome of Class I and II Restorations with and without an Intermediary Layer of a Flowable Composite after 24 Months: A Prospective, Randomized, Split-Mouth-Designed, Controlled and Single-Blinded Clinical Trial. *Appl. Sci.* **2023**, *13*, 4224. https://doi.org/10.3390/app13074224

Academic Editor: Angela Pia Cazzolla

Received: 12 March 2023
Revised: 24 March 2023
Accepted: 25 March 2023
Published: 27 March 2023

1. Introduction

Today, resin-based direct composite restorations in the posterior teeth have become a well-established and common procedure in dental practice [1–3]. These restorations meet the demands of the patient and the practitioner for an aesthetic and minimally invasive therapeutic concept. Marginal adaptation followed by secondary caries is still a well-known problem with composite restorations, in particular on the approximal wall of Class II restorations [4]. Insufficient marginal sealing has been correlated with postoperative sensitivity, restoration failure, and secondary caries [5]. Furthermore, the main intention of using flowable composites as cavity liners is to avoid occlusal and particularly approximal leakage.

However, the effect of flowable composites applied as cavity liners on the long-term success of composite restorations remain inconclusive and no common consensus exists [4,6–10]. Despite the limited scientific evaluation, there is an increased use in the general practice of a flowable resin composite as a cavity lining and stress-relieving gingival increment in Class I and II restorations [11–13]. The flowable composite (Grandio®SO

Heavy Flow) used in the present study is a flowable nano-hybrid composite with a higher viscosity (Table 1). Due to these properties, it could be used as a flowable composite lining in the posterior teeth instead of a conventional flowable composite when increased strength is required [14]. While some flowable composites in combination with conventional composite materials have already produced promising in vitro results and good clinical experience [1,15,16], clinical data for a flowable composite exhibiting a higher viscosity are scarce. Considering the positive in vitro studies of a high-viscosity composite [17,18], it was the aim of the present study to test the clinical performance of such a material as a cavity liner.

Table 1. Material properties of the composites used in this study.

Parameter	Grandio®SO Heavy Flow (VOCO GmbH, Cuxhaven, Germany)	Grandio®SO (VOCO GmbH, Cuxhaven, Germany)
Main components	Monomers: Bis-GMA, Bis-EMA, TEGDMA Fillers: glass ceramic, functionalized SiO_2 nanoparticles	Monomers: Bis-GMA, Bis-EMA, TEGDMA Fillers: glass ceramic, functionalized SiO_2 nanoparticles
Filler degree	83 wt.% = 68 vol.%	89 wt.% = 73 vol.%
Modulus of elasticity	11,850 MPa	16,650 MPa
Shrinkage	2.96 =%	1.61%
Compressive strength	417 MPa	439 MPa
Flexural strength (3 point)	159 MPa	187 MPa
Surface hardness	175 MHV	211 MHV
Curing depth (800 mW/cm^2)	>2.5 mm/20 s	>2.8 mm/20 s

Therefore, the objective of the study was to determine whether the additional use of a flowable composite in combination with a nano-hybrid composite is suitable for the restoration of Class I and II occlusion-bearing cavities and that the combination of both increased the performance of the restorations.

The following main hypothesis was stated:

1. The main objective of this study was to investigate the impact of an additional use of a flowable composite layer (Grandio®SO Heavy Flow) in combination with a nano-hybrid composite (Grandio®SO) on the clinical success of Class I and II restorations.

The objectives of the study were as follows:

1. The differences in different criteria (secondary caries, tooth vitality, postoperative sensitivity, filling integrity/fracture, proximal contact, surface roughness, marginal adaption, marginal discoloration, and color match) should be identified.
2. Is the dentin-bonding system Futurabond® DC (VOCO GmbH, Cuxhaven, Germany) used in the self-etch modus capable of ensuring a long-lasting seal of the fillings in the enamel and dentin over time? Can Futurabond® DC effectively prevent postoperative pain?
3. How does the nano-hybrid composite Grandio®SO, which has been on the market since 2010, perform in terms of abrasion, shade stability, and surface roughness in occlusal-loaded Class I and II cavities?

2. Materials and Methods

2.1. Study Design

Fifty patients who had at least two premolars or molars requiring Class I or II restorations were included in the present study. The study design was approved by the Ethic Committee of the Martin Luther University Halle-Wittenberg, Germany (protocol number: 225/17.11.10/8). All patients received verbal and written information on the study and signed consent forms to participate. The inclusion criteria for this study were as follows: Patients had to be at least 18 years old, with a restorative need of at least two Class I or II restorations in molars or premolars and also have a positive vitality. Furthermore, these

included teeth should be in antagonistic contact and, for Class II restorations, in contact with adjacent teeth. The bucco-oral extent of the cavities should be at least 1/3 of the cusp distance. Teeth with deep carious lesions receiving indirect pulp capping were, following the study protocol, also included. Indirect pulp capping was performed using a calcium hydroxide preparation (Calcicur®, VOCO GmbH, Cuxhaven, Germany). The subjects agreed to receive restorations as part of the study and signed the informed consent form. The following criteria led to the exclusion of participation: severe systemic diseases, proven allergies to the ingredients, bruxism, pregnancy or lactation period, and poor oral hygiene (e.g., plaque index > 1 and gingival index > 0), or not completed hygiene phase. Included teeth must demonstrate sound pulpal conditions; this means teeth with signs of pulpal inflammation, endodontic treatment, or direct pulp capping are excluded. Patients who were not expected to be able to attend the recall appointments were also excluded.

2.2. Clinical Procedure

Treatment planning included a medical history, dental examination, and initial radiographic diagnosis to evaluate restorative needs, caries lesions, and apical pathologies. As the clinical investigation was planned in a split-mouth design, two almost comparably sized defects were selected per patient, which were randomly assigned to the respective treatment group (control and test group). Photographs of the teeth before and after restoration were taken. The fillings of the control group were placed with the nano-hybrid composite. In the test group, an additional dentin-covering layer of Grandio®SO Heavy Flow was applied. Isolation of the tooth to be restored was ensured by the use of rubber dam. Cavity preparations were performed using 80 µm diamonds and the cavity margins were finished using 25 µm diamonds. If necessary, after removal of the insufficient filling or caries, a punctual indirect capping of the areas close to the pulp was performed using $Ca(OH)_2$ preparation. After cavity preparations, Futurabond® DC, used in self-etch modus, was scrubbed into the tooth with a microbrush for at least 20 s, starting on enamel. The applied material was blown by a stream of air removing excess and forming a thin, homogeneous, and glossy film on the surface, which was polymerized for 10 s with a high-power LED light unit (Celalux® 2, VOCO GmbH, Cuxhaven, Germany). The fillings of the control group were layered in single increments of maximum 2 mm thickness of the nano-hybrid composite. In the test group, a thin dentin-covering layer of maximum 0.5 mm flowable composite was applied to all cavity walls and polymerized beforehand. Each increment was polymerized for 30 s using the above-mentioned polymerization device. The fillings were then finished with fine-grained diamonds (Komet, Brasseler, Lemgo, Germany) and polished to a high gloss with polishers (Diamanto®, VOCO GmbH, Cuxhaven, Germany) under maximum water cooling. Finally, fluoridation with Bifluorid 12® (VOCO GmbH, Cuxhaven, Germany) was applied on the restored teeth. All restorations were placed by one experienced dentist.

2.3. Report (Baseline, 6 Months, 12 Months, 24 Months)

All follow-up examinations were performed by one blinded experienced and instructed examiner. The baseline examination was performed approx. 2 weeks after the filling was placed, the first follow-up examination was repeated after 6 months, and the second follow-up examination after 12 months. If necessary, professional tooth cleaning or filling polishing was done. Photo documentation was performed using a digital reflex camera (Canon EOS 60D, EF-S 60 mm f/2.8 Macro USM, Canon, Tokyo, Japan) at baseline and all phases of follow-up. The clinical evaluation was based on the modified USPHS/Ryge criteria (Table 2) [19–21]. The lateral view of the test teeth in occlusion as well as the single occlusal view were documented photographically. In addition, the following findings were recorded: pulp status per cold vitality test (Endo-Frost®, Roeko, Langenau, Germany), postoperative sensitivity, marginal discoloration, marginal adaptation, secondary caries, contact situation, surface texture, shade adaptation, proximal contacts, fracture of the

restoration, loss of filling as well as gingival index (GI), and proximal plaque index (PI) proposed by Silness and Löe, 1964 (Table 3) [22,23].

Table 2. Summary of the modified USPHS/Ryge criteria used for the clinical evaluation.

		Modified USPHS/Ryge Criteria
Secondary caries	Alpha	No clinical diagnosis of caries along the margin of the restoration
	Delta	Clinical diagnosis of caries
Tooth vitality	Alpha	Positive
	Delta	Negative
Postoperative sensitivity	Alpha	No hypersensitivity
	Bravo	Complaints only for a short time after placement, no treatment necessary
	Charlie	Medium complaints, no treatment necessary
	Delta	Permanent complaints, bearable, treatment planned
Filling integrity/fracture	Alpha	No chipping, cracking or wear of the filling material
	Bravo	Chipping (>100 µm), crack formation, detectable with a probe
	Charlie	Continuous crack formation, wear > 200 µm
	Delta	Bulk fracture of the restoration
Proximal contact	Alpha	Contact is tight, and it is possible to place one metallic matrix band (50 µm) between the restoration and the adjacent tooth
	Bravo	Contact is slight, and it is possible to pass two metallic matrix bands (50 µm), or contact is too strong (metallic matrix band cannot be placed)
	Charlie	Contact is too slight, but no trauma of the papilla
	Delta	Trauma of papilla (Food impaction)
Surface roughness	Alpha	Surface is smooth, and the adjacent tissues showed no irritation
	Bravo	Surface of the restoration is slightly rough or pitted but can be refinished
	Charlie	Surface is deeply pitted or shows irregular grooves, which were not related to the natural anatomy and could not be refinished
	Delta	Surface is fractured or flaking
Marginal adaptation	Alpha	No visible evidence of a crevice along the margin into which an explorer will catch
	Bravo	The explorer catches a crevice along the margin, but there is no exposure of dentin or base
	Charlie	Visible evidence of a crevice with exposure of dentin or base
	Delta	The restoration is fractured, mobile, or missing
Marginal discoloration	Alpha	No existing marginal discoloration at all
	Bravo	Presence of discoloration at the margins between the restoration and the tooth structure; discoloration does not penetrate along the margins of the restoration toward the pulp
	Charlie	The discoloration penetrated along the margins in a pulpal direction
Color match	Alpha	The restoration cannot be detected with a mirror
	Bravo	The restoration is visible, but there is no mismatch in color, shade, and/or translucency between the restoration and the adjacent tooth structure
	Charlie	There is a mismatch in color, shade, or translucency, but not outside the normal range of tooth color, shade, and/or translucency
	Delta	The mismatch is outside the normal range of tooth color, shade, and/or translucency

Table 3. Plaque index and gingival index (Silness and Löe).

Grade	Plaque Index	Gingival Index
0	No plaque	No swelling
1	Thin visible plaque, difficult to identify	Mild swelling, no swelling after gentle probing
2	Thick visible plaque, easily detected	Moderate to severe gingival swelling, bleeding after air drying
3	Presence of plaque filling the interproximal region	Severe inflammation; redness and edema; ulceration; spontaneous bleeding tendency

2.4. Statistical Analysis

The sample size was calculated upon the assumption that the primary endpoint (annual failure rate) will be 1.5 in the test group and 2.1 in the control group with a standard deviation of 1 in both groups. This clinically relevant difference can be detected with 80% power by a *t*-test to the 5%-level if 44 patients (44 restorations per arm using split-mouth design) will be included. To allow some moderate dropout, 50 patients (50 restorations per arm) were included.

Statistical analysis was performed by SPSS® 25.0 (IBM®, Ehningen, Germany). To determine statistically significant differences between investigated groups, the Mann–Whitney U-test was used at a 5% level of significance.

3. Results

3.1. Study Population

In the study, 29 female and 21 male patients (Figure 1) were initially included and restored with 100 Class I and II restorations (Figure 1).

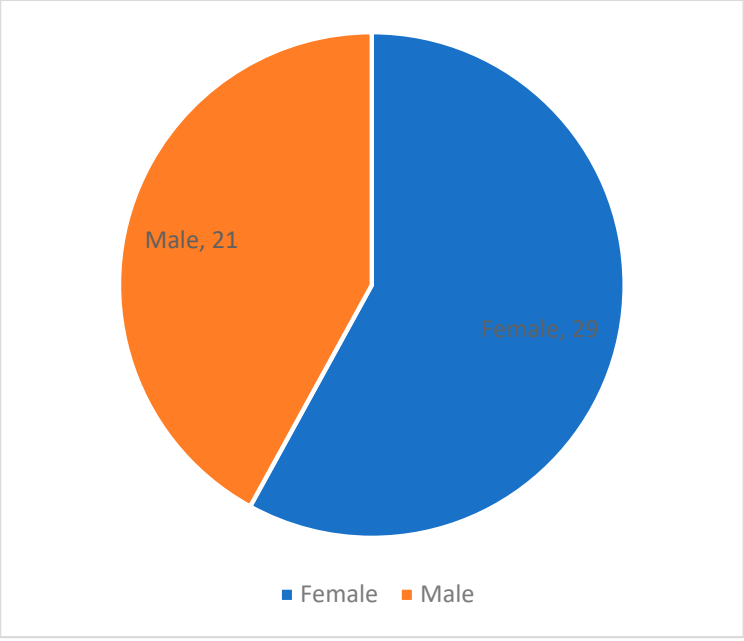


Figure 1. Gender distribution of the included patients.

In total, 32 Class I and 68 Class II fillings were placed at baseline, with a ratio of 20:30 in the control group and 12:38 in the test group (Figure 2).

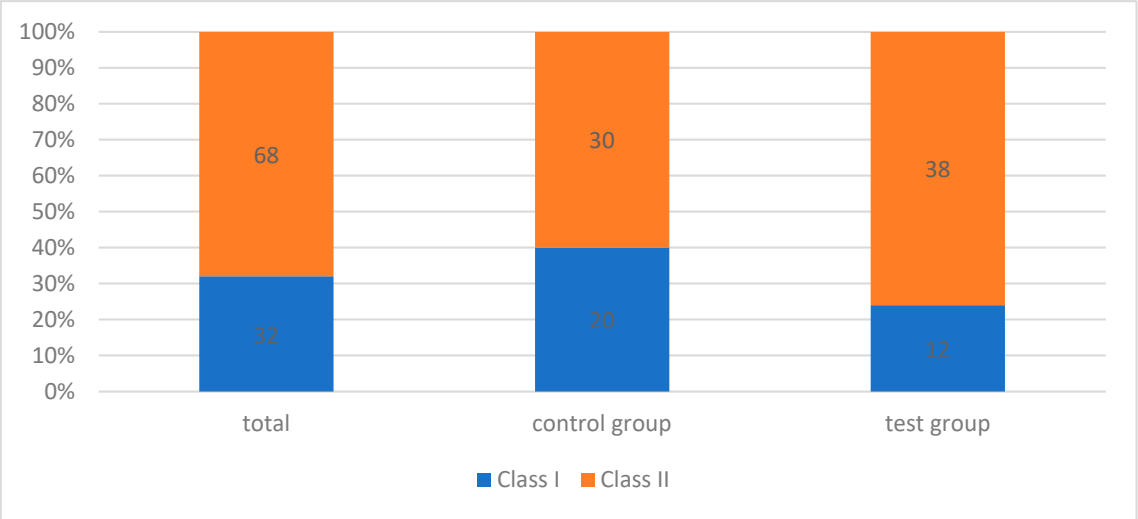


Figure 2. Black's classification of dental lesions included in the study.

Of the total 42 premolars, 22 teeth and, of the total 58 molars, 28 cavities were assigned to the control group (Figure 3).

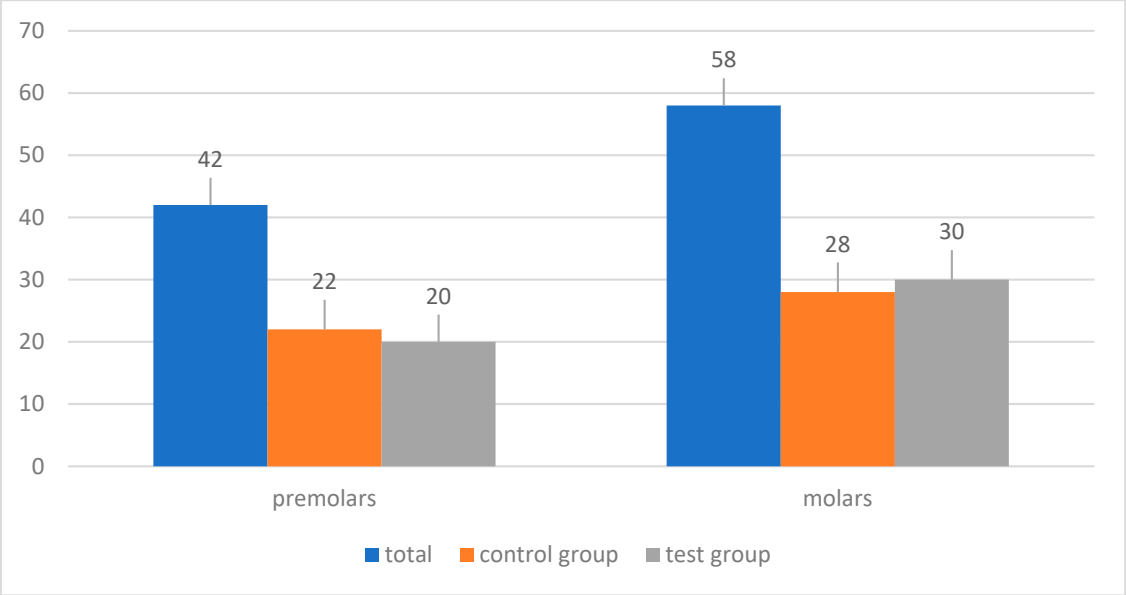


Figure 3. Distribution of the study teeth at baseline.

3.2. Success after 24 Months

After 24 months, 47 patients out of 50 could be followed up. This is equivalent to a recall rate of 94%. At this point, 28 female and 19 male patients with 94 Class I and Class II restorations could be re-examined. Altogether, 30 Class I and 64 Class II fillings with a contribution of 19:28 in the control group and 11:36 in the test group were evaluated. The cumulative survival rate for all restorations after 24 months was 96.8%. Three restorations (3.2%) failed. Three of the failed restorations were located in the test group (6.4%), and none in the control group (0%), resulting in a cumulative success rate in the control group of 100% and 93.6% in the test group. Finally, these findings resulted in significantly different annual failure rates (AFR) of 0% and 3.2%, respectively ($p < 0.05$; Mann–Whitney U-test).

3.3. Secondary Caries

After 24 months, none of the 94 restorations in both groups (the control and test group) exhibited any signs of secondary caries (Table 4).

Table 4. Summary of evaluated parameters (A = Alpha, B = Bravo, C = Charlie, and D = Delta).

Parameter	Control Group (n = 47)	Test Group (n = 47)
Secondary caries	47 × Code A	47 × Code A
Tooth vitality	47 × Code A	44 × Code A; 3 × Code D
Postoperative sensitivity	47 × Code A	47 × Code A
Filling integrity/fracture	47 × Code A	45 × Code A; 2 × Code B
Proximal contact	47 × Code A	47 × Code A
Surface roughness	47 × Code A	47 × Code A
Marginal adaption	47 × Code A	46 × Code A; 1 × Code B
Marginal discoloration	45 × Code A; 2 × Code B	44 × Code A; 3 × Code B
Color match	47 × Code A	47 × Code A
Plaque index	42 × Index 0; 5 × Index 1	42 × Index 0; 5 × Index 1
Gingival index	45 × Index 0; 2 × Index 1	45 × Index 0; 2 × Index 1

3.4. Tooth Vitality

Following the initial restoration, three out of 94 teeth required endodontic treatment (Code Delta). Therefore, they were recorded as failures. The suffering teeth were located in the test group. The other 91 included teeth showing a positive vitality of the pulp (Table 4).

3.5. Postoperative Sensitivity

With the exception of the three endodontically treated teeth, all the teeth examined showed regular sensitivity after two years. Immediately after filling therapy, nine patients reported increased sensitivity to temperature and biting (Code Bravo). However, the complaints were of short duration, so no additional treatment was indicated. At the time of the baseline examination, the patients reported a clear improvement. Six months after the filling therapy, no increased sensitivity of the restored study teeth was detectable (Code Alpha). The clinical re-examination after 24 months showed no signs of increased sensitivity. Therefore, it was rated as Code Alpha in all cases (Table 4).

3.6. Filling Integrity/Fracture

Two fillings of the test group showed a discreet chipping of the superficial composite material of the distal margin at the first re-examination after 12 months (Code Bravo). After the smoothing and polishing of the defect, the fillings could remain in situ without the loss of proximal contact or other functions. This situation showed satisfactory stability after 24 months and was scored again as Code Bravo (Table 4).

3.7. Marginal Discoloration

Regarding marginal discoloration, after 6 months, the included restorations showed three discolored filling margins in two patients (Code Bravo). One restoration was found in the control and two in the test group. Between 12 and 24 months, this number increased to four patients and finally five restorations revealed the marginal discoloration of the filling margins (Code Bravo). The ratio, based on the distribution of the investigated groups, is now 2:3 (Figure 4). The difference was not statistically different ($p > 0.05$, Mann–Whitney U-test, Table 4).

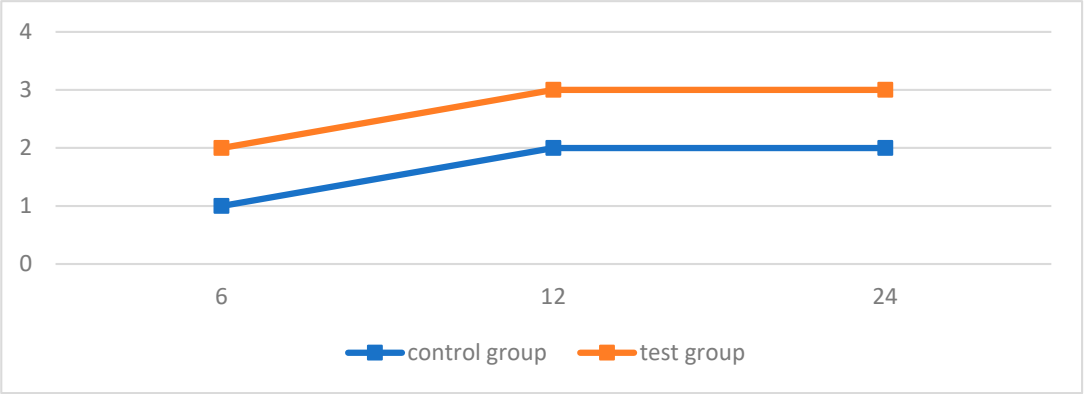


Figure 4. Marginal discoloration within both groups.

3.8. Other Parameters

The examinations of proximal contact, surface roughness, marginal adaption, and color match showed no abnormalities in the control group after 24 months. Regarding the parameter marginal adaption, one restoration was rated as Code Bravo in the test group. (Table 4). The statistical comparison of both groups regarding these parameters showed no significant differences ($p > 0.05$, Mann–Whitney U-test) (Figures 5–7).

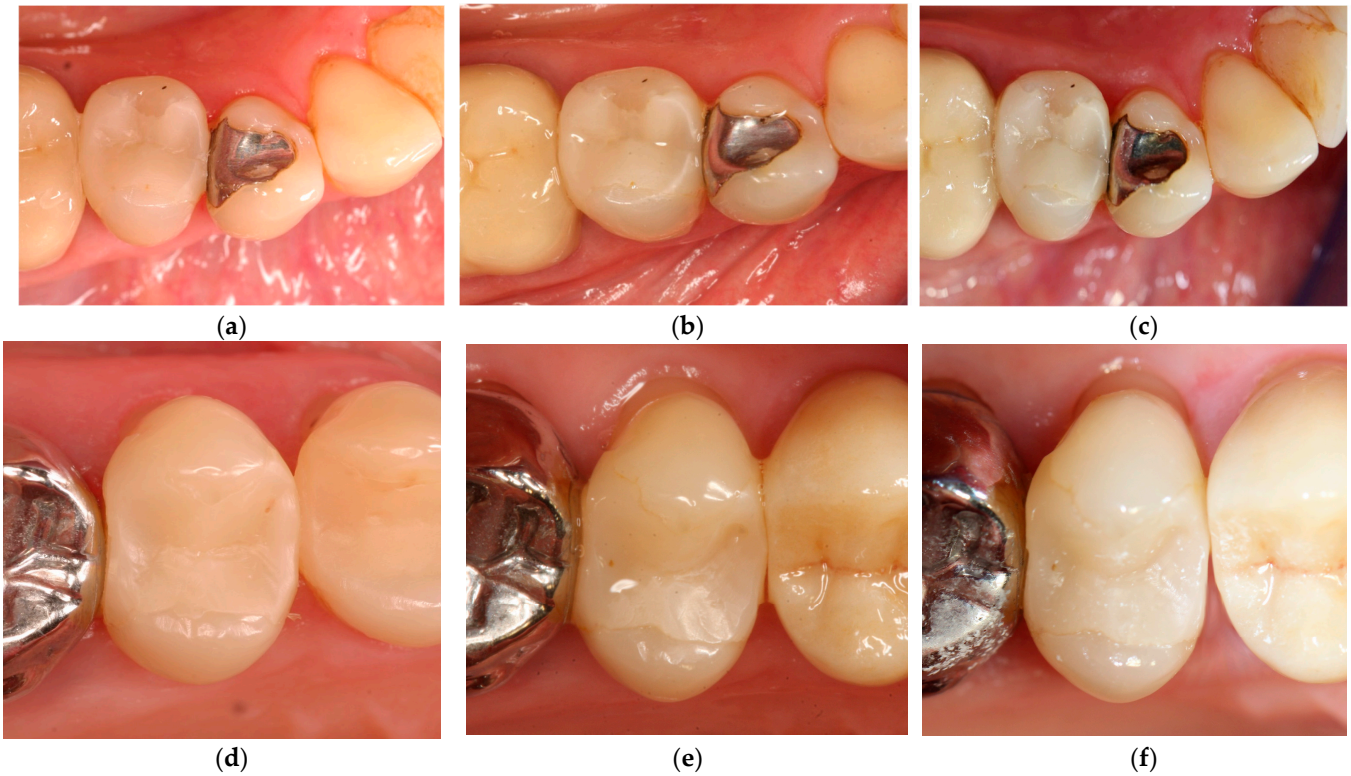
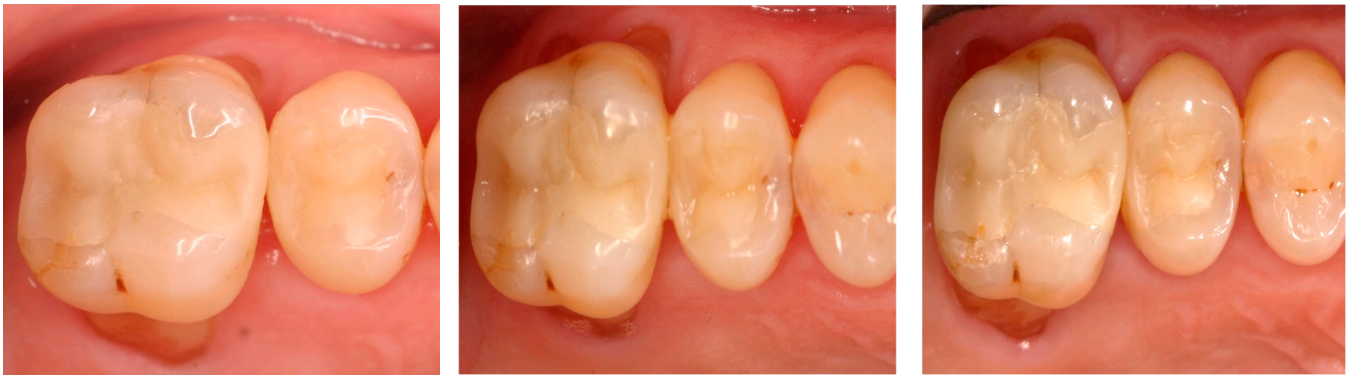
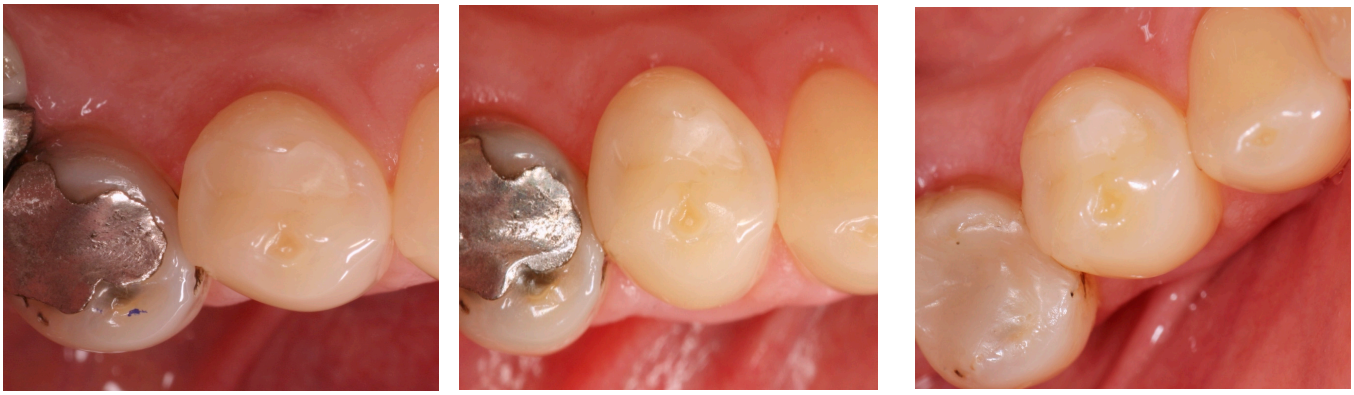


Figure 5. Clinical situation of Pat. No. 16: filling 45 mod without flowable composite: control group, all criteria were rated Code Alpha: (**a**) baseline; (**b**) after 12 months; and (**c**) after 24 months. Clinical situation of filling 15 mod with flowable composite as intermediate liner: test group, all criteria Code Alpha except margin discoloration was evaluated as Code Beta: (**d**) baseline; (**e**) after 12 months; and (**f**) after 24 months.



(**a**) (**b**) (**c**)

Figure 6. Clinical situation of Pat. No. 18: filling 15 od without flowable composite: control group, all criteria Code Alpha; filling 16 mod with flowable composite as intermediate liner: test group: margin adaption was evaluated as Code Beta all other criteria were rated Code Alpha: (**a**) baseline; (**b**) after 12 months; and (**c**) after 24 months.



(**a**) (**b**) (**c**)

Figure 7. Clinical situation of Pat. No. 6: filling 44 od with flowable composite: test group, all criteria Code Alpha. (**a**) baseline; (**b**) after 12 months; and (**c**) after 24 months.

3.9. Plaque and Ginigval Index

Regarding the plaque index at baseline, six subjects and, after 6 months, seven patients had an index of 1; i.e., a thin plaque film was visible when scraped with a dental probe. This trend of seven study participants continues after 12 months. After 24 months, there is a reduction to five patients showing a plaque index of 1 (Figure 8). In contrast to the plaque index, only two patients showed a gingival index of 1, i.e., low inflammation with slight discoloration of the gingiva without bleeding (Figure 9). After 24 months, no significant difference with regard to PI and GI could be detected between the control and test group ($p > 0.05$, Mann–Whitney U-test, Table 3).

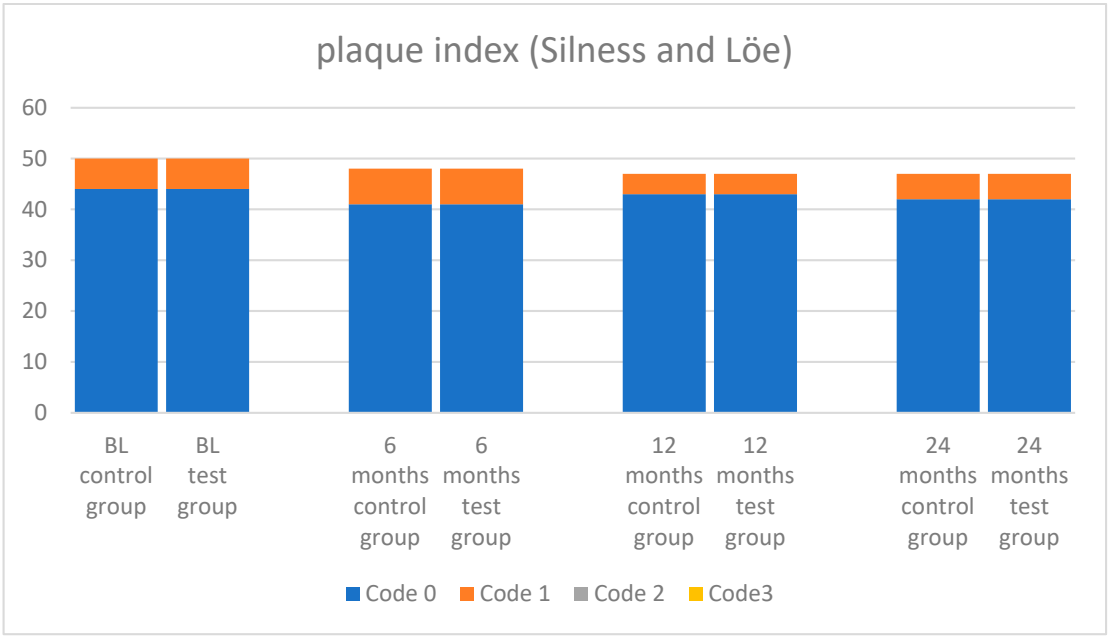


Figure 8. Plaque index (Silness and Löe) [22,23].

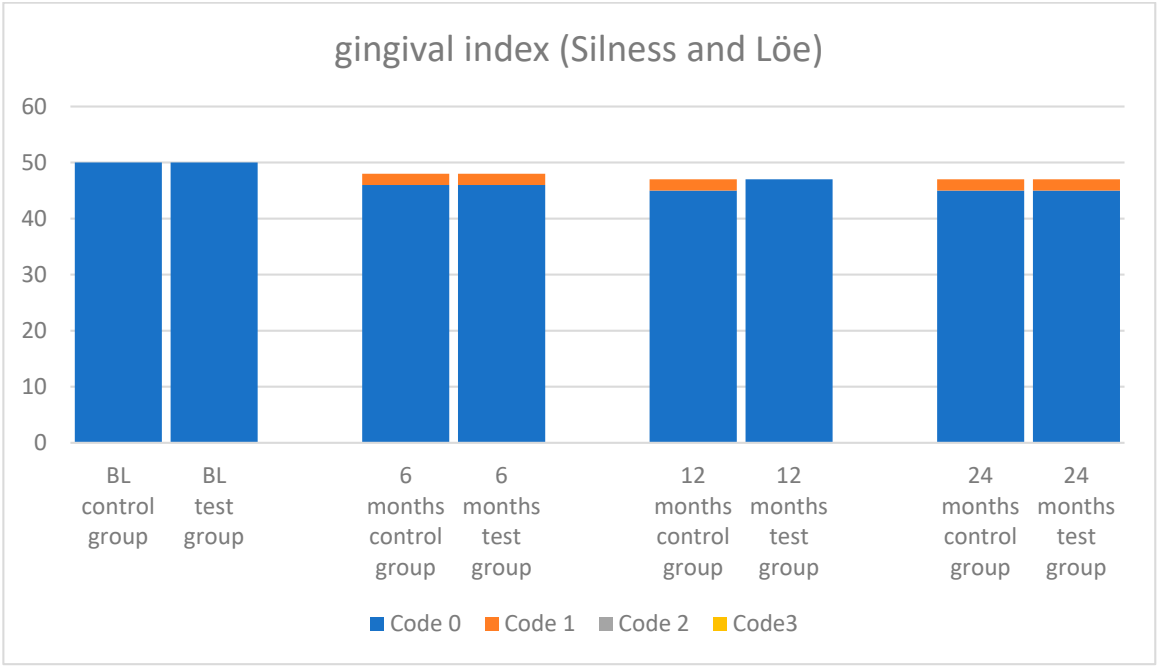


Figure 9. Gingival index (Silness and Löe) [22,23].

4. Discussion

This clinical study evaluated the clinical performance and effectiveness of a flowable composite as an intermediate stress-breaking cavity liner in posterior cavities combined with a conventional nano-hybrid composite material. This study was conducted in vivo and in a split-mouth design; consequently, the individual differences with regard to risk factors such as oral hygiene, saliva composition, and dietary habits can be almost eliminated [24–28]. Furthermore, the study was performed in a randomized-controlled, single-blinded manner, thus increasing internal validity [29,30].

This study showed a recall rate of 94% after 24 months. In comparison with other studies evaluating the 24-month results, this is an acceptable recall rate as demonstrated in

similar clinical trials (recall rate: 89.9% [18], recall rate: 95% [31]). The overall cumulative survival rate after 2 years, combining all Alpha and Bravo codes, was 96.8% according to the modified USPHS/Ryge criteria, considering both groups with and without the additional use of a flowable composite together. Significant differences in the cumulative success rate between the control group (100%) and the test group (93.6%) could be detected within the observation period. After 24 months, three restorations out of the test group showed Code Delta because of negative tooth vitality and root canal treatment. One of these teeth received an initial Class I restoration and developed an approximal lesion on the mesial aspect of the tooth within the following 24 months leading to irreversible pulpitis with endodontic treatment needs. The second endodontic-treated tooth of another patient underwent endodontic therapy abroad. The third endodontically treated tooth was diagnosed with irreversible pulpitis within the first 24 months. In this case, the possible impact of temperature changes during polymerization might be an explanation for the loss of vitality. It is known that these temperature changes can cause pulpitis [32]. However, in all three cases, endodontic therapy was necessary due to pulpal inflammation after deep caries excavation prior to restoration. In all three cases, indirect pulp capping using a calcium hydroxide liner (Calcicur®, VOCO GmbH, Cuxhaven, Germany) was performed. The applied restorations showed no secondary caries or marginal failures. Based on these facts, it can be assumed that these three teeth were correctly restored using both of the composite materials. The fact that all teeth were assigned to the test group must be rated as a random incident. Unfortunately, according to our study protocol and the used USPHS/Ryge criteria, the three teeth had to be rated as failures. Comparing the success rates with another randomized clinical trial of the same conventional and heavy flowable composites Grandio®SO, no Code Charlie or Delta was detected as well after 24 months (survival rate 100%) [18]. Another clinical trial on composite filling by Ernst et al. [31] showed that 92.8% of composite restorations placed with the additional use of a flowable composite as a liner survived compared to a 94.6% survival rate without the flowable composite. These results are in accordance with our findings. Other authors described further clinical layering approaches, which might help to perform quick, predictable, and natural-looking restorations, reducing the need for occlusal adjustments [33]. This is different from our dentin lining using a flowable composite to increase adaption to the dentin and avoid polymerization stress. Among the 94 teeth, 12 indirect capping procedures with a calcium hydroxide preparation were performed [34,35]. Seven teeth from the control group and five teeth from the test group were indirectly capped. It is remarkable that nine of twelve teeth showed a positive and regular sensitivity after 24 months of observation. Three teeth of the test group had to receive endodontic treatment (see above). Only one tooth in the test group showed an increased sensitivity to temperature and occlusion immediately after capping. However, the complaints were of short duration, so no therapeutic intervention was indicated. At the time of the baseline examination (2 weeks after restoration), the patient reported an improvement and, at the first follow-up examinations, that tooth showed regular sensitivity without complaints.

Postoperative sensitivity is, in principle, a possible complication after composite restorations and therefore often a secondary outcome measure in clinical trials while examining composite materials [16,36]. Many authors focused on the impact of the used dentin adhesive system regarding the presence or absence of postoperative sensitivity [37–41].

Nevertheless, despite the significant improvements of adhesive systems, the bonded interface remains the weakest area of the composite restorations. The failure or degradation of this interface can result in poor marginal adaption, marginal discoloration, and the subsequent loss of retention or secondary caries of the restoration, as typical clinical findings. The interface between the tooth and restorative material is subjected to varying stresses during its lifetime. The volumetric shrinkage of the resin material during polymerization is dependent on the properties of the material used, the volume of resin material cured, filler type and amount, degree of polymerization, C-factor, monomer content, and application technique [42]. Laboratory and clinical studies have demonstrated excellent success rates for

total-etch adhesives over the years [43–47]. Unfortunately, many clinical investigations have shown that postoperative hypersensitivity after a complete cavity etching is still a problem. To reduce technique sensitivity and the risk of postoperative sensitivity by dentin etching, self-etch adhesives that operate by acid etching with simultaneous monomer infiltration were developed. It is expected that self-etch adhesives prevent or reduce postoperative sensitivity due to their less aggressive and more superficial interaction with dentin [48,49]. In the present investigation after 24 months, no postoperative hypersensitivity was detected (0%). Comparable results are difficult to evaluate in other studies, because the number of trials directly comparing the self-etch and etch and rinse system is small [36]. All fillings in this study were placed under absolute dryness using a rubber dam; the adhesive system was applied according to the manufacturer's instructions as a self-etch system. The recommended layer thickness and light-curing time of the placed composite materials was obeyed. The fact that one experienced dentist placed all the restorations might provide a further explanation. In addition, all the fillings were prepared under water cooling with the same grain size of the diamond burs. The present undesirable reactions of the pulp–dentin unit are therefore not due to gross processing errors of the materials investigated.

Secondary caries was not detected after 24 months in any case. This is a comparable result to the research of Torres et al. [18]. Trials exist that showed secondary caries after two years with the additional use of a flowable composite as a liner [31,50]. However, the number of secondary caries is very low [31]. Furthermore, two fillings of the test group showed a discreet chipping of the superficial composite material of the distal margin after 12 months (Code Bravo). These fillings could remain in situ without the loss of proximal contact or other functions and showed satisfactory stability after 24 months. These findings are in accordance with the results of other studies [1,18]. Regarding marginal discoloration, higher abnormalities were detected in comparable studies after 24 months [18,31]. Recently published studies showed that polymerization time improved the mechanical properties of composite materials [51]. In the present study, each increment was light-cured for 30 s. This might explain the favorable outcome regarding the quality of the placed restorations (surface roughness, marginal adaption, marginal discoloration, and color match) in the present investigation. While the study of Torres et al. with the same composite material Grandio®SO evaluated Code Bravo at 39.5% in the test group and 32.5% in the control group, Ernst et al. detected Code Bravo at 23.6% in the test and 32.1% in the control group. For the use of flowable composites as an intermediate stress-breaking layer, a number of in vitro studies [7,12,13,52] describe a reduction in marginal microleakage and internal cavities as well as an improved adaptation of the composite to the tooth structure, while other studies did not find any positive effects on marginal adaptation [7,53,54]. The effect of flowable composite materials as an intermediate stress-absorbing layer in Class I and II cavities compared to the use without using this layer has been investigated in few clinical studies so far [55,56]. Furthermore, the present study supports the findings that there is no significant influence of the flowable composite on the clinical quality of the fillings. Since, in our study, the adhesive system Futurabond® DC was used as a self-etch system on dentin as well as on enamel, this must be taken into account when evaluating the marginal seal. Some studies show the advantages of selective enamel etching for the bond between the tooth structure and the composite [57,58]. Regarding the used adhesive system in the self-etch modus, the authors have shown that the bond strength values are comparable between the etch and rinse and self-etch modus when testing Futurabond® DC in both application modes [59]. Furthermore, this system is known to be effective in establishing a sufficient bond to tooth structures [60]. This might be an explanation for the present finding, that restorations in both groups showed no abnormalities after 24 months in the deterioration of the marginal adaptation. On average, the formation of a marginal leakage and subsequently secondary caries is more than 2 years [1,61–64], so longer assessment periods are required.

Considering that biofilm is an important parameter in the etiology of caries formation around composite restorations [24], patients with an initial plaque accumulation were

encouraged to improve their oral hygiene, and a thorough professional dental cleaning including oral hygiene instructions was performed. As a result, after a follow-up at 2 years, plaque accumulation was reduced from seven to five patients. In the case of study results obtained by in vivo examinations, individual differences must be taken into account. In the present study, a split-mouth design was used to avoid the impact of individual concerns. However, the different oral hygiene of the individual subjects is a parameter that can be influenced but not directly controlled. Finally, this depends on the compliance of the patient. To minimize this complication, good oral hygiene was taken into account when selecting the study participants. These findings are in accordance with the absence of secondary caries in all re-examined teeth. The improvement of oral hygiene might be the relevant factor. Unfortunately, one tooth developed an approximal lesion followed by endodontic treatment in the test group.

In summary, in vitro and clinical data do not significantly support any particular method or material type in achieving an optimal performance in restoring Class I and II restorations with current composites [65–68].

5. Conclusions

Apart from the three endodontic treatments, the materials for direct adhesive restorations in this study provided an acceptable clinical performance in the posterior teeth of Class I or II over a period of 24 months in both groups. After 2 years, the results of the additional use of a flowable composite ultimately led to significantly different annual failure rates (AFR) of 0% and 3.2%, respectively ($p < 0.05$; Mann–Whitney U test). Beside the differences regarding the tooth vitality, success rate, and AFR, no significant influence of the flowable composite on the different evaluated clinical parameters could be observed at this time. Therefore, the application of an additional layer of the flowable composite might have neither a positive nor a negative effect on composite restorations in clinical practice. However, further long-term studies are required for a final evaluation of pluggable composites and the advantage of an additional use of flowable composites as a liner.

Author Contributions: Conceptualization, C.R.G.; methodology, C.R.G.; validation, C.R.G. and M.M.; formal analysis, C.R.G., A.D.N., M.M. and N.P.; investigation, C.R.G. and M.M.; resources, C.R.G.; data curation, A.D.N., M.M., N.P. and C.R.G.; writing—original draft preparation, C.R.G., A.D.N. and N.P.; writing—review and editing, C.R.G., A.D.N. and N.P.; visualization, A.D.N., M.M. and N.P.; supervision, C.R.G.; project administration, C.R.G.; funding acquisition, C.R.G. All authors have read and agreed to the published version of the manuscript.

Funding: This research was funded by VOCO GmbH, Cuxhaven, Germany. No. 31308004KZEP.

Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved by the Ethics Committee of the Medical Faculty of the Martin Luther University Halle-Wittenberg, protocol number: 225/17.11.10/8.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data are available upon request from the corresponding author.

Conflicts of Interest: The authors declare no conflict of interest.

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Influence of Cavity Lining on the 3-Year Clinical Outcome of Posterior Composite Restorations: A Randomized Controlled Clinical Trial

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Abstract: The purpose of this randomized, split-mouth-designed controlled and single-blinded clinical study was to evaluate the 3-year clinical performance of Class I and Class II resin composite restorations placed with or without cavity lining with a flowable composite. Fifty patients with treatment needs in two premolars or molars were included. One of the teeth was restored using the nanohybrid composite (Grandio®SO, control group), in the test group a high viscosity flowable composite was additionally applied as a first layer. In both groups, the same self-etch adhesive system was applied. Clinical evaluation after 3 years was carried out using the modified USPHS/Ryge criteria. At the 3-year follow-up the recall rate was 92%. Four restorations failed in the test group (8.7%), three due to the loss of vitality and one after fracture. The control group exhibited a cumulative success rate of 100%, while the test group achieved a success rate of 91.3%. This led to significant differences in the annual failure rate (AFR) between the two groups, with rates of 0% and 2.9% ($p < 0.05$; Mann–Whitney U-test). After 3 years the cumulative survival rate including all restorations was 95.7%. Statistical analysis revealed significant differences for the parameters: tooth vitality, marginal discoloration, success rate, and AFR. The other parameters exhibited no significant differences. Consequently, the nanohybrid composite demonstrated excellent performance over a 3-year period, whereas the utilization of a flowable composite for the cavity lining did not appear to exert a beneficial influence on clinical outcomes.

Keywords: nanohybrid composite; flowable composite materials; clinical study; direct restoration; randomized clinical trial

Citation: Nguyen, A.D.; Pütz, N.; Michaelis, M.; Bitter, K.; Gernhardt, C.R. Influence of Cavity Lining on the 3-Year Clinical Outcome of Posterior Composite Restorations: A Randomized Controlled Clinical Trial. *Dent. J.* **2024**, *12*, 128. https://doi.org/10.3390/dj12050128

Academic Editors: Keyvan Moharamzadeh and Samir Nammour

Received: 26 December 2023
Revised: 20 February 2024
Accepted: 30 April 2024
Published: 7 May 2024

1. Introduction

As is known from numerous publications in the field of adhesive and aesthetic dentistry, direct composite restorations have become an accepted and widely used alternative to other directly usable materials or indirect restoration procedures using laboratory- or CAD/CAM-fabricated restorations made of metal or ceramic materials in posterior teeth [1–4]. Today, direct composite restorations showed comparable long-term results to other indirect restoration possibilities [2,5–8]. Furthermore, their use fits in the actually recommended aesthetic, tooth-saving, minimally invasive, and cost-effective therapeutic concept [9]. Regarding clinical success in restorative dentistry, marginal adaptation or marginal leakage followed by secondary caries or postoperative hypersensitivity are the most common clinically observable complications over time, in particular in deep dentinal-bonded approximal lesions [10–12]. Furthermore, a clinically very difficult to detect phenomenon is inadequate internal bonding of the adhesive materials to tooth hard tissues resulting in insufficient internal and marginal adaption [13]. This problem is often

described to be correlated with the occurrence of postoperative sensitivity, restoration loss, and finally caries [14]. Therefore, several publications recommended the supplementary application of a flowable composite for the cavity lining to reduce polymerization stress and improve adaption of the adhesive filling materials [13,15]. Their conclusion was that the main intention of this clinical protocol is to avoid prospective complications such as microleakage and the above-mentioned subsequent clinical problems for our patients [16,17]. However, focusing on the clinical effect of this protocol using flowable composites as cavity liners concerning all important and already mentioned consequences, the clinical impact on longevity of composite restorations remain unclear and is controversial in the literature [6,18–22]. However, despite the scientific discussion regarding the clinical value of a lining protocol, there is an observable ongoing increased use of flowable resins as a cavity lining and stress-relieving increment during the placement of composite restorations in general dentistry [17,23–26]. Seemann et al. published the results of a survey in Germany which found that 80.1% of the participating dentists use a flowable composite for cavity lining [27]. Compared to most of the used flowable composite materials for this procedure the flowable resin material (Grandio®SO Heavy Flow, VOCO GmbH, Cuxhaven, Germany) used in our clinical long-term study is a so-called heavy flowable nanohybrid composite with a relatively high viscosity compared to other flowable materials [28,29].

Many investigations evaluating the influence of lining with flowable composites on the clinical long-term performance of direct composite restorations [5,29–31] reported favorable results. However, valid clinical data and evidence, particularly regarding a longer observation time than 24 months, especially for the high-viscosity flowable composite used, which might be more effective when used as a liner in the posterior teeth requiring increased strength [28], are still rare [29,32]. The aim of the present paper, following the study protocol developed and approved in advance [29] and examining the clinical outcome of the described material and material combinations over an observation period of several years, was to report the results after 3 years.

The primary goal outlined in the study protocol, as presented in the 24-month results, was to assess the efficacy of incorporating a flowable composite as a lining material alongside a nanohybrid composite for the restoration of Class I and II cavities over a period of 3 years.

The secondary goal was to evaluate the clinical outcome and behavior of the used nanohybrid composite material regarding different parameters over the observation period of 3 years. The third goal was to examine if the used self-etch adhesive system is suitable for providing a long-term success of the restorations over 3 years.

2. Materials and Methods

The comprehensive study protocol of this clinical trial is included in the previously published interim report [29]. However, for better readability of the work, parts of the methodology are also described in the current publication focusing on the 3-year results.

2.1. General Study Design

Initially, 74 patients exhibiting restorative treatment needs in a minimum of two teeth underwent screening. Following the prospective study protocol, fifty patients who met the inclusion criteria (Table 1) having at least two posterior teeth (premolars or molars) with treatment needs for direct composite restorations (Figure 1) were included. The study protocol received approval from the Ethics Committee of the Medical Faculty of Martin Luther University Halle-Wittenberg, Halle, Germany (protocol number: 225/01.12.10/8). The clinical study was registered at the German Clinical Trials Register (DRKS), the German WHO primary registry, located at the Federal Institute for Drugs and Medical Devices (Germany, registration number or DRKS-ID: DRKS00033585).

Table 1. The used inclusion and exclusion criteria.

Inclusion Criteria	Exclusion Criteria
• adults (≥18 years) • signed consent form available • 2 molars/premolars with Class I/II cavity lesions with: - antagonist - approximal contact - bucco-oral extension at least one third of the spacing of tooth cusps - positive vitality • teeth needing indirect pulp capping	• minors (<18 years) • systemic diseases • allergies related to materials • pregnancy or breastfeeding • inadequate oral hygiene • preoperative pulpal symptoms • endodontically treated teeth • teeth needing direct pulp capping • bruxism impossibility of absolute drainage by means of rubber dam • patients who are not able to attend recall examinations

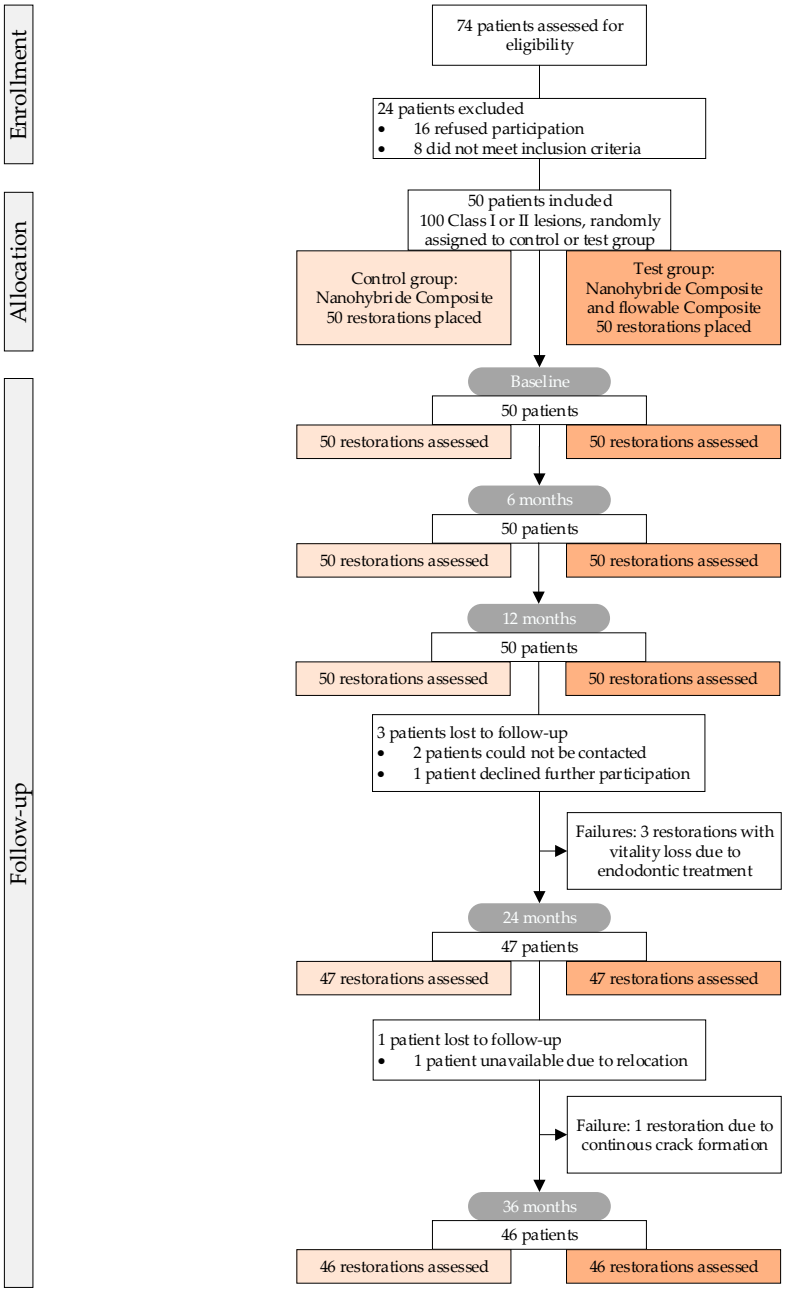


Figure 1. CONSORT Flow Chart: Enrollment, allocation, and follow-up representing the relevant appointments and information.

Screened participants were extensively informed and additionally received written information about the entire study in advance, and signed the consent forms indicating their willingness to be part of the investigation. Teeth with profound carious lesions that underwent indirect pulp capping during the restorative process were also included, following the study protocol. Given the split-mouth design of the clinical investigation, two defects of nearly comparable size were allocated at random to the two different treatment groups (control and test group) using a randomization list provided by the statistician for each patient. Throughout the trial, all clinical procedures, as per the study protocol, were conducted by a single experienced dentist (Figure 1).

2.2. Clinical Process

At the beginning, a thorough medical history, dental, and radiographic examination were performed to assess restorative needs, coronal, and apical pathologies, following the same procedure as reported in the 24-month results [29]. Restorative treatment in all cases was carried out after local anesthesia and adequate rubber dam isolation of the affected and selected teeth using the nanohybrid composite. In class-II cavities, an additional matrix system was used. The two restorations on both sides following the split-mouth design were placed in one session. In the test group, an additional layer of flowable composite (Grandio®SO Heavy Flow) was applied on the cavity floor (maximal increment of 0.5 mm) using a dental explorer. If needed, after removing inadequate extensive fillings and deep caries, punctual indirect pulp capping was performed using a calcium-hydroxide-containing liner (Calcicur, VOCO GmbH, Cuxhaven, Germany).

In both groups, following cavity preparation, a self-etch adhesive system (Futurabond® DC, VOCO GmbH, Cuxhaven, Germany) was scrubbed into the surface for a minimum of 20 s using the provided brushing device, commencing on enamel. The material was spread to a thin layer using compressed air and polymerized for 10 s (Celalux® 2, VOCO GmbH, Cuxhaven, Germany, approximately 1300 mW/cm^2, wavelength range 450–480 nm). Restorations were layered in increments of a maximum thickness of 2 mm and polymerized for 30 s. Finally, the surfaces of the restorations were finished using differently grained diamonds (Komet, Gebr. Brasseler GmbH & Co. KG, Lemgo, Germany) and polished.

2.3. Re-Examniation Protocol (Baseline, 6 Months, 12 Months, 24 Months, 36 Months)

The clinical re-examinations were done by a second blinded, experienced, and calibrated dentist who was not involved in the restoration procedure. A baseline examination was performed two weeks after the restorative procedure. Follow-up appointments were performed after 6, 12, 24, and 36 months. The modified USPHS/Ryge criteria were used for clinical assessment of the restorations in both groups (Table 2) [33–35]. Furthermore, different oral hygiene parameters were used to determine the quality of individual oral hygiene, the impact of the applied instructions and periodontal health: the gingival index (GI) and proximal plaque index (PI) proposed by Silness and Löe [36,37].

Table 2. Summary of the modified USPHS/Ryge criteria used for the clinical evaluation [29].

Modified USPHS/Ryge Criteria	Alpha	Bravo	Charlie	Delta
Secondary caries	No clinical signs of caries along the margin			Clinical diagnosis of caries
Tooth vitality	Positive			Negative
Postoperative sensitivity	No hypersensitivity	Minimal complaints only for a short timespan after placement, no treatment necessary	Medium complaints, no treatment necessary	Permanent complaints, bearable, treatment planned
Filling integrity/fracture	No chipping, cracking or fracturing of the filling	Chipping, crack formation, detectable with a probe	Continuous crack formation, visible	Bulk fracture of the restoration

Table 2. *Cont.*

Modified USPHS/Ryge Criteria	Alpha	Bravo	Charlie	Delta
Proximal contact	Tight approximal contact point	Slight approximal contact point	No approximal contact, no food impaction	No approximal contact point, trauma of papilla and food impaction
Surface roughness	Smooth, polished surface	Slightly rough surface, polishing is possible	Rough surface, polishing is not possible any longer	Fractured or flaking surface
Marginal adaption	No detectable margin (dental explorer)	Detectable margin without exposure of dentin or enamel	Visible margin with exposure of dentin or enamel	Fractured marginal interface, mobile, or lost restoration
Marginal discoloration	No marginal discoloration	Presence of superficial marginal discoloration	Presence of penetrating marginal discoloration	
Color match	Invisible restoration, perfect color match	Visible restoration without severe color mismatch	Clearly visible restoration with color mismatch in the normal range of tooth color	Highly visible restoration with color mismatch outside the normal range of tooth color

2.4. Statistical Considerations

In cooperation with the Institute for Medical Epidemiology, Biometrics and Informatics, Interdisciplinary Centre for Health Sciences at the Martin Luther University Halle-Wittenberg, sample size calculation was performed in advance, prior to ethical approval. This calculation was based on the expectation that the defined primary endpoint, the annual failure rate (AFR), would be 1.5% in the test group and 2.1% in the control group, combined with an assumed standard deviation of 1. Detecting clinically relevant differences with 80% power at a 5% significance level required the inclusion of 44 patients (with 44 restorations per arm in a split-mouth design). Taking a potential moderate dropout rate into account, a total of 50 participants (representing 50 composite restorations per arm) should be finally included [29]. All statistical analysis were conducted using SPSS® 25.0 (IBM®, Ehningen, Germany). Mann–Whitney U-test was employed at a 5% level of significance to detect statistically significant differences between the investigated groups.

3. Results

3.1. Demographic and Clinical Characteristics of the Study Population at Baseline

The gender distribution within the study population was homogeneous. After screening 74 patients, 29 women and 21 men were included in the study (Figure 1). In addition to the randomization that was conducted, the process was determined by the indication of the teeth to be treated. At baseline, a total of 42 premolars and 58 molars were treated. Furthermore, 22 of the included 42 premolars and 28 of the 58 molars were assigned to the control group (Figure 1). The observable distribution within the test and control group was not significantly different. A total of 32 Class I and 68 Class II lesions were restored and evaluated. The distribution within the control and test groups was comparable (Table 3).

Table 3. Distribution and Black's classification of dental lesions of the included study teeth.

	Premolar	Molar	Class I	Class II
Test group	20	30	20	30
Control group	22	28	12	38
Total number	42	58	32	68

3.2. Development of the Study Population over 36 Months

After 36 months of observation, 46 patients out of 50 (28 female, 18 male) could be re-examined, resulting in a recall rate of 92% after 3 years. Compared to baseline, the 12-month and 24-month follow-up saw the loss of four patients. Three patients could not be relocated, one patient declined further participation. They were excluded (Figure 1).

3.3. Survival Rates after 36 Months

After 3 years the cumulative survival rate for all restorations was 95.7%. Four restorations failed. Compared to baseline, 12 months, and 24 months this means that another restoration failed in the last 12 months (Table 4). Every unsuccessful restoration, totaling 8.7%, was observed exclusively in the test group, with none occurring in the control group (0%). Consequently, the control group achieved a cumulative success rate of 100%, while the test group attained a rate of 91.3%. Regarding the annual failure rate, this resulted in significant difference between both groups: AFR of 0% in the control group and 2.9% in the test group ($p < 0.05$; Mann–Whitney U-test).

Table 4. Summary of evaluated parameters according to the modified USPHS/Ryge criteria (Code Alpha/Bravo/Charlie/Delta) and Plaque index/Gingival index (Code 0/1/2/3): Examination at baseline, 24 months [29], and 36 months.

Parameter		**Control Group**			**Test Group**		
Interval		**Baseline**	**24-Months Follow-Up**	**36-Months Follow-Up**	**Baseline**	**24-Months Follow-Up**	**36-Months Follow-Up**
Biological properties	Secondary caries	50/0/0/0	47/0/0/0	46/0/0/0	50/0/0/0	47/0/0/0	46/0/0/0
	Tooth vitality	50/0/0/0	47/0/0/0	46/0/0/0	50/0/0/0	44/0/0/3	43/0/0/3
	Postoperative sensitivity	50/0/0/0	47/0/0/0	46/0/0/0	50/0/0/0	47/0/0/0	46/0/0/0
Functional properties	Filling integrity/fracture	50/0/0/0	47/0/0/0	46/0/0/0	50/0/0/0	45/2/0/0	44/1/1/0
	Proximal contact	50/0/0/0	47/0/0/0	46/0/0/0	50/0/0/0	47/0/0/0	46/0/0/0
	Surface roughness	50/0/0/0	47/0/0/0	46/0/0/0	50/0/0/0	47/0/0/0	46/0/0/0
	Marginal adaption	50/0/0/0	47/0/0/0	45/1/0/0	50/0/0/0	46/1/0/0	44/2/0/0
Aesthetic properties	Marginal discoloration	50/0/0/0	45/2/0/0	41/5/0/0	50/0/0/0	44/3/0/0	43/3/0/0
	Color match	50/0/0/0	47/0/0/0	46/0/0/0	50/0/0/0	47/0/0/0	46/0/0/0
Plaque index		44/6/0/0	42/5/0/0	39/7/0/0	44/6/0/0	42/5/0/0	39/7/0/0
Gingival index		50/0/0/0	45/2/0/0	42/4/0/0	50/0/0/0	45/2/0/0	42/4/0/0
n assessed		50	47	46	50	47	46
Recall rate (%)		100	94	92	100	94	92
n failure (cumulative failure %)		0 (0%)	0 (0%)	0 (0%)	0 (0%)	3 (6.8%)	4 (8.7%)
AFR (%)		0%	0%	0%	0%	3.4%	2.9%

3.4. Results of Parameters with Recognizable Findings after 36 Months

3.4.1. Secondary Caries

After 36 months no secondary caries could be observed in any case. None of the 92 restorations placed in both groups showed any sign of secondary caries (control and test group, Table 4).

3.4.2. Tooth Vitality

Following the initial restorative procedure at baseline, three out of 92 teeth required non-surgical initial endodontic treatment (Code Delta) within the first 24 months and were rated as failures (Figure 1 and Table 4). All affected teeth, successfully endodontically treated, appertained to the test group. After 36 months recall no additional teeth lost their vitality. So, the remaining 89 included teeth reacted positively to the pulp vitality test (Table 4).

3.4.3. Postoperative Sensitivity

The initially reported postoperative sensitivity immediately present after the restorative therapy could not be detected during the 3-year clinical examination. All teeth showed no signs of hypersensitivity and were rated as Code Alpha (Table 4).

3.4.4. Filling Integrity/Fracture

Initially, after 12 months two restorations located in the test group showed a discreet chipping of the superficial composite material located at the distal margin (Code Bravo). One of the two teeth showed a continuous crack formation after 36 months and had to be rated as Code Charlie and considered as a failure (Table 4).

3.4.5. Marginal Adaption

Initially, at baseline and after 12 and 24 months none of the initially applied restorations showed any findings regarding the parameter marginal adaption. After 36 months two restorations in the test group and one in the control group were rated as Code Bravo. (Figure 2, Table 4).

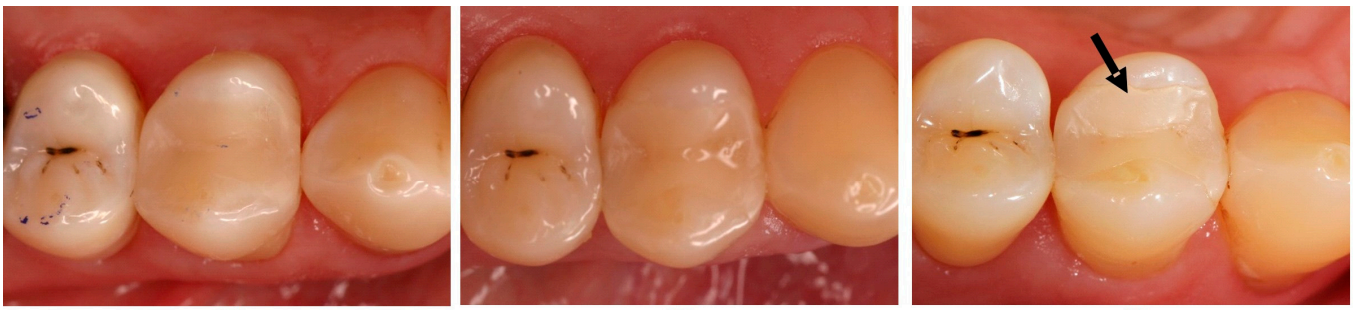


Figure 2. Clinical situation (Patient number 6): restoration tooth 14 (mod) without cavity lining: control group, (**a**) baseline: all criteria were rated Code Alpha; (**b**) after 12 months: all criteria rated as Code Alpha; (**c**) after 36 months: marginal adaption was rated as Code Bravo (arrow).

3.4.6. Marginal Discoloration

Already at the first re-examination appointment after 6 months, three restorations exhibited discolored restoration margins in two patients which were rated as Code Bravo. One restoration was located in the control and two in the test group. The number of affected fillings increased within the 2 years to five restorations in four patients showing superficial marginal discoloration (Code Bravo). Up to 36 months, this number increased to eight restorations revealing superficial marginal discoloration (Code Bravo). The difference between both groups was statistically significant ($p < 0.05$, Mann–Whitney U-test, Table 4). The control group (used without cavity lining) showed significantly more restorations with marginal discoloration compared to the test group (Figures 3 and 4).

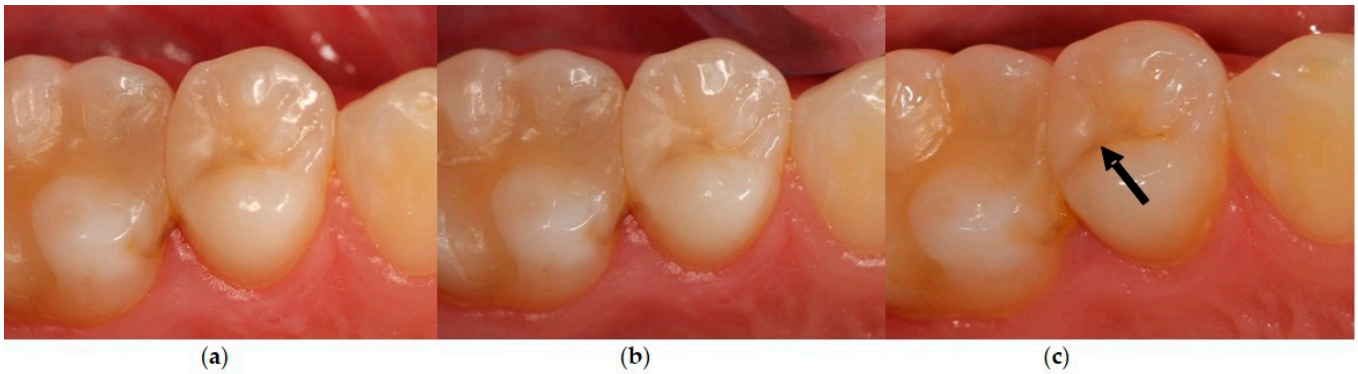
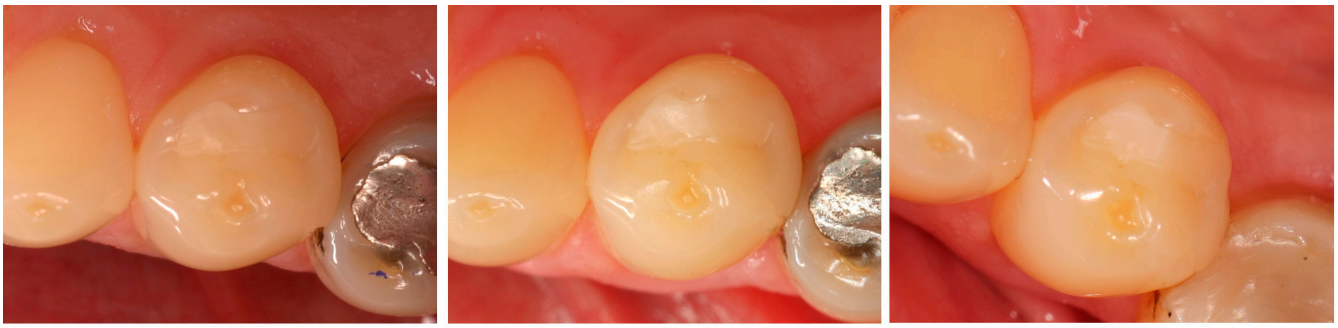


Figure 3. Clinical situation (Patient number 47): restoration tooth 15 (od) without cavity lining: control group, (**a**) baseline: all criteria were rated Code Alpha; (**b**) after 12 months: all criteria Code Alpha; (**c**) after 36 months: marginal discoloration was rated as Code Bravo (arrow).



(a) (b) (c)

Figure 4. Clinical situation (Patient number 25): restoration tooth 34 (od) with cavity lining: test group, (**a**) baseline: all criteria were rated Code Alpha; (**b**) after 12 months: all criteria Code Alpha; (**c**) after 36 months: all criteria Code Alpha.

3.5. Results of Paramters without Any Findings after 36 Months

All other parameters—proximal contact, surface roughness, and color match—comparable to the 24 months interval, showed no findings in both groups after 3 years. In the case of the marginal adaption parameter, three restorations were rated as Code Bravo, one in the control and two in the test group (Table 4). Compared to the previously published 24 months results this means no significant increase of one restoration in both groups ($p > 0.05$, Mann–Whitney U-test).

3.6. Results of Oral Hygiene Indexes after 36 Months: Plaque and Gingival Index

After 36 months seven patients showed a PI of 1 and four patients exhibited a GI of code 1. After 3 years no significant differences were detectable regarding both the oral hygiene indexes PI and GI between both groups ($p > 0.05$, Mann–Whitney U-test). Compared to the baseline results (6 patients), the 6-months results (7 patients), the 12-months results (7 patients), and the 24-months results (5 patients) recorded a PI of 1, no further changes in oral hygiene deficiencies were visible after 36 months. Regarding the GI, in four patients a GI of 1 was found. This means the gingiva showed no inflammation, no bleeding but just a slight discoloration of the gingiva margin. Compared to the 24-months results there is an increase of two patients.

4. Discussion

After 36 months, 46 patients could be re-examined. At the beginning of the study, after screening 74 patients, 50 patients passed the inclusion and exclusion criteria and could be included. After 24 months, three patients had to be excluded and 47 could be re-evaluated. Two patients moved away and could not be contacted, and one patient refused further participation in the study [29]. At the present stage, after 36 months another patient had to be excluded because of leaving the region and not being able to attend further examinations (Figure 1). After 3 years 46 patients could be re-evaluated leading to a recall rate of 92% compared to 94% after 24 months, 100% after 12 months, and 100% after 6 months. Comparing this recall rate with other published studies focusing on the clinical success of restorative procedures over 3 years [26], the recall rate of 94% in the present investigation is quite high [38]. This might be an indicator for a carefully performed screening process including the exact medical and study information of the included patients. Taking the actual observation period of 36 months into account, the actual recall rate is comparably high and might allow evaluation of valid and representative results also with regard to the ongoing study over a longer period up to at least 48–60 months. Furthermore, the study protocol intended a randomized-controlled, single-blinded design, thus increasing internal validity [39,40].

Regarding the main aim of our clinical study, the overall cumulative survival rate, pooling both groups after 36 months regarding the successful codes (Alpha, Bravo), was

95.7%. Regarding both groups, the statistical analysis showed significant differences in the cumulative success rate of the control (100%) and test group (91.3%) within the observation period of 3 years. Comparing the present results with the results from a previously published clinical trial combining a regular and heavy flowable nanohybrid composite showed similar outcomes with no detectable Code Charlie or Delta ratings [32]. A clinical investigation by Ernst et al. [41] also showed similar results regarding the cavity lining group (92.8%) and the control group without any lining (94.6%). Their results are well in line with our findings after 3 years. Furthermore, other investigations described further clinical layering techniques, which might be useful to create highly successful and predictable restorations for our patients [42,43]. These publications, improving the clinical handling during the restorative procedure, are different from our cavity and dentin lining approach. In the present study a high-viscosity flowable composite was used to increase adaption to dentinal cavity walls and avoid higher polymerization stress.

As recently published concerning the results after 24 months and after 36 months of observation, three teeth with restorations assigned to the test group underwent endodontic treatment between the 12- and 24-months recall appointment and were rated as Code Delta [29]. Unfortunately, in all cases endodontic treatment had to be initiated due to irreversible pulpitis. All of these teeth initially had deep caries lesions and therefore they all had in common that indirect pulp capping using calcium hydroxide was necessary. Following the study protocol, teeth with deep caries lesions and the need for indirect pulp-capping procedures were not excluded (Table 2). Therefore, it is remarkable that a considerable high number, 12 out of 92 teeth re-examined after 36 months, received indirect pulp capping [44,45]. Out of these 12 teeth, seven teeth were assigned to the control and five to the test group. After 3 years, beside the three teeth receiving endodontic treatment, the other nine teeth remained vital and showed a positive sensitivity. Furthermore, regarding the endodontic treated teeth, the composite restorations of these suffering teeth exhibited no signs of secondary caries or marginal failures. Taking this fact into account, it can be stated that the cavities were restored successfully. The circumstance that all endodontically treated teeth were located in the test group might be due to the initial randomization procedure at the beginning. However, following the study protocol, these teeth had to be rated as failures (Code Delta). Furthermore, one filling of the test group showed continuous occlusal crack formation and had to be rated as a failure (Code Charlie) after 36 months resulting in an overall AFR of 2.9%.

Focusing on parameters such as secondary caries, marginal adaption, postoperative sensitivity, color match, and surface roughness after 36 months of observation, all re-examined restorations showed acceptable clinical results (no Charlie and Delta scores, Table 4).

Postoperative sensitivity is one possible complication after adhesive procedures and is discussed depending on the adhesive protocol used and the presence of internal and marginal leakage following polymerization stress and shrinkage [46–48]. Nevertheless, despite significant enhancements of commercially available dentin adhesive systems, the interface between dental hard tissues and the restoration materials remains the most vulnerable area within the originally established adhesive layer. Therefore, any malfunction, failure or complete loss of this interface results in a compromised internal or even marginal adaption followed by a subsequent retention loss of the restoration. The polymerization shrinkage of the used composite material depends on the composition, the filler type and amount, the degree of conversion during polymerization, the monomer content and finally on the polymerization time [45,49]. In the present paper, within the clinical procedure, each composite increment was light-cured for 30 s. Beside the improved properties of the high-viscosity flowable material used, this prolonged polymerization time might explain the improved outcome of the placed restorations in both groups.

Several in vitro studies have reported a decrease in marginal micro-leakage and internal cavities, along with an enhanced adaptation of the composite to dental hard tissues when utilizing low-viscosity, flowable composites as an intermediate cavity lining and

stress-breaking layer [17,19,24,50]. However, it's worth noting that contrasting findings exist, as some investigations did not identify positive effects on the marginal adaptation parameter [16,19,51]. However, clinical trials showed comparable results [25,52]. This is in accordance with our results. The benefit of cavity lining could not be shown after 3 years with regard to these parameters.

In the case of marginal discoloration, a significant difference after 36 months of observation could be detected. Marginal discoloration was significantly more frequently evaluated in the control than in the test group combined with a flowable composite for cavity lining. In some recent studies it is known that preconditioning of the enamel with phosphoric acid results in better marginal integrity [53,54] and accordingly there is less marginal discoloration [54]. In our trial, all restorations in both groups were placed using the adhesive system in self-etch mode without prior conditioning. This could explain the comparatively high occurrence of marginal discoloration in both groups (10.9% in the control and 6.5% in the test group) in general, however, another control group to evaluate this point in which pretreatment with phosphoric acid was performed is missing. Currently, there are no studies that have investigated the influence of an intermediate liner in composite restorations on marginal discoloration. Concerning the marginal discoloration parameter, even higher scores were reported in analogical investigations. Regarding the study of Torres et al., evaluating the same composite material (Grandio®SO), Code Bravo was reported in 39.5% of the cases in the test group and 32.5% in the control group [32]. Further studies from Ernst et al., also using the same material, detected Code Bravo for 23.6% of the cases in the test and 32.1% in the control group [41]. It might be possible that the observable marginal discoloration could be the beginning of a debonding process, leading at the end to marginal discrepancies which could affect further parameters in subsequent prolonged follow-up evaluations. Regarding the self-etch adhesive system used in the present investigation, it is known from several published studies that bond strength to dentin is comparable between the etch-and-rinse and self-etch systems [55,56]. These results might explain the present findings. All restorations in both groups showed no increased rating scores in case of the marginal adaptation after 3 years. However, regarding other publications the formation of a marginal leakage and subsequently secondary caries is known to need more than 3 years [5,49,57–59], so prolonged long-term periods might be useful. Focusing on the use of flowable composites in adhesive dentistry, a remarkable number of in vitro studies describe an improved internal and marginal adaption [7,12,13]. On the other hand, numerous studies did not prove these positive findings [7,58,59]. Additionally to these in vitro studies the positive effect of flowable composite materials as cavity liner in posterior restorations compared to the application without using this lining technique has been investigated in comparable clinical studies [60,61]. Compared to most of the common flowable composite materials, the flowable resin material applied in our clinical long-term study is a so-called heavy flowable nanohybrid composite with a relatively high viscosity. Many investigations, evaluating the influence of lining with flowable composites on the clinical long-term success of direct composite restorations reported favorable results [32,43,62,63]. The present results using the high-viscosity flowable composite, which might be more effective when used as a liner in the posterior teeth requiring increased strength did not support these findings. After 3 years the estimated positive effects were not observable. Therefore, a prolonged observation period might show the improved quality of the restorations placed in combination with a high-viscosity flowable material. Considering the pivotal role of oral hygiene for caries development around composite restorations [61], patients initially displaying plaque accumulation were from the beginning actively encouraged to enhance their oral hygiene. At each appointment, a comprehensive professional dental cleaning, coupled with oral hygiene instructions, was administered. This might be the explanation for the relatively low levels of plaque accumulation and both associated indices at the 3-year follow-up. It's crucial to acknowledge that individual subjects' oral hygiene is a variable that may be influenced but not consistently controlled. To mitigate this aspect's impact, the screening process and selection of study patients took into account the emphasis on good

oral hygiene. The current findings from both indices align with the sustained absence of secondary caries after 3 years. Additionally, the clinical trial's adoption of a split-mouth design serves to minimize individual differences related to caries risk factors such as oral hygiene deficiencies, saliva composition, and dietary habits [60,61,64–66]. Contrary to previous published investigations reporting the presence of secondary caries even two years after employing a flowable composite as a liner [41,67], the present investigation observed no instances of secondary caries. The thoroughly planned and established study protocol might be an explanation for these findings. However, a longer observation time might show different developments.

5. Conclusions

Initially, as already seen after 12 months of observation, three teeth receiving endodontic treatment due to vitality loss were rated as failures and one further restoration had to be rated as a failure after 3 years due to continuous crack formation in the test group used with the flowable cavity lining. Taking the endodontic origin of these failures into account, the nanohybrid composite material showed excellent clinical outcomes in posterior teeth over the observation period of 3 years. Regarding the impact of cavity lining, the results of the test group used with the high-viscosity flowable composite showed significantly increased annual failure rates (AFR) of 2.9% compared to 0% in the control group ($p < 0.05$; Mann–Whitney U test). Furthermore, except differences in tooth vitality, success rate, marginal discoloration, and AFR, no significant effects of the flowable composite on the other parameters were detectable. However, a prolonged observation time regarding several years might reveal more differences between both groups and could show an influence of flowable composites on restoration success. In conclusion, cavity lining with an additional layer of a high-viscosity flowable composite could be a clinical treatment possibility, because it might help dentists to improve the material adaption to the cavity walls and might reduce polymerization stress at the margins.

Author Contributions: Conceptualization, C.R.G.; methodology, C.R.G.; validation, C.R.G. and M.M.; formal analysis, C.R.G., A.D.N., M.M. and N.P.; investigation, restorative procedure, follow-up examinations, C.R.G. and M.M.; resources, C.R.G. and K.B.; data curation, A.D.N., M.M., N.P. and C.R.G.; writing—original draft preparation, C.R.G., A.D.N. and N.P.; writing—review and editing, C.R.G., A.D.N., N.P. and K.B.; visualization, A.D.N., M.M. and N.P.; supervision, C.R.G.; project administration, C.R.G.; funding acquisition, C.R.G. All authors have read and agreed to the published version of the manuscript.

Funding: The study was funded by VOCO GmbH, Anton-Flettner-Strasse 1–3, 27472 Cuxhaven, Germany. No. 31308004KZEP.

Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved by the Ethics Committee of the Medical Faculty of the Martin Luther University Halle-Wittenberg, protocol number: 225/17.11.10/8. The clinical study was registered at German Clinical Trials Register (DRKS), the German WHO primary registry, located at the Federal Institute for Drugs and Medical Devices (Germany) (registration number DRKS-ID: DRKS00033585).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data are available upon request from the corresponding author.

Conflicts of Interest: The authors declare no conflicts of interest.

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Review

Class-I and Class-II Restorations with the Application of a Flowable Composite as an Intermediate Layer—A Narrative Review of Clinical Trials

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Abstract: The objective of this review is to investigate the effect of an additional layer of flowable composite for cavity lining on the clinical outcome of direct posterior composite restorations. The PICO question (patient, intervention, comparison, and outcome) was stated as follows: Does the additional application of a flowable composite as a cavity liner improve the clinical outcome of Class-I and Class-II restorations? The electronic databases MEDLINE, Web of Science, LILAS, and BBO were assessed for identifying relevant clinical studies. After removal of duplicate records, 309 records could be identified and, after a screening of the title and abstract, 20 articles were selected for full-text analysis. Finally, six studies met the eligibility criteria and were included in this review for further investigation. Four of the included studies have a follow-up period of two years, while the other two studies had an observation period of three and seven years, respectively. No significant differences in annual failure rates were observed between restorations with and without a flowable composite liner. Consequently, the additional usage of flowable composites as a cavity liner seems to have no effect on the clinical longevity of direct composite restorations in Class-I and Class-II cavities. Therefore, the application of a flowable composite is a possible option in everyday dental clinical practice.

Keywords: adhesive dentistry; cavity lining; composite restoration; posterior restorations; flowable composite; clinical trials; clinical success; restorative dentistry

Academic Editors: Lavinia Cosmina Ardelean, Laura-Cristina Rusu and John W. Nicholson

Received: 5 February 2025
Revised: 18 March 2025
Accepted: 18 March 2025
Published: 20 March 2025

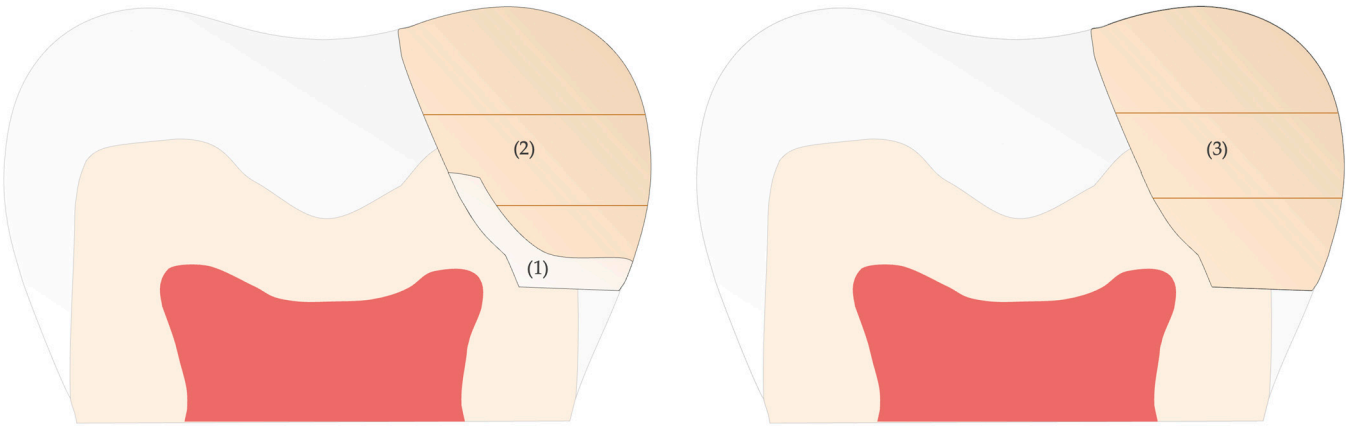
Citation: Nguyen, A.D.; Bitter, K.; Gernhardt, C.R. Class-I and Class-II Restorations with the Application of a Flowable Composite as an Intermediate Layer—A Narrative Review of Clinical Trials. *J. Funct. Biomater.* **2025**, *16*, 111. https://doi.org/10.3390/jfb16030111

1. Introduction

The practice of operative dentistry remains a fundamental aspect of modern dentistry and constitutes a substantial component of the oral healthcare. A considerable part of operative dentistry encompasses the prevention and diagnosis of dental caries and the restoration of teeth requiring treatment due to the loss of dental hard tissue. The application of composite materials in the discipline of adhesive dentistry has thus become a well-established practice for direct restoration procedures in anterior and posterior teeth [1,2]. The aforementioned restorations are in accordance with the expectations of both the patient and the practitioner with regard to an esthetically pleasing and minimally invasive therapeutic concept [3]. Leakage, marginal adaptation and subsequent secondary caries remain considerable concerns with composite restorations, particularly on the proximal region of posterior teeth restorations. Insufficient marginal sealing has been identified as a potential contributing factor in postoperative sensitivity, restoration failures, and secondary caries [4]. Therefore, some authors recommend using flowable composites as a cavity lining material to increase internal adaption. Moreover, the primary objective in

the application of flowable composites as cavity liners is the prevention of occlusal leakage, particularly in the approximal region of deep carious lesions [5]. A subset of in vitro studies has demonstrated the efficacy of a flowable liner under composite restorations in mitigating marginal adaption and reducing microleakage [6–8]. This finding stands in contrast to the results observed in other studies [9–12]. Moreover, the handling of flowable composites is reportedly advantageous due to their reduced viscosity during application [13,14].

Accordingly, some authors have advised the additional use of a flowable composite for the lining of cavities (Figure 1), with a view to minimizing polymerization stress and enhancing the adaptation of the adhesive filling materials [15,16]. The defining characteristic of flowable composites is their reduced proportion of filler particles, which results in a reduction in their viscosity [13]. Consequently, flowable composites exhibit an elastic modulus that is 20–30% less than that observed in conventional composite materials [17,18]. The diminished elasticity modulus endows low-viscosity flowable composites with the capacity to absorb stress induced by polymerization shrinkage and mechanical loading on the teeth during their functional use [19]. Furthermore, they are distinguished by their enhanced handling during the clinical application of the filling [20].



(**a**) (**b**)

Figure 1. (**a**) A schematic illustration of a tooth restored by receiving a cavity lining with a flowable composite (1) and the subsequent application of the composite material using an increment technique (2). Structures: enamel (white), dentine (yellow), pulp (red). (**b**) A schematic illustration of a tooth restored without a cavity lining and only with the application of the composite material using an increment technique (3). Structures: enamel (white), dentine (yellow), pulp (red).

The results of a survey of dental practitioners in Germany indicate that 80.1% of the 1449 participating dentists utilize a flowable composite for cavity lining [21]. The current state of research on the impact of flowable composite materials on the long-term outcomes of composite restorations is fragmented and lacks a comprehensive consensus [6,11,15,22]. Although the scientific evaluation of these materials is still limited, there has been a notable rise in the use of flowable composites as a cavity liner in the treatment of damaged teeth with carious and non-carious lesions [23–27]. Nonetheless, there is currently a controversy in the literature regarding the additional application of a flowable composite liner under composite restorations. There is currently no consensus as to whether a cavity liner is advantageous for the adhesive restoration of Class-I and Class-II cavities [6,11,28–30]. For this reason, the aim of this review is to provide an overview of the longevity and outcome of composite restorations in order to compare this debate in the clinical setting. A number of studies have been performed on bulk-fill composites, which are distinguished by their higher layer thickness of approximately 4 mm per increment during application in comparison to other flowable composite materials [5,15,31–34]. Bulk-fill restorative

materials have been widely integrated into clinical practice due to their ability to enhance the efficiency of dental treatments by reducing procedural time, while also demonstrating favorable esthetic properties, making them a valuable advancement in contemporary restorative dentistry [35]. The authors of the present review chose to exclude this group of materials, as they exhibit different workability during placement of the restorations due to their chemical composition, which could make a comparison of the studies with conventional methacrylate-based composites difficult.

The aim of the present review is to ascertain whether the additional application of flowable composites as a cavity liner affects the clinical outcome of direct restorations in the posterior region of Class-I and Class-II cavities. For this purpose, only clinical trials are considered for the selection of studies. The null hypothesis stated that the additional cavity lining of Class-I and Class-II has no impact on the longevity and marginal integrity of composite restorations compared to restorations without an intermediary layer of flowable composites.

2. Materials and Methods

2.1. PICO Question

The following research question was developed to guide the search strategy: Does the additional application of a high-viscosity flowable composite as a cavity liner improve the clinical outcome of Class-I and Class-II restorations?

In accordance with the PICO framework, the population comprised patients with direct composite restorations of Class-I or Class-II cavities in permanent teeth. The intervention involved the application of a flowable composite as an intermediate layer in Class I or Class II cavities, while the comparison was made with composite restorations that did not include an intermediate layer. The outcomes were evaluated in terms of restoration failures observed in the clinical studies.

2.2. Search Strategy

The electronic databases MEDLINE, Web of Science, LILAS, and BBO were assessed for identifying relevant clinical studies. A comprehensive search of all databases was performed on 26th October 2024. No restrictions were imposed with respect to the publication medium, the publication date, or the language. The search strategy was developed on the basis of the initially formulated PICO question. Therefore, we used the following search strategy for Medline (via PubMed):

((((((((((((occlu*) OR occlu* proximal) OR class I cavitie*) OR class II cavitie*) OR class I) OR class II) OR approximal lesion*) OR proximal lesion*) AND composite [MeSH Terms]) OR composite*) OR resin* composite) OR conventional composite*)) AND ((((((((((occlu* proximal) OR class I cavitie*) OR class II cavitie*) OR approximal lesion*) OR proximal lesion*) AND flowable hybrid composite[MeSH Terms]) OR flowable hybrid composite) OR flowable composite) OR flow line) OR flowable resin*) AND (((((cavity lining) OR cavity liner) OR intermediate layer) OR intermediary layer) OR liner).

This search strategy was then adapted for the Web of Science database and the following search strategy was applied:

((TS = (flowable composite OR flowable hybrid composite OR flowable OR flow line)) AND TS = (occlu* OR occlu* proximal OR class I cavitie* OR class II cavitie* OR class I OR class II OR approximal lesion* OR proximal lesion*)) AND TS = (cavity lining OR cavity lining OR intermediate layer OR intermediary layer OR liner).

Furthermore, the two electronic databases LILACS and BBO were assessed for the screening of relevant articles according to our inclusion criteria. Therefore, the following

terms were used for search strategy: ((cavity lining) OR (cavity liner) OR (intermediate liner) OR (intermediate lining)) AND (flow* composite).

2.3. Study Selection

The records from MEDLINE and Web of Science databases were collected in a reference management software (EndNote™ Version 20.6, Clarivate™ Analytics, Philadelphia, PA, USA), and any duplicates were subsequently removed. Two authors of the review (A.D.N., C.R.G.) then evaluated the titles and abstracts of the studies in accordance with the established eligibility criteria. Studies not matching the inclusion criteria or which clearly had no relevance for the review were then excluded. Subsequently, the authors checked the full text of the potentially relevant studies against the eligibility criteria, determining their inclusion or exclusion in the review. Furthermore, the references were screened during the full-text analysis to guarantee that potentially relevant literature was not missed. In the case that follow-up studies have been published at varying time points, the most recent investigation with the longest period is considered. Finally, the studies selected by both authors were included in the review.

2.4. Inclusion/Exclusion Criteria

The following table summarizes all inclusion and exclusion criteria of published clinical trials for selection progress (Table 1).

Table 1. A summary of the inclusion and exclusion criteria of published clinical trials.

Inclusion Criteria	Exclusion Criteria
• representing all search terms used	• articles without apparent relevance
	• case reports, case series, editorials, case reviews, reviews
• clinical trials	• laboratory studies
• permanent teeth	• primary teeth
• class-I and class-II restorations	• class-V restorations
• composite resins	• glass ionomer cements, provisional materials, and bulk-fill composites

3. Results

The search strategies identified 309 records after the removal of duplicates. After an examination of the title and abstract, 289 records were excluded, and the remaining 20 articles were checked for eligibility by analyzing the full text. A further 14 studies were excluded for various reasons, which are summarized in Figure 2.

A hand search in LILACS and BBO databases and a screening of the references during full-text analysis could not detect further relevant studies for inclusion according to our eligibility criteria. Finally, 6 studies were included for the present review (Figure 2): 5 randomized clinical studies and 1 clinical trial with no random allocation employed.

Of these included studies, 4 had a follow-up period of 2 years [36–39], 1 had a follow-up period of 3 years [40], and the last study had a follow-up period of 7 years [41]. The main characteristics concerning study type and setting, follow-up periods, cumulative survival rate, and the annual fracture rate (AFR) were summarized in Table 2. Moreover, the tested composite materials and adhesive systems as well as their conditioning mode are listed in Table 2.

Table 2. Characteristics and outcomes of all included clinical trials of this review.

Study	Study Design/Setting	Follow-Up [Years]	No. Patients (Restorations) at Baseline	Recall Rate	Cumulative Survival Rate	AFR	Rubber Dam Isolation	Restorative Materials	Adhesive System [Modulus]	Assessment Criteria
Boeckler et al., 2012 [36]	Split-mouth/ university	2	50 (100)	88%	F: 100% C: 97.7%	F: 0% C: 1.2%	yes	FL: Tetric Flow [1] CR: Tetric Ceram [1]	AdheSE One [1] [SE]	Modified USPHS/Ryge
Efes (1) et al., 2006 [37]	Split-mouth/ university	2	27 (54)	96%	F: 100% C: 100%	F: 0% C: 0%	no	FL: Filtek Flow [2] CR: Filtek Supreme [2]	Single Bond [2] [ER]	Modified USPHS/Ryge
Efes (2) et al., 2006 [37]	Split-mouth/ university	2	27 (54)	89%	F: 100% C: 96%	F: 0% C: 2%	no	FL: Admira Flow [3] CR: Admira [3]	Admira Bond [3] [ER]	Modified USPHS/Ryge
Ernst et al., 2003 [38]	Split-mouth/ university	2	50 (116)	95%	F: 92.8% C: 94.6%	F: 3.6% C: 2.7%	70%	FL: Revolution [4] CR: Prodigy [4]	Optibond Solo Plus [4] [ER]	USPHS/Ryge
Nguyen et al., 2024 [40]	Split-mouth/ university	3	50 (100)	92%	F: 91.3% C: 100%	F: 2.9% C: 0%	yes	FL: GrandioSO Heavy Flow [3] CR: GrandioSO [3]	Futurabond DC [3] [SE]	Modified USPHS/Ryge
Stefanski et al., 2012 [39]	Split-mouth/ university	2	48 (96)	96%	F: 97.8% C: 97.8%	F: 1.1% C: 1.1%	no	FL: Filtek Flow Supreme XT [2] CR: Filtek Supreme XT [2]	Adper Scotchbond 1 XT [2] [ER]	Modified USPHS/Ryge
Van Dijken et al., 2011 [41]	Split-mouth/ university	7	48 (118)	96%	F: 86% C: 84.2%	F: 2% C: 2.3%	no	FL: Tetric Flow [1] CR: Tetric Ceram [1]	Excite [1] [ER]	Modified USPHS/Ryge

Abbreviations: No. = number; F = restoration group with cavity lining; C = restoration group without cavity lining; FL = flowable composite liner; CR = packable composite resin; AFR = annual failure rate; SE = self-etch mode; ER = etch-and-rinse mode. [1] Ivoclar Vivadent GmbH, Ellwangen, Liechtenstein. [2] 3M ESPE, St. Paul, MN, USA. [3] VOCO GmbH, Cuxhaven, Germany. [4] Kerr Corporation, Orange, CA, USA.

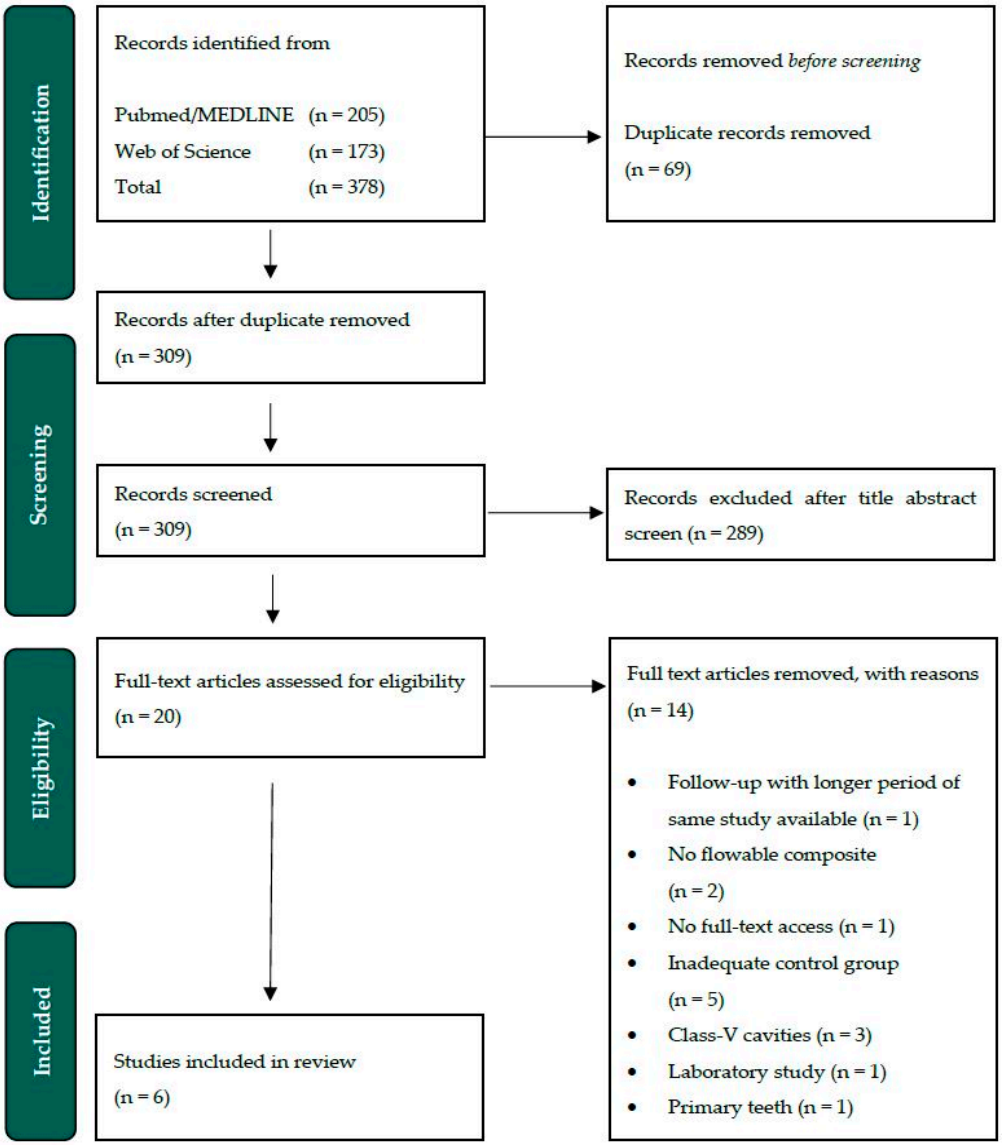


Figure 2. A schematic illustration of the used search strategy and final study-selection process according PRISMA guidelines for reviews [42].

4. Discussion

This review aims to evaluate the clinical outcome of direct composite restorations placed with an intermediary layer of flowable composites as cavity lining material in Class-I and Class-II cavities. Although the use of flowable composites in clinical practice is very common [21], the number of available clinical trials suitable for the present review is considerably limited. Only six studies met the inclusion criteria and were included into the review.

4.1. Methodology

All of the included studies used the USPHS/Ryge-criteria [43] for evaluation of the clinical outcome of the placed direct posterior restorations. The following parameters were applied by all authors for the assessment at baseline and the follow-up investigations: secondary caries, surface texture, marginal adaption, marginal discoloration, and color match (Table 3). The parameters tooth vitality, postoperative sensitivity, proximal contact, and anatomic form were not covered by all authors. The observation period in four of the studies [36–39] was limited to two years, which is a relatively brief period for identifying

differences between the test and control groups. A further limitation is the paucity of six studies meeting the inclusion criteria, which makes it difficult to draw conclusions for clinical application due to the short observation period and the small number of included studies.

Table 3. A summary of the failure reason of parameters that were evaluated in all studies [%]; F = restoration group with cavity lining; C = restoration group without cavity lining; n.r. = not reported.

Study/Group	Parameter	Anatomical Form	Secondary Caries	Tooth Vitality	Filling Integrity	Surface Roughness	Marginal Adaption	Marginal Discoloration	Color Match
Boeckler et al. [36]	F	n.r.	0	0	0	0	0	0	0
	C	n.r.	0	0	0	0	2.3	0	0
Efes (1) et al. [37]	F	n.r.	0	n.r.	0	0	0	0	0
	C	n.r.	0	n.r.	0	0	0	0	0
Efes (2) et al. [37]	F	n.r.	0	n.r.	0	0	0	0	0
	C	n.r.	0	n.r.	4.2	0	0	0	0
Ernst et al. [38]	F	5.5	1.8	1.9	n.r.	5.5	5.5	0	0
	C	3.6	0	0	n.r.	3.6	3.6	0	0
Nguyen et al. [40]	F	n.r.	0	6.5	4.3	0	0	0	0
	C	n.r.	0	0	0	0	0	0	0
Stefanski et al. [39]	F	2.2	0	n.r.	n.r.	0	0	0	0
	C	2.2	0	n.r.	n.r.	0	2.2	0	0
Van Dijken et al. [41]	F	8.8	3.5	n.r.	n.r.	0	8.8	0	0
	C	12.3	5.3	n.r.	n.r.	0	12.5	0	0

One study investigated only Class-I cavities [37], three studies only Class-II cavities [38,39,41] and two studies included both cavity Classes I and II [36,40]. Also, the first mentioned study [37] only included maxillary molars, whereas the remaining five studies [36,38–41] included premolars and molars located in both jaws.

The published clinical trial of Ernst et al. [38] did not perform a random allocation of the selected teeth to the different experimental groups, which could result in decreased internal validity [44]. Furthermore, a high number of dentists (n = 10) were involved in the restoration process. Although they had undergone a calibration process on phantom models beforehand, it is challenging to compare the restoration quality in a clinical setting. This may be a contributing factor in the clinical outcome when considering the higher AFR in both tested groups compared to the other studies, which remains within clinically acceptable and comparable ranges. The remaining five studies had a maximum of only two calibrated operators and examiners, with only one study failing to report blinding [39]. The examiners for the follow-up evaluations of the other four studies were not involved in the clinical restoration process [36,37,40,41], decreasing the risk of bias.

4.2. Used Composite Materials

In our review, we solely included studies using conventional methacrylate-based composite materials and excluded studies using glass ionomer cement, provisional restorative materials, and bulk-fill composite resins (Table 1). The study of Efes et al. [37] investigated both material groups, a nanofilled methacrylate composite resin and an ormocer-based composite material. We included this study due to the study design, methodology, and clinical procedure of the restorations, as well as the comparable parameters evaluated. Ormocer-based composites were also considered, although they have other physical and chemical properties compared to methacrylate-based composite resins [45,46].

In one study [40], a so-called high-viscous or heavy flowable composite was used for cavity lining. This group of materials can be used as an alternative to regular viscous flowable composites, as it demonstrated comparable outcomes in several in vitro publications [17,47]. It is characterized by its higher filler content and modulus of elasticity compared to regular viscosity flowable composites [48]. While numerous clinical studies have examined the combination of conventional flowable composites with packable composites, the number of clinical studies investigating high-viscosity flowable composites remains limited and is controversial. In accordance with the results of the clinical trial

of Ñaupari-Villasante et al. [49], the high-viscosity flowable composites showed significantly higher failure rates than the low-viscosity flowable composites and ormocer-based flowable composites when used for cavity lining after an observation period of 48 months. In contrast, Torres et al. [50] demonstrated that neither low-viscous nor high-viscous flowable composites exhibited superior clinical outcomes, which align with the results of Nguyen et al. [40]. A comparison of the AFR with studies using regular viscosity flowables [36–39,41] indicates that there is no discernible impact of viscosity on the longevity of restorations, as the AFR seems to have clinical acceptable values.

In our study-selection process, we implemented no restrictions concerning the used adhesive system of the clinical trials. In the field of modern adhesive dentistry, bonding systems are typically classified into two categories, depending on the mechanism of dissolution employed to remove the smear layer [51]. The etch-and-rinse adhesives require a 35–40% phosphoric acid gel for preconditioning enamel and dentin before applying the bonding agent [52]. The additional phosphoric acid application is not mandatory when using self-etch adhesives due to their ability of conditioning enamel and dentin using acidic monomers [53]. Nonetheless, studies have demonstrated superior bond strength values for self-etch adhesive systems when these were previously conditioned with phosphoric acid in the enamel area [30,54].

Recent studies have demonstrated increased marginal integrity when the enamel of the cavity was conditioned with phosphoric acid prior using the adhesive material, which is associated with a reduction in marginal discoloration [30,55–57]. The study of Boeckler et al. [36] using a self-etch adhesive showed less occurrence of marginal discoloration at the 2-year follow-up, whereas a notable increase in Code Bravo rating was observed by Nguyen et al. [40] after 3 years compared to the evaluation after 2 years. In comparison to Stefanski et al. [39] and Ernst et al. [38], where etch-and-rinse adhesives were used as bonding agent comparable results were evaluated after 2 years. However, there are no existing studies that have investigated the effect of an intermediate liner in composite restorations on marginal discoloration and the used adhesive system. Regarding the results of all included studies concerning marginal discoloration, no restoration was rated as a failure (Table 3).

4.3. Clinical Procedure

Three of the included studies perform an isolation of the operative field using a suction device and cotton rolls during the placement of filling materials [37,39,41]. In contrast, rubber dam isolation was used for two other studies [36,40], and one study performed absolute isolation in 70% of the cases [38]. A recently published clinical in situ study of Falacho et al. [58] showed superior outcomes for adhesive restorations placed under rubber dam isolation, particularly with regard to the humidity control of enamel and adhesive bond strength. However, a 2014 review by Cajazeira et al. [59] indicated that isolation with a rubber dam has no effect on the longevity of restorations. Nevertheless, it seems that there is no discernible impact on the clinical outcome of the studies with respect to the cumulative success rate and AFR (Table 2).

Three studies [38–40] performed indirect capping [60,61] in deep carious lesions, with one study using a glass-ionomer-cement base [38] and the other two using calcium hydroxide [39,40]. The inclusion of teeth with deep carious lesions indicating indirect pulp capping is more closely aligned with the clinical setting of dental practice. Accordingly, one dropout was recorded in the study of Ernst et al. [38] and three failures in the study of Nguyen et al. [40] due to loss of vitality. Stefanski et al. [39] performed indirect pulp capping, yet tooth vitality was not subjected to any form of assessment. Two additional studies likewise did not conduct tooth vitality tests during the follow-up evaluations, analogous to Stefanski et al. [39], which eliminates a criterion for a dropout. Consequently,

the failure rate may be higher than indicated (Table 2). Boeckler et al. [36] did not observe any loss of tooth vitality in the teeth examined in their clinical trial.

Four studies provided data about the layer thickness of their used liner material: one study [40] applied a 0.5 mm layer, another study [37] 1 mm, and two studies [39,41] 1–1.5 mm. The results of two in vitro studies indicated a correlation between increasing liner thickness and a decline in marginal integrity [62,63]. In contrast, a meta-analysis yielded no discernible effect of whether the flowable layer thickness was below or above 2 mm [64]. Ernst et al. [38] recorded more dropouts in both tested groups due to unacceptable scores of the marginal adaption (Table 3) compared to the other studies with a 2 year-follow-up. In the absence of data regarding layer thickness, it is not possible to draw any conclusions regarding the correlation between thickness and marginal quality. Van Dijken et al. [41] also reported a high percentage of unacceptable scores in marginal adaption in both groups (with flowable liner: 8.8%, without flowable liner: 12.5%) applying a 1–1.5 mm thick layer of the lining material. In comparison, Stefanski et al. [39] observed no instances of failure due to a lack of marginal adaptation in the group that used a flowable liner, which had the same thickness for cavity lining. However, one tooth in the other group was rated as a failure due to lack of marginal integrity, which aligns with the results of the meta-analysis [64], that the layer thickness does not correlate with bond strength and as a result with the marginal adaption of the restoration.

This review has several strengths, such as the inclusion of clinical trials with an observation period longer than two years and a corresponding large sample size that increases the quality of the findings. Additionally, only studies regarding methacrylate-based composite resins were included, which enables the characterization of the specific material class. However, a limitation of this study is the low number of clinical trials that could be included. This might influence the outcome of the PICO question of this review.

5. Conclusions

With regard of the limited number of clinical trials and the short follow-up period of two years of four studies from a total of six included studies, a conclusion for practicing dentists is difficult. The use of flowable composites as a cavity liner does not appear to have any clinical effect on the clinical longevity of direct composite restorations. Further studies with a longer observation period are necessary to draw a clear conclusion. The disparate methodologies and measured parameters employed in the analyzed studies also presented a challenge in terms of comparing the results. However, the available data do not indicate any clinical disadvantage of the additional use of flowable composite materials as an intermediary layer. Furthermore, the evaluated studies may indicate the implementation of a flowable material as a liner, which constitutes a viable option within the scope of restorative therapy for daily clinical practice among dentists due to easier handling properties and the ability of realizing better marginal adaptation. This approach exhibits neither distinct advantages nor disadvantages in terms of the treatment and clinical longevity of composite restorations in Class-I and Class-II cavities. Therefore, the application of a flowable composite as a cavity liner is a possible option in everyday clinical practice of dental practitioners and has some positive but no negative aspects.

Author Contributions: Conceptualization, A.D.N. and C.R.G.; methodology, A.D.N. and C.R.G.; validation, A.D.N., K.B. and C.R.G.; formal analysis, A.D.N. and C.R.G.; resources, C.R.G. and K.B.; data curation, A.D.N. and C.R.G.; writing—original draft preparation, A.D.N., K.B. and C.R.G.; writing—review and editing, K.B. and C.R.G.; visualization, A.D.N.; supervision, C.R.G.; project administration, C.R.G. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: Not applicable.

Data Availability Statement: Not applicable.

Conflicts of Interest: The authors declare no conflicts of interest.

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Danksagung

Aus Datenschutzgründen entfernt