DENTSPLY
DETREY

x-flow™

Universal Flowable Composite

Flow straight to the point!

With the compliments of

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SCIENTIFIC COMPENDIUM

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1 Introduction: A New Restorative Concept

Recent developments in dentistry, particularly with regard to an increase of prevention, lead to a decrease in the typical cavity size. Therefore, there is a strong need for materials suitable for the restoration of very small cavities in a minimal-invasive technique. For these very small cavities, shrinkage and subsequent marginal leakage are not as important as for larger cavities. Therefore, flowable materials have been developed that have been optimised for adaptation of the restorative material to the cavity. The viscosity behaviour of flowable materials is one of the key-functions for both improved handling properties and improved application.

On the other side exists a tendency for the use of higher filled restorative materials. Due to the limited ability of these materials to adapt to cavity walls, frequently flowable materials are used as cavity liners. This application also requires an improved viscosity behaviour.

2 The X-flow System

The subsequent chapters describe the chemical principles of X-flow, as well as the most important properties of this new restorative material.

X-flow is a smooth flowing, light curing, radiopaque composite material which makes it ideal for restoration of small cavities, for lining, and for luting of indirect ceramic or composite restorations.

X-flow is delivered in Compulas[1] for direct intra-oral application and available in the following Vita[2] shades B1, A2, A3, A3.5, A4, and U, a greyish shade lighter than C1.

X-flow adapts to the cavity walls without the use of hand instruments.

[1] The Compula combines a **Comp**ules®Tip with a steel can**ula** for precise dosage and placement.

[2] Vita® is a registered trademark of Vita Zahnfabrik.

X-flow is used following acid conditioning with e. g. DeTrey® Conditioner 36 and application of Prime&Bond® NT, a universal self-priming dental adhesive designed to bond the restorative to enamel and dentine.

With X-flow the resin matrix system, based on new multifunctional methacrylates, and the filler particles are ideally adjusted resulting in superior flow properties behaviour.

X-flow has the following composition:
Barium alumoborosilicate glass
Highly dispersed silicon dioxide
Modified fluoroapatite
Iron pigments
Titanium pigments
Di- and multifunctional methacrylate resins
Photoinitiators
Butylated hydroxy toluene and other stabilisers

The photo-initiated multifunctional methacrylates polymerise with each other, forming a three-dimensional network that incorporates the filler particles. The polymeric network is mechanically stable in itself, but it is further strengthened by the filler.

Stabilisers added to X-flow guarantee the desired long shelf life and a long working time that is as twice as high as demanded by ISO 4049 standard.

The curing mechanism is practically identical to the photo-initiated free-radical polymerisation of light-curing composite materials (Spectrum™ TPH, Esthet-X™, SurFil™), compomers (Dyract®, Dyract® AP) and ORMOCERS (Definite).

3 The New Compula™ Delivery System

In the past, flowable restoratives were always difficult to apply. Now X-flow is delivered in a new Compula with a unique metal cannula that allows an easy and precise application of the material exactly to the spot where it is required.

4 Material Properties

4.1 Viscosity Behaviour

The quality of minimal-invasive restorations is determined mainly by how well the material can be incorporated into the cavity. Therefore, the rheological behaviour is an important handling property of a flowable material.

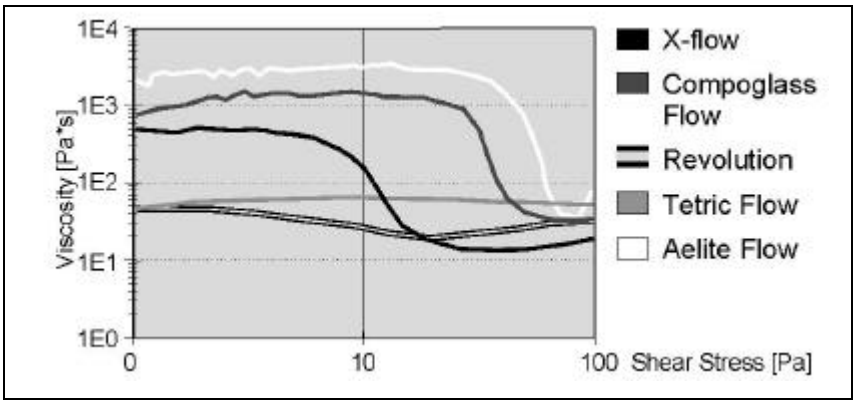

Figure 1 Rheological behaviour of X-flow

exhibits the rheological behaviour of X-flow compared to some competitive flowable materials. These data were obtained using a Bohlin rheometer CS 50 at 23°C.

Two different groups of flowable materials can be distinguished: the first group (Aelite-Flo and Compoglass Flow) exhibits at high shear stress a low viscosity which increases upon reduced shear stress. That means they do not flow if no shear stress is applied. This flow behaviour, however, contributes to a poor adaptation once the material is extruded and placed into the cavity.

The second group of materials (Revolution and Tetric Flow) exhibit a low viscosity over a broad shear stress range. Due to their low viscosities the latter materials tend to flow beyond the margins of the cavity preparation especially in class V situations.

In contrast, X-flow exhibits a well balanced thixotropic flow behaviour: this means its initial viscosity is significantly decreased under shear stress applied during the extrusion from the Compula, but contrary to the first group discussed above, the viscosity of X-flow builds up again at a much lower shear stress allowing for adaptation to the cavity walls during placement of the material.

4.2 Compressive Strength

Flowable restorative materials are indicated for the restoration of small cavities and as cavity liners. Therefore, mechanical properties are not quite as important as with composite materials used e.g. in stress bearing class II situations. However, mechanical strength is necessary to ensure form stability and abrasion resistance.

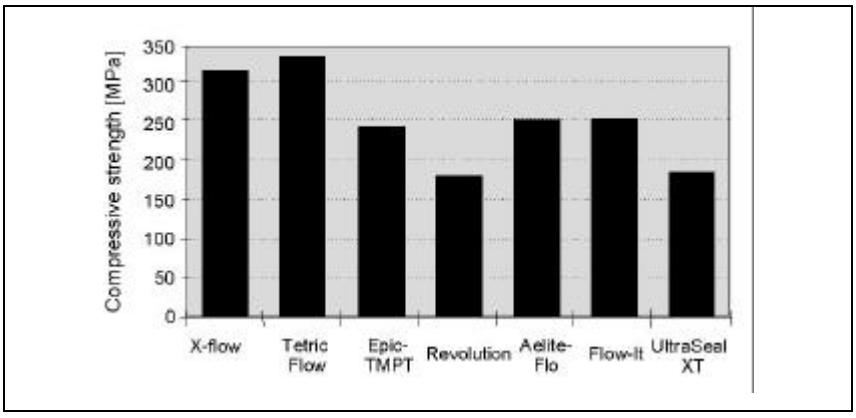

Figure 2 Comparison of compressive strength (after 24 h storage in water at 37°C) of X-flow with other competitive flowable restoratives

As demonstrated in Figure 2 X-flow exceeds most of the competitive flowable restoratives with regard to compressive strength. X-flow has a compressive strength that is typical for restorative materials while most of the competitive materials exhibit lower compressive strengths.

4.3 Flexural Strength

The typical flexural strength of X-flow is about 82 MPa after 24-h water storage at 37°C (Figure 3) which is in the range of other flowable materials

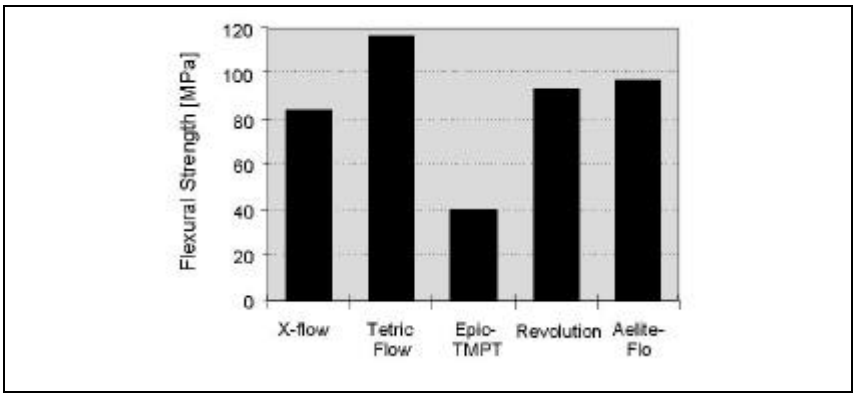

Figure 3 Comparison of flexural strength (after 24 h storage in water at 37°C) of X-flow with other competitive flowable restoratives (measured in accordance with ISO 4049)

4.4 Surface Hardness

It is well known that the abrasion resistance of a material correlates among other parameters with its surface hardness. A common method to determine surface hardness is to investigate the Vickers hardness. The penetration depth of a diamond tip loaded with a defined weight is measured.

The results in Figure 4 demonstrate that X-flow has by far the highest surface hardness (54.4 ± 0.9) of the materials examined.

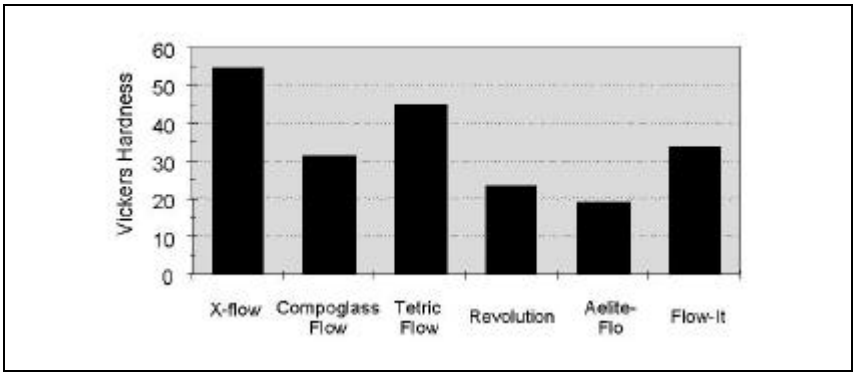

Figure 4 Vickers hardness of selected flowable materials

4.5 Optical Properties

X-flow is available in the following shades: A2, A3, A4, B1, C2, translucent and opaque.

The colour stability of X-flow ($\Delta E < 2$) is comparable to Aelite Flo (2.7). It is significantly higher than the colour stability of Compoglass Flow (4.6), UltraSeal XT (5.0) and Tetric Flow (6.4).

Different applications of flowable materials such as for minimal invasive treatment, as cavity liner and to cover metal restorations or coloured tooth structure require flowable restoratives with low, middle and high opacities.

Due to the optimised adaptation of refractive index of matrix resins and fillers, the opacity of translucent X-flow is 9.8 % only (Figure 5). The coloured shades have an opacity of 40% and the opaque shade has an opacity of 70%. Therefore, X-flow offers a wide range of opacities between 9.8 and 70%.

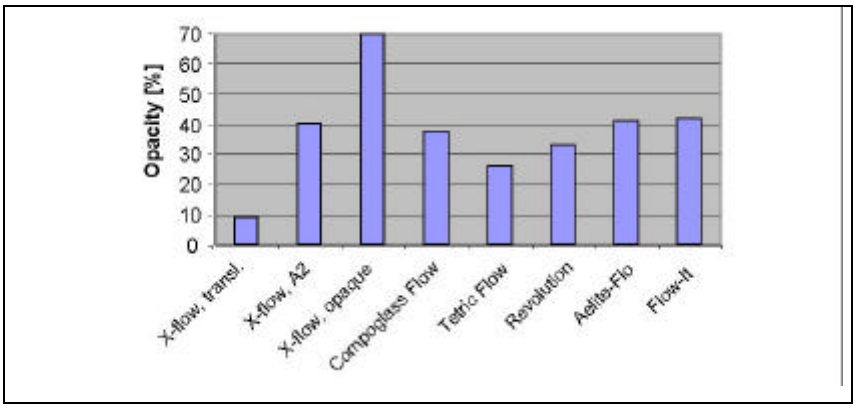

Figure 5 Opacities of X-flow compared to competitive flowable restoratives

The radio-opacity of X-flow is as high as that of enamel (2 mm Al).

4.6 Polymerisation Properties

The depth of cure of a restorative material can significantly influence the long-term clinical success. As the geometry of restorations may vary, complete polymerisation of X-flow even at higher depths has to be guaranteed.

The depth of cure of X-flow depends on the colour of the material. For the A2, A3 and A4 shades, the polymerisation depth is 3 mm; for B1, it is 4 mm (according to ISO 4049). This is very similar to the polymerisation depth of the other flowable materials examined (Tetric Flow 4 mm, Epic-TMTP 3.9 mm, Revolution 3.2 mm, Flow-It 3 mm, Aelite-Flo 2.5 mm).

A restorative material has to have a certain stability towards the light of dental operation lamps. The sensitivity to ambient light is determined according to ISO norm 4049 at an irradiation of 10000 lux. X-flow has a fairly low sensitivity to ambient light of 115 s, compared to that of other flowable materials (Tetric Flow 80 s, Aelite Flo 85 s, Flow-It 38 s).

4.7 Polymerisation Shrinkage

Due to the relatively low filler content the polymerisation shrinkage of flowable materials is higher than that of higher filled composites. Generally, flowable materials have a polymerisation shrinkage between 5 and 7%; for X-flow, the shrinkage is 5%.

4.8 Solubility

The solubility of X-flow is very low (0.34 µg/mm^3) compared to the limit of 7.5 µg/mm^3 given in the ISO 4049 norm.

4.9 Polishability and Wear Resistance

The aesthetic quality of a restoration depends on colour, opacity and surface roughness. The initial surface roughness is influenced by the polishability of a material, whereas the wear resistance decide on long-term roughness and substantial lost.
Therefore, the polishability was studied by Salomon. For each tested sample, five different measurements at different orientations were realised. As is shown in Table 1 the surface roughness of Flow X is completely comparable to Tetric flow.

Polishing	Flow X Ra / µm	Tetric flow Ra / µm
Sof-Lex	0,09 (0,02)	0,09 (0,01)
Enhance	0,16 (0,04)	0,16 (0,05)
PoGo	0,06 (0,01)	0,06 (0,01)

Table 1 Surface roughness Ra (mean, standard deviation) according to the finishing-polishing procedure and the material tested

Restorative materials are subjected to abrasive conditions within the mouth, particularly during food intake and tooth cleaning.

In this regard X-flow was subjected to a strict examination by established methods. The details of the abrasion measurement according to the ACTA method can be found in the literature (De Gee, P. Pallov, J. Dent. **21** [1993]).

X-flow and three other flowable materials were examined for their abrasion behaviour by the ACTA wear method. The loss of material was determined as a function of time. X-flow was found to have the same abrasion resistance as the competitive materials (Table 2).

Time of storage in water [days]	X-flow	Compoglass Flow	Tetric Flow	Revolution
1	97 ± 1	94 ± 4	96 ± 2	96 ± 3
4	85 ± 1	85 ± 2	86 ± 2	88 ± 1
7	79 ± 1	81 ± 1	83 ± 2	80 ± 2
28	75 ± 2	84 ± 2	81 ± 2	79 ± 3
56	78 ± 1	80 ± 1	79 ± 2	76 ± 2

Table 2 Wear resistance of X-flow compared to other competitive flowable restoratives (200000 cycles at 15 N and 15% slip)

4.10 Compatibility with other Restorative Materials

The question whether X-flow can be combined with other light curing restorative materials has been investigated by corresponding bond strength measurements. The bond strength between X-flow and various composites (Spectrum TPH, Esthet-x, SureFil, Tetric Ceram, Filtek Z250 and Prodigy), a compomer (Dyract AP) and an ORMOCER (Definite) was tested. As shown in Figure 6 the adhesion of X-flow to composites varies between 13 and 25 MPa. In conclusion, sufficient bond strength between X-flow and other restorative materials was observed. Hence, X-flow can be regarded as fully compatible with other light cured composites, compomers and ORMOCERs.

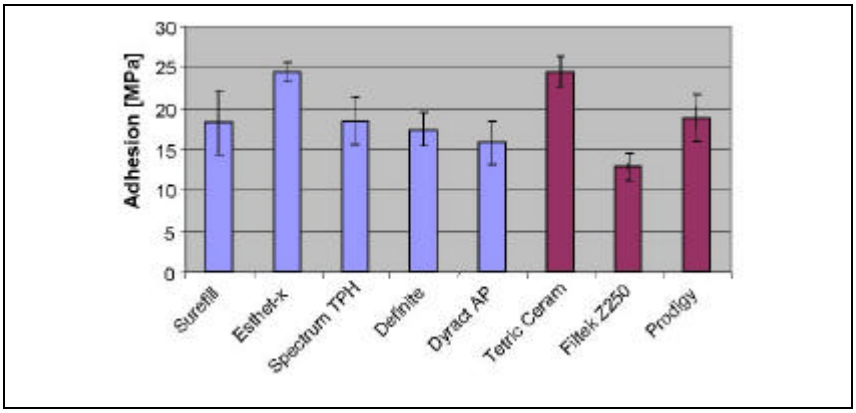

Figure 6 Bond strength of X-flow to various light cured restoratives

5 Indications

- Minimal invasive restorations – this comprises
  - Small, non occlusal stress-bearing restorations in anterior and posterior teeth
  - Extended pit & fissure sealings
  - Shallow cervical lesions
- Margin repair of direct and indirect restorations
- Cavity lining
- Adhesive luting of indirect porcelain or composite inlays, onlays, veneers, and crowns if they allow sufficient light transmission to the tooth-restoration interface
- Blocking out undercuts in connection with preparation of indirect restorations

6 Contraindications

- Use on patients with a known allergy to dimethacrylate resins and other components of X-flow.
- Permanent restorations of occlusal stress-bearing cavities in permanent posterior teeth.
- When moisture control cannot be guaranteed during application (deep subgingival cavity margins).

7 Warnings

- DeTrey Conditioner 36 contains 36 % phosphoric acid which can cause burns of soft tissue. Avoid contact with oral tissues, eyes, and skin. If accidental contact occurs, immediately rinse with plenty of water and seek medical attention. Do not take internally.
- X-flow contains methacrylates that may be irritating to the eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- X-flow may cause sensitisation by contact with skin or mucous membranes in susceptible persons. After accidental contact, wash immediately with plenty of soap and water or rinse with plenty of water. If sensitisation has occurred, discontinue use.

- Use a gentle, even motion when exerting pressure on the applicator gun. Use of excessive force or sudden movement could create a potential hazard with extrusion.

The following adverse reaction has been associated with the use of acrylate monomers:

- Reversible inflammatory changes of the oral mucosa after accidental contact.

8 Interactions with Dental Materials

Eugenol containing dental materials should not be used in conjunction with this product because they may interfere with hardening and cause softening of the polymeric components of the material.

9 Step-by-Step Instructions

9.1 Direct Restorations

9.1.1 Conditioning and Bonding Procedure

Prior to the application of X-flow, the cavity surface has to be conditioned and treated with a suitable adhesive system.

The following products are recommended:

Prime&Bond NT – Nano-Technology Dental Adhesive
following conditioning with DeTrey Conditioner 36 (Figures 7 and 8)

or

Xeno III – Single Step Self-Etch Adhesive (Figures 9 and 10).

For the application procedure, please consult the directions for use for the respective adhesive.

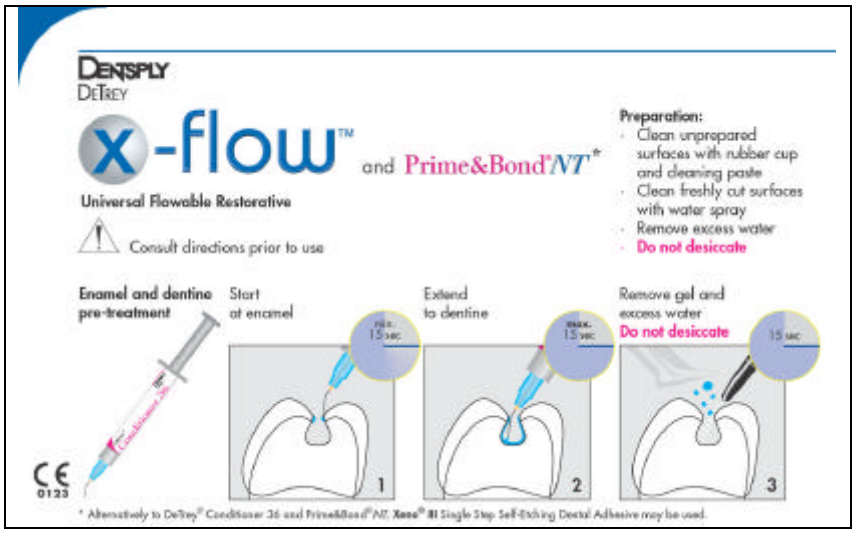

Figure 7 Conditioning with DeTrey Conditioner 36 prior to bonding procedure with Prime&Bond NT and application of X-flow

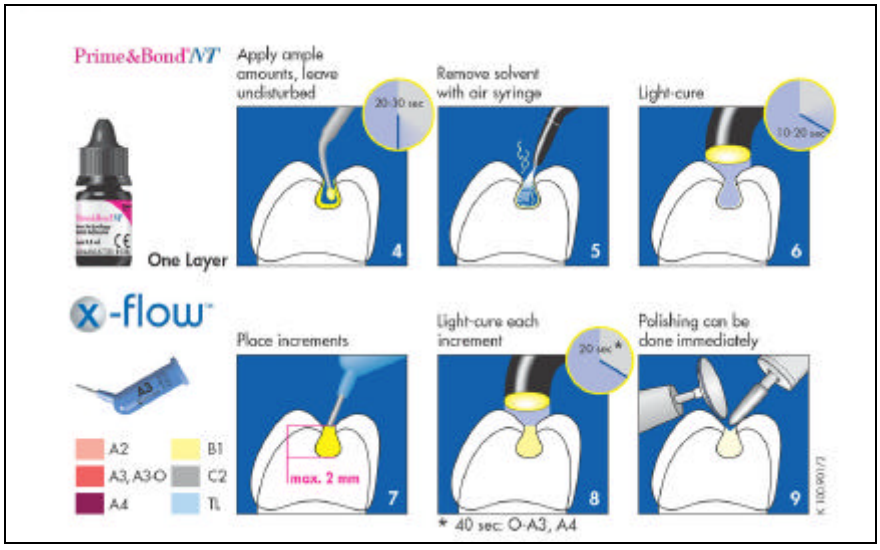

Figure 8 Bonding procedure with Prime&Bond NT (following conditioning with DeTrey Conditioner 36) and application of X-flow

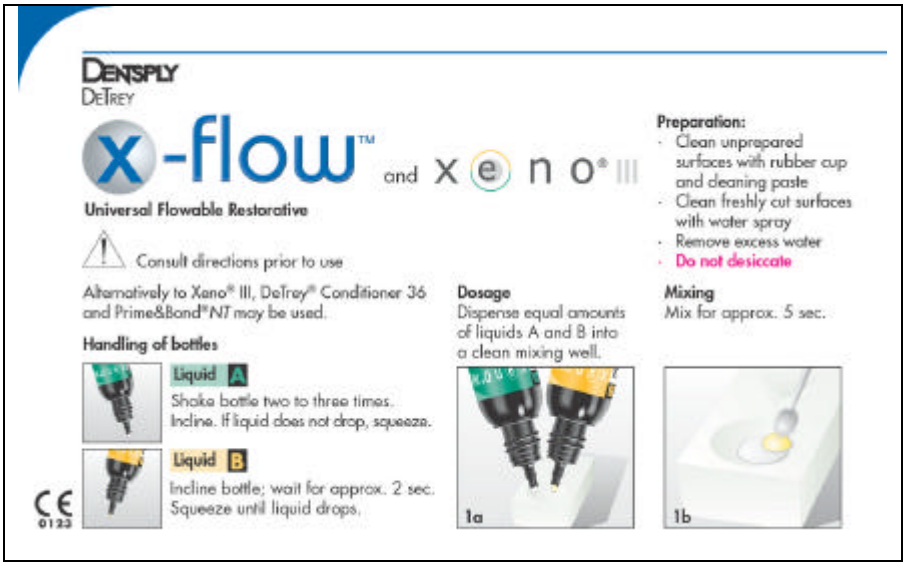

Figure 9 Dosage and mixing of Xeno III prior to application of X-flow

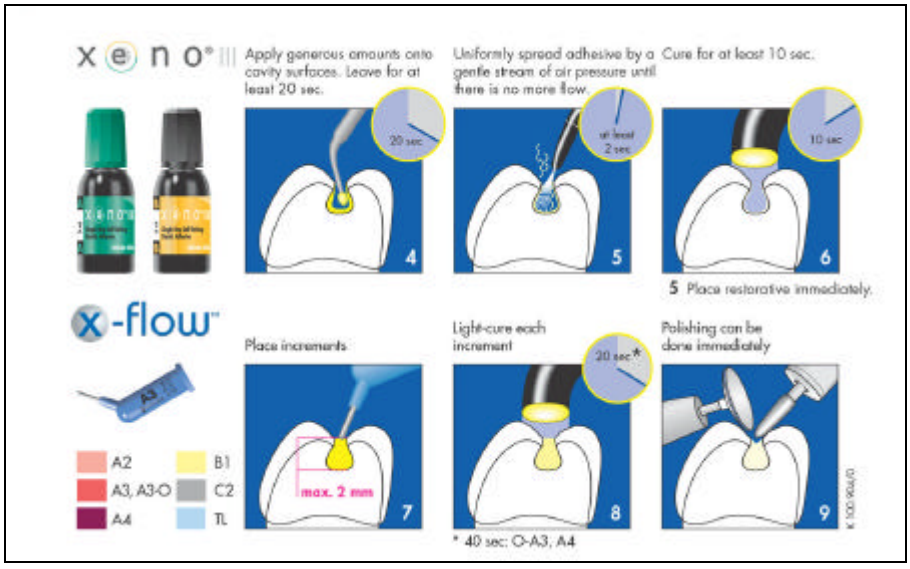

Figure 10 Bonding procedure with Xeno III and application of X-flow

9.1.2 Placement of X.*flow*

a) Insert Compula into the notched opening of the applicator gun barrel.
Be certain that the collar on the Compula is inserted first.

b) Remove the coloured cap from the Compula.

c) The Compula may be rotated to gain the proper angle of entrance into the cavity.

d) To dispense the material, use a slow, steady pressure . Excessive force is not necessary. If more than gentle pressure is required, remove from patient field and check for obstruction.

e) Dispense X *flow* directly into the cavity preparation. In deep cavities, incremental placement and curing (in 2 mm layers or less) is recommended to minimise polymerisation shrinkage.

9.1.3 Curing

Cure each increment separately with a VLC dental polymerisation unit for at least 40 seconds[4]. The tip of the light guide should be held as close as possible to the restoration during curing.
Important: Be sure to expose each area of the entire restoration to the curing light. Additionally, the restoration should be cured through lingual or buccal enamel walls.

9.1.4 Finishing

Finish immediately after curing. Gross excess material may be removed with fluted finishing burs or diamonds. Finishing is best achieved by using Enhance® Finishing and Polishing Discs and interproximal finishing and polishing strips. A high final lustre can be obtained by applying PoGo™ One-Step Diamond Micro-Polisher or Prisma® Gloss and Prisma Gloss Extra-Fine polishing pastes.

9.2 Indirect Restorations

9.2.1 Pre-Treatment of Restoration

The internal surfaces should be treated according to the manufacturers' recommendations.

9.2.2 Moisture Control

Surface cleanliness is paramount for the development of adhesion.

9.2.3 Enamel and Dentine Pre-Treatment

Clean enamel and dentine prepared during a previous appointment with a rubber cup and pumice or a cleaning paste such as Nupro Prophylaxis Pastes. Wash thoroughly with water spray and then air-dry. Clean freshly cut enamel and dentine with water spray and then air-dry.

9.2.4 Conditioning and Application of Prime&Bond NT

For conditioning of enamel and dentine and application of Prime&Bond NT, please consult the directions for use for this adhesive.

9.2.5 Dispensing of X-flow

Dispense X-flow onto the restoration and/or onto the tooth preparation.

9.2.6 Placement of Restoration

Place restoration. Apply pressure and then release to allow the hydraulic pressure to dissipate. Repeat this procedure at least one more time and ensure that the restoration is completely seated.

Remove as much excess as possible before the composite is light-cured.
If any excess composite remains after curing, remove with curette, scalers or finishing burs/discs, or strips.

9.2.7 Light Curing

Expose all surfaces of the restorations to the dental curing light for 40 seconds[4] each. Depending on the number of surfaces of the restoration, the diameter of the curing light outlet, and the size of the tooth, this results in up to 5 curing cycles per restoration.

9.2.8 Occlusal Adjustments and Finishing

Make occlusal adjustments and finish the margins with finishing burs.
Remove excess from proximal surfaces with diamond strips or with the diamond tips for the EVA contra-angle handpiece.

Use polishing discs (Enhance) on inlay margins where accessible. Use polishing pastes (Prisma Gloss and Prisma Gloss Extra Fine) additionally or alternatively. Work interdentally with aluminium oxide strips.

10 Clinical Investigations

Prototype material, the composition and physical properties of which correspond to X-flow, are being investigated clinically by the Universities of Liverpool and Michigan.

10.1 Investigation for Class I and II Restorations conducted by The University of Liverpool

10.1.1 Research Team

Budenburg A, Cooper N, Jedynakiewicz N M, Martin N, Orme D

10.1.2 Design, Method and Materials

Longitudinal, uncontrolled trial evaluating the performance of small Class I and II restorations of at least 30 subjects. Standard rotary instruments were used for cavity preparation. The restorations were bonded with Prime&Bond NT after application of the self-etching primer NRC. Performance was rated according to Ryge.

10.1.3 Results at 1 Year

All 33 restorations available for review were clinically satisfactory. None of the restorations placed had to be replaced.

Criteria	12-mth assessment (Scores given as a percentage of the total of 33 restorations)			
	Alpha	Bravo	Charlie	Delta or Oscar
Colour match	100	0	0	n/a
Marginal adaptation	100	0	0	0
Surface texture	100	0	0	n/a
Anatomic form	100	0	0	n/a
Interprox. contact	100	0	0	0

10.1.4 Conclusion

The material X-flow has been demonstrated to be a satisfactory restorative material for the restoration of minimal-invasive, load-bearing Class I & II cavities in permanent teeth over a

period of 1 year.

10.2 Investigation for minimal invasive Class I Restorations in Permanent Teeth at The Universityof Michigan

10.2.1 Research Team

Briskie D, Krusky J B, Nedley M P, Peters M C R B

10.2.2 Design, Method and Materials

In a descriptive, longitudinal clinical investigation, 62 subjects with incipient caries received 89 restorations (1 to 3 restorations per patient).
Preparation was performed using air abrasion technology (Air Touch™ system) and micro abrasion (SONICSYS micro).

The flowable restorative was used in combination with the self-etching primer NRC and the adhesive Prime&Bond NT. Modified Ryge criteria were used for evaluation of safety and performance.

10.2.3 Results at 1 Year

62 restorations (71%) were available for examination and evaluation at 1 year.

Ryge criteria (modified)	1-year scores (Scores given as a percentage of the total of 62 restorations)		
	Alpha	Bravo	Charlie Delta Oscar
Pulpal response	100	0	0
Colour match	100	0	0
Marginal discolouration	95	5	0
Marginal integrity	94	6	0
Anatomic form	100	0	0
Surface texture	100	0	0
Absence of caries	100	0	0

All teeth were vital, none showed increased sensitivity.
Only 3 restorations (5%) showed a minor localised discolouration at the margin.
4 restorations (6%) showed a minimal catch with an explorer.

The surface texture was rated Alpha for all restorations including the few restorations that had scored Bravo at the 6-month recall. This positive change might indicate a "self-polishing" effect by mastification.
There was no caries present in close proximity to the restorations.

10.2.4 Conclusion

1-year data show good clinical performance. The use of a flowable and the concept of minimum intervention dentistry was clinically successful in a caries-prone population.

11 Conclusion

As a result of our extensive investigations a X-flow is guaranteed to give long-term clinical success.