G-ænial® Universal Flo from GC

High-strength injectable restorative composite

TECHNICAL MANUAL

Table of Contents

The tooth colours mentioned in this manual are Vita shades or GC shades.
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1.0 Introduction

The use of flowable composites has increased since their introduction in 1995. At that time, the main indication for flowable composites was as a liner, mainly under posterior composite restorations. Their flowability ensures a perfect adaptation to cavity preparation walls, decreasing the risk of air entrapment and the inclusion of voids and helping to reduce the stress at the margins of the restoration.
The reduced filler load in flowable composites increases their flowability so that the material is easily dispensed and flows smoothly for easy placement.

Traditional flowable composites have limited indications due to their poor physical and mechanical properties relative to other types of composites, and can only be used as liners, for small cavities and tunnel preparations.
As a result of extensive research, GC now offers two products that solve these problems:

- G-ænial Universal Flo:
  A high-strength injectable composite whose physical properties are equal to current composite materials (i.e., non-flowables) which allows for a durable and safe use in all direct restorations (Classes I-V).
- G-ænial Flo X:
  A highly flowable composite with a high level of radiopacity suited to the classical flowable indications, with a viscosity that allows for easy and smooth placement.

This technical manual provides information on the unique formulation and properties of G-ænial Universal Flo that allow it to be used for all types of direct composite restorations while still offering the convenient handling and ease-of-use of an injectable composite.

2.0 Product description

G-ænial Universal Flo is an injectable, light-cured, radiopaque restorative designed to provide a true Universal restorative material that can be used for a variety of indications while offering excellent viscosity and perfect direct syringe application.

3.0 Indications

G-ænial Universal Flo is indicated for:

- Direct restorations for all Class I, II, III, IV and V cavities.
- Minimum Intervention cavities
- Splinting: fixation of mobile teeth
- Indirect chairside technique
- Veneer luting

4.0 Features and benefits

G-ænial Universal Flo offers intelligent and convenient solutions to improve the characteristics of a flowable composite:

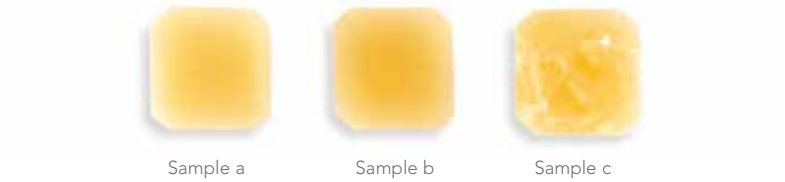
Longevity and endurance
G-ænial Universal Flo benefits from the design, amount and dispersion of fillers that result in an improved physical performance that is similar to a regular composite and the ability to use this injectable composite for all classes of direct composite restorations.

Superior handling properties
Being runny and not easy to keep in place, to achieve a restoration with a traditional flowable composite is not always easy.
One of the exclusive advantages of G-ænial Universal Flo is its viscosity, which is carefully balanced in order to provide a material that flows smoothly for easy placement in the cavity and that is also thixotropic thereby allowing it to stay in position when placed.

The design of the syringe has also been adapted to offer ergonomic and precise application of the material.

Astonishing Polishability
G-ænial Universal Flo benefits from high polishability, resulting in excellent aesthetics. The gloss rate that can be achieved just by finishing and removing the inhibition layer is very impressive, and in this regards G-ænial Universal Flo can be considered a self-polishing material.
Furthermore, G-ænial Universal Flo maintains its high polish over time.

Figure 1: Unpolished composite samples.



The three samples are of different composites: samples A & B are competitive products and sample C is G-ænial Universal Flo. All composites were cured according to the manufacturer's instructions. The last composite layer for all samples was cured under an air barrier to avoid creation of an air inhibition layer. The results demonstrated the high initial gloss that can be achieved with G-ænial Universal Flo prior to any polishing, and in comparison with competitive materials.

Low shrinkage stress
G-ænial Universal Flo has low shrinkage stress, helping to conserve tooth structure by preserving the margins and avoiding nanoleakage and cracks.

Superb aesthetics
G-ænial Universal Flo offers outstanding aesthetics without any compromises. As an integral part of the G-ænial family, superb aesthetics results are assured. Thanks to its broad range of 15 shades and 3 different levels of translucency, it is possible to easily achieve highly aesthetic restorations.

Figure 2: Aesthetic Class I and V restorations with G-ænial Universal Flo, courtesy Dr J Sabbagh, Belgium, 2010

5.0 Composition

G-ænial Universal Flo has been developed with the objectives of providing an injectable material with excellent physical properties suitable for use for all direct restorations.
In order to obtain a flowable viscosity, flowable composite resins generally exhibit a lower filler content than paste-type composites and poorer physical properties. This is not the case with G-ænial Universal Flo, as the formulation was developed using the following approaches:

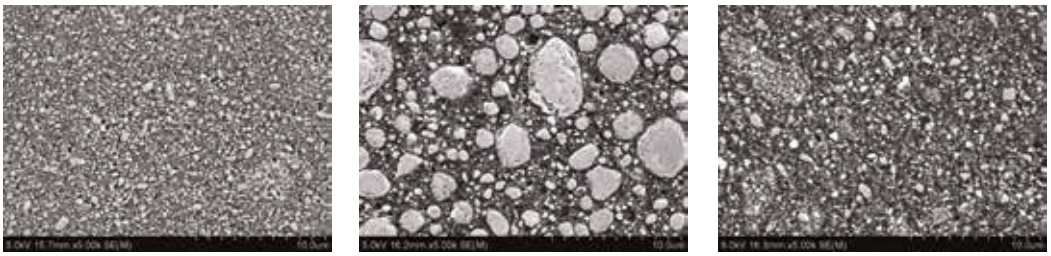
1. Adopting new glass particles: **ultra fine strontium glass**. These fillers provide the following benefits:
   a. Reduced risk of filler drop-out during occlusal loading due to the small filler size (on average 200nm).
   b. Combination of high radiopacity and superior translucency due to the radioapacity of the fillers and their low refractive index.

2. A new **silane surface treatment** of the ultra fine strontium glass fillers. This provided in turn:
   a. A higher filler load of 69%, with homogeneous dispersion of the fillers
   b. Improved bonding between the particles and the matrix which together with the filler dispersion enables the material to achieve **high strength and wear resistance**

G-ænial Universal Flo		Content
Matrix	Urethanedimethacrylate	31 % wt
	Bis-MEPP	
	TEGDMA	
Filler	Silicon dioxide (16nm)	69 % wt 50 % vol
	Strontium glass (200 nm)	
	Pigment	
Initiator	Photo initiator	Trace

Table 1: Main composition of G-ænial Universal Flo

Figure 3: SEM Observation (Magnification X 5000) of G-ænial Universal Flo, Filtek Supreme XT Flow and Tetric Flow showing homogeneous dispersion of ultra fine fillers in G-ænial Universal Flo

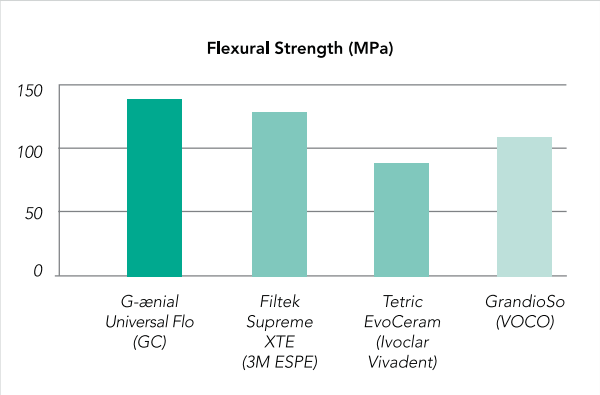


6.0 Physical properties

6.1 Flexural strength

Definition: Flexural strength is defined as a material's ability to resist deformation under load.

Figure 4: Flexural Strength of various composite and flowable composite materials. This flexural strength test was conducted following the ISO 4049 specifications.
Source: Dental Materials Research Foundation, University of ACTA, Amsterdam. Data on file.



Within the limitations of this test, it can be concluded that G-ænial Universal Flo shows a **flexural strength similar or superior to the paste-type composites tested**.

6.2 Modulus of elasticity and fracture toughness

6.2.1 Modulus of elasticity

Definition: The modulus of elasticity (Young's modulus) is a measure of the rigidity of the material and is defined by the initial slope of a stress-strain curve.
A high modulus of elasticity means that the material is rigid and stiff. A material with a low modulus of elasticity is more flexible and is better able to buffer the masticatory pressure.

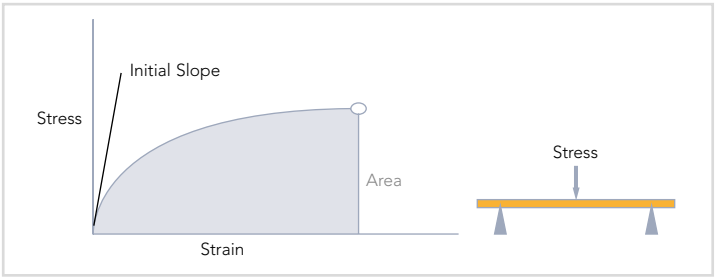
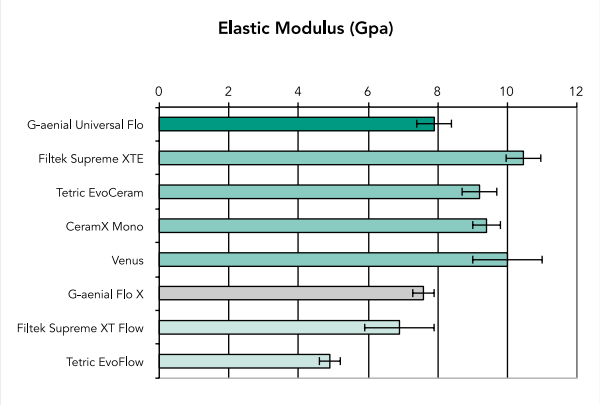


Figure 5: Modulus of elasticity of various composite and flowable composite materials. This test was conducted according to the ISO 4049 specifications.
Source: GC Corporation, R&D department, 2014.

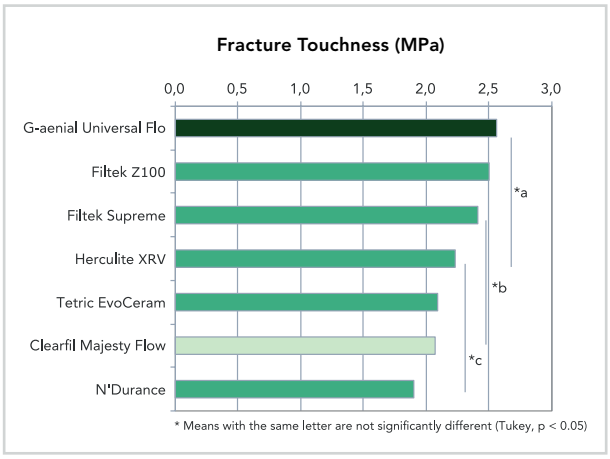


Within the limitations of this test, it can be concluded that G-ænial Universal Flo exhibits **higher flexibility than conventional composites and a similar flexibility compared to the flowable composites tested**.

6.2.2 Fracture toughness

Definition: Fracture toughness is a measure of the material's ability to resist the propagation of a formed crack, also defined as the toughness against bending stress. The toughness is related to the energy absorbed in the bending process.

Figure 6: Fracture toughness of various composite materials.
This test was conducted according to the Chevron Notched Beam (CNB) Method
Source: De Munck et al., Belgium, K.U.Leuven -BIOMAT, abstract presented at CED-IADR meeting Budapest, Sept. 2011'.

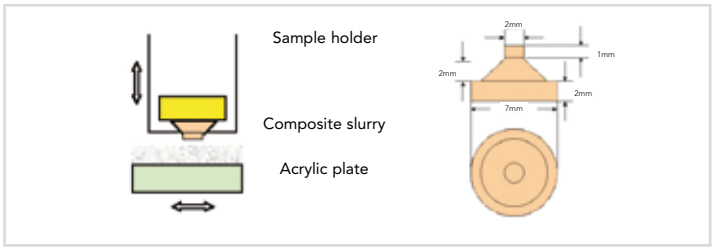


Within the limitations of this test it can be concluded that **G-ænial Universal Flo shows a similar or higher ability to resist to propagation of cracks compared to conventional composites.**

6.3 Three–body wear

Definition: Wear is the loss of material resulting from the contact of two or more material. The three-body wear test is used to obtain a closer reproduction of the wear in the oral cavity, including contact with opposing dentition, and the presence of a bolus (using a slurry of PMMA and glycerol in the test).

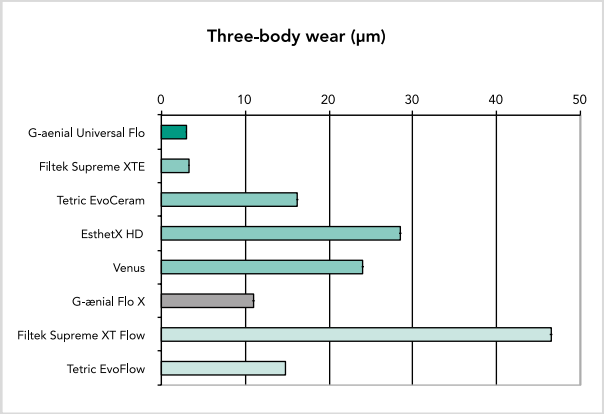
Figure 7: Three-body wear test set-up



Composite specimens were prepared using a metal mold and cured according to the manufacturer's instructions for use. All specimens were stored in water at 37 °C for 24 hours and wear resistance tests were performed with a three-body wear machine. The abrasive slurry was prepared by mixing 100 g of PMMA powder with 100 ml of glycerol and was then spread over a PMMA plate stage.

Specimens were moved up and down along a 5 cm path at a rate of 50 strokes per minute and held in indirect contact with an acrylic plate under a load of 350 g.f. Simultaneously, the sample holder was moved horizontally along a 10 mm path at a rate of 50 strokes per minute. After 100,000 cycles (one complete lateral and vertical movement counts for one cycle), wear of the material was evaluated by the height loss.

Figure 8: Three-body wear of various composite materials.
Source: GC Corporation, R&D department, Japan, 2014



Within the limitations of this test, it can be concluded that **the wear resistance of G-ænial Universal Flo is superior to all tested flowable and paste-type composites** with the exception of Filtek Supreme XTE which demonstrated similar results.

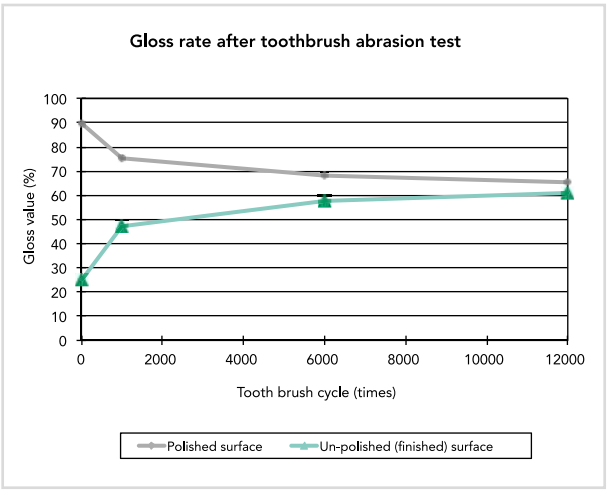
G-ænial Universal Flo exhibits an **exceptional ability to resist wear**, superior to most paste-type composites on the market.

6.4 Polishability

Tooth brush abrasion test set up:
The toothbrush abrasion test was performed on polished and unpolished surfaces of G-ænial Universal Flo using a GC Prospec hard toothbrush and White & White dentifrice, under a load of 200 g for 12,000 cycles (equivalent to 1 year, assuming 15 laps twice daily).

6.4.1 G-ænial Universal Flo gloss rate over time

Figure 9: Gloss rate after Toothbrush Abrasion test of polished and unpolished surfaces of G-ænial Universal Flo.
Source: GC Corporation, R&D department, Japan, 2010



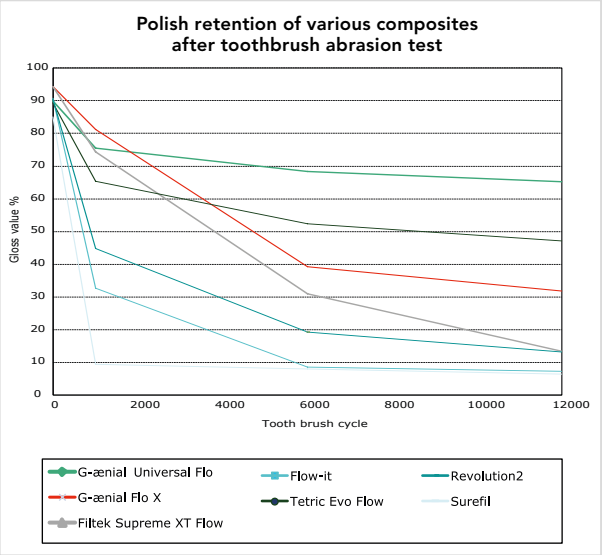
The toothbrush abrasion test shows that the gloss rate that can be achieved with G-ænial Universal Flo after toothbrushing cycles is the same regardless of whether or not the samples were originally polished.

G-ænial Universal Flo offers a unique self-polishing property, such that even unpolished surfaces will gain and maintain gloss over time.

6.4.2 G-ænial Universal Flo vs. competitors

Figure 10: Gloss rate after Toothbrush Abrasion test of different composite materials.
Source: GC Corporation, R&D department

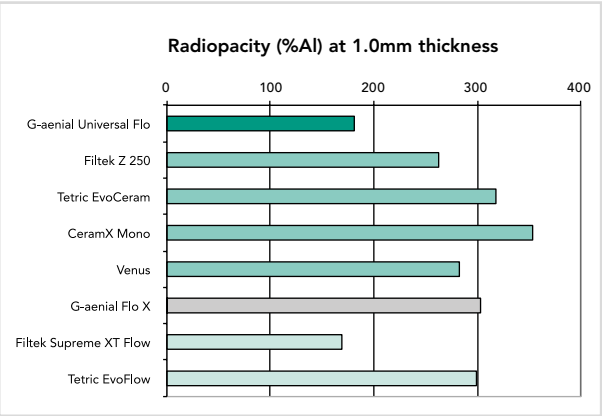
Within the limitations of this test, it can be concluded that **G-ænial Universal Flo is capable of maintaining a high level of gloss** in comparison with competitor composite material.



6.5 Radiopacity

Figure 11: Radiopacity of various composite materials
Source: GC Corporation, R&D department, Japan, 2014

Thanks to the use of ultra fine strontium glass fillers, G-ænial Universal Flo exhibits a **clinically relevant radiopacity** superior to the radiopacity of dentin, while maintaining an aesthetic translucency.



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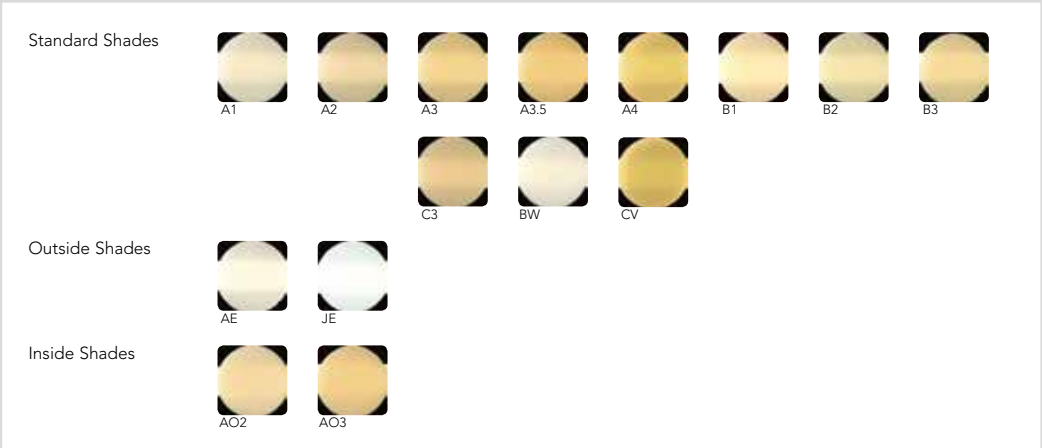
6.6 Summary of physical properties

G-ænial Universal Flo is able to achieve **physical performance comparable to or better than conventional composites** especially in regards to the **high flexural strength and wear resistance**, due to its homogeneously dispersed and extremely fine silane treated filler particles. These fillers also make it possible to obtain a **high gloss in very few steps** and to increase gloss of unpolished surfaces over time (due to its self-polishing property).

7.0 Shading

The shade system of G-ænial Universal Flo has been developed following the same shade concept used for G-ænial Anterior. This allows the material to be used as a **true filling material for all indications**.

Figure 12: Fifteen shades are available for G-ænial Universal Flo



In order to achieve high aesthetic results, 15 shades are available in 3 clearly differentiated shade groups:

- **Standard shades:** Using these shades, a single shade restoration can be placed.
  - Most of the Standard shades are following the Vitapan Shade Guide: A1, A2, A3, A3.5, A4, B1, B2, B3, C3
  - BW (Bleach White) is a unique bleach shade
  - CV (Cervical) is designed for cervical restorations
- **Outside Special shades:** For more elaborate techniques, and where aesthetic demands are higher, two outside shades are available: JE (Junior Enamel) and AE (Adult Enamel). These shades are placed over the standard shades. The shade selection follows the same age concept as G-ænial A & P: Junior enamel is whiter with a higher value compared to Adult enamel.
- **Inside Special Shades:** AO2 and AO3. Placed underneath Standard shades when needed, these provide opacity to mask dentin discolorations in posterior cavities and block the dark shine-through sometimes observed in class IV cavities.

In most cases, 1 shade will be sufficient for the restoration.

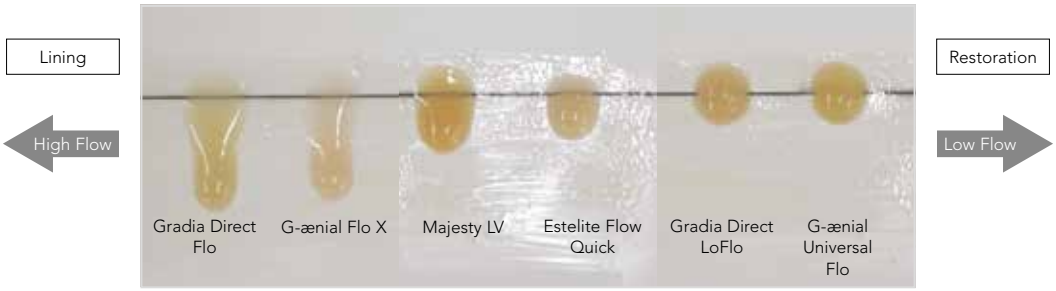
Figure 13: Occlusal restoration using G-ænial Universal Flo A2 shade. Courtesy of Dr Miyasaki, Japan, 2010

8.0 Viscosity and handling

8.1 Viscosity

Test set up
G-ænial Bond was applied on an acrylic plate and light-cured. Some composite material was applied on the plate and the plate was left to stand vertically for 60 seconds at 37° C.

Figure 14: Viscosity of G-ænial Universal Flo - GC Corporation, R&D department, Japan, 2010-2014



The viscosity of G-ænial Universal Flo is higher than a flowable composite such as G-ænial Flo X and behaves more like a restorative material. **The viscosity of G-ænial Universal Flo was designed to improve handling of the material in restorative situations such as cervical cavities.** It is thixotropic, meaning that it will stay in place and makes it possible to contour the material after placement (for example, using a probe).

8.2 Application

The unique syringe design makes direct application of the material into the preparation easy. The tapered end and texture of the tip prevent the composite from sticking to the tip.

Figure 15: Unique mixing tip design

Tapered tip end

Secured screwed tip insertion

In addition, the tip is very thin with a long nozzle to easily reach the base of posterior restorations. The tip is also screwed directly on the syringe, offering a joint strength that is 8 times higher than for other flowable composite syringes.

Figure 16: Cervical restoration using G-ænial Universal Flo, shade A3.
Courtesy of Dr Miyasaki, Japan, 2010

The shape of the syringe allows an easy direct application in the cavity. The material can then be contoured with a probe before light-curing.

The overall grip of the syringe is comfortable, and only minimal pressure is needed to extrude the material.

9.0 Field evaluation

In the development phase, a field test of G-ænial Universal Flo was conducted in June and July 2010, with twenty-eight dentists. Almost 500 cases were restored using G-ænial Universal Flo, as follows:

- Restorations: 40%.
- Lining and base indications: 36%.
- Sealants: 5%,
- Root surfaces restorations: 5%
- Tunnel preparations: 5%

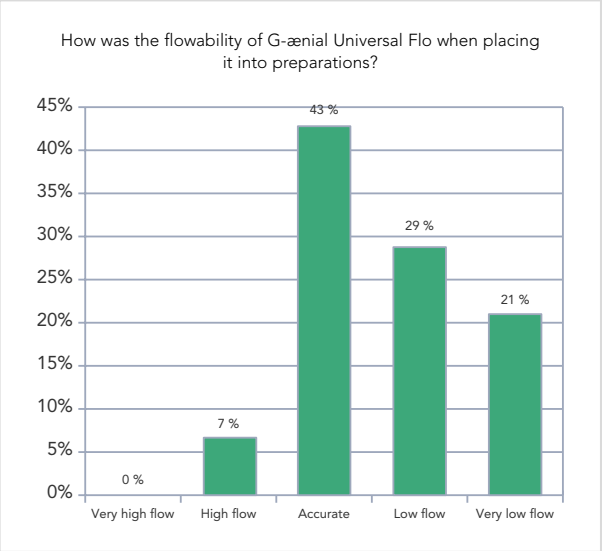
9.1 Handling

	Very easy	Easy	Difficult	Very Difficult
Ease of dispensing	25 %	71 %	4 %	0 %
	Very good	**Good**	**Acceptable**	**Poor**
Stickiness	25%	54%	18%	4%
Thixotropic property	18%	43%	29%	7%
Adaptation to cavity walls	32%	29%	21%	7%
Avoidance of excess paste extruding due to residual pressure	25%	50%	18%	7%

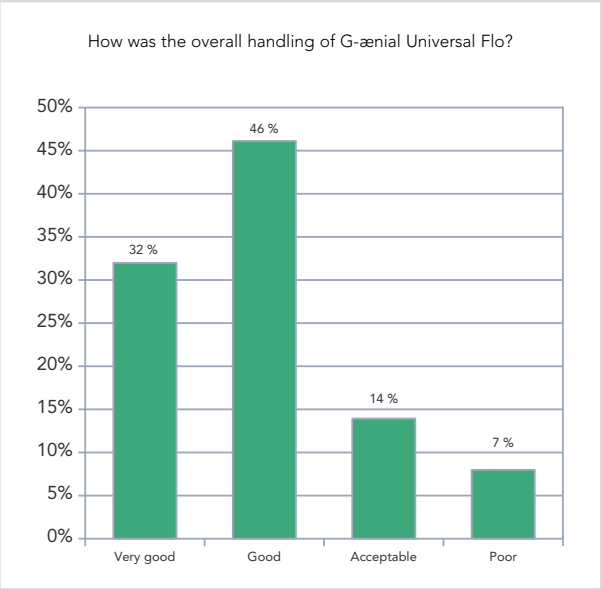
Several factors that are of prime importance when placing a restoration were assessed during this field test with the following results:

- The new syringe design was well accepted: 96% very easy or easy.
- The paste did not stick to the instrument: 79% very good or good.
- Absence of extrusion of paste due to residual pressure: 75% very good or good.
- Thixotropic material, not runny and stays in place once dispensed into the preparation: 61% very good or good.
- The adaptation to the cavity wall or bonding agent was also rated well: 61% very good or good.

Regarding the flowability of the material, it was considered appropriate by 43% of users. Most of the other users judged the material as low or very low flowing, which is in line with the stated properties of the material and is useful when considering its indications.

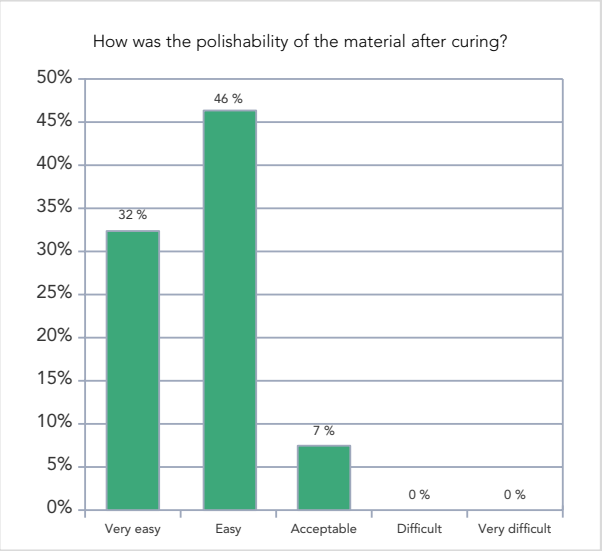


Overall, 79% of the testers rated the handling of the product as good or very good

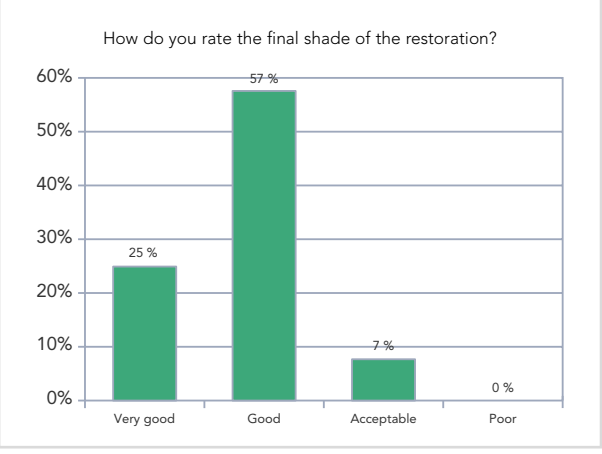


9.2 Aesthetics

The extreme ease of polishing was confirmed in this test where 79% of users found the product easy or very easy to polish.

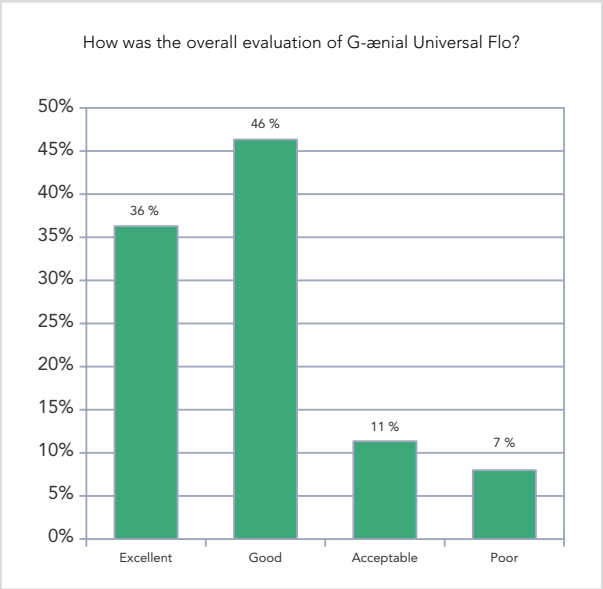


The aesthetics of the restorations was also positively assessed by the users, with 82% judging the final shade as being very good or good.



9.3 Overall evaluation

Overall, 82% of the testers judged G-ænial Universal Flo as being excellent or good. When commenting on the product, they stated that G-ænial Universal Flo behaved more like a composite with flowable properties than like a flowable composite.



10.0 Literature

1. Characteristics in Polymerization Shrinkage of Latest Low-shrinkage Resin Composite Restoratives. T. Maseki, T. Nitta, M. Yamase, T. Yamada, S. Ogawa, T. Kimishima, Y. Nara and I.L. Dogon. Abstract 457 – AADR 2010, Washington DC, USA
2. Wear resistance of new flowable composite resins. M. Nakayama, F. Fusejima, T. Kumagai and T. Sakuma. Abstract 3271 - AADR 2010, Washington DC, USA
3. Mechanical Properties of Various Latest Resin Composite Restoratives. M. Yamase, T. Maseki, T. Nitta, T. Kimishima and Y. Nara. Abstract 464 – AADR 2010, Washington DC, USA
4. Evaluation of Vickers Hardness and Surface Roughness of Composites. I. Okada, Y. Kumashiro, D. Kita and A. Ishikawa. Abstract 2016 – IADR 2011, San Diego, USA
5. In vitro localized wear of current composite restoration materials. K.Tsubota, M. Miyazaki, W.W. Barkmeier, M.A. Latta. Abstract 1188 – IADR 2011, San Diego, USA
6. Polish Retention of a Nanohybrid Flowable Composite. J.A. Platt, M. Macpherson and B. Rhodes. Abstract 1175 – IADR 2011, San Diego, USA
7. Early No Interfacial-Gap Incidence vs. Flexural Modulus with Injectable Composites. M. Irie, Y. Tamada, Y. Maruo, G. Nishigawa, M. Oka, S. Minagi, K.Suzuki and D.C. Watts. Abstract 3203 – IADR 2011, San-Diego, USA
8. Surface characteristic of new injectable composite resin. M. Wako, M. Nakayam, T. Kumagai and T. Sakuma. Abstract 3287 – IADR 2011, San-Diego, USA
9. Volumetric Shrinkage and Mechanical Properties of Injectable Resin Composite. T. Takamizawa, Y. Ogura, H. Kurokawa, S. Ando, M. Miyazaki and M.A. Latta. Abstract 605 – IADR 2011, San-Diego, USA
10. Flowable vs restorative composites: flexural strength and fracture toughness. N.D. Ruse. Abstract 163 –IADR March 2012, Tampa, USA
11. Volumetric Polymerization Shrinkage of Flowable Dental Composites. K. Knecht, Y. Fan, A. Ripps, X. Xu. Abstract 862 – IADR March 2012, Tampa, USA
12. Thermal degradation of Universal Composite Resins. H. Tanaka, M. Nakayama, K. Ikushima, T. Kumagai, T. Sakuma. Abstract 1029 – IADR March 2012, Tampa, USA
13. Adhesion of Bulk-Filled Flowable Composites in Posterior Class I Cavities. A. Van Ende, J. De Munck, K. Van Landuyt, M. Peumans, A. Poitevin, B. Van Meerbeek. Abstract 513 – IADR Finland 2012
14. The effect of thermal degradation of new composite resin. W. Suzuki, T. Ueno, T. Kumagai, T. Sakuma. Abstract 3135 – IADR Seattle 2013.
15. Colorimetric Comparison Amongst Various Composite Brands with Identical Shade Codes. L. Moreau, J.L. Ferracane, P. Zyman, P. Jonas, J-P. Salomon. Abstract 236 – Conseuro Paris 2013
16. Evaluation of GIC-surface treatment on bond strength of resin composite. Y. Hokii, K. Tanaka, F. Fusejima, T. Sakuma. Abstract, 26th Annual Scientific Meeting of IADR-SEA, Hong Kong, 2012
17. G-ænial Bond & G-ænial Universal Flo:V Class Clinical Evaluation. M.G. Tricarico, and M. Ferrari. Abstract 68 – IADR Firenze 2013, Italy
18. G-ænial Bond+G-ænial Universal Flo in Class I and II restorations. C. Caldarella, M.G. Tricarico, and M. Ferrari. Abstract 69 – IADR Firenze 2013, Italy

11.0 Packaging

SHADES

A1, A2, A3, A3.5, A4, B1, B2, B3, C3, AO2, AO3, BW, CV, JE, AE

STORAGE

Store in a cool and dark place (4° C - 25° C / 39.2 °F - 77.0°F) away from high temperatures and direct sunlight

(Shelf life: 3 years from date of manufacture)

PACKAGES

1. Syringe 3.4 g (2.0 mL), 20 Dispensing Tips III Plastic, 1 light-protective cover
2. Dispensing Tip III Plastic: 30 dispensing tips, 2 light protective covers
3. Dispensing Tip III Needle (metal): 30 dispensing tips, 2 light protective covers

Notes

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