The Heliomolar® Family:

Heliomolar®

Heliomolar® Flow

Heliomolar® HB

Scientific Documentation

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1. Introduction

In the last few years, the growing call for invisible restorations and the search for alternative materials to amalgam have led to an increase in the demand for composite materials. In 1984, Ivoclar Vivadent introduced Heliomolar, which has become one of the most widely accepted dental composite materials. In 1994, CRA wrote that Heliomolar was being successfully used all over the world since its introduction in 1984 and even eleven years after its launch it continued to be one of the best composite materials. In April 1999, Heliomolar Flow, a flowable version of Heliomolar, was introduced to cover all the requirements of dentists in terms of indications and application procedures. Furthermore, in December 2000, a condensible product variant called Heliomolar HB was launched, completing the range of Heliomolar materials.

1.1 Heliomolar

Heliomolar falls into the category of inhomogeneous microfilled composites. In dentistry, microfillers are materials whose filler particles are smaller than 1µm. Prepolymers may be added to the microfilled composite to enhance its consistency and physical properties as well as to increase its filler content. The prepolymers used in Heliomolar are microfilled pre-polymerized composites that exhibit virtually the same properties as the matrix.

1.2 Heliomolar Flow

Heliomolar Flow is a flowable version of Heliomolar. The monomer content is slightly higher than that of the original Heliomolar to render the material flowable. Because of its flowable consistency, Heliomolar Flow is particularly indicated for Class V defects, mini-cavities of all kinds, preventive resin restorations as well as the repair of composite and ceramic veneers. Furthermore, many dentists use Helimolar flow as a first thin increment under Heliomolar or Heliomolar HB restorations because the flowable consistency facilitates adaptation to the cavity bottom and walls.

1.3 Heliomolar HB

Heliomolar HB is the latest member of the Heliomolar family. The adjunct HB stands for Heavy Body. Heliomolar HB falls into the category of what are known as packable or condensible composites. Ivoclar Vivadent offers Heliomolar in three different consistencies to meet the varying requirements placed on the handling properties of composites. Heliomolar HB is particularly suitable for direct restorations in the posterior region.

Two slight alterations of the original Heliomolar were required to obtain the heavy-body consistency of Heliomolar HB. Firstly, the material was rendered less sticky by slightly modifying the proportional composition of the monomer mixture, ie the portion of the comparatively large copolymers was lowered while the portion of microfillers was slightly raised. As a result, the viscosity of the material increased. Secondly, a rheology modifier in the form of an organically modified compound silicate was added to the material. The compound silicate, which contains surface linked, long chain organic groups, increases the firmness of Heliomolar HB but does not compromise the material’s modelling properties.

2. Technical Data

Standard composition	Heliomolar	Heliomolar HB	Heliomolar Flow
Bis-GMA, Urethane dimethacrylate	19	18	32
Decandiol dimethacrylate	3	5	-
Triethylene glycol dimethacrylate	-	-	8
Highly dispersed silicon dioxide, Prepolymer, Ytterbium trifluoride	77	76	59
Stabilizers, catalysts and pigments	< 1	< 1	< 1

(Figures in wt%)

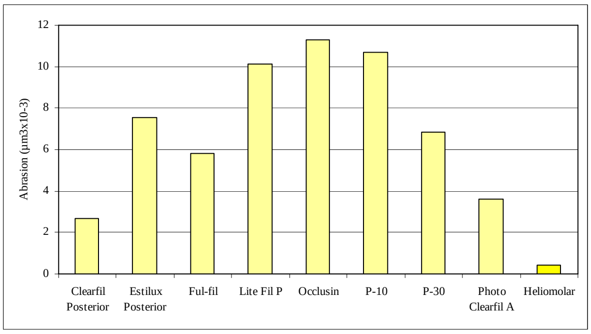
Physical properties	Unit	Heliomolar	Heliomolar HB	Heliomolar Flow
Flexural strength	MPa	100	125	96
Modulus of elasticity	MPa	6000	6500	4400
Compressive strength	MPa	340	315	260
Vickers hardness	MPa	350	415	300
Water absorption	$\mu g/mm^3$	25	24.9	< 30
Water solubility	$\mu g/mm^3$	1	1.5	< 3
Radiopacity	% Al	250	265	200
Total filler content	wt %	66.7	66.7	51
Total filler content	vol %	46	46	30

In accordance with: ISO 4049 – Polymer-based filling, restorative and luting materials

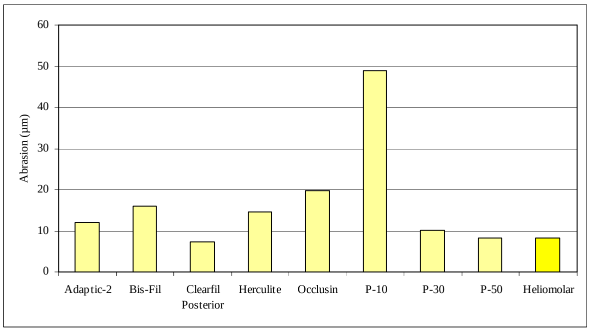
3. Physical Studies

3.1 Abrasion

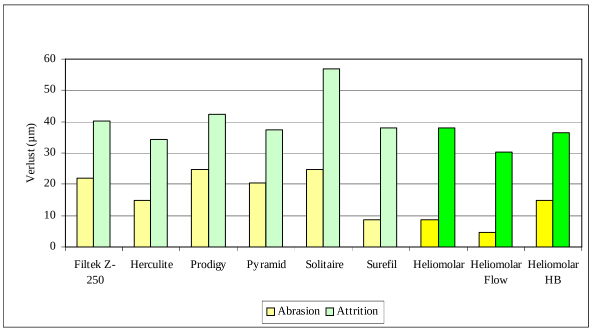
When Heliomolar was introduced, it set a new standard in terms of resistance to abrasion of composite materials. In 1987, Tani et al published a study, in which Heliomolar's high resistance to abrasion was confirmed. Furthermore, in a study conducted by Leinfelder in 1991, Heliomolar was shown to be one of the materials that exhibited the lowest wear. The experimental of this study included 400,000 cycles of repeated stress and PMMA pellets as the abrasive. While the majority of the composite materials against which Heliomolar was compared in 1987 and 1991 are no longer available, Heliomolar as well as Heliomolar Flow and Heliomolar HB, the two new Heliomolar versions, still rank among the leading composites in terms of resistance to abrasion (Sorensen 2000, Report on file).



Tani et al (1987)



Leinfelder (1991)



Sorensen (2000)

Wear of Heliomolar, measured in three independent studies: The results of Tani and Leinfelder are taken from the above-mentioned studies. The results of Sorensen are on file.

3.2 Shade stability

Heliomolar exhibited a high degree of shade stability in trials involving artificial ageing (Powers et al, 1988). With regard to most of the parameters examined, Heliomolar demonstrated the least change when subjected to artificial ageing.

	ΔY	ΔS	ΔK	ΔCR
Heliomolar	-1.6	-0.02	0.021	0.003
Herculite	-1.9	0.13	0.043	0.070
P-30	-9.3	0.07	0.017	0.068
Bis-Fil II	-2.3	0.04	0.039	0.021
Estilux Posterior	4.8	0.32	-0.006	0.122
Distalite	1.6	0.03	-0.14	0.006

Optical stability of Heliomolar
ΔY = Change in the degree of transmission
ΔS = Change in light scattering
ΔK = Change in the absorption coefficient
ΔCR = Change in opacity

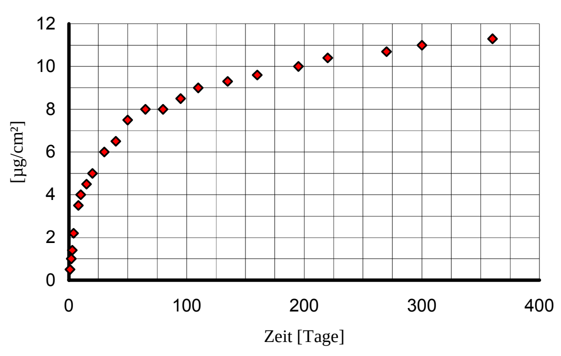
3.3 Physical data

	Compressive strength [N/mm²]	Flexural strength [N/mm²]	Flexural modulus [GPa]
Heliomolar HB	380	114	7.3
Tetric Ceram HB	338	138	13.2
P-60	524	170	15
Solitaire	412	54	3
Alert	399	119	10
SureFil	426	131	11
Prodigy Condense	371	104	8
Tooth enamel	384	90	84

Munoz (Loma Linda University, California, USA)

3.4 Fluoride release

Arends und Ruben (1988) measured the fluoride releasing capabilities of dental composites. Heliomolar was proven to continuously release fluoride for over one year. Moreover, Arends and Zee (1990), who conducted a study using an artificial mouth model, showed that dentin and enamel take up the fluoride released by Heliomolar



Fluoride release of Heliomolar (Arends and Ruben 1988)

3.5 Polymerization shrinkage

Among all the composites commercially available, Heliomolar is one of the materials that demonstrates the lowest polymerization shrinkage (Feilzer et al, 1988; Soltez, 2000).

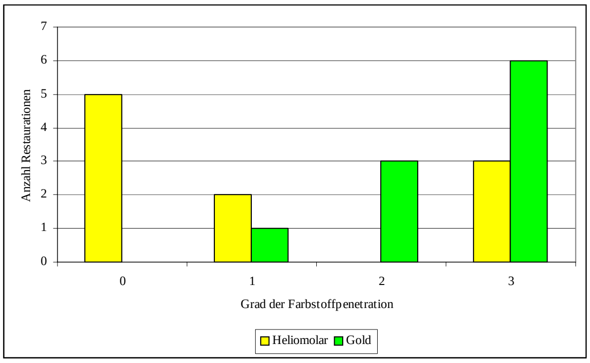
	Feilzer et al, 1988	Soltez, 2000
Heliomolar	2.2 ± 0.1	1.96 ± 0.07
Heliomolar HB		2.19 ± 0.10
Tetric Ceram		2.76 ± 0.05
Tetric Ceram HB		2.55 ± 0.01
Esthet X		2.62 ± 0.04
Point 4		3.01 ± 0.10

Brilliant Lux	3.5 ± 0.0	
Clearfil Posterior	4.5 ± 0.5	
Herculite	3.0 ± 0.2	
P-30	2.6 ± 0.3	
Prisma Fil	3.3 ± 0.2	

Polymerization shrinkage in vol %, 1 hour after curing. The data of Soltez (Fraunhofer Insitut Werkstoffmechanik, Freiburg, Germany) were measured for Ivoclar Vivadent.

3.6 Marginal adaptation

In a study conducted by Stähle and Ackermann in 1991, 70 percent of the occlusal restorations fabricated of Heliomolar demonstrated tight margins after they were exposed to cyclic loading at 200 N. By contrast, none of the gold inlays, which were inserted using zinc phosphate, exhibited tight margins.



Study on marginal integrity by Stähle and Ackermann (1991)

Depth of dye penetration:

0 = no dye penetration
1 = dye penetration into the upper half of the restoration
2 = dye penetration into the lower half of the restoration
3 = dye penetration down to the cavity floor

4. Clinical Studies

4.1 Heliomolar

Heliomolar was launched in 1984. Since then, several three- and five-year studies on the material have been accomplished.

3-year studies

Knibbs and Smart (1992) conducted a comparative three-year study with Heliomolar and amalgam. Fifty-two fillings of each material were placed and monitored in terms of marginal adaptation, surface quality, anatomical shape, and proximal antagonist contact. No significant difference in the performance of Heliomolar and amalgam was found; both materials produced favourable clinical results.

Lundin et al (1990) monitored the clinical performance of six different dental composites over three years. The materials, which were placed in Class II cavities, showed very low failure rates. Heliomolar demonstrated the lowest abrasion of all six materials

Taylor et al (1994) summarized the data of ten clinical three-year studies on the wear of restorative materials. Heliomolar ranked second among the 28 composites examined.

In a clinical three-year study conducted by CRA in the US, Heliomolar produced the best results among the 21 restorations investigated. The following aspects were monitored: abrasion, marginal adaptation, surface quality, antagonist abrasion, resistance to fracture and shade adaptation.

Clinical Research Associates Newsletter, Volume 18, Issue 5 May 1994: Comparative performance of 21 class 2 materials at 3 years

5-year studies

In a clinical study conducted by Leinfelder (Mazer and Leinfelder, 1992), 68 Class I and II restorations were placed using Heliomolar. The mean abrasion was as low as 7.7 µm/year.. According to Leinfelder, the Heliomolar restorations were characterized by a high degree of shade stability, surface smoothness, resistance to abrasion and acceptance by patients throughout the five years. During the first two years, none of the restorations demonstrated secondary caries. Only two restorations showed signs of incipient secondary caries. Leinfelder attributes the low rate of secondary caries to the fact that Heliomolar releases fluoride ions.

	Abrasion after 2 years	Secondary caries after 2 years
Heliomolar	12 µm	0 %
Herculite	30 µm	3 %
Bisfil-1	42 µm	4.5 %
P-10	135 µm	2 %

The authors compared the data on abrasion and secondary caries with the corresponding data of other materials. Heliomolar restorations demonstrated the lowest abrasion and were the least prone to developing secondary caries (Mazer and Leinfelder, 1992).

Setcos and Phillips (1995) compared Heliomolar and amalgam in a clinical study on Class I and II restorations. The observation period was five years and the following aspects were monitored: shade stability, marginal discoloration, anatomic shape, marginal integrity, secondary caries, abrasion and sensitivity to temperature. The results prove the favourable clinical performance of Heliomolar.

A CRA Newsletters (1989) summarized the results of clinical trials conducted on 21 different dental composites placed in Class II cavities. In the trials, which lasted between two to five years, the following aspects were monitored: marginal adaptation, proximal contact areas, postoperative sensitivity, secondary caries, surface quality, discoloration and shade. The Heliomolar restorations were attested favourable ratings with regard to all of these aspects. Moreover, Heliomolar demonstrated the lowest abrasion of all the materials tested.

If the results of the 3- and 5-year studies are all added up and a loss analysis according to Kaplan-Meier is conducted, very high survival rates are observed.

	3-year studies	**5-year studies**
Base line	100%	100%
1 year	99.6 ± 0.4	100%
2 years	98.0 ± 0.9	100%
3 years	96.3 ± 1.2	98 ± 1%
4 years		97 ± 2%
5 years		93 ± 2%

Conclusion: **Heliomolar is one of the most proven and clinically successful dental composites on the market.**

4.2 Heliomolar HB

Clinical studies to examine Heliomolar HB have been initiated. The 12-month results are available.

Head of study: Dr Jim R Dunn, D Carlos Munoz
Loma Linda University, California, USA

Objective: Examine the clinical performance of Heliomolar HB

Experimental: Fifty Class II cavities were placed in a total of 32 patients, using Heliomolar HB and Excite dentin adhesive. Heliomolar HB was applied in increments. The restorations were examined after six and twelve months. The next follow-up evaluation is due to be conducted 24 months after placement.

Results:

	Heliomolar HB		
Criteria	1 months	6 months	12 months
Restorations evaluated	44	48	43
Marginal adaptation	100% A	100% A	88% A
Interproximal anatomical shape	98% A	100% A	95% A
Post-operative sensitivity	90% A	96% A	91% A
Secondary caries	100% A	100% A	100% A
Marginal discoloration	96% A	98% A	88% A
Proximal contact areas	86% A	96% A	91% A
Surface polish	100% A	100% A	100% A
Retention	100 %	100%	98% A

Conclusion: **The evaluation conducted six months after placement showed excellent results for Heliomolar HB. After 12 months only one restoration had to be replaced and no other Charlie ratings were observed.**

Head of study: Dr Giovanni Dondi dall'Orologio
University of Bologna, Italy

Objective: Examine the clinical performance of Heliomolar HB, placed in Class I and II cavities. Place an initial base layer of Heliomolar Flow in half of all the restorations. After 6 months all patients and after 12 months 62 patients could be evaluated. The next recall is planned after 24 months.

Experimental: Restorations fabricated of Heliomolar HB and Heliomolar Flow/Heliomolar HB were placed in 62 patients according to a split mouth design. Excite was used as the adhesive. Heliomolar HB was placed in increments. The restorations were evaluated after six months. The next follow-up evaluation is due to be conducted at 12 months after placement.

Results:

	Heliomolar HB		
Criteria	Baseline	6 months	12 months
Marginal integrity	100% A	100% A	87% A, 13% B
Discoloration	100% A	100% A	100% A
Secondary caries	100% A	100% A	100% A
Surface quality	100% A	100% A	100% A
Anatomical shape	100% A	100% A	100% A
Post-operative sensitivity	97% A, 3% B	97% A, 3% B	91% A, 9% B
Retention	100% A	100% A	100% A

	Heliomolar Flow & Heliomolar HB		
Criteria	Baseline	6 months	12 months
Marginal integrity	100% A	100% A	100% A
Discoloration	100% A	100% A	100% A
Secondary caries	100% A	100% A	100% A
Surface quality	100% A	100% A	100% A
Anatomical shape	100% A	100% A	100% A
Post-operative sensitivity	98% A, 2% B	98% A. 2% B	100% A
Retention	100% A	100% A	100% A

Conclusion: **The evaluation conducted six months after placement shows favourable results for both kinds of Heliomolar HB restorations, i.e., those placed with Heliomolar Flow and those placed without Heliomolar Flow. The 12 months results confirm the excellent clinical success of Heliomolar HB. The data indicate that in the long term the use of Heliomolar Flow as first thin increment may result in better margins.**

5. Toxicology

Heliomolar is applied directly into the cavity. The resin is light-cured in the oral cavity.

The following toxicological risks had to be investigated:

- Acute oral risk: patients may accidentally swallow the portion of uncured Heliomolar placed in the cavity
- Local incompatibility with surrounding tissue that comes into contact with the material
- Possible sensitizing reactions
- Peroral long-term risk by eluted low-molecular components
- Mutagenic potential of eluted low-molecular components

5.1 Acute oral toxicity

Tests on the acute oral toxicity of the uncured formulation produced the following values:

LD_{50} (rats) oral p.o. > 5000 mg/kg [1]

ISO filler RO = HELIOMOLAR RO without ytterbium trifluoride

LD_{50} (rats) p.o. > 5000 mg/kg [2]

Ytterbium trifluoride

LD_{50} (rats) p.o. > 5000 mg/kg [3]

5.2 Compatibility with the mucous membrane and local irritation of skin

A primary irritation index of 0.3 was measured in the mucuous membrane. On the basis of this result, the material may be regarded as having a minimally irritating effect in an uncured state [4]. The skin irritation index was also 0.3, indicating a minimal primary irritation effect on skin [5].

5.3 Elution tests

A mutation assay was conducted to assess the effect of oral long-term exposure to possible eluates [6, 7]. Total migration of 230 µg/cm² was measured.

5.4 Ytterbium trifluoride

The toxicity of ytterbium trifluoride in Heliomolar RO is discussed in a comprehensive report by Dr Manfred Herbst [8]. This report reaches the conclusion that ytterbium trifluoride does not involve any health risk if it is used as a component of a polymethacrylate-based filling material.

5.5 Sensitization

Uncured Heliomolar was subjected to a sensitization (maximization) test in guinea pigs. In this rigorous test [9], slight irritation occurred. However, it may be assumed that the cured material has no sensitizing effect.

5.6 Mutagenic properties

Mutation did not occur in an Ames test (reversible mutagenicity assay) under the conditions chosen, neither in the HGPRT genes of V79 cells (Chinese hamster) [10] nor in Salmonella typhimurium strains (TA 1535, TA 1537, TA 1538, TA 98 and TA 100) [11]. Furthermore, in a chromosome aberration assay conducted on Chinese hamsters, no chromosomal mutations occurred in correlation with Heliomolar [12]. On the basis of these tests, mutagenic effects of Heliomolar are not indicated.

Conclusion:

On the basis of the data on hand, an acute or chronic risk for patients is not indicated, if Heliomolar is used properly.

The results of the clinical studies and the general toxicological data on composite materials support the above conclusion.

The chemistry of Heliomolar Flow and Heliomolar HB are similar to that of Heliomolar. The monomer content and the filler composition have only been slightly changed to modify the consistency of the materials.

Thus, the toxicological data on Heliomolar also apply to Heliomolar Flow and Heliomolar HB.

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