

# SCIENTIFIC REPORT

## GrandioSO – 4-year clinical study

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**The Nanohybrid composite GrandioSO is characterised by outstanding physical properties, which are also very similar to those of natural dental hard tissue. A 4-year clinical study conducted by Prof. Abdalla at Tanta University in Egypt investigated whether these properties also produce restorations with long-term integrity under real conditions in the oral cavity.<sup>[1]</sup>**

57 patients participated in the 4-year study, with a prerequisite being that they presented with at least two comparable class I or class II carious lesions. A total of 120 cavities were prepared and restored with four different composites. In each case the adhesive used came from the same manufacturer as the composite:

- GrandioSO / Futurabond DC (VOCO)
- Silorane / Adper SE Plus (3M ESPE)
- Majestic / Clearfil SE Bond (Kuraray)
- Tetric Evo Ceram / AdheSE One F (Ivoclar Vivadent)

**Table 1:** Distribution of materials with respect to cavity classes

	Class I	Class II	Total
GrandioSO	15	15	30
Silorane	14	16	30
Majestic	17	13	30
Tetric-Evo Ceram	14	16	30
<b>Total</b>	60	60	120

All the fillings were placed by a dentist in accordance with the manufacturer's specifications. The restorations were evaluated by two independent experts based on the following USPHS criteria.

- Retention
- Shade match
- Marginal adaptation
- Anatomical shape
- Marginal discoloration
- Secondary caries
- Postoperative hypersensitivity
- Surface quality

The evaluations were performed at the time of treatment (initial) and then after 12, 24, 36 and 48 months. Table 2 shows the recall rates and retention rates for the assessment periods. The results for the criteria of shade match, anatomical shape, marginal adaptation and marginal discoloration are shown in Figures 1-4.

**Table 2:** Recall and retention rates

	Initial	12 months	24 months	36 months	48 months
Restorations	120	114	108	108	98
Recall rate	100%	95%	90%	90%	82%
Retention rate	100%	100%	98%	96.3%	93%



**Figure 1:** Shade match

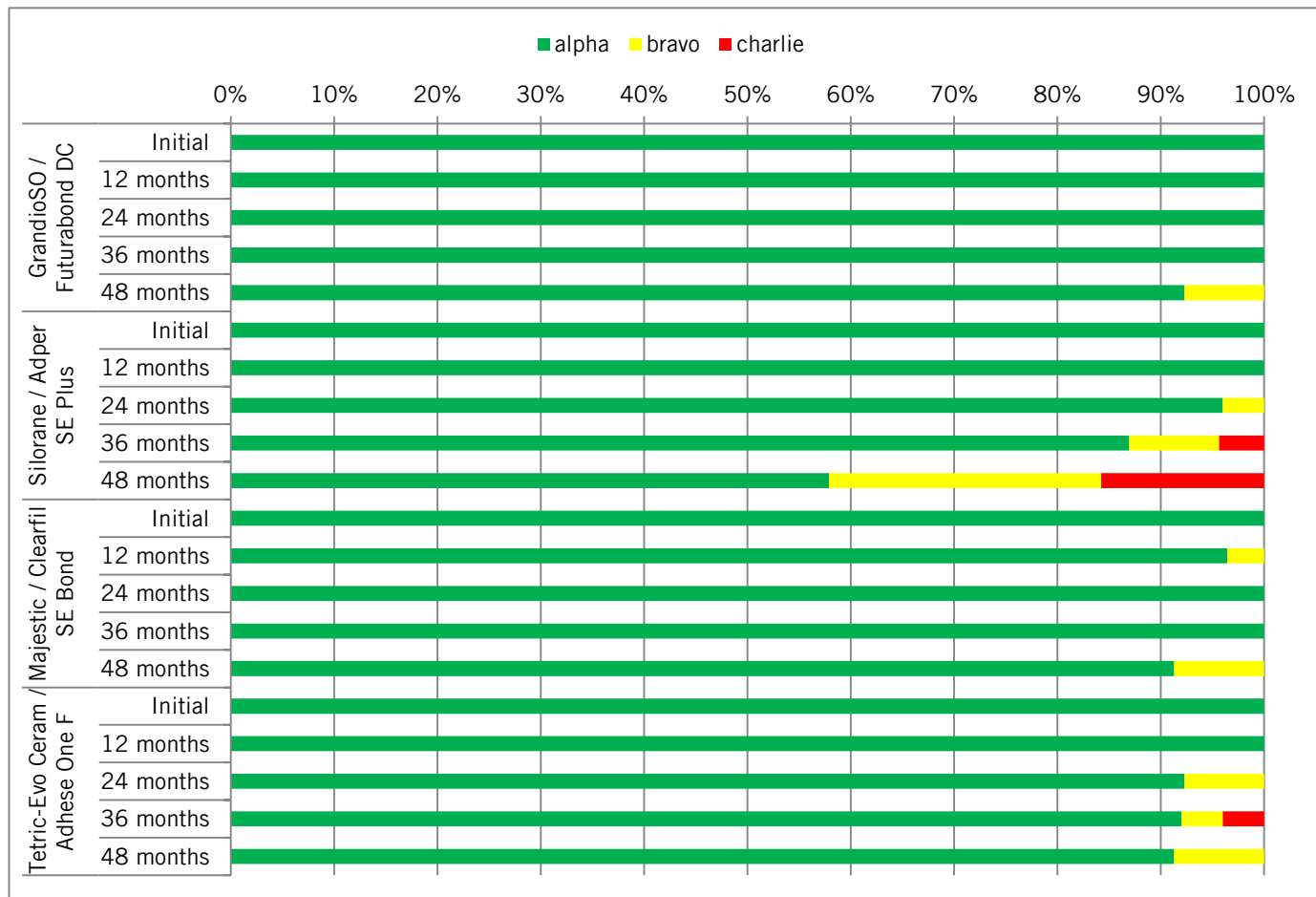


Figure 2: Anatomical shape

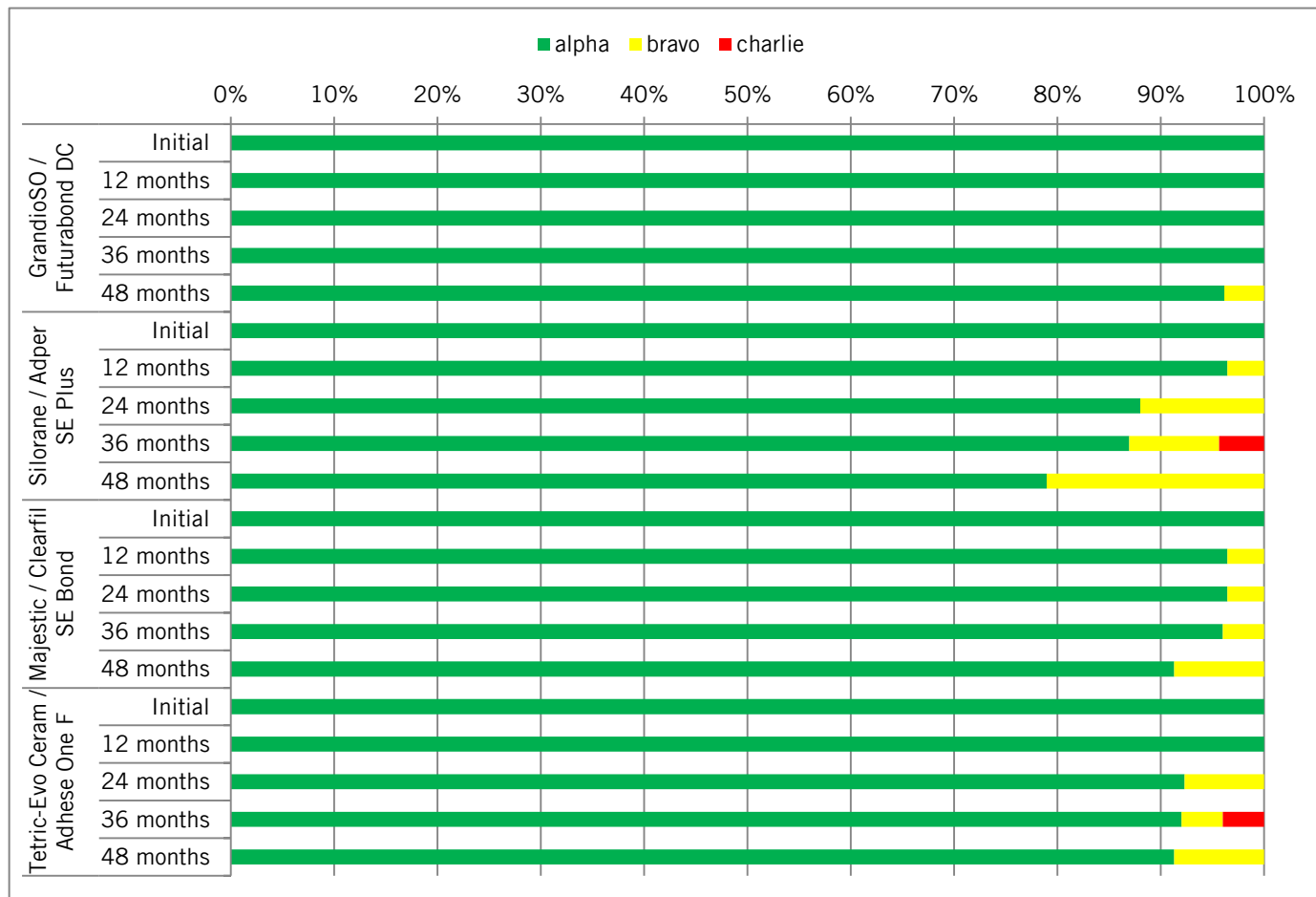
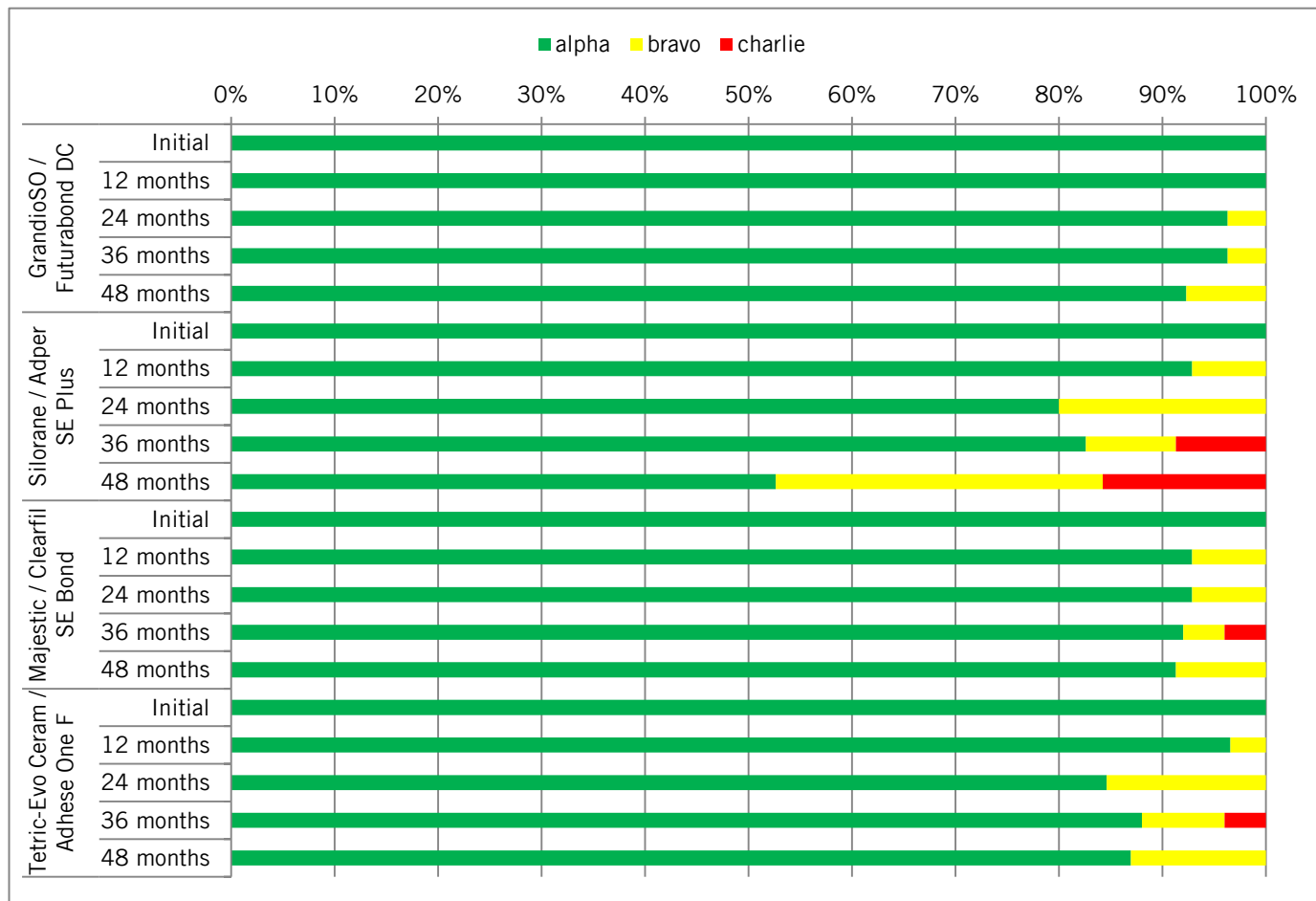


Figure 3: Marginal adaptation



**Figure 4:** Marginal discoloration

All 30 GrandioSO fillings are still intact after 48 months. In 100% of the patients, all the restorations were evaluated as excellent (alpha) with regard to the following three factors: secondary caries, surface quality and postoperative hypersensitivity. Very convincing results were also recorded for the parameters of marginal adaptation, anatomical shape form, shade match and marginal discoloration. In fact, only one restoration was assessed as bravo for the criteria of marginal adaptation after 48 months. For the parameters of anatomical shape, shade match and marginal discoloration, only two restorations were evaluated as bravo after four years. In summary, what the findings of the 4-year study mean for the dentist is that the high-quality product characteristics of GrandioSO generate long-term patient satisfaction, and that GrandioSO is certainly suitable for use as a permanent restorative material.

**Conclusion: The 4-year clinical study demonstrates impressively that GrandioSO gives outstanding results over a period of four years. 100% of the 30 fillings placed were still intact after four years.**

[1] A. Abdalla, Tanta University, Egypt, Report for VOCO, March 2014