

Effectiveness of a Compliance Indicator for Clear Aligners

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Patient compliance is crucial in orthodontic treatment involving removable appliances. This is especially true for adult patients, who have no growth remaining to help compensate for poor cooperation. The orthodontist's ability to predict a given individual's level of compliance is also important, because patients who are not expected to be cooperative may be better treated with fixed rather than removable appliances. Studies have shown no association, however, between patient cooperation and such factors as quality of life, socioeconomic status, and educational level,¹⁻³ although females have been found to be generally more compliant than males.⁴ Assessing cooperation is equally challenging: a study of the reliability of patient reports and clinicians' ratings of compliance found that neither had an accuracy rate of more than 43%.⁵

Attempts to improve compliance through behavior modification using a reward system have yielded mixed results; although such efforts have been found to have a positive effect on patients who were already more compliant than average,

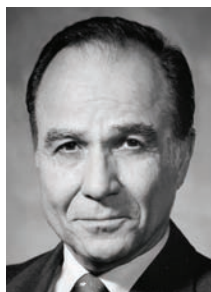
they had little effect on patients with below-average cooperation.⁶ The degree of patient motivation and the rapport between the patient and the orthodontist seem to be more significant.^{7,8}

Align Technology recently introduced a "compliance indicator" for teen-agers being treated with the Invisalign system.* Although patients are generally required to wear each set of the clear

*Registered trademark of Align Technology, Inc., 881 Martin Ave., Santa Clara, CA 95050; www.aligntech.com.



Fig. 1 Aligner with encapsulated color compliance indicator.



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Align Technology, Inc.	Non-Adult Comprehensive Treatment Study
Site# _____	<div style="display: flex; justify-content: space-between;"> Subject ID _____ Subject Initials _____ </div>

Patient Aligner Wear Diary

Please fill out how many hours you wore your aligners each day

Aligner use diary: Aligners are to be worn at all times, except when eating, drinking, and brushing teeth. Please record below the amount of time you wore your aligners each day.

Week 1

Day	Hours Worn
1	
2	
3	
4	
5	
6	
7	

Week 2

Day	Hours Worn
1	
2	
3	
4	
5	
6	
7	

Week 3

Day	Hours Worn
1	
2	
3	
4	
5	
6	
7	

Week 4

Day	Hours Worn
1	
2	
3	
4	
5	
6	
7	

Fig. 2 Aligner wear diary to be completed by patient.

removable aligners for a total of 300-400 hours, it has been impossible to monitor their actual wear time until now. This article reports the results of a study measuring the clinical effectiveness of the compliance indicator over a three-month period.

Materials and Methods

The study sample consisted of 14 patients (five females, nine males) who were participating in a larger, ongoing prospective clinical study on clear aligner treatment in teen-age patients. That study involves patients in four private practices,

located in Kalamazoo, Michigan; Princeton, New Jersey; Oklahoma City; and Philadelphia. Parents who allowed their children to participate in the present study were given fee discounts of approximately 20%, and patients who kept every study-related appointment were rewarded with gift certificates. Written informed consent was obtained from all patients and their parents before enrollment in the study.

The 14 patients in the study were given Invisalign clear aligners with compliance indicators made of encapsulated, food-grade dye embedded in each posterior segment, usually of the upper

Subject ID _____

Subject Initials _____

Site# _____

Compliance Indicator Color Table

Please record a check mark (✓) in the appropriate column in the tables below according to the Invisalign teen compliance indicator Instructions for Use.

0-4.5 months

	2 weeks	4 weeks	6 weeks	8 weeks	10 weeks	12 weeks	14 weeks	16 weeks	18 weeks
									
									
									
									
									

6-24 months


	6 months	9 months	12 months	15 months	18 months	21 months	24 months
							
							
							
							
							

Fig. 3 Compliance indicator color table to be completed by orthodontist or staff. Left column of colored dots refers to “slow” dissolution indicator; right column is for “fast” dissolution indicator.

aligner (Fig. 1). The dye fades from dark blue to clear over the 300-400 hours of recommended wear during a two-week period. Each aligner contains two different formulations, with “fast” and “slow” dissolution rates to account for variations in salivation.

The daily and total number of hours of prescribed aligner wear varied slightly according to the patient’s individual treatment plan, but each set of aligners was worn for the prescribed two weeks. Each patient recorded his or her daily aligner wear time on a form distributed at the beginning of the study (Fig. 2). The patients wore a total of 84 sets of aligners during the 12-week period, but 34 sets were excluded because some patients did not consistently record the number of hours of wear on the

daily log, leaving 50 sets in the study. Two patients were dropped from the study due to incomplete patient logs.

Patients turned in their used aligners for evaluation of the compliance indicator colors, and a table was used to record the colors of each pair of indicators, with possible combinations ranging from dark blue/dark blue to clear/clear (Fig. 3). To eliminate clinician bias, the aligners were also sent to Align Technology for a blind recording of the degree of color fade.

Results

The color changes recorded for the compliance indicators correlated with the number of

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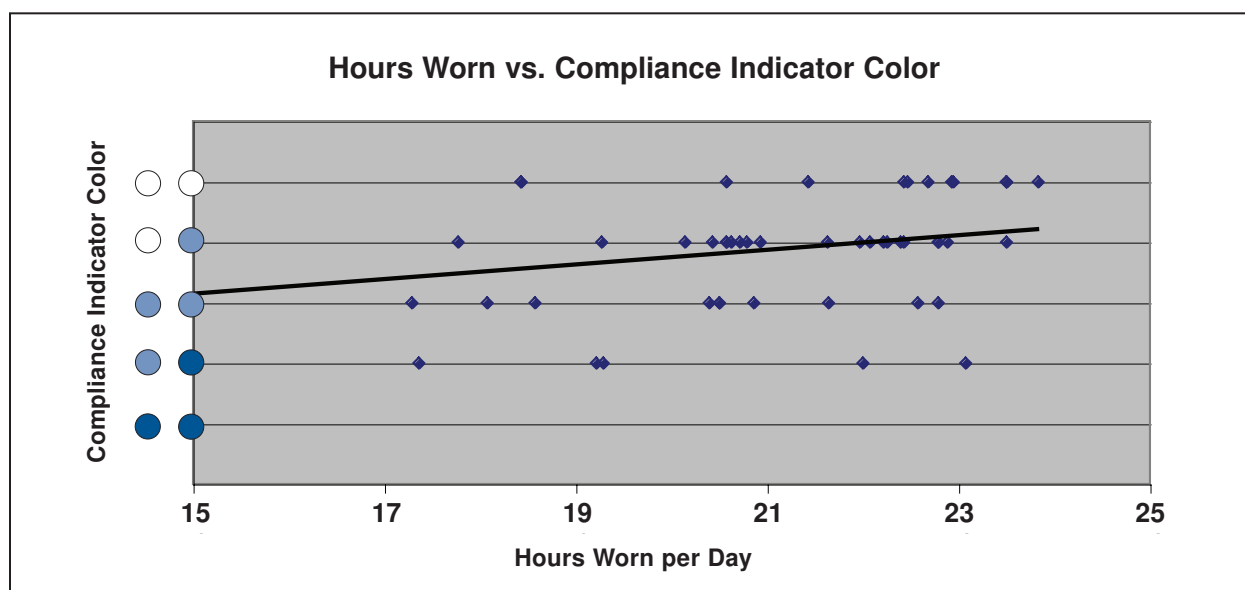


Fig. 4 Correlation of compliance indicator color with number of hours of wear per day reported by patients ($R^2 = .083$).

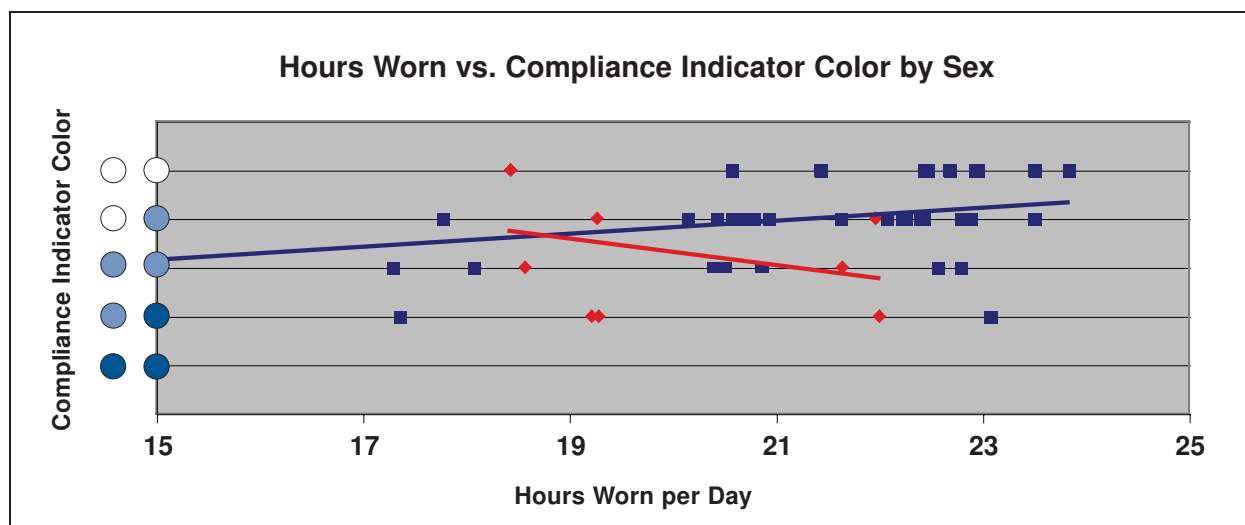


Fig. 5 Correlation of compliance indicator color with number of hours worn per day by sex (blue = male patients, $R^2 = .135$; red = female patients, $R^2 = .116$).

hours of wear recorded by the patients (Fig. 4). A stronger correlation was found, however, between compliance indicator color and the number of hours of reported wear for male patients than for female patients (Fig. 5).

Discussion

Specific intraoral devices designed to assess the compliance of orthodontic patients with remov-

able appliances have generally produced disappointing results. For example, timers used to monitor headgear wear have served more to police compliance than to enhance it. When patients are informed that their headgear wear time is being electronically monitored, they tend to wear the headgear more than other patients do, but still not as much as instructed.⁹ Typically, patients significantly overreport their headgear wear.¹⁰ Another approach intended to help estimate the wear time

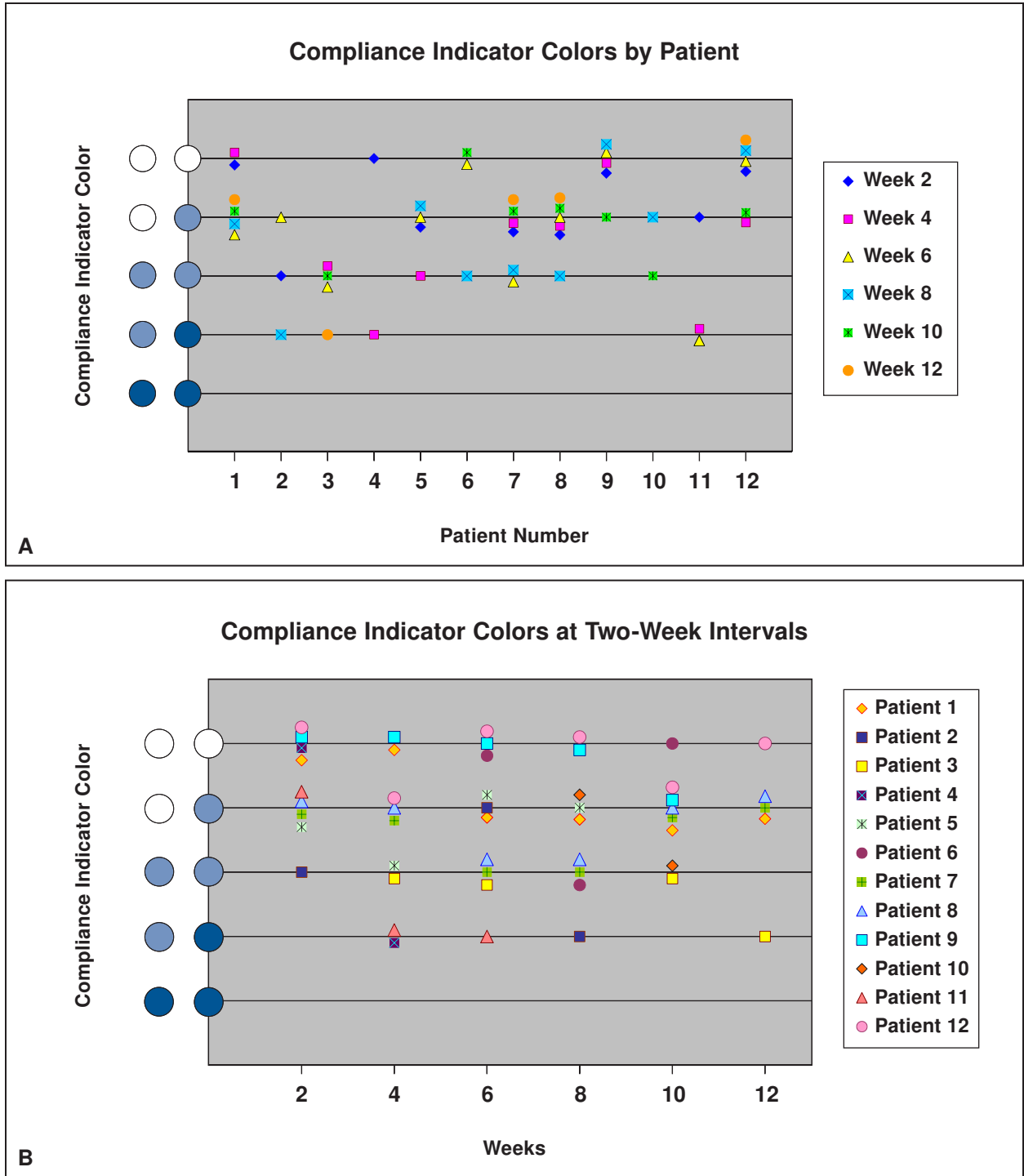


Fig. 6 A. Compliance indicator colors by patient. B. Compliance indicator colors by patient at biweekly intervals, up to 12 weeks of treatment.

of removable appliances—measuring the dissolution rate of water-soluble glass rods placed in molar tubes—was found to be inaccurate.¹¹

The recently introduced Smart Retainer** uses an electronic reader to record the amount of time the retainer is worn.¹² Preliminary data indicate that this device, which is similar to the previously introduced headgear timing devices, is effective in improving patient compliance. Nevertheless, it is based on the same concept of policing patient cooperation. Although this may be effective to some degree, we believe that the continual monitoring and feedback permitted by the compliance indicator for clear aligners may be better accepted and thus more effective in achieving compliance, especially in older patients. The use of color fading to indicate duration of use or wear of intraoral devices is not new; a similar approach is used in Oral-B manual and electric toothbrushes*** to remind the user when to switch to a new brush or brush head. With the aligner indicator, patients can participate in monitoring their own wear time by checking the color themselves.

The possibility that patients in our study tried to fool the system, as was sometimes done with the headgear timing devices, seems unlikely because the results were consistent across the study subjects and in all centers. Moreover, the manufacturer's laboratory evidence suggests that due to the high molecular weight of the polyvinyl alcohol material used to encapsulate the food-grade dye, the blue coloring will remain embedded unless exposed to moisture and temperatures greater than or equal to body temperature. Therefore, the color will not fade in a glass of cold water, but could be affected by submersing the aligner in extremely hot water for some time. Of course, at temperatures that high, the aligner itself would be distorted to the point of being unusable. The laboratory data suggest that the color does not change when used with Invisalign cleaning crystals, because the water used to dissolve the crystals at the bathroom

**Scientific Compliance, 3575 Piedmont Road, Suite 1040, Atlanta, GA 30305; www.scicomply.com.

***Oral-B Consumer Services, 1 Gillette Park, South Boston, MA 02127; www.oralb.com.

or kitchen sink would be merely lukewarm.

In our study, each patient tended to have a consistent amount of indicator color fade from one set of aligners to another (Fig. 6). Therefore, any deviation from this “baseline” color fade over the course of treatment could prompt the orthodontist to discuss the issue of compliance with the patient. Checking the color indicators on the used aligners every two weeks confirms that the patient is wearing the appliances as instructed.

The results of our study demonstrate that the color compliance indicator has considerable promise for improving the efficiency and effectiveness of orthodontic treatment with clear aligners.

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