

When compliance fails, which is to blame: the patient or the appliance?

The interpretation of article results

In the early years of my life as an orthodontist I sometimes heard comments about the behavior of patients undergoing treatment. These comments were targeted at patients' compliance in the use of the orthodontic appliance itself or its accessories, such as intermaxillary elastics, headgear, etc.. Such remarks were often uttered disapprovingly. "That's a lousy patient. Never wears his headgear," or "No way, she'll never wear her removable appliance." That's the crux of this editorial. When compliance fails, which is to blame: the patient or the appliance?

This issue is deeply rooted in the scientific method and in the design of different clinical trials as well as in how we read and understand research articles. To illustrate this point, try to envisage the following hypothetical scenario.

A study is conducted to compare the efficacy of two different treatment protocols. A total of 300 patients are involved in the research and are randomly distributed among three groups. One hundred patients for treatment A, 100 for B and 100 in a control group. These treatments could be, for example, (A) new device for Class II correction and (B) extraoral appliance. In this study, 82 patients completed the treatment in group A (new appliance) and 93 in group B (headgear). The hypothetical results, excluding the control group, are gathered in Table 1.

The results of our study show different hypothetical success rates. Treatment A (new appliance) had a success rate of 97.5% while treatment B

(headgear) had a success rate of 92.5%. Now comes the intriguing question: Which is the best treatment in light of these results?

The answer is clear. Treatment B (headgear), with a 92.5% success rate, apparently proved BETTER than treatment A (new appliance), with a 97.5% success rate. That's right, the treatment with the lower success rate was the best treatment for Class II correction. Why?

The number of individuals who completed the treatment in both groups was different. It was smaller in treatment A (new appliance) than in treatment B (headgear). We have compelling reason to take this difference into account as part of the treatment outcomes. In other words, most people give up on the new appliance because it is unsightly, or very uncomfortable, or because it has some negative feature that leads to lower rates of compliance. This fact should always be weighed when comparing treatments, or even when evaluating a series of cases.

TABLE 1 - Results of a hypothetical trial that compares two Class II treatments, one using a new appliance (A) and one using headgear (B). In this example, significant differences were found between the treatments.

TREATMENT*	SUCCESS N (%)	FAILURE N (%)	TOTAL
A (new appliance)	80 (97,5)	2 (2,5)	82 (100)
B (headgear)	86 (92,5)	7 (7,5)	93 (100)

* There are statistically significant differences between hypothetical treatments A and B.

Let's bring another example. Let's say the same results were found by a cancer center when comparing two different chemotherapeutic drugs to treat a certain type of cancer. The group with the highest dropout rate probably used a drug that causes more side effects or complications than the other. It has, therefore, shown higher rates of non-compliance.

If no one can be called a lousy user of chemotherapy, why would someone be a lousy headgear (or other appliance) user? In actuality, they are not. It so happens that different treatments entail different patient responses. For example, many patients simply cannot sleep with the headgear on and refrain from wearing it in social settings. We, as health professionals, are expected to manage a wide variety of patients as well as their ease or difficulty in complying with treatment and we must understand the difficulties faced by patients.

This fact has been historically overlooked in the orthodontic literature worldwide. Scientific methodology provides a specific conduct to address this issue whenever it arises. It is called intention to treat analysis. In this approach, researchers confronted with a given case monitor all patients from the earliest stage of the investigation down to its very end. The stated goals are to highlight and report the reasons for non-completion of therapy

for each subject included in the study. Whenever possible, these cases are to be comprised in the statistical analysis. This research conduct highlights with a greater degree of accuracy the experience of patients undergoing therapy.

Inadequacies or misinterpretation of study outcomes have historically resulted in erroneous treatment and overtreatment indications. Thus, certain diseases treated by dentistry have suffered more than others from our difficulties in reviewing the scientific literature. One such example are temporomandibular disorders (TMD).

The article receiving the seal of the editor in this issue - Orthodontics and temporomandibular disorders, the state of the art -, by Dr. Paul Conti, provides a clear picture of the state of our current knowledge regarding TMD. Today, TMD treatment is straightforward and uncontroversial. Readers of Dr. Conti's article will enjoy a bird's-eye view of the relationship between orthodontics and TMD treatment.

Be critical and good reading.

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