

In the land of no evidence, is the salesman king?

Kevin O'Brien^a and Jonathan Sandler^b

Manchester and Chesterfield, United Kingdom

Several years ago, while presenting the results of a randomized clinical trial about early Class II treatment at a national conference, we reported that there was a limited effect of early functional appliance treatment on the skeletal relationship. When it came to question time, a delegate explained that we did not get skeletal changes in our Twin-block group because “we had clasped the lower first molars which reduced the orthopedic effect of the appliance on mandibular growth.” Our reply was that we found it hard to believe that a “little piece of wire” would change the genetically controlled growth pattern for the children in the study. We must confess to feeling a little disappointed that the question seemed to have missed the point of our presentation. This led us to the conclusion that a thorough understanding of contemporary orthodontic research and its interpretation was sadly lacking and that, as a specialty, we are not really adopting evidence-based orthodontic care. As a result, we wrote this editorial, which we hope is an account of “where we are now.” We have tried to adopt the viewpoint of people who have been involved in the transition from a specialty with a low evidence base to one that, we hope, is slowly improving.

When we consider the changes in orthodontic research over the past 20 years, 2 notable milestones coincide with an acknowledgment that all was not well. The most well-known quote is that of David Sackett,¹ an American-based medical researcher and a doyen of the “evidence-based care” movement. When asked to review the quality of orthodontic research at the Moyers Symposium of 1986, he stated that “orthodontics is reliant on an evidence base that is on a par with podiatry, chiropractic and aromatherapy.” This was soon followed by the conclusions of a review into the “functional” appliance literature by Tulloch et al,² published in 1990. They concluded that “the literature was so weak, in terms of reliance on poorly controlled, retrospective studies, poor sample

size calculations and inappropriate use of statistical tests, that it was not possible at that time to support or dismiss the growth modifying effects of functional appliances.”

This then begs the question, “have we moved forward since then?” Many people would say that we have, since there has been general acceptance that most orthodontic interventions should be supported by the results of randomized controlled trials, when and if they are available. Many important studies have been published about a variety of treatments including early Class II treatment, bracket types, retainer regimens, management of displaced canines, and extraoral headgear.³⁻⁸ These articles should not only have changed the orthodontic practice of more enlightened clinicians but should change the practice of everyone.

Although the advantages of randomized controlled trials are undeniable, the findings of orthodontic trials are not always universally accepted, because they tend to challenge long-held beliefs that are often ingrained into our treatment approaches. This reluctance to change beliefs is not unexpected, but it demonstrates a poor understanding of statistics. This was concisely summarized by Meikle,⁹ who pointed out that “clinical opinion is still strongly influenced by anecdotal evidence and the training and experience of the clinician, not always by the statistical artifact reported by the mean.” In other words, we remember our “good cases,” which are often “several standard deviations from the mean.” These are the cases we show at meetings and on which we try to base our training. We forget, however, that a scientific analysis of outcomes is not based on our collection of “precious things” but on the mean effect of treatment for the average child. Such a concept is admittedly not as attractive as an impressive case report but is a more rational, pragmatic, and valid basis on which to make treatment decisions. It can be argued that we all start a patient’s treatment with the aim of achieving a fantastic response and an excellent outcome. The unfortunate truth, however, is that orthodontic therapy has a variable response, and we should acknowledge that the “miracle” or perfect treatment, despite our best intentions, sadly does not occur for all our patients.

A common criticism is that the findings of clinical trials are not relevant to patients in private practice, because the operators in trials are working to such tight protocols that their treatment bears no resemblance to the real

^aProfessor of Orthodontics, University of Manchester, Manchester, United Kingdom.

^bConsultant orthodontist, Royal Hospital, Chesterfield, Derbyshire, United Kingdom.

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world.¹⁰ Again, whereas on the surface this seems to be a reasoned criticism, it has been answered to a certain extent by multi-center trials that have bridged the gap between dental schools and more real-world settings.⁶

Our specialty is often unwilling to accept the results of well-conducted, scientifically valid trials of common treatment methods but enthusiastically embraces treatment methods that have not been clinically tested to a level of evidence that withstands scientific scrutiny but are perhaps beautifully described and illustrated in marketing brochures.

Current examples of this include the promotion and widespread adoption of noncompliance Class II correctors, temporary anchorage devices (TADs), and self-ligating brackets. As clinicians, we constantly aim to provide treatments that are quicker, easier, and more comfortable for our patients. This involves not only the search for effective methods of treatment as alternatives to headgear, but also appliances offering less friction in the bracket systems, and perhaps even the development of totally new philosophies, which do not necessarily stand up to scientific critique.¹¹

If we look at the use of TADs as an alternative to other forms of anchorage supplementation, it is clear that, despite their great potential, they are as yet unproven with respect to their effectiveness in anchorage reinforcement. Nevertheless, the advertising material suggests that TADs are not only a safe and effective alternative to headgear, but also comfortable; they reduce the need for extractions, speed up treatment, and lead to less orthognathic surgery. However, we must not confuse the cold, hard facts of science with the dreams and aspirations of the “pioneers” who are developing the latest techniques, particularly when their objectivity is somewhat opaque.

When we critically review the literature on these devices, it unfortunately appears that, despite 3500 articles reporting on TADs, there are no randomized trials that scientifically evaluate these claims. The current state of knowledge is that we know that a microscrew can be placed easily and relatively painlessly and has approximately an 80% chance of staying where we place it, even after forces are applied to move nearby teeth. We know nothing about their effectiveness compared with other forms of anchorage. The use of TADs is now widespread but has been overshadowed by the wholesale acceptance of self-ligating brackets, often accompanied by a new treatment philosophy. What is the evidence for this clear change in treatment delivery? One source of information is the marketing literature available both directly from the manufacturing companies and indirectly from orthodontists’ websites. Interestingly, this advertising is directed not only to the

profession but also often to our patients and their parents. This is a worrisome trend.

Where is the evidence behind these claims? The advertising material often quotes research that is at a low scientific level and published in journals that are not refereed; some of these are actually produced by the manufacturers. Paradoxically, several randomized clinical trials and a systematic review have shown that self-ligating brackets confer none of the claimed advantages over conventional brackets with regard to the speed of initial alignment or increased comfort for the patient.¹²⁻¹⁸ More importantly, no high-quality studies have followed a group of patients to the completion of treatment with self-ligating vs conventional brackets. This will be the ultimate test of the claims concerning self-ligating brackets, and we await the results of these studies with great interest.

It may be that orthodontists who bought the new brackets and philosophy based on the promise that they reduce treatment time and discomfort with less need for extractions will come to believe that a compelling case of misselling has taken place. In retrospect, it is somewhat remarkable that manufacturers can make claims with no apparent checks on the validity or veracity of their statements, while at the same time we struggle for support for scientific research.

In summary, it is clear that, over the last 20 years, orthodontics has begun to develop a strong scientific basis to support some of our treatment modalities. This evidence base is likely to have had its origins after the introduction of proper research methodology into our dental schools and curricula. Unfortunately, there is a tendency for our specialty to forget its research base when “new and better treatments” are developed. We fear that we are currently ignoring our scientific knowledge with the increasing pressure to provide treatment that is “faster, better, and more comfortable.”

If we are to have the respect of our colleagues and our patients, we must very carefully consider the claims of sales representatives and interpret them with due consideration of our scientific knowledge. If we do not do this every time a new product hits the marketplace, we are in serious danger of letting down not only the general public but ultimately the entire profession.

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