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COMMENTARY

More Than the Trajectory of the Teeth, We Need to Know About the Treatment Trajectory of Patients

Commentary on Minagi et al. Predictors of side effects with long-term oral appliance therapy for obstructive sleep apnea. *J Clin Sleep Med*. 2018;14(1):119–125.

Marc Baltzan, MDCM, FRCPC, FAASM[1,2,3]; Dorrie Rizzo, PhD(c)[4,5]

[1]Sleep Disorders Clinic, Department of Medicine, Mount Sinai Hospital, Montreal, Québec, Canada; [2]Institut de Médecine du Sommeil, OSR Sleep Disorders Center, Montreal, Québec, Canada; [3]Department of Epidemiology and Biostatistics and Occupational Medicine, McGill University, Montreal, Québec, Canada; [4]Department of Psychiatry, Jewish General Hospital, [5]Department of Biomedical Sciences, University of Montreal, Montreal, Québec, Canada

The management of a chronic disease requires long-term monitoring and, when appropriate, intervention. Intervention research is concerned with efficacy as measured by outcomes such as disease parameters, symptoms and measures of quality of life. Adverse outcomes are by explicit necessity documented in clinical trials for administrative approval and scientific publication. Clinical trials tend to be short in duration (3–12 months) and are oriented towards publication or government acceptance of the intervention.

Longer term study of outcomes and adverse effects is usually investigator-initiated. These are generally case reports, case series, or small cohorts that are based upon clinic records or administrative data such as a systematic chart review or a structured query of an appropriate database.

Oral appliance therapy (OAT) has been in use for over 35 years.[1] During this time, studies have documented long-term outcomes including adverse effects for a minority of the available OAT devices. To add to the complexity of the assessment of outcomes, over 100 OAT devices are available and vary throughout the world.[2,3] Trends in OAT development have changed in the past 25 years; the devices with the most history and published experience such as the Klearway™ have in practice been replaced by newer devices.[4–6] Can we extrapolate the outcomes from the older devices to the currently used devices? Perhaps.

What is clear is that the field of sleep medicine, including dental sleep medicine, needs much more explicit long-term studies of OAT.[3,7,8] Such studies would best evaluate outcomes including objective disease control, tolerance, adherence and eventual failure of therapy. This could include loss of control of the disease, unacceptable adverse effects requiring a stop to OAT, or important procedures to manage adverse effects such as orthodontic, temporo-mandibular joint, or restorative interventions.[9–11] Nonetheless, such studies would require robust selection protocols to increase effectiveness in predicting treatment response of OAT.[12,13]

Newer OAT devices are designed with more than control of disease in mind. Issues of materials, engineering, cost and work-flow come into play.[14] Once in the hand of the dental sleep medicine clinician, methods of assessment, titration, and follow-up vary widely worldwide.[15–17] The prevention, management and documentation of adverse effects presumably also vary considerably worldwide. Observational studies are what we can expect in the future to inform the sleep medicine community on the long-term effects of OAT. Consistent pro-active documentation of a clinical OAT population at regular intervals for years establishes a *de facto* clinical cohort. Academic clinics may function this way, as well as some non-academic clinics. The potential wealth of data available harbors an opportunity to document the various rates of stable effective OAT as well as patients who drop out, eventually lose control of their disease with OAT and adverse outcomes.

Dr. Minagi and colleagues working in Osaka, Japan, report in this issue of the *Journal of Clinical Sleep Medicine* the cephalometric changes in an academic clinic population.[18] While using an acrylic monobloc device over a mean follow-up of 4.3 years, they found reductions in overjet, overbite and increased angulation of the lower incisors, all effects observed in other clinical populations (see reference 13 in their study). They also demonstrate logical and significant risk factors for reduction in overjet over 1 mm. They did not report symptomatic adverse effects, loss of control of the disease, drop outs or terminations of OAT. Yet their study remains important in that it informs us about the long-term orthodontic changes in a Japanese population with the use of their type of appliance.

What current questions need to be answered? More than the trajectory of the teeth, we need to know more about the treatment trajectory of patients. What treatment option was first offered to them? Who and how many patients terminate OAT within the first 6 months? Why do they terminate OAT? What factors lead to later loss of control of sleep apnea? How long will most patients who initially tolerate OAT continue on without symptomatic adverse effects? How and when are the orthodontic changes seen in long-term OAT therapy symptomatic?

In summary, little is known about the trajectory patients follow from initial diagnosis to the end of effective treatment.

Most studies agree that the long-term effects of treatments are not currently evaluable.[8] Treatment recommendations are drawn from evidence of limited duration; more research is needed about OAT long-term health outcomes.

CITATION

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Address correspondence to: Dr. Marc Baltzan, 5690 Cavendish Blvd, Montreal, QC, H4W 1S7, Canada

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