# On Diverse Approaches to Prosthodontic Research: The Case Series Approach to Clinical Research

Winfried Walther, Dr Med Dent, PhD Vice Director Academy for Continuing Professional Development Karlsruhe Karlsruhe, Germany E-mail: winfried.walther@za-karlsruhe.de

Case studies have a long tradition in medicine. They are the classic scientific instrument for studying the efficiency and effectiveness of medical interventions. Beyond that, evaluating the course taken by individual patients is part of medical routine. It enables the physician or dental clinician to control the therapy in each case and gain experience. From each case observation, a specific pattern of efficiency is learned.

In clinical research, however, the case series approach and observation of individual cases are not paid great attention. Within the hierarchy of evidence, case studies have a low rank. The reason is that clinical findings obtained without a control group and without randomized assignment of patients provide only uncertain conclusions. For this reason, it is rather rare to find contributions dealing systematically with the methodology and potential of case series.

And yet, case series as well as individual case observations will remain an important tool of clinical research practice in the future. They allow a detailed review of medical routines and make it possible to test clinical effects before initiating more extensive scientific work. The systematic observation of individual cases or case series can thus be used to aid clinical decision making based on medical experience. The question is what level of evidence can be reached by this approach.

Another reason why this question is of immediate interest is today's demand for the general verification of the epistemologic and practical value of clinical scientific procedures.<sup>1,2</sup> In a study on clinical therapeutic knowledge, Ashcroft arrived at the following conclusion: "In particular, further work is needed on the theory of evidence and inference; causation and correlation; clinical judgment and collective knowledge; the structure of medical theory; and the nature of clinical effectiveness."

#### **Hierarchy of Evidence**

In the scientific community, focus remains on systematic reviews followed by randomized clinical trials as the gold standard of clinical research. Studies not adopting this methodologic approach are considered to be unsatisfactory with regard to the evidence obtained, because their results are susceptible to bias. This view, which can be found in textbooks as well as in the guidelines of medical organizations, has a long scientific tradition. According to Kiene,<sup>3</sup> the gold standard of evidence-based medicine is determined by the following paradigms:

- Paradigm of experiment, Francis Bacon, "Novum Organon," 1620
- Paradigm of repeated observation, David Hume, "An Enquiry Concerning Human Understanding," 1843
- Paradigm of control by comparison, John Stuart Mill, "A System of Logic," 1843
- Paradigm of randomization, Ronald Fisher, "The Design of Experiments," 1935

The paradigms listed above establish an abstract, quantitative, statistical method of causality assessment. They assert that conclusions drawn from single observations and observations without controls are insignificant, and that the observed patients must be distributed to verum and control groups by chance.

These paradigms have imposed a strict discipline on clinical research. Since the methodology they require provides quantitative data on the effects of therapy with greater assurance, new standards of clinical research were defined. The objective was to introduce an empiricist methodology of comparing therapies, thus ensuring the reliable identification of the therapy of greatest benefit to ensure the greatest possible degree of safety.

What then is the significance of the case series approach in view of this initial position? Two aspects will be discussed in the remainder of this paper. In practice, therapeutic decision making is usually a dynamic process. It evolves-and this applies especially to dental prosthetic treatment-from a sequence of individual decisions in which each step influences the subsequent decision and therapy as a whole. An example would be the selection of abutment teeth and their successive preparatory treatment. Thus, the choice of the appropriate type of therapy is just a partial aspect of the decision. Such dynamic conditions cannot be reproduced in a randomized experiment that depends on defined clinical protocols. The outcome of the therapy chosen in clinical reality can therefore only be evaluated by observing the treated cohort itself. Being aware of treatment risks in everyday practice, however, is of fundamental importance if patient care is to be improved. Therefore, it will be a challenge in the future to provide case observations with the methodologic potential to achieve an adequate rank within the hierarchy of evidence.

Another reason for paying greater attention to the case series approach is that this approach is open to qualitative procedures. The empiricist experiment depends on ratios. Qualitative nonstatistical approaches are not used within its framework. Nevertheless, it is to be expected that the methodology of qualitative case evaluation will be further developed and become more important in the future. Tendencies to apply qualitative methods of causality assessment are known from alternative medicine.<sup>4</sup> The use of qualitative methods means upgrading both the single-case analysis and the case series approach.

## **Case Series: Potential**

Because case series have the advantage of reflecting clinical reality, most quantitative data concerning the reality of patient care have been derived from this scientific approach. The data obtained can be used to challenge treatment routines. Clinical quality management is not conceivable without a consistent documentation of treatment outcomes.

When case series are used, special priority is given to identifying treatment risks, eg, by applying the Kaplan-Meier estimation. There are also statistical methods that can be used for risk analysis, but not for the comparison of different therapies. Thus, these methods are a special domain of the case series approach. The CART method, for instance, can be used to identify risk subgroups within a case series. The results will show which initial findings may influence the risk and should therefore be used to reconsider the suitability of treatment indications in the test group.

Data-mining methods go one step further and generate prognostic rules based on the documented course taken by the case. For instance, by means of the PART algorithm, rules can be laid down that will establish a prognosis for the survival of abutment teeth. By means of an electronic decision-support system, the results can be directly used for treatment planning of the prosthetic restoration.<sup>5</sup> These procedures, too, serve the intrapopulation analysis of risk factors and not the comparison of different therapies.

## Future Demands: Do We Need a Dental Ontology?

Dental science still knows very little about the reality of clinical care. An important future project for broadening our basis of knowledge would be to organize large databases facilitating the research of actual treatment strategies. However, so far no systematic approach to evaluating the success of dental treatment has been developed. There are many factors relevant to this issue: physiologic parameters, maintenance of oral structures, incidence of complications, costs, patient satisfaction, and quality of life indexes. In order to establish compatible databases, a consensus on the criteria to be documented would have to be reached. Besides patient evaluation, case history, and self-assessment by the patient, the documentation of health system variables would also be required. Dental research thus needs a taxonomy establishing a standard for the documentation of treatment courses. This is a requirement in many areas of research and has already initiated comprehensive research projects. The objective of such projects can be summarized in the following way: "A common backbone taxonomy of relevant entities of an application domain provides significant advantages over the case-by-case resolution of incompatibilities. This common backbone taxonomy is referred to by information scientists as an *ontology*."<sup>6</sup>

Therefore, another significant challenge for the future is to provide a common backbone taxonomy to achieve a joint effort for a multifacetted approach to assessing treatment outcomes.

#### Conclusions

The case series approach is an indispensable part of clinical research in dentistry. It offers:

- · Access to clinical reality
- Intrainstitutional quality promotion
- · Intrapopulation analysis of risk factors
- · Dental experience subject to scientific analysis

Case series help clinicians understand clinical reality and represent their dental experience, and will gain increasing importance in the future. We must take care of our experiences.

## References

- Ashcroft RE. Current epistemological problems in evidence based medicine. J Med Ethics 2004;30:131–135.
- Lambert H. Accounting for EBM: Notions of evidence in medicine. Soc Sci Med 2006;62:2633–2645.
- Kiene H, Schon-Angerer T. Single-case causality assessment as a basis for clinical judgement. Altern Ther Health Med 1998; 4:41–47.
- 4. Kiene H. Komplementäre Methodenlehre der Klinschen Forschung. Heidelberg: Springer, 2001.
- Walther W. Systematisierung therapeutischer Strategien durch induktive Lernverfahren. Dtsch Zahnärztl Z 2002;57:591–593.
- Smith B. Ontology. In: Floridi L (ed). Blackwell Guide to the Philosophy of Computing and Information. Oxford: Blackwell, 2003:155–166.

Copyright of International Journal of Prosthodontics is the property of Quintessence Publishing Company Inc. and its content may not be copied or emailed to multiple sites or posted to a listserv without the copyright holder's express written permission. However, users may print, download, or email articles for individual use.