EDITORIAL

Investigational Clinical Research in Implant Dentistry: Beyond Observational and Descriptive Studies

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We are very pleased to publish this special clinical research supplement this month on implant dentistry. We hope that our readership will find that this issue contains a valuable collection of advances in the field that can benefit researchers, clinicians, and, ultimately, our patients. These advances range from the better understanding of genetics in the osseointegration process (Nishimura, 2013) to the impact of oral pathogens on peri-implant infections (Dabdoub *et al.*, 2013) to randomized controlled trials (Muller *et al.*, 2013). We find that as a part of innovations moving the field of implant dentistry, protocols are generally considered as safe and predictable. However, the documentation of treatment outcomes is associated with a number of limitations due to traditional concepts and attitudes to study design and outcome variables without biological and technical complication reporting (Bassi *et al.*, 2013). Thus, results are mostly described in terms of survival rates of implants and prosthetic reconstructions, while data assessed on a patient basis are less frequently reported. The documentation

of treatment outcomes in this field is mostly confined to *efficacy* evaluations (*i.e.*, the probability of an intervention being beneficial to patients under ideal conditions) of small patient groups, while information on evaluation of *effectiveness* (*i.e.*, the care provided to the general population under conditions found in practice) is less prominent. These challenges may be due in part to capabilities in performing multicenter trials with different categories of clinicians (*e.g.*, specialists or dentists in general practice).

In a recent consensus report from a study design European Workshop, reporting and clinical outcomes related to implant dentistry were carefully evaluated (Tonetti and Palmer, 2012). It was stated that there is great confusion in terms of study design and terminology in the field and that case series are often, incorrectly, termed *cohort studies*. There is no doubt that most studies in clinical implant dentistry are descriptive in their character and describe treatment outcomes in a defined group of patients who all received a similar therapy. Irrespective if such a description refers to a prospective or retrospective design, the study should nevertheless be termed *case series*. This study design does not include comparisons to a

control group or allow evaluations of associations (Grimes and Schulz, 2002). However, case series may be justified to generate hypotheses and provide information for designing appropriate study protocols. Indeed, descriptive observational studies in medicine have provided significant contribution to the understanding of severe diseases (*e.g.*, HIV infection and AIDS). Development of subsequent research has resulted in important progress for diagnosis and treatment. From a historical perspective, however, a similar development has not been achieved for clinical research in implant dentistry. The case series study design still prevails in this research field, and results from such protocols are often inappropriately used to assess associations between exposure and outcomes.

The questions on appropriate patient samples and study designs in implant dentistry are of high priority. Controlled studies are few and rarely evaluate critical questions, such as comparisons of outcomes among different patient groups, clinician categories, treatment procedures, and implant systems. Although the demand for long-term prospective studies is understood, the problem with small sample sizes remains in multicenter trials due to considerable

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dropout rates (Berglundh *et al.*, 2002; Tomasi *et al.*, 2008) and insufficient reporting of final outcomes using life tables. A further limitation in longitudinal prospective studies is the fact that the time for recruitment of patients with the intended follow-up period is extensive and the products/components to be analyzed may no longer be in use when the study is completed. To ensure transparency and quality in research, prospective longitudinal studies should be registered in open websites (e.g., Clinical Trials, <http://www.clinicaltrials.gov>) when the study commences. Since 2011, the *Journal of Dental Research* requires clinical trial registration for all randomized investigations (Giannobile, 2012).

So with the above challenges in moving the field, how can we advance forward? With a mutually held goal of improving clinical trial design and execution of investigations in implant dentistry, future research should include the following: (1) patient-centered outcomes in different participant categories with regard to systemic diseases and age, (2) health economy evaluations, including cost-effectiveness appraisal of treatment methods and aspects on benefit and costs in relation to various treatment methods, (3) treatment outcomes in different demographic groups of patients and in which recruitment and baseline characteristics are well defined, and (4) comparisons among different methods and evaluation of the influence of training and skill level among clinicians on treatment outcome.

The present supplement of *Journal of Dental Research* is dedicated to clinical research in implant dentistry and includes studies representing different designs, including randomized controlled trials, case-control studies, prospective case series, and systematic reviews. The randomized controlled trials have addressed important questions on patient-centered outcomes (Hamdan *et al.*, 2013), the effect of immediate load on biological markers (Prati *et al.*, 2013),

and the influence of abutment-implant connections on crestal bone changes (Enkling *et al.*, 2013). Cost-effectiveness in implant-supported single-tooth restoration versus tooth-supported fixed dental prosthesis was evaluated in a case-control study (Zitzmann *et al.*, 2013). Two prospective case series described early implant placement with contour augmentation and 3-dimensional evaluations of ridge alterations after tooth extraction (Buser *et al.*, 2013; Chappuis *et al.*, 2013). Finally, systematic reviews assessed the outcome of dental implants installed in irradiated jaws (Chambrone *et al.*, 2013) with another assessing outcomes of reconstructive procedures in treatment of peri-implantitis (Khoshkam *et al.*, 2013). We hope you enjoy this special supplement, and we give special thanks to the authors who targeted this supplement to disseminate their research findings to the field of implant dentistry!

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