Some issues in applied statistics in clinical restorative dental research
Tobi, H.

Chapter 1

General introduction
Chapter 1

**General Introduction**

Clinical research is complicated and laborious but indispensable to predict clinical behavior of dental materials and effectiveness of operative procedures. The objective of this dissertation is to enlarge, within clinical restorative research, the attention for and awareness to methodological matters. The methodology of good clinical research encompasses a range of issues from the design of the study to the report of results. In between those two, one could think of themes like randomization, reliability of the evaluations, predictive validity of the variables under study, relative influence of operator and patient to the treatment effect, the comparison of treatments with respect to costs as well as effectiveness and, of course, the statistical analysis best tailored to the research question and data at hand. The aim of this thesis is to show and suggest some options to deal with some of the frequently encountered issues mentioned above. Three themes were selected and each is represented by two chapters. All data used in these chapters is real and obtained from controlled clinical trials.

The first theme is "observer variation". The reliability of the assessments is essential for the quality of clinical research. Often, the reliability of clinical assessments is regarded questionable and hence often two, and sometimes more, observers are used for the direct assessments. There are different ways of expressing observer variation. In Chapter 2 different measures for describing observer variation are compared using data on marginal adaptation from two controlled clinical trials. In one trial composite resin restorations are assessed four years after placement, in the other amalgam restorations are evaluated fifteen years after placement. In general practice a lack of marginal adaptation is reported one of the main reasons for replacement of restorations. So a reliable assessment of marginal adaptation is important for research into the durability of restorations. Chapter 3 uses log-linear modelling and Cohen's kappa for looking into observer agreement, taking material performance into account.

The second theme is the handling of "durability and replacement data obtained in a split-mouth design". Often a design is used in which different restorative materials are used within the same mouth. If this allocation of different materials within the same mouth is randomized and controlled, one may speak of a so-called split-mouth design. This way, in principle, each patient is her or his own control: all experimental conditions are represented in the same mouth. In the statistical analysis of durability or replacement data this type of design is often ignored. The restorations are analyzed as if they were
completely independent while in fact there is a natural and logical
dependence: part of the restorations is indeed in the same mouth.
In Chapter 4 several ways to handle survival data in a split-mouth design are
described and illustrated using data on Class II amalgam restorations which
were followed for 15 years after placement. One of these methods, logistic
regression with a random component, is also used in Chapter 5 to compare
replacement risks for four amalgam treatment modalities.

In public health care, there is great concern over the increasing cost and
demand which necessitate critical allocation decisions. In dentistry too, this is
becoming a big issue. Hence, the third theme is “cost-effectiveness analysis”.
In this field dentists, economists, public health researchers and statisticians
need to cooperate to yield the kind of information necessary for policy and
allocation decisions. In Chapter 6 the outline of a systematic approach is given
for the economic evaluation of dental treatments. The outline addresses
issues as definition of the study question, choice of evaluation, benefit
measurement and statistical analysis. Since there are many amalgam
restorations which will need replacement in the future, in Chapter 7, the cost-
effectiveness of composite resins and amalgam is compared for the
replacement of Class II amalgam restorations.