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Some issues in applied statistics in clinical restorative dental research

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Chapter 1

General introduction
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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.
Chapter 2. Different materials for restorations should be applied and used in different situations. The different materials have different properties and characteristics that make them suitable for different types of restorations.

One of the main factors in selecting a material is its physical properties. Some materials are more resistant to wear and tear, while others are more flexible and can conform to the shape of the tooth. Additionally, the material should be compatible with the patient's oral environment and not cause any adverse reactions.

Another important factor is the esthetics of the material. Materials that closely match the natural color and texture of the teeth are preferred to ensure a natural-looking restoration.

Cost is also a significant factor in material selection. Some materials are more expensive than others, and the cost should be considered when selecting a material for a restoration.

Overall, the selection of a material for a restoration should be based on a variety of factors, including physical properties, esthetics, compatibility, cost, and the patient's oral environment. It is important to carefully consider these factors to ensure that the restoration is effective and provides long-term benefits for the patient.