INTRODUCTION

The general public poses high and diverse demands on the quality of new medical technologies or devices (Kumar, 1999). Medical technology assessment (MTA) aims at the evaluation of the quality of these technologies concerning medical and economical, social, legal, ethical, organizational or technical criteria. Its outcomes intend to influence clinical and policy decision-making. Generally, the medical technology under assessment has completed its development process, and has been introduced into the clinical market. In this clinical practice, information is gathered to evaluate the effects of the applications of this technology. When the technology is in an early stage of diffusion, the information is often restricted to medical criteria. When the technology is in an advanced stage of diffusion, the available information is more comprehensive, yet the assessment’s influence on changing the established clinical practice meets more resistance (Collingridge, 1980). So due to the restricted information used in the assessments, or to the timing of application that does not attune to the socio-dynamics of technological change, the current MTAs exert only a limited influence on decision-making with regard to clinical practice and policy.

In order to increase the influence of MTA, its scope needs to be broadened by including the development process of a medical technology (Koch, 1995). Constructive technology assessment (CTA) aims to estimate the technology’s quality before this technology’s clinical introduction. Its outcomes can support the actors that are involved in the development and clinical application of a technology to proactively improve this technology’s quality. Nonetheless, the existing methods of CTA fail to influence the actors that make the decisions that shape the technology. These actors often disagree with the outcomes of the assessment, and contest the quality of the outcomes. Moreover, the outcomes provide them no practical solutions to enhance technology development and application.
This thesis aims to develop an adequate method of CTA to influence decision making about the development and clinical application of a medical technology. The adequacy of this method is related to the timing of its application, the information used in the assessment, the consensus formation about, and the quality of the assessment outcomes. This method of CTA should be applied before the clinical introduction of the medical technology. The timing of application during the development stage of the technology needs to attune to the dynamics of technological change. Furthermore, this method is to evaluate the quality of a technology based on a comprehensive set of criteria. This evaluation needs to reflect the perspectives about the quality of the technology of the various actors that shape technological development and clinical application. These actors need to be satisfied with the degree of consensus they attain about the outcomes, and the quality of the outcomes. In addition, the outcomes need to be of sufficient quality for these actors to derive practical guidelines that effectively enhance the technology’s later quality in clinical practice.

Saaty’s analytic hierarchy process (AHP) seems to be an adequate tool to support CTAs (for an overview of its methodology, see appendix A). This technique for multi-criteria decision analysis quantitatively supports the evaluation of alternative solutions with regard to quantitative and even qualitative criteria (Saaty, 1989). It has, for example, been successfully applied to support the selection of new projects for medical technology development. Its use could be extended to influence the development and clinical application of new medical technologies. It needs to address those decisions the diverse technological and user groups have to make to successfully shape the technology and its application.

Chapter 2 describes the traditional paradigm of MTA, and its limitations. The need for a new paradigm is discussed that takes into account the dynamics of technological change. Corresponding to this paradigm, the outlines of a new method of CTA are proposed. This method involves systematic discussions between the diverse groups involved in technological development and clinical application, quantitatively supported by the AHP.

Chapter 3 focuses on the dynamics of technological change during the development process. It analyses the contents and the timing of the inter-group communication that effectively shape technological change. In a case study, a model that views new product development as being punctuated by periods of rapid change (Gersick, 1989) is externally
validated for the context of medical technology development. This model provides guidelines for the appropriate timing of the application of our method of CTA. Namely during the start-up, at a break point roughly halfway the development process, and during the conclusion of the project, inter-group discussions appear to be most influential to steer technological change during the development process.

Chapter 4 presents a pilot study on the use of the AHP in multidisciplinary groups. The members of the groups that shape technology development and application have diverse disciplinary backgrounds. Since the AHP commonly supports a single decision maker or a mono-disciplinary decision-making group, we screened its support for multidisciplinary decision-making groups. We applied the AHP to support two multidisciplinary groups to make respectively a simple and a more complex decision of which the consequences would affect all group members. The satisfactory outcomes of these four applications underline the appropriateness of using the AHP in a multidisciplinary panel, such as intended in our method of CTA. Moreover, these applications allow the readers a glimpse behind the scenes of a university, a common partner in medical technology development.

Chapter 5, 6 and 7 elaborate our method of CTA respectively during the start-up, around the temporal midpoint, and during the conclusion of development projects. During the start-up of the first project, the CTA focused on the definition of the quality of the technology as pursued by the technological developers and users in comparison to the quality of a competing technology. Around the temporal midpoint of the second project, the assessment focused on the comparison between the attained quality of the prototype, the pursued quality of the prototype, and the quality of a competing prototype. During the conclusion of the final project, the assessment focused on the comparison of the attained quality of the prototype and the quality of two competing technologies applied in clinical practice. All comparisons were based on a versatile range of product requirements. On the basis of the CTAs, the developers and users derived practical guidelines to steer technological change.

Finally, chapter 8 focuses on Team Expert Choice, a commercially available group decision support system that incorporates the mathematical procedures of the AHP. It presents the effects of this system on the processes and outcomes of the CTAs. This system not only quantitatively supports the analytical comparisons between the technologies’ quality, it also supports the exchange of information and the formation of a consensus between the diverse technological developers and users. Its use enhances the quality of the outcomes of the CTAs.
All chapters combined provide a first impression of the adequacy of this new method of CTA. The technological developers and envisaged clinical users were satisfied with the degree of consensus about and quality of its outcomes, and showed commitment to proactively fine-tune the properties of the technology to improve its later clinical quality. Based on these first results, this method appears to provide an adequate means to include decision-making focused on the development and clinical application of a medical technology into the scope of MTA.

References