

Chapter 1

Aim of the thesis

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The cornea is a transparent and colorless tissue that serves as the window of the eye. Together with the pre corneal tear film it may be considered as a functional unit. In addition to a regular curvature, the transparency is essential for a useful vision. The corneal function may be compromised by disorders of the epithelium, stroma and endothelium. Once there is irreversible damage to this tissue, transplantation of a donor cornea is the standard surgical approach.

In the beginning of the 20th century, a corneal graft was performed with tissue directly taken from the eye of a living donor. The surgeon himself evaluated the quality of the donor cornea by examining the transparency, the presence or absence of scars and other pathology.

The proven suitability of postmortem tissue during the mid 1930s has had a great impact on corneal transplantation. More donor tissue became available and eye banking started. At that time the sole function of eye banks was the collection of donor tissue. After inspection by the surgeon the donor cornea was usually transplanted in the same hospital. With the improved success of corneal transplantations the demand for donor corneas increased. When in the 1970s the preservation of excised corneoscleral discs in tissue culture medium was introduced, the function of the eye banks changed in the sense that a closer relationship between the eye bank and surgeon was the result. It is generally agreed that the ultimate responsibility for the acceptance of donor tissue lies with the operating surgeon; however the surgeon depends heavily on the skills of the local eye bank staff for the preservation and quality control of the donor tissue. Initially this relationship was based on trust.

The present day patient's demand for near perfect results in the management of health care by physicians next to the more generally accepted policy that trust does no longer apply but should be replaced by control, emphasises the importance of quality control in eye banking. Eye banks have become well designed laboratories with well trained staff. At the end of the 20th century several eye banking staffs felt the need for continuous improvement by the implementation of quality managements systems.

Quality management systems have become legally required by the EU directives in 2004 (2004/23/EC) and 2006 (2006/17/EC, 2006/18/EC) and have been adopted in national legislation.

To complete the quality managements systems in eye banks, data regarding clinical outcomes of corneal grafts are essential. EU legislation already requires notification of serious adverse events and serious adverse reactions with the objective to identify risks. Quality control, nowadays a commonly accepted concept in the eye banks put on its turn emphasis on quality management in the clinical setting.

Many aspects of clinical outcome in corneal transplantation have been studied. Although the importance of careful handling of the donor tissue was already mentioned in the very first report on corneal transplantation, aspects of donor cornea tissue quality have hardly

been the subject of studies on graft outcome. In recent years more clinical outcome results regarding corneal transplantation are available. This is essential for the validation of the eye bank procedures.

The aim of this thesis is to perform validation studies for procedures used in the Cornea Bank Amsterdam. With this kind of results trust in eye banks can be converted to control.

These studies focus on:

- Storage methods
- Selection parameters
- Eye bank processing
- Quality aspects in the eye bank applying organ culture

With this focus we intend to achieve continuous improvement of the donor tissue for the benefit of the patient.

