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Research Paper

Design of a novel heating device for infusion fluids in vitrectomy

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HIGHLIGHTS

- A novel device for heating infusion fluids during vitrectomy surgery has been designed.
- The device allows to control the temperature of infusion fluids during vitrectomy.
- The temperature of infusion fluids during surgery is kept in mild hypothermia range.
- Post-operative complications due to low temperature can be reduced by using the device.

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ABSTRACT

The aim of this paper is to present a novel device for heating the infusion fluids during vitrectomy surgery, to be used to avoid deep hypothermal conditions inside human eyes. The key aspect of the proposed device concerns its ability to control the temperature of infusion fluids and keep it within the mild hypothermia range, in order to reduce the post-operative complications due to low temperature. The operation of the heater has been analysed by means of a transient numerical model developed by the authors, taking into account the presence of the pipes inside which the fluids flow. Two main case studies have been considered in the present work, regarding the possible ways to operate the device that are based on preheating and no-preheating the pipes before the surgery. The numerical analysis carried out in the present study shows that the proposed device may be effectively used to obtain a favourable increase in the temperature of the infusion fluids and to avoid deep hypothermal conditions.

1. Introduction

Computational Fluid Dynamic tools are significantly developed in the last two decades, making this technique a valid instrument to investigate and design innovative devices in many scientific fields, with a significant reduction of time and costs with respect to experiments [1–3].

Vitrectomy is an intraocular surgical procedure that involves removal of vitreous gel to release the vitreoretinal traction in order to treat the retinal tear and epiretinal proliferation. The procedure requires the continuum infusion of fluids such as Balanced Salt Solution (BSS) or air [4,5], with the primary aim to maintain a constant intraocular pressure during the removal of vitreous gel. Since ocular tissues are small and sensitive, the surgical process is meticulous and specific measures are needed during the procedure. Even though medical devices employed for vitrectomy are sophisticated, temperature control of the infusion fluids and, as a consequence, of the ocular tissues is still challenging. Studies based on medical devices employed for surgical process were performed on different human organs [6–11]. During vitrectomy, hypothermal condition can occur, bringing the temperature down to values significantly lower than 35 °C, with consequent influence on the biological changes in ocular tissues that affects the normal operating condition of human body. The importance to control eye temperature during vitrectomy and maintain it close to the normal human body temperature has been proven [12,13]. Various techniques like infusion of air or chemicals are implemented to control the temperature inside eye during vitrectomy, but more research effort on this topic is required to make the process effective.

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Nomenclature

h	convective heat transfer coefficient (W/m^2 K)
k	thermal conductivity (W/m K)
p	pressure (Pa)
R	radial coordinate (m)
T_{amb}	ambient temperature (K)
T	temperature (K)
T_s	temperature at solid region (K)
T_f	temperature at fluid region (K)
t	time (s)
u	velocity (m/s)
z	axial coordinate (m)

Greek symbols

α	thermal diffusivity (m^2/s)
μ	viscosity (Pa s)
ρ	density (kg/m^3)

Subscripts

f	fluid
r	radial component
s	solid
z	axial component

Several experimental studies have been carried out on the basis of fluctuations in temperature, intraocular pressure and other sensitive parameters at vitreous chamber, anterior chamber, and retinal surface of the eye. In the study reported by Romano et al., the temperature variation in vitreous cavity was assessed during vitrectomy in vivo on human eye [12]. The temperature of vitreous cavity at the beginning and end of fluid infusion during vitrectomy was found to be 26.8 °C and 24.8 °C respectively, while during air infusion, an increase of temperature was observed [12]. In another study of Romano et al., a sensitivity analysis of different fluids employed for temperature control during vitrectomy has been carried out with respect to variations of the intraocular temperature and pressure [13]. A deep hypothermal state has been observed at retina and choroid during faster infusion of fluids. The rheological variations of silicone oil and PFCL have been studied before and after the infusion of these fluids. The study proposed silicone oil as an effective infusion fluid for maintaining a temperature of 35 °C for vitrectomy. Tamai and Toumoto have undergone an experimental study on vitrectomy in rabbits to analyse the hypothermal effects on retina and blood aqueous barrier for different fluctuating pressure [14]. The study based on ElectroRetinoGraphy (ERG) signal output with respect to fluctuating pressure shows that hypothermal conditions prevent damage of the blood aqueous barrier. In another study of Armington et al. on output signals from ERG, the vitreous cavity temperature has been lowered during vitrectomy, with consequent aberrant function of retina [15]. Horiguchi et al. have studied the effects of infused fluids in vitreous cavity temperature in human eyes using ERG [16]. They have observed the signal variation in ERG retinal side with a vitreous cavity temperature of 27 °C. Lachapelle et al. have studied the changes in ERG readings during cooling of retina in ex-vivo study in rabbits [17]. They have observed significant changes in ERG reading confirming that retinal cooling affects normal operating condition of the retina. All the above studies have shown the influence of temperature that affects the normal operating conditions of ocular tissues during vitrectomy. Biological changes due to hypothermia occurring in ocular tissues have been reported. So far, maintaining the vitreous cavity temperature close to normal human body temperature during vitrectomy has been mainly obtained by means of infusion of fluids or endolaser treatment.

On the basis of the authors' knowledge, a device dedicated to the temperature control of infusion fluids during vitrectomy is not currently employed by surgeons and has never been studied in the available literature. Therefore, in the present paper, a novel device employed for temperature control of the infusion fluids (air and BSS) before injecting into vitreous cavity is analysed numerically. The study presents the apparatus in order to obtain air and BSS temperatures close to vitreous cavity temperature, to prevent hypothermia conditions. The present study is a part of broader research activity that will also take into account the experimental characterization of the proposed device. It has to be understood as a proof-of-concept, to report the novelty concerning the use of the proposed heating device applied to the vitrectomy procedure, never investigated in the literature, and to gain some insight into the actual physics of the overall process.

The paper is organized as follows: a description of the medical equipment is reported in the following section. Sections 3 and 4 report the numerical procedure employed and the obtained results, respectively, while in Section 5 some conclusions are drawn.

2. Medical equipment

2.1. Medical apparatus and procedure

The medical apparatus considered in this study for vitrectomy is composed by the machine which injects the infusion fluids at a controlled flow rate and by the tubular PVC pipes for air and BSS connection from this machine to a sharp needle that is placed by the surgeon inside the vitreous chamber during the surgical procedure. The surgeon also employs another sharp needle, of specific gauge to cut the vitreous. The surgery is based on different stages starting from vitrectomy procedure followed by epiretinal procedure, air and oil infusion and endolaser treatment [12,13]. The present study focuses on the infusion of air and BSS. These fluids are sent from the injection machine towards a sharp needle through the pipes, which have a length of about 1.8 m with external and

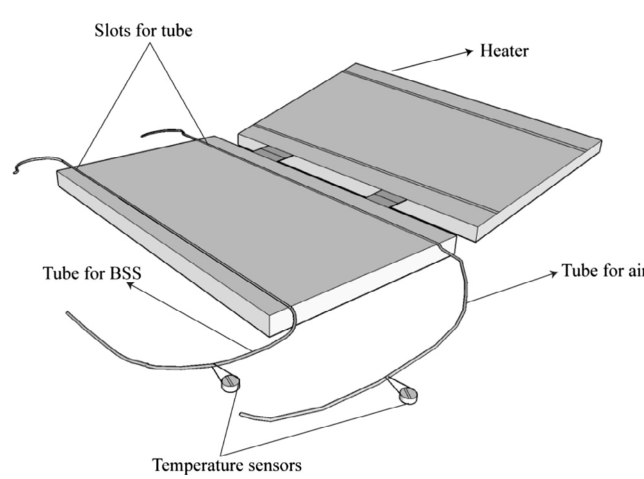

Fig. 1. Sketch of the proposed heating device employed for vitrectomy.