Biomaterial Latex Manufactured Occlusion Contact Lens: Proposal for Amblyopia Treatment

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Abstract*—Amblyopia is an ophthalmic disorder that consists in low visual acuity in an eye that was not developed adequately during childhood, commonly known by lazy eye. The products presently used for treatment of amblyopia are conventional occluders, fixed with adhesive tape directly on the eye region of the child. These products generate aesthetic damage and also enable its removal by the child which brings considerable problems to the treatment. This article presents a new proposal of latex applicability in patients with a tendency to develop amblyopia, a visual acuity failure. It is idealized in a contact lens derived from natural latex for total and gradual occlusion of the eye as a new tool for the treatment of this disease. To develop the proposal, a prototype was built and its analysis was carried out based on biomaterial which already has several applications in tissues with satisfactory results.*

***Keywords*— Amblyopia, contact lens, latex.**

I. INTRODUCTION

Visual development is a complex process that involves maturation, the result of a genetic code and a continuous and normal visual experience to keep scarce vision present at birth and to promote its further development. The etiology of amblyopia is the flaw in normal development of the visual system of one or, more rarely, both eyes during maturation period of the Central Nervous System (CNS), that leads to unilateral or bilateral deficiency of visual acuity (VA) [1,2].

This paper aims to present the implementation of occluder contact lens (LENCOC®), made of biosynthetic biomaterial -based on natural latex (extracted from the rubber tree *Hevea brasiliensis*) – with complete absorption of light, to occlude the patient's good eye in order to prevent the passage of light from the external environment, to stimulate the amblyopic eye with more comfort for the patient.

Literature include three main causes: i) strabismus (squint) – the image of the squint is suppressed to avoid double vision, and the child uses only the best eye; ii) refractive error – when one eye has more myopia, hyperopia or astigmatism than the other, the eye with blurred vision (out of focus) is deleted and can becomes amblyopic and iii) opacity in transparent media of the eye – any factor that prevents to focus the image properly can lead to develop amblyopia. Being the most common visual defect in children, its diagnosis and early treatment brings satisfactory results [3,4].

The classical and best known technique to treat amblyopia is still the occlusion of the eye with best vision. If amblyopia is not treated until the age of six it is considered irreversible. The time for occlusion depends on the intensity and the age of the patient.

In most cases, amblyopia must be detected and treated before school age, when the vision is still in full development. Meanwhile, it is not easy to be detected, mainly for the children themselves since they do not realize they see with only one eye.

Early treatment of amblyopia is critical to achieve best results in visual acuity and should be individualized depending on the cause of amblyopia. It requires good cooperation between the pediatrician and ophthalmologist, performing visual acuity screening before the age of 4, paying special attention to children with family history of this disorder.

The duration of treatment depends on the degree of visual loss as well as the speed of visual acuity recovery. Every case should be evaluated individually, as well as whether the child is still under the age of treatment.

A biomaterial is a material, synthetic or not, used to replace part of a living system or to work in direct contact with a living tissue to replace, repair or assist in organ function or damaged tissue in a safely, responsibly, economically and physiologically acceptable manner [5, 6, 7].

Material that develops appropriate tissue responses in the host system when used in specific applications is characterized as biocompatible, it does not necessarily

have to be absolutely inert or innocuous as previously believed. Bio functionalization is present since it plays the desired functions due to its mechanical, chemical, optical, electrical, and other properties.

In addition to biocompatibility, biomaterials must possess bio functionalization, i.e. the ability to perform properly the desired function given its mechanical, physical, and chemical properties. Standard biocompatibility tests represent approval and disapproval criteria to control the material in the market. These tests also work as parameters to study interactions of the organism and the material in contact with it and aim to establish testing standards in order to describe and graduate responses from both the host and the material, eliminating toxicity or establishing a criterion of tolerance to the material risk level.

Natural latex has been discovered by researchers as a healing natural rubber; since then, studies have been developed to prove its characteristics to induce neovascularization and tissue repair.

The first known study that used latex for medicinal purposes was developed by a researcher at the University of Ribeirão Preto. He was trying to reproduce an esophageal prosthesis model already known when replaced some constituent by natural latex. To the surprise of the team, the results were positive and stimulated researches that continue nowadays. That study proposed the replacement of a 4 to 6 cm segment of cervical esophagus in dogs, by a prosthesis based on natural latex, with different times of permanence [8, 9].

When searching for a material to be used in lens (LENCOC®) production, we realized latex has been used in various areas of medicine. It is a simple material, easy to handle and inexpensive. In literature there are many studies on latex application as implant material used in various tissues, all with satisfactory results.

Latex is a whitish secretion (also called "Milky sap") produced by the stem of the rubber tree (*Hevea brasiliensis*), through an incision in the bark, called "sangria".

Essentially, the natural function of latex is to heal the tree injured tissue. Immediately after the sangria, the latex flows quickly, slowing down to a uniform speed until stops flowing. The flow stop is due to the latex vessel obstruction caused by the clot formed in the cuts [10].

The aim of this study is to evaluate the construction of latex lens of different techniques and make a preliminary investigation about their occlusion.

II. MATERIALS AND METHODS

Latex, plus other substances, was initially used to heal injured esophageal walls through development of a biosynthetic esophageal prosthesis model which was successful in rebuilding dogs' esophagus [8]. Results revealed that biomembrane of natural latex and *polylysine* present biochemical characteristics that interfere in tissue repair process favoring the rapid and regular formation of a new tissue. As an easy to handle material, complex techniques for production and use are eliminated [8, 9]. These studies show that new replacements for veins are being searched.

Based on these data, other studies using of latex have been conducted [11], to assess the biocompatibility and strength of seven latex membranes in twelve New Zealand breed rabbits. Six types of latex membranes made in Chemical Technology Laboratory at the University of Brasilia (LATEQ-UnB) were implanted. Implants were removed after fifteen days and submitted to histological examinations. Results obtained concluded that membranes offered suitable resistance for implantation to repair muscle sheath in rabbits; however, the immune reaction contraindicates its use in this species. Latex was also used to make esophageal prosthesis, biomembranes and *esophageal flow control module* [8, 9, 12].

An experimental model named LENCOC® occluder contact lens was developed using natural latex as raw material. Based on existing techniques and models of various objects used in the medical field, a physical and material model was exposed for the proposed application which aims to allow the total occlusion of the good eye to treat the pathology. Most of the development process of making the lens was carried out in the BioEngLab® and tests were conducted at Crystal Optics in Goiania-GO. The process of making LENCOC® lens was conducted in two main steps: mold preparation and manufacturing process of the product.

III. RESULTS AND DISCUSSIONS

Manufacturing process

The experimental model of occluder lens was developed using natural latex extracted from the rubber tree *Hevea brasiliensis* as raw material. Latex used was purchased on the domestic market. A few liters of different providers in the southeast, south and mid-west of Brazil were purchased, based on some needed standard features such as the amount of low sulfur and high viscosity. High concentration of sulfur, after vulcanization, gives latex sticky and low viscosity features. Due to these features the process of production required a high manufacturing time. Thus, vendor that meets these criteria was defined – latex extracted from rubber plantations in Florianópolis – Santa Catarina – Brazil; BI-centrifuged at 8000 xg, in α-Laval-centrifuge A-4.100, with continue passage, water cooled.

From natural latex, a final compound was prepared through the addition of chemical substances following the steps proposed in [8]. The objective was to give the

product (LENCOC® Lens) features that are essential for lens such as: elasticity, softness, strength, impermeability and hypoallergenic standards. After preparing the compound to use in the lens manufacturing process the steps of filtration and dilution in distilled water should follow. The entire procedure should preferably be performed in low temperature (less than 20ºC), to prevent prevulcanization of the liquid, due to the presence of heat. To handle latex, glass rods were used as well as a whisk to mix, a glass container to store, nylon paper to protect from air contact, aluminum foil to protect from light and cotton flannel to clean. Latex is a compound which, on contact with the skin (due to body heat ≈36ºC), vulcanizes, becoming sticky. For removal, only water is used. To reduce ammonia inspiration the use of a mask is important in order to avoid allergies, irritations and headaches, which were observed by the authors.

Molds preparation

The first step was to study the eyeball and its peculiarities.

During the development process the mold was first produced, made of plastic material and coated with a layer of acrylic glass. The template was designed based on the anatomy and characteristics of the eye. As a model for the prototype the anatomical format of a marble was followed. The occluder lens manufacturing process was completely individualized; its shape and proportions follow faithfully the characteristics of the patient's eyes in order to provide greater comfort.

To make the latex sheet we used i) a holder and ii) a mold. Fig. 1 illustrates the tecnil holder to be attached to the glass mold used in lenses confection and Fig. 2 shows the mold to produce latex sheet.

Figure 1. Image of holders made of tecnil to be attached to the glass base to produce latex lens sheet.

Figure 2. Image that shows in A) the holder; B) glass mold and C) assemblage to generate latex sheet with the technique proposed.

The first step of the manufacturing process of the occluder lens was to prepare the molds. Molds are previously washed with soapy water, dried with hot air and sterilized in a stove.

Biomaterial originated from natural latex of rubber tree *Hevea brasiliensis*, presents low cost as well as being a raw material of high quality and durability that presents physical and chemical biocompatible characteristics such as impermeability, elasticity, softness, flexibility and strength. These characteristics are in accordance with the most current scientific studies to favor the comfort of the patients, control the temperature and reduce the risk of developing allergies [1, 12].

At this stage, the elaboration process of the lens occurred into two main steps: preparation and characterization of the product. At this time, indispensable requirements of the product were taken into account such as softness, comfort and total occlusion of the light. At this stage, the latex used had already been subjected to a centrifuge process to decrease the amount of proteins naturally present in it, many of them responsible for allergic reactions. Sulphur and resin suspension were added in order to give the final compound the elasticity and strength needed [8, 9].

Lens manufacturing process

In the lens manufacturing process a technique consisted on successive immersion baths was used. During that process the molds were plunged slowly in perpendicular position in the final compound of latex, followed by heating in a thermostat oven at 40° C. New techniques were also used such as drip, brush stroke and Van Gogh (name given in the lab based on Van Gogh's painting), in which brush-strokes are "hits" to cover the mold completely using a cotton swab.

The molds were then heated in the oven at 40ºC during ten minutes for sterilization and then removed and immersed in latex during 1 minute, taken slowly and gradually. Then they were placed inside the oven (subjected to heating at a temperature of 40 degrees C for

vulcanization) at intervals of two hours. Immersion and heating were repeated four times to obtain the proper thickness for occlusion. After this step, the molds remained for more 24 hours inside the oven.

It is important to mention that immersion and heating steps were repeated until the lens reached a thickness of 0, 3 mm. So, after the period of vulcanization, the lens stayed 24 hours at room temperature to finish the manufacturing process. However, the whole process takes an average of three to four days since the structure and format of the lens must be very well vulcanized in every millimeter which demands a more thorough preparation process.

At the end of the process, the parts were removed from their molds under running water (latex layer formed was removed slowly to avoid the piece damage).

After finishing the lens manufacturing process, the piece was subjected to visual inspection to detect any molding or assembly defects in Fig. 3.

Figure 3. Lens made using Van Gogh's technique.

Product characterization

Tests were carried out to verify the resistance of the lens, the format uniformity and optometry test. We used visual inspection to detect any molding or assembly defects associated to, for example, the format of the surface, the grooves, through the use of a caliper and a ruler.

Tests were submitted to assess whether the lens made followed the standards of a normal lens, observing their occlusive characteristics. To evaluate these occlusive properties and to verify optometry, that is, to mark the optical center of the lens, where rays suffer the slightest deviation, in which low reflection matches with the reflection of low surface, an optometry test was carried out.

The lenses were made by observing the evolution history with several different protocols until a model respecting the main features: light occlusion, thickness and applicability.

Occlusion of light was obtained through measures in a digital calibrated lens meter and observing the variance of the Prism (Δ) deviation of light, axes S, C related to the degree of lens and A to the axis. Axis equal to zero means the lens is flat. During tests a measuring error in the device was observed, which presents a flat and irregular lens due to the technique used in the manufacturing process in Fig. 4. This fact generated a significant change, there is no passage of light, i.e. measurement errors proved occlusion and opacity. A caliper was used to measure the thickness of the lens. While thickness of a contact lens is 0.03 mm LENCOC® occluder lens is 0.2 mm.

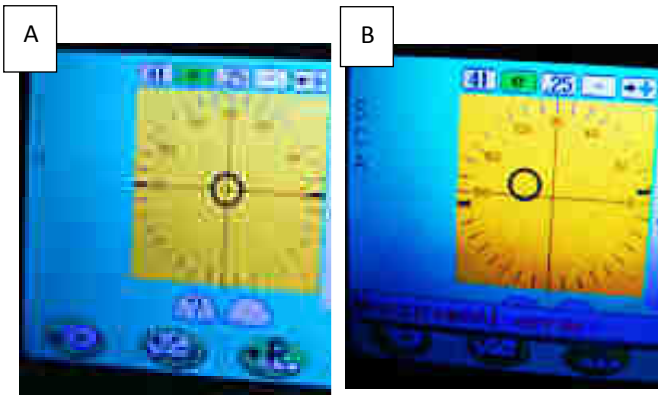

Figure 4. Digital measurement of lens. In A normal lens and in B LENCOC® lens.

IV. CONCLUSION

To sum up, we realize that it is difficult to develop an occluder device. Considering the current studies and our contribution it is possible to say we moved forward, although a complete assessment of the full function (physiological, biological, mechanical and microscopy) is essential to better orient the direction to be taken in regard to visual impaired. The use of LENCOC® will provide a better understanding of the relationship between amblyopia and occluder lens in direct contact with the eye (cornea). Medical judgment in situations where the empiricism is factor of great importance is relevant. One of the main objectives is to improve via biotechnological science and engineering a therapy to disturbances related to visual disease, improving the quality of life of patients and thus reducing the possibility of future problems. Finally, this research group will conduct future studies to achieve those goals to refute or validate this proposal.

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