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DESIGN AND DEVELOPMENT OF AN ULTRAPORTABLE CORNEAL TOPOGRAPHER FOR SMARTPHONES AS A LOW COST NEW TOOL FOR PREVENTING BLINDNESS CAUSED BY KERATOCONUS

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Abstract – The high cost of devices used for preventing eye diseases that cause blindness still represent a limiting factor for those preventive strategies of public health around the World. Before this scenario, it can be clearly observed that the development of a new ultraportable device, light, with a low cost and using the functionality of processing and communicating of a smartphone for screening patients, represents a unique innovation to combat blindness. From this context, this research aimed at designing and developing a functional prototype of a new ultraportable corneal topographer for smartphones as a tool to combat blindness by keratoconus. This prototype was designed and developed by the CIÊNCIA ILUSTRADA Studio®, a startup company, incubated by the INOVA Metrópole at the Federal University of Rio Grande do Norte (UFRN). The hardware was designed by using the CorelDRAW X6, and its 3D modelling used the Pro Engineer Wildfire 5.0 software. The hardware printing was performed through the 3D Dimension Elite STRATASYS printer, and the printed circuit board was made by using the ProtoMat S62 machine. The application was developed using the Xcode 5 program. Its final calibration was performed applying stainless steel spheres with known radius. The inventor's exclusive rights over the intellectual property for the creation of the device were assured by a patent application. At the end, it was developed a low cost device that can be coupled to a smartphone, and an application running under the IOS platform to process acquired images. After calibrating the set, it allowed the acquisition, processing and analysis of Placid rings, projected over the surface of the examined cornea, providing images, maps, indexes and other ways of measuring. It was made available a new ultraportable corneal topographer, with low cost, and able to work as a mass screening tool for corneal diseases, such as keratoconus.

Keywords - Cornea, Keratoconus, Corneal topography of keratoconus, Image processing.

I. INTRODUCTION

Keratoconus is a disease that causes the deformation and progressive thinning of the cornea, what takes to an irregular astigmatism and progressive loss of sight [1]. This disease appears during the childhood, usually affecting the eyes in a bilateral way, reaching an incidence of 1 case in 400 inhabitants in some populations [2]. With the evolution of this disease, patients begin demanding rigid contact lenses to keep a useful sight, but they experience limitations in their education and employment opportunities, what cause psychological, social and economic irreparable problems [3,4].

From the early diagnosis, a person affected by keratoconus can stop its evolution with an effective and low cost treatment designated corneal cross linking [5,6]. However, the most currently used corneal topographers to perform the early diagnosis of keratoconus are expensive devices, with large dimensions, coupled to conventional computers and without portability, what makes hard performing a mass initial screening examination to identifying initial cases.

In Brazil, the cost of those devices is usually between US$ 15,000 and US$ 100,000, what makes it inaccessible for most of the population. Hence, most of the bearers of keratoconus have their diagnosis delayed and loose the chance of stopping the disease by applying the corneal cross-

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linking. As a consequence, about 21.2 to 40.2% of those people progress to more advanced stages of that disease, what demands a corneal transplant, where the patient has to receive a new cornea from a dead body to recover the sight and make possible performing labor activities [7]. For that reason, nowadays, keratoconus still represents the main cause of corneal transplants in Brazil and in the World, what results in high costs for health care systems [8-10].

From the exposed, it can be clearly observed that the invention of an ultraportable corneal topographer, with low cost and high mobility, represents a unique innovation, what brings a significant advance to the evolution of these kind of devices used to diagnose keratoconus.

II. MATERIALS AND METHODS

The present study refers to the design of a device (hardware) to be couplet to a smartphone, and the development of an application (software) to process those images generated by the reflection of light rings projected by the hardware on the examined corneal surface. When coupled to an iPhone 4 smartphone (Apple Inc, Cupertino, CA, USA), with the previously installed application, that set (hardware, smartphone, and application) is able to measure and analyzing the corneal curvatures, creating an ultraportable corneal topographer. This project was developed by the CIÊNCIA ILUSTRADA Studio® (startup company incubated by the INOVA Metrópole, from the Instituto Metrópole Digital-IMD at the UFRN), during 12 months.

The hardware was designed by using the CorelDRAW X6 (Corel Corporation, Ottawa, Canada), a vectorial drawing software, in a way that it could be coupled to an iPhone 4 smartphone, allowing the user to freely access its screen, command buttons, and without compromising its camera functionality.

That hardware was composed by a support cover, a printed circuit board with LEDs (light emitting diodes), an optical system for magnification, a cone with transparent and black concentric rings (principle of Placid) and a dome. LEDs were supplied by batteries, kept in a compartment designed within the cover, and activated by a switch. The 3D modeling of the cover, cone and dome were performed by using the Pro Engineer Wildfire 5.0 (PTC Corporate Headquarters, Needham, MA, USA), as shown in Figure 1.

The cover, cone and dome were printed using ABS plus plastic in a Dimension Elite (STRATASYS, Eden Prairie, Minnesota, USA) 3D printer, whose result is shown in Figure 2.

The printed circuit board, responsible for the electrical connection and supplying the LEDs used as luminous sources for the projection of luminous rings on the cornea, was made by using the ProtoMat S62 (LPKF Laser & Electronics AG, Garbsen, Germany) machine.

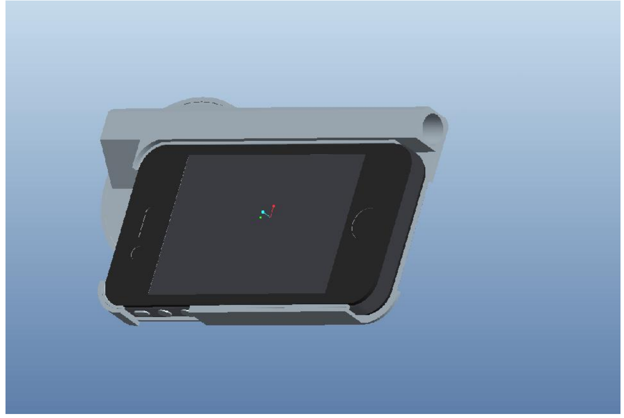

Figure 1. 3D hardware modelling.

Figure 2. 3D printing of the prototype.

The prototype assembly consisted in adjusting all of its components: cover, optical system, cone, and dome. Once assembled, that prototype (Figure 3) allowed the development of specific software for processing and analyzing all the captured images.

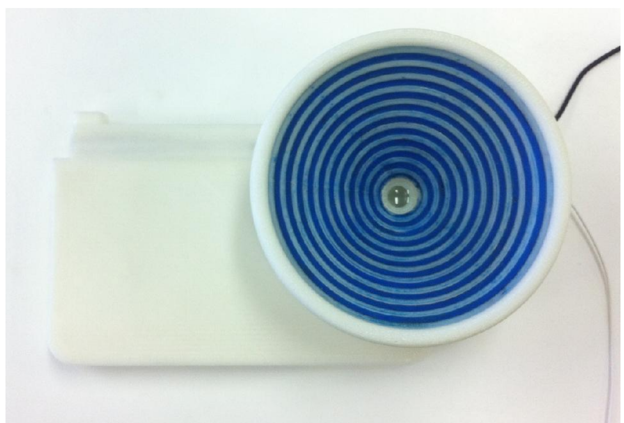

Figure 3. Prototype assembly.

That software (application), responsible for processing, analyzing and generating data, was developed by using the Xcode 5 (Apple Inc, Cupertino, CA, USA) program, to be used within the IOS (Apple Inc, Cupertino, CA, USA) platform. The software's main screen is shown in Figure 4. The calibration of the set was performed using stainless steel spheres, with radius of 60 mm, 75mm, and 100mm (Figure 5). Images reflected by their surfaces were captured by the prototype to be used as standard references for the software in later captures.

The inventor's exclusive rights over the intellectual property for the creation of this device were assured by a patent application at the INPI, under the BR 10 2013 03 1050-6 registration number. Figure 6 shows the device as presented in that documentation.

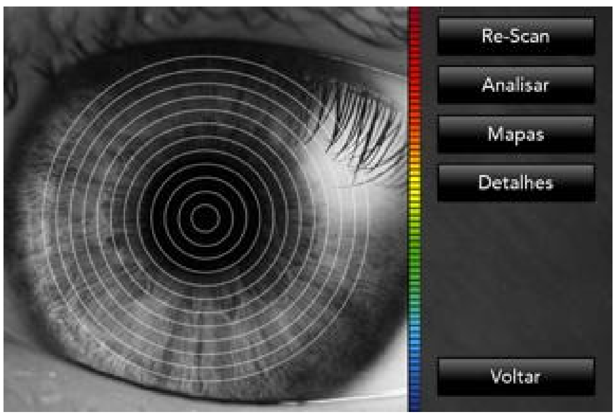

Figure 4. Developed software.

Figure 5. Spheres for the device's calibration.

III.RESULTS E DISCUSSIONS

The CIÊNCIA ILUSTRADA studio® startup developed and registered the patent request of the device designated 'ultraportable corneal topographer', which is coupled to a smartphone, where is installed an application also developed by the same startup, making it able to diagnosis keratoconus.

The ultra-portability of the invention consists in an innovation of extreme relevance, because it allows the user to perform a preventive ophthalmic examination of high complexity and cost, as the corneal topography, reaching poor places with difficult access. Besides having low cost of manufacturing and execution, this invention also contributes to massify the early diagnosis of corneal diseases, what favors the definition of a treatment on time to avoid high costs to the public healthcare system and potential irreversible damage to the sight. As this device has a significant innovative character and a high socioeconomic impact, it can also be used for partnerships both with the private sector and the public sector, as this second one can use it in preventive strategies of public health to combat blindness.

Most of the available devices, on the market, to perform the corneal topography are installed in fixed stations, without mobility. Trying to make available a device to perform an accurate corneal topography, many devices have been developed through the years, feeding a set composed by devices in many ways, sizes, different designs and costs. However, the implementation of new advances influenced also a progressive raise in costs of current corneal topographers as a result of the increasing in their complexity, what involves the need for a support cabinet, the incorporation of a monitor, keyboard, and a central processing unit. The inclusion of all these accessories makes harder moving the examination station, and the portability becomes unfeasible to be used in screening programs. These programs would aim at detecting, in an early way, corneal diseases in a population, especially keratoconus, that when not early diagnosed bring high monetary costs for the health system, besides irreparable social and psychologic damage to patients.

Figure 6. Product showed in the patent request (above) and working (behind).

Considering that keratoconus is a disease that attacks 1 for each 400 people and that the estimated cost with the treatment through the life of only one patient can reach about US$ 25,168, it clarifies the importance of having an ultraportable diagnose device, with low cost and easy to handle to perform mass preventive screening by using just a smartphone.

Besides the low mobility, another limiting factor to perform examinations with conventional corneal topographers is the impossibility of examining some specific groups: little children, patients held in a hospital bed, wheelchair users, besides patients with diseases that compromise extending the neck. However, the biggest limitation realized in those corneal topographers available on the market refer to their impossibility of examining the patient on the pre-operative, intra-operative and immediate post-operative periods, when he is lying in bed. Any alternative to perform the corneal topography during these operative periods would represent, with no doubt, a significant advance to improve results in corneal surgery.

From the improvements in mechatronic, it has been reported some tries of developing a smaller device or even a portable one. As a result of those tries, it was created a portable corneal topographer, with an American patent registration conceived under the number 6152565 A [11]. Despite being presented some improvement in mobility, that invention still presents some limitations. As other devices, the cost makes hard the access to the new technology. The need of connecting it to a computer (laptop or desktop), having many interconnected parts, and those connections being made by wires, allow improvements by the development of smaller device, with mobility, no wires for its operation and provided with computational capacity and ultra-portability.

As anteriority, Carvalho developed a 'computerized instrument to measure the corneal topography during the surgery'. In this invention, the researcher presented an instrument to perform the corneal topography during the surgical procedure by using a cone with Placid rings, illuminated and set in an objective lens of a surgical microscope. In other paper, a team of researchers, which included the previous one, presented a new system to measure the corneal topography using a personal minicomputer, i. e., a portable computer [12,13].

According to the Brazilian health ministry, only in 2011, from 23,397 transplants performed in Brazil, 14,838 were corneal transplants, being keratoconus one of the main causes [14]. Additionally, performing a corneal transplant demands a multidisciplinary team composed by technicians, nurses, psychologists, social works and specialized ophthalmologist doctor, besides surgical materials, equipment and a complex hospital structure that raises too much the cost of this medical procedure. Some researches show that the cost of only one corneal transplant can vary from US$ 3,025 to US$ 3,750, while the estimated average cost of treating a patient with keratoconus, during his whole life, is about US$ 25,168 [15,16].

As keratoconus represent the main cause of corneal transplant in Brazil and the cost of only one transplant can reach about US$ 4,000, it is expected that a low cost too, able to be used outside ophthalmic clinics, making possible diagnosing and avoiding the advance of a bilateral disease that takes to blindness and irreparable psychological, social and economic damage, represents an unprecedented technological advance. Besides that, the fact that the device is coupled to a smartphone allows it to be used by lay persons because of its easy handling, what makes possible also creating a data base, through the process of geolocation, promoting the reduction of costs and optimizing preventive strategies for the public health. It can also be glimpsed that, in a near future, the application of the ultraportable corneal topographer for smartphones can be expanded to schools in the whole world, and basic school teachers can use them, yearly, for examining their students. Hence, those results can be sent, through the internet, in a fast and practical way to a diagnosis central, creating a worldwide network of prevention of keratoconus.

After the development of hardware and software, the prototype will be subjected to improvements, aiming at assuring a better ergonomics and reproducibility of results, besides higher durability to be used in large-scale. After the development and industrial improvements, the new device will be subjected to a comparative clinical analysis with two conventional corneal topographers available on the market.

IV. CONCLUSIONS

From the exposed, it can be concluded that the invention of an ultraportable corneal topographer, light, with low cost, and without the need of wiring and connecting it to a conventional computer (laptop or desktop), also using the functionality of processing and communicating of personal devices, such as smartphones, represents a recognized technological innovation, which brings a significant advance to the evolution of devices applied to preventive diagnosis of diseases that can cause blindness.

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