Development of a wearable device for the early diagnosis of neurodegenerative diseases

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Abstract. The progressive evolution of information and sensing technologies is giving pulse to the development of wearable mobile devices in search of life quality improvement. A relevant field of application is healthcare, with the development of wireless unobtrusive wearable solutions for the continuous remote health monitoring of patients. These wearable devices are particularly important for neurodegenerative diseases due to the possibility of early stage diagnoses through continuous monitoring to collect earlier significant data. Discovering specific symptoms and early defining medical treatments can delay, if not stop, the pathology progress whereas, once major symptoms like restricted or impaired mobility has appeared, the patients already underwent relevant and irreversible brain damage. The aim of this work is to show the development of the Neuroglass, a wearable smart glasses device for early stage diagnosis and monitoring of Parkinsonian-type neurodegenerative diseases. The designed frame is compliant to the standards and in order to embed the sensors to collect data from head and eyes movements since one of the early symptoms of Parkinson's disease has proven to be eye tremors. Preliminary laboratory tests, e.g. head accelerations measurements for different body movements, were carried out in order to choose properly the characteristics and positioning of the sensors; afterwards the device’s frame was designed by means of a 3D parametric CAD and built by additive manufacturing. The design was validated by first experimental test on monitoring eye movements and blinks.

1. Introduction

The fast evolution towards more and more miniaturized electronic systems is enabling the development of lighter and more powerful portable devices. Wearable devices, until today restricted to leisure and outdoor uses, are becoming important for more technical applications in everyday life. Among technical applications, wearable devices for medical use are of paramount importance for the improvement of personalized medicine and early diagnoses of illnesses and diseases [1]. Wearable devices will have a strong impact on patients’ life quality by avoiding the commuting to medical centers or to be hospitalized. In the future, it will be an ideal situation when the usual living environment of the patients will remain untouched and the diagnoses will not be biased by any external factor. Indeed, wearable devices are not invasive and will not affect the way of life and the routines of the examined patients, as well as their interactions with other people.

Among the various wearable devices, watches are well known, but there are other solutions such as wristbands, arm or chest bands, balaclavas and helmets, and eyeglasses [2]. Chest bands are used since many years to diagnose heart and respiratory syndromes [3]. Balaclavas are produced and distributed for neurological diagnoses. In both cases size limitations are not so strict and this justifies the fact that such devices were developed several years ago. Miniaturization of the electronics allows to extend the applications to other fields and devices. The Neuroglass project takes advantage of the expertise of different partners, from specialized eyeglasses to medical diagnostics, to develop a special type of eyeglasses with sensors aimed at measuring signals coming from head and eye movements which can be correlated to some neurological diseases. Of course, the realization of this type of wearable device is made possible only by the availability of microelectronic sensors and components, as well as miniaturized batteries and electrical connections. In fact, to produce a really wearable set of eyeglasses the dimensions and weight must be compatible with practical limitations to allow for sufficient comfort, for example avoiding disturbances to the patient's vision and hearing [4]. Possibly this specialized eyewear should be stand-alone, without external connection in the form of wiring (unless during charge of the batteries that will occur at relatively long intervals that can correspond to resting or sleeping times). Collected data from measurements could be either stored in an internal memory and then uploaded to some external equipment for the analysis or transferred continuously by means of some wireless communication system, or both [5]. Both methods can give complementary information and so have advantages and disadvantages.

The present work will summarize the development of the structure of the Neuroglass which included a strong and continuous interaction with the developers of the electronic parts. Contributions of the authors of the present work included evaluation of the measurements of the biomechanical data, the study and design of the structure including some analysis of the mechanical behavior to comply with standard requirements for eyewear construction, and the development of the prototype by using the additive manufacturing technique. By the way, the use of additive manufacturing will be not restricted only to the prototype but could be an effective option in the perspective of personalized medicine [6,7].

2. Use of a wearable device for early diagnoses

The Parkinson disease, a well-known and seriously invalidating syndrome, is characterized by muscular rigidity with resistance to passive movements, tremors during resting states that can worsen with anxiety and bradykinesia that can prevent the completion of voluntary movements [8]. Tremors (at frequencies around 3-6 Hz) during rest are the most frequent symptoms (70-100% of all cases). According to the medical researchers eye-tracking can help diagnosing this neurological syndrome [9]. With an eye-tracking device ocular tremors were registered in more than a hundred patients, contrarily to a sixty people comparison group where ocular movements were measured in only two cases.

Therefore, the measurement of eye and head movements could be a very effective method for an easy early diagnosis of this disease [10] to monitor the evolution of the disease and to manage the treatments in real-time according to each patient's state. Typically the error in diagnosing the Parkinson disease is around 30%. With the eye-tracking techniques this error can be dramatically reduced. The Parkinson disease cannot, as of today, be healed but the symptoms can be reduced so that the patients can continue living a normal life, especially if treated in the first phases of the illness.

Ocular tremors [11] are also related to head movements and gait disorders [12]. Therefore, head oscillations evaluation is another way to monitor the disease.

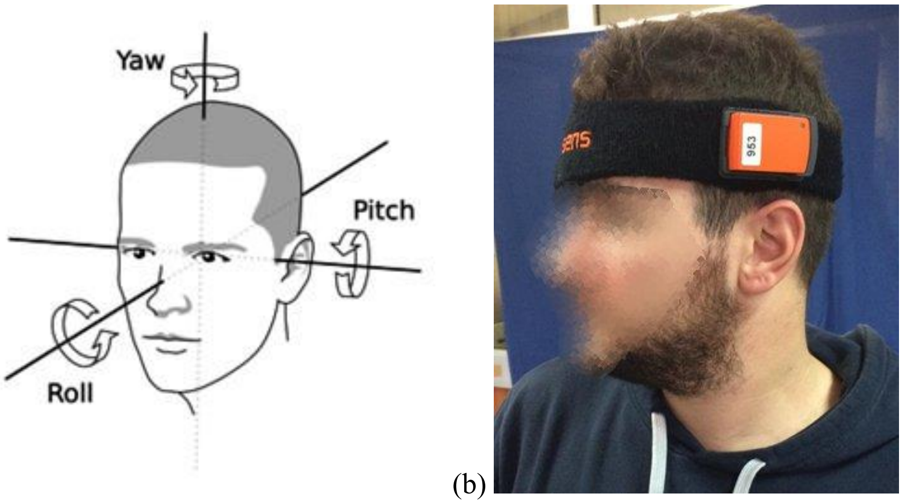
To this purpose a preliminary analysis of head movements was carried out to evaluate their characteristics and to identify the best solutions for an effective measurement. In particular to understand where to place the movement sensors in the Neuroglass.

2.1. Biomechanical measurements

To correctly select and position the sensors inside the frame, a campaign of biomechanical measurements was carried out. In the "Measurements Laboratory" of the Department of Mechanical Engineering of the University of Genoa several acquisitions of human head accelerations were taken while performing a series of simple movements, complying with ISO 9001:2008 (Fig. 1):

- rotation around the vertical axis of the head (yaw)
- rotation around the vertical axis with the contribution of the chest, too

- rotation around the longitudinal axis of the head (roll)
- rotation around the lateral axis (pitch)



(a) (b)

Fig. 1 - Measured head movements: (a) definitions; (b) example of the sensors setting during experimental measurements.

All movements were performed alternately and dynamically, starting from low speed values and increasing them during the test, up to obtaining limit values representing jerk conditions and therefore detectable as experimental maximums. To acquire the data, IMU Awinda Xsens sensor was used and a sampling rate of 100 Hz was chosen. Angular velocities and linear accelerations along the 3 orthogonal axes were directly supplied by the sensor; angular accelerations were obtained by calculating the numerical derivative of the functions that provided the time trends of the respective speeds. As an example, the time trends of the graphs acquired during the roll rotation are shown in Fig 2.

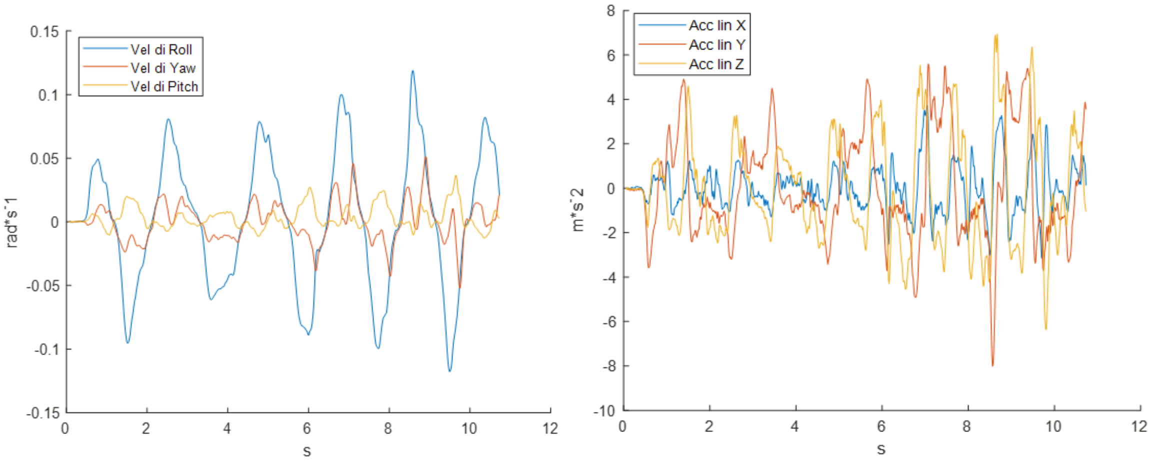


Fig. 2 - Example of measured quantity during test head movements.

For each performed movement, the velocity component having greater oscillation amplitude was considered, turning out to be in each case the characteristic speed of the rotation under examination; by analyzing the graphs, the following values were found:

- Roll: by performing a movement with the head only, a peak value for the angular velocity of about 7 rad/s was detected in a time interval of 0.325 s, corresponding to an acceleration peak of 22.75 rad/s^2;
- Pitch: by performing a movement with the head only, a peak value for the angular velocity of about 8.75 rad/s was detected in a time interval of 0.25 s, corresponding to an acceleration peak of 35 rad/s^2;
- Yaw: by performing a movement with the head only, a peak value for the angular velocity of about 17.5 rad/s was detected in a time interval of 0.2 s, corresponding to an acceleration peak of 87.5 rad/s^2. By performing a movement with the whole chest, a peak value for the angular velocity of about 13.13 rad/s was detected in a time interval of 0.45 s, corresponding to an acceleration peak of 28 rad/s^2.

In order to check the validity of the measurements, the existing literature about head accelerations was examined and the distribution of the same accelerations in the different points of the human head was studied referring to some typical kinematic models [12,13].

3. Sensorization of the Neuroglass

The Neuroglass project started with a list of eight possible physiological measurements:

- head movement, velocity, and acceleration
- body temperature
- blood pressure
- blood oxygenation
- electroencephalogram
- electro-oculogram
- trans-cranium impedance

For each measurement, the Neuroglass team analyzed the medical efficiency for disease diagnostics, the measurement quality of signal and the sensor availability with particular attention to their integration. Finally, as explained in previous paragraph, it was decided to start the first prototype with two sensors: the inertial measurement unit (IMU) and the electro-oculogram (EOG) sensor.

The IMU sensor was positioned in the left temple: paying attention to firmly wear the glass to the patient, the head movements and tremors could be finely reconstructed from the signal with some low pass filtering.

The EOG sensor was positioned in the left temple too, but it was connected to ocular muscles with a pair of dry electrodes inserted in the nose pads. The dry electrodes were developed by L.I.F.E. partner for the Neuroglass project; the muscular signals then were converted with the Texas Instruments 24-bit Analog to Digital Converter ADS1299; also in this case, a low pass filtering was necessary to eliminate annoying spikes due to electronics noise.

All the signals were acquired at 400 Hz sample rate and published on a web server where the notebook client can get in real time streaming with a wireless connection.

The power supply for electronics was integrated in the right temple with the recharge circuitry; the frontal frame was used only for connection from electronics to battery and to nose electrodes, new sensors in future development would be integrated in this free space.

4. Prototype design and production

4.1. Material selection

Grilamid is a type of polyamide. PA12 marketed by EMS-GRIVORY and produced by means of lauryl-lactam polycondensation. PA12 is a techno-polymer employed for various and demanding uses, being characterized by numerous advantageous properties [14,15], such as:

- high impact resistance
- high resistance to environmental conditions

- high resistance to chemical agents
- excellent characteristics of abrasion and sliding resistance
- low water absorption and good dimensional stability
- excellent impact resistance at low temperatures
- high barrier characteristics (low gas permeability)
- biocompatibility according to: EN ISO 10993-1

In particular, Grilamid was used due to its properties of high strength to weight ratio, low hygroscopicity, resulting in improved dimensional stability, and processability, as it can be used with both extrusion both injection and blow molding technologies, and even with additive manufacturing processes [16]. This material is very transparent to light as its structure is amorphous, and its molecule is made up of combined aromatic and cycloaliphatic units, thanks to which it is equipped with the wide range of considered remarkable properties. Other important properties include excellent resistance to bending fatigue, which facilitates its use in applications under dynamic load, and a low susceptibility to the stress-cracking phenomenon, mainly linked to the chemical structure of the material; the resistance to atmospheric agents and UV rays is good too. Thus, Grilamid can be used for the design of components with both structural and esthetic requirements, such as wearables devices, and in particular for manufacturing of spectacle frames. Therefore this material has been chosen to realize the structural parts of the prototype considering its low specific weight, the high mechanical characteristics, the remarkable dimensional stability, the transparency and its hypoallergenicity, which make it suitable for the manufacture of wearable devices when it is required that they are simultaneously comfortable and impact resistant.

4.2. Prototype design

Design of the Neuroglass was based on a simple standard shape as previously used in FONDA Srl for some of their products (such as special eyeglasses for visually impaired people).

Preliminary structural verifications were performed on the basis of the international standard EN ISO 12870. This standard defines various specifications for commercial eyeglasses and their test procedures. Among the various specifications there are dimensions and weight, classes of materials, settings for comfort requirements. Mechanical tests (Fig. 3) are a bending test requested to ensure that residual deformation (due to possible misuse of the frame) remains under prescribed limits.

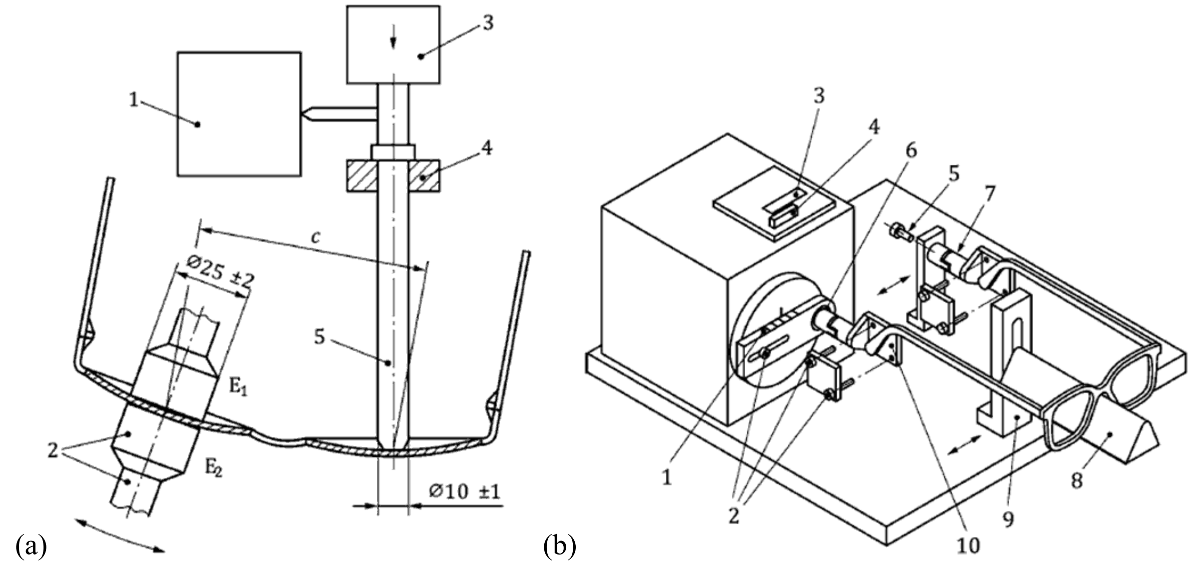


Fig. 3 - Tests on the eyeglasses frame according to EN ISO 12870: (a) frame bending (with a 5 N force the deformation must remain below 2% without visible damage); (b) durability testing (the frame must withstand 500 load cycles without visible fractures).

In this preliminary phase only, the bending test was performed. Various simplifications including the behavior of the material were adopted, considered acceptable for a first phase of the design with proper safety margins. Elastic modulus of the lenses was estimated by vibration analysis. The FE model of the prototype is shown in Fig. 4(a) with the applied boundary conditions to simulate the experimental bending test of Fig. 3(a). A snapshot of the basic results from this simulation are in Fig. 4(b). Although the Von Mises equivalent stress cannot be considered the best quantity for a strength evaluation of the polyamide used for the frame, the very low values of stress justify this assumption as well as for the simplifications in terms of material model which was considered simply linear elastic. The relatively low values of stresses suggests that a structural optimization should be carried out: such possible improvements, however, were not exploited in this preliminary phase also because other requirements either practical (shape of the frame to adapt to the face) or technical (placement of electronic circuits and wiring) requirements prevented some further modifications, at least in the initial prototyping phase.

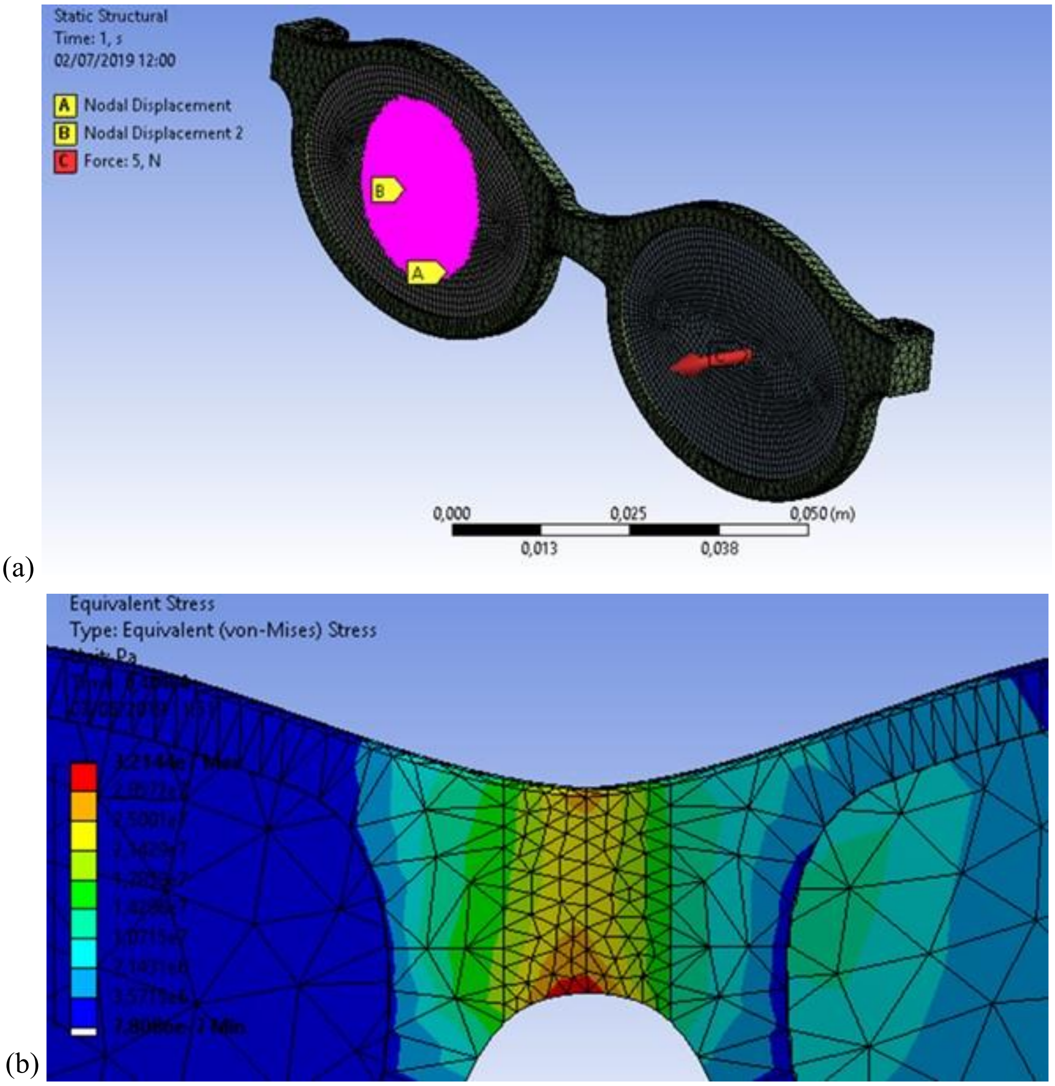


Fig. 4 - FE model of the Neuroglass: (a) Structure with the boundary conditions applied; (b) detail of the results in terms of stresses in the bridge.

4.3. Prototype construction

After identifying the sensors and establishing their location within the frame, the geometric modeling phase was carried out using a CAD 3D parametric software. The design derived from an already existing model of reference glasses, produced by the Fonda company, but it has been modified and adapted, both by enlarging some appropriate dimensions and by creating proper slots inside the frame, with the aim of obtaining the necessary housings for the electronic cards that connect sensors, batteries and other conditioning elements of the data acquisition system (Fig. 5).

Fig. 5 - Side view of the Neuroglass with a detail of the slots for the electronic circuits.

The adopted pantoscopic angle is 2°, while the geometric characteristics of the glasses have been specifically modified to meet certain needs as the maximizing of the cards areas surface still maintaining dimensions which do not make the glasses perceived as distressing. The dells in which the electronics are inserted are curved, for ergonomic reasons, and through prototypes (PCB) it was verified that the curvatures may allow the internal cardboard to bend without damage. To maximize the contact area between the head and the glasses frame where the electrodes necessary for the electro-oculogram are located, the design has been step by step improved until the best fit was obtained with a medium-sized virtual head, checking the adequacy of the modifications through the analysis tools available in the software. The shape of the rims is appropriate for the insertion of pantoscopic type lenses, which are the most commonly used for conventional prescription glasses. The closure between the two parts that make up the front is made by screws, while the doors in the rods are closed with snap-fit joints. The rods have openings in which the serial ports and the power button are located; the elements which come into contact with the ears, have been designed separately and they connect with the remaining parts of the rods always by interlocking. The most critical parts addressed in the modeling phase were the bevels, i.e. the seats in which the lens are inserted, as they take up a lot of space from the electronic board positioned on the front, as well as being an important factor for the mechanical tests that must be performed on the frame. Other carefully studied areas include the hinges, which are critical structures both for the screws holes and the deformation of the circuit connections (between the boards in the rod and those in the front) that occurs when the rods open and close (Fig. 6). The shape of the hinges was derived minimizing the stresses acting on the filaments of the cables, by means of two-dimensional FEM simulations of the mechanism motion. The nose pads and the bridge have openings (5 mm diameter holes) for the settlement of the electrodes and the internal structure is hollow near these points, to allow the electrodes connection directly to the board without using wires which would reduce the quality of the measured signal. Solutions with a deformable rather than a fixed nose piece, which could be tackled in the future to make the glasses more adaptable to the different anatomical shapes of a human skull, were also considered.

Fig. 6 - Detail of the hinges of the Neuroglass.

The developed model was prototyped with a Prusa i3 MK3S 3D printer [7], using the molten deposition modeling technique and programming the printing operation through the open source software CURA [8]. Currently, the material used for the printing of the various parts is a polyamide (from the same family as the Grilamid) and the prototype complies with the specifications both in terms of weight and size (Fig. 7).

Fig. 7 - Front view of the 3D printed Neuroglass prototype.

Circuits and sensors were finally mounted and the electronics was implemented. The Neuroglass fits comfortably on some voluntary people, including the authors of the paper. From first tests (Fig. 8) it appeared that measurements were possible although some further improvement in the placement and in the electrical connection must be done.

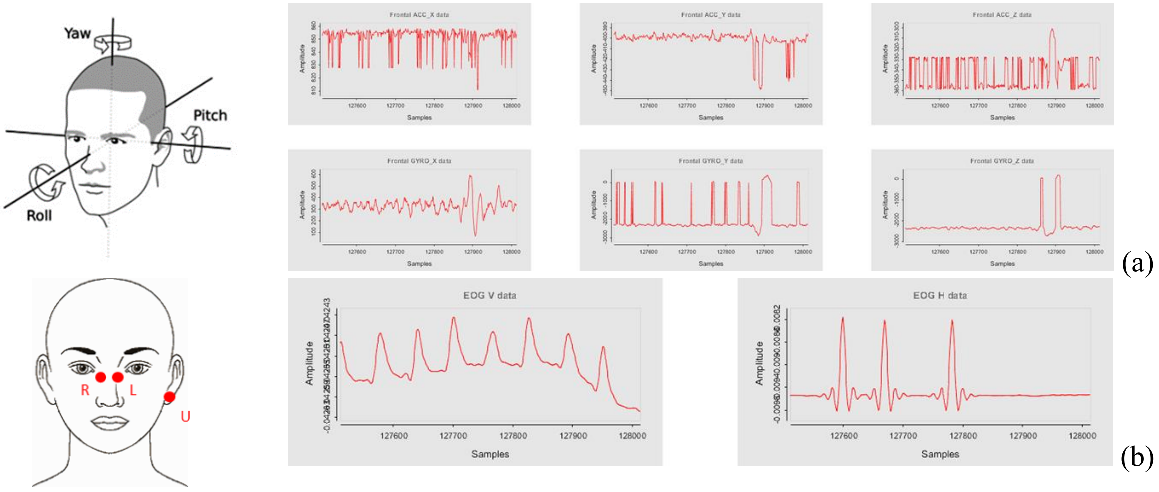


Fig. 8 - Examples of measurements obtained from the Neuroglass: (a) head tremors (through an inertial measurement unit, IMU); (b) ocular tremors and eye blinking (through electro-oculogram, EOG).

5. Conclusions

Development of a wearable medical device was reported in the paper. The device is a kind of specialized eyeglasses with sensors aimed at a preliminary diagnosis of some seriously impairing neurological disorder. In particular, on the basis of the measurement of tremors in the head and eyes it has been shown that Parkinson disease can be identified in an early phase. Early phase diagnosis is recognized to be essential to treat the disease and alleviate the serious consequences to the patients' health and life.

The development of this wearable medical device called Neuroglass was carried out in a Regional Project with the cooperation of a staff including medical and ICT experts. This paper illustrates the development of the structure and of the prototype of the Neuroglass.

The design started from the experimental analysis of the head movements to understand the optimal positioning of the sensors and the choice of the more suitable measurement devices. The following stage was the selection of the material for the frame and lenses and some preliminary structural analyses to define and qualify a draft design of the product. Structural verifications, although simplified, showed that the basic design was acceptable and even suggested that structural optimization is possible. Finally a prototype of the Neuroglass was built by additive manufacturing with a fused filament fabrication equipment. During some preliminary verifications, the prototype respected the basic requirements of construction and solidity, and compatibility with the electronic circuits and other accessories. The Neuroglass prototype was wearable and some measurements of biomedical quantities were effectively possible.

Verification of the effectiveness of the Neuroglass in diagnosing Parkinson or possibly other neurological diseases are ongoing in the medical laboratories of the University of Genoa, and will be the basis for further improvements and optimization of the product.

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