







Parametric Design and Data Visualization for Orthopedic Devices

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Abstract. The paper aims to illustrate the ongoing research based on the development of orthopedic devices, characterized by the integration between parametric design and data visualization, for the product customization on specific morphologies and needs of users, and the return of information of the course and therapeutic advancement made readable for both, patients and doctors.

As highlighted by the scientific literature and by the state of arts, nowadays always more the convergence between design, medicine, and data analysis/mining, is the experimental field for the research and develop of innovative biomedical devices, which integrate users as proactive part of the design and treatment processes, thanks to the integration of different methods and techniques of design: as Sabine and Dietrich affirm, design of orthopedics devices based on systems of parametric and generative prototyping, let’s get a high level of personalization of medical devices (2017), which can be enriched by the integration of different kind of sensors which returns complex and scientific information. The extraction, analysis, and translation of these data, make it possible to represent this complexity in visual form making it readable not only for the scientific community of reference but for a wider range of users (Stoll 2014).

Keywords: Parametric design · Biomedical design · Data visualization · Orthopedic devices

1 Introduction: Traces of Interdisciplinary Convergence for the Development of Innovative Devices

In recent years, the rapid evolution of science and technology has led to the emergence of a new scenario based on the collaboration between design and science (Ito 2016) whose products have a deep effect on people’s way of life, on their opinions and choices (Langella 2019). The increasingly fitting innovation of science and technology is therefore transferred to society through images, objects, communication devices, services, or tangible and intangible artifacts, which through the relationship established with individuals allow conveying knowledge by offering, moreover, the possibility of metabolizing and use it consciously (Olson 2000).

Such a scenario leads design to become more than ever a strategic choice, as it is not only a *trait d'union* between individual technical/scientific disciplines but also a medium for the enjoyment of individuals. In this sense, hybridizing the research and development process with different methods and techniques of the project and above all with different knowledge and professions, allows design to translate the complexity and technicality of the scientific community of reference into artifacts that enable people to relate with these devices - whether tangible or intangible - which thus become in all respects part of everyday life.

To arrive at the creation of artifacts similar to those described above, designers cannot ignore a fundamental question, linked to ethical responsibility (Chan 2018) and beyond. Designers are in a position to give shape to objects related to the universe of scientific disciplines, and for this reason, they must fully understand their methods and contents, interpret them, assimilate them and translate them (Langella, *ibidem*), ensuring a faithful and effective and efficient use. What has been said requires designers not only to always keep direct comparison and dialogue with the scientific community of reference open but above all to acquire the skills necessary to be considered proactive part of the process of joint definition of common and shared languages and of the process of research and development.

When this process converges towards the realization of medical devices, designers are called to intertwine their research and experimentation activity with the method and results of science, actively collaborating with scientists and research centers, sometimes physically entering chemistry laboratories, physics and biomedical, to develop innovations with a high content of design thought, as well as science. It is these dynamics that favor the creation of contact points, intersections and opportunities for contamination between designers and scientists, which allow them to cooperate to derive mutual benefits in their research activities (Ito 2016) and prefigure together possible futures: in this optics scientists provide designers with the theoretical foundations on which to develop innovative products characterized by the scientific method - therefore constituted by the rigor in observing protocols and verifications -, at the same time designers can provide science with indications on new directions and research topics to be undertaken that respond to the needs of society and the market and cultural changes, or to stimulate the creative capacity of science with points of view and design-matrix approaches.

An example of what has been said, as it will be articulated in detail in the following paragraphs, is the ever-greater integration of digital environments and tools in the design processes of medical and therapeutic devices, as well as interaction with them, in which the possibilities offered from parametric design, from additive production and finally from data analysis and visualization, it allows to reach levels of innovation that not only facilitate and optimize treatment but above all make available, in open format, the data that in this way become the basic element for the verification and dissemination of technical/scientific knowledge related to the medical field of reference.

2 Biomedical Design: Open Issues and Unsolved Needs

The last decade has led to a significant advancement in medical research concerning the testing of new techniques that allow achieving a form of improvement in the quality of

life, both for patients undergoing transitive treatment and for those reporting permanent trauma. This advancement, made possible also by the constant research activity carried out on techniques and materials for the production of medical devices, still leaves open some questions and, consequently, unsolved needs related to various stages of development, production, and use of devices such as orthoses, braces, and prostheses.

In particular, for the research conducted, are considered as open issues those related to:

- Acquisition techniques. To date, the method used still requires that the parts of the body to be subjected to therapeutic medical treatment are examined and detected in an artisanal way, for example through the creation of a plaster cast used as a mold for plastic casting. This produces an inaccurate result, as it is subject to human error by the health worker who takes care of the realization of the survey, easily improved with the integration of modern survey technologies and acquisition of three-dimensional digital images through, for example, 3D scanning or photogrammetry.
- Production techniques. As a direct consequence of the deficits of the acquisition phase, the production of immobilization devices, such as plaster, through the artisanal method implies many limitations, among which we highlight those relating to the production time and human errors of the operator – don't forget that these devices are commonly produced by hand, and for this reason the production phase may also require several revisions and modifications.
- Costs. If you look at the context of the market for orthoses, braces, and prostheses, it is easy to understand why these products are considered excessively expensive: first of all, this kind of devices can be for transitive or permanent use, in variable term, subjected to the modifications due to the change of patient's treatments or physique. The high cost is not even due to the materials used, because those most commonly used are extremely inexpensive. So neither the duration nor the materials directly impact on the cost, but the latter mainly depends on the workforce, that is, on the manual skills and the time that the health worker will spend in making the product, aware of the critical issues highlighted above.
- Comfort. Always starting from the analysis of the devices currently on the market, it is possible to notice and understand what are the reasons that lead patients to complain about numerous inconveniences due to the use of therapeutic devices: they, first of all, have shown - in most cases - to be uncomfortable, cumbersome for carrying out daily movements and actions, produced with heavy and not very breathable materials that often cause redness and irritation due to the heat and the low washability of the materials used. These critical factors only worsen the psychophysical condition of the patients, who in this way also feel uncomfortable because of the device worn.
- Aesthetics. If we consider the traditional production methods of orthoses, braces, and prostheses, the customization possibilities are somewhat limited. The resolution of this deficit through the use of additive production technologies would facilitate the psychological acceptance of the patient, who in this way will not see the therapeutic device only as an imposition by his doctor, who once integrated into the decision-making process and the realization it will feel part of it.

2.1 Clinical Efficacy

Clinical efficacy is a central aspect that must be taken into account by designers in the development and production phase of products dedicated to medical treatments, as it directly impacts all phases of the design and use process of medical devices.

In the first phase, relating to the detection of the part to be subjected to treatment, the digital acquisition of the geometry of the anatomical part would allow obtaining a greater correspondence to the real morphology, perfectly shaped, therefore, on the patient. This phase, as seen previously, could be improved, through the integration of innovative detection methods, which provide for the use of 3D scanners or photogrammetry for 4 or more points that return as output clouds of points or photographic shots attributable, in both cases, with three-dimensional models perfectly faithful to the detected part.

After the detection phase, if one of the aforementioned methods has been used, it is possible to proceed with the development of the device through specific three-dimensional modeling software, which allows obtaining optimal results especially if implemented by the parametric approach, through which automate the project phases. The tools offered by 3D modeling software allow to circumvent the problems deriving from artisanal modeling by eliminating the critical issues due to the health worker's workforce.

Finally, adopting additive manufacturing as a production technology would make it possible to obtain artifacts characterized not only by specific performance properties but also by the possibility of customizing them according to the tastes of the patient, who in this way becomes involved in the decision-making process.

All the previously mentioned elements converge strategically in the development of a device that is not only therapeutic, as orthoses, braces, and prostheses that patients consider more comfortable and conform to their tastes, are worn more continuously, consequently having a direct effect on the clinical efficacy, without leading to patients' refusal of treatment.

This is even more emphasized if sensors are integrated in the devices that allow returning exact measurements on the progress of the treatment, as evidenced by the ever-increasing diffusion of medical e-health products in which tools based on information and communication technologies allow to monitor the treatment of pathologies and consequently manage their lifestyle, in order to pursue optimal clinical efficacy.

As highlighted by the scientific literature and the state of the art of reference, choose, in the development and design of medical devices, to make use of the methods and techniques outlined, to achieve the creation of orthoses, braces, and prostheses characterized by better wearability, greater patient participation and awareness and, therefore, greater rehabilitation capacity.

2.2 Psychological Acceptance

A further open question, which the ongoing research has highlighted and to which it tries to answer, is that relating to psychological acceptance, as it is believed that to ensure that patients are aware of the importance of wearing products for orthopedic rehabilitation it is necessary to convey to them how much the use of these devices is fundamental in order to achieve complete recovery of mobility in the shortest possible time.

Acceptance of treatment is one of the main issues to be taken into consideration for the pursuit of an optimal outcome of orthopedic therapies that involve the use of specific devices, numerous studies have underlined how patient compliance is closely related to final results so that the good outcome of the treatment appears to retrospectively influence the patient's judgment (Katz and Durrani 2001; Landauer et al. 2003; Sifert et al. 2009).

Therefore, the acceptance of orthotic treatment is a matter strictly related to the quality of life and the psychological factors of the patients who derive it (Rivett et al. 2009; MacLean et al. 1989). Therefore, alongside the clinical efficacy of short and/or medium-term treatment, it becomes fundamental to succeed in the realization of devices that can be accepted more easily, that is, less bulky, with less aesthetic and functional impact on the subject's life, for the same effectiveness of the final result.

The importance of these aspects makes the collaboration between medicine and design particularly significant since the design is able to provide design solutions that considerably improve many of the aspects related to compliance, such as the aesthetic aspect, comfort, acceptability, wearability, and lightness.

3 Biomedical Design and Digital Technologies

Based on what has been previously reported, it is possible to affirm that the scenario outlined by the interdisciplinary convergence between design and science, and more particularly between parametric design and medicine, today finds a consistent response in the design of biomedical devices, focus of increasing interest and field experimentation for designers who draw from the scientific method the analysis models as well as the ability to follow rigorous protocols and verifications and from the design methods the task of translating these models into forms which, aligned with patient compliance, return highly effective devices from the clinical point of view and at the same time acceptable from a psychological point of view. With this in mind, it is specified that biomedical design is characterized by many constraints linked above all to the need to integrate with the physical, physiological and psychological factors of patients, to which medical research tries to respond thanks to continuous research and rapid evolution of methods and techniques. This implies that this rapidly expanding sector will increasingly need to integrate designers into the research and development process.

The particularly incisive role of design can be found in all phases of the project, which offers as final output objects that directly impact on the quality of life of users and, more generally, on society. Think, for example, of the pharmaceutical packaging sector, to be considered not only as a market-oriented product - like all types of packaging - but above all as a communication medium containing all the technical/scientific information that designers are required to translate in order to make them readable and understandable for the widest possible number of users. This translation operation, as we will be able to articulate more in detail later, puts the designers in the condition to acquire, analyze and extract from the totality of the information related the constraints and specificities related to the different pathologies to which the drugs are addressed (Langella et al. 2019), to develop visual systems for the dissemination of knowledge that users must be able to correctly decode.

Technological innovation and the evolution of scientific knowledge, therefore, allows conceiving devices that provide innovative ways of use, offering possible alternatives to conventional methods and techniques. In particular, the area of intervention consisting of orthopedic medical supports, such as braces, orthoses, and prostheses, characterized by a strong need for customization due to the variation both of the anatomical characteristics of people, and the type of trauma or pathology, requires the design of characterize these products with specific solutions, promoting the improvement of therapeutic efficacy.

Thanks to parametric design, the study of projects that optimize the therapeutic conditions, with particular attention to the well-being and quality of life of the patients, it is possible to overcome the critical issues of an artisan approach adopted by companies and healthcare facilities for the creation of therapeutic devices, also in consideration of the diffusion of digital technologies and their introduction into the process.

The numerous implementations that can be pursued thanks to digital tools, environments, and techniques of design and production, allows not only designers and companies in the sector to make use of automatisms that would reduce human error and would allow to increase production capacity, but above all to make orthopedic devices closer to the daily needs of patients, also in terms of access to knowledge.

As highlighted by the state of the art, the development of e-health medical products that can integrate a specific sensor system contributes not only to the creation of strategic databases for the storage and future availability of information useful for the study of the different realities pathologies that assume increasing importance with the increase in the international circulation of citizens and the number of patients but above all to improve the access and use of treatments, contributing to increase the general efficiency and sustainability of the health sector.

An example of what has been stated is the Fastfocus wearable device, which constantly monitors vital parameters such as blood pressure, patient movements, as well as oxygen saturation in the blood with minimal impact on the patient's quality of life because it is worn behind an ear - like a hearing aid. The information collected by the device helps doctors in remote monitoring of patients and also facilitates the triage phase in case of hospitalization.

Finally, it is specified that the outlined issues that see the use of digital technologies as possibilities for making therapeutic devices more efficient are closely linked to numerous international actions, as demonstrated by the Horizon Europe Development Programs - in force since 2021 - and the UN Sustainable Development Goals.

4 Data Visualization for the Therapeutic Field

The scenario outlined above has highlighted how the possibility of developing therapeutic products through the tools of digital technologies, allows not only to achieve the creation of innovative artifacts characterized by customization, clinical efficacy, and psychological acceptability, through the use of methods and more performing development and production techniques, but to be able to integrate, thanks to the ever-greater miniaturization of the sensor systems, detection, and measurement tools, which become data generators. Just as Big Data represents the massive set of data that describe the complexity of contemporaneity, coming from different types of sources including devices

equipped with detectors and sensors, the data produced by the use of e-health devices can become material translation, of a flow of data related to the medical field which, once displayed, facilitates the acquisition and transfer of data and, therefore, the monitoring of the therapeutic path.

The possibility of translating complex data and information from the so-called hard sciences - and not only - such as physics, mathematics, chemistry and biology (De Vries et al. 1993) into visual form is not a new thing, but according to Cairo (2014), the first diagrammatic visualization experiments, which provided for a process of analysis and synthesis of the contents, could be placed in the eighteenth century (2014), when in particular the use of statistical cartography began to spread as a tool for the dissemination of information from the technical/scientific sector of reference.

The need to represent data visually to communicate complex ideas with precision and efficiency (Tuft 1987), which boasts consolidated roots as evidenced by the institution in 1979 of the Information Design Journal¹, today defines important experimentation field mainly due to two factors: on the one hand, the quantity and complexity of the data available and that users contribute to producing through the use of software, web platforms or digital devices is increasing more and more; on the other contemporary society, known with the neologism Knowledge Society², wants more and more access to data, to be not only aware but also proactive concerning emerging facts and issues.

At the same time, it should be borne in mind that the representation operation that scientists used to carry out for the communication and presentation of the results achieved among peers, is no longer sufficient, even compared to the Citizen Science³ strategy, included in the Horizon Europe development program, that provides for an increase in the level of scientific literacy through the democratization of science.

These considerations cannot be considered extraneous to the research conducted, rather it is necessary to understand how and above all in what forms the representation and visualization of data are linked to the development and design of therapeutic devices.

Starting from the assumption that data is the key element of our time, it is evident how technologies are transforming the times and spaces of health, in particular through the continuous monitoring of people - at home, during free time, and also in the workplace - radically changing the traditional doctor-patient relationship (Collecchia 2018).

From this point of view, it is life itself that becomes a pertinence of medicine, as it can be objectified in medical terms. The new wearable technologies, useful for studying pathological conditions, highlight the importance that many people attribute, in today's

¹ The Information Design Journal first placed the visualization of data as a relevant design theme at the center of the cultural debate for the identification of issues relating to fields of opportunity in which design, thanks to the convergence between art and science, could become a strategic vehicle for the diffusion of knowledge.

² Society that generates, shares and makes available to all members of society knowledge that can be used to improve the human condition. The knowledge society differs from the information society, in that the latter disseminates only raw data, while the former intends to transform information into resources that allow the company to act effectively. The spread of this form of the company derives, among other things, from the innovation of information technologies - IT.

³ Citizen science is the involvement of the public in scientific research – whether community-driven research or global investigations. The Citizen Science Association unites expertise from educators, scientists, data managers, and others to power citizen science.

culture, to monitoring their health conditions, reinforcing the idea of a data-driven world (Henke et al. 2016).

The main tools of digital medicine, in addition to the technology of electronic records, online services for consulting diagnostic and specialist reports, and the tools used for doctor-patient interaction, are therefore enriched with wearable devices, consisting of one or more biosensors, inserted on clothing items such as watches, T-shirts, shoes, bands, etc., useful for non-invasive measurement, can detect and measure various biological parameters - such as heart rate, respiratory parameters, oxygen saturation, body temperature, blood pressure, glucose, sweat, brain waves, etc. - and provide information on the user's lifestyle - physical activity, sleep, nutrition, etc. - as well as on specific therapeutic procedures - for example magnetotherapy, diabetes management through skin patches, EEG monitoring for epileptic patients, etc. - (Fig. 1). The collected data are available as raw data which, through the techniques of data analysis and machine learning, can be transformed into visible information, as demonstrated by many commercial devices available today - such as FitBit, Apple Watch, etc. - (Kamišalić et al. 2018).

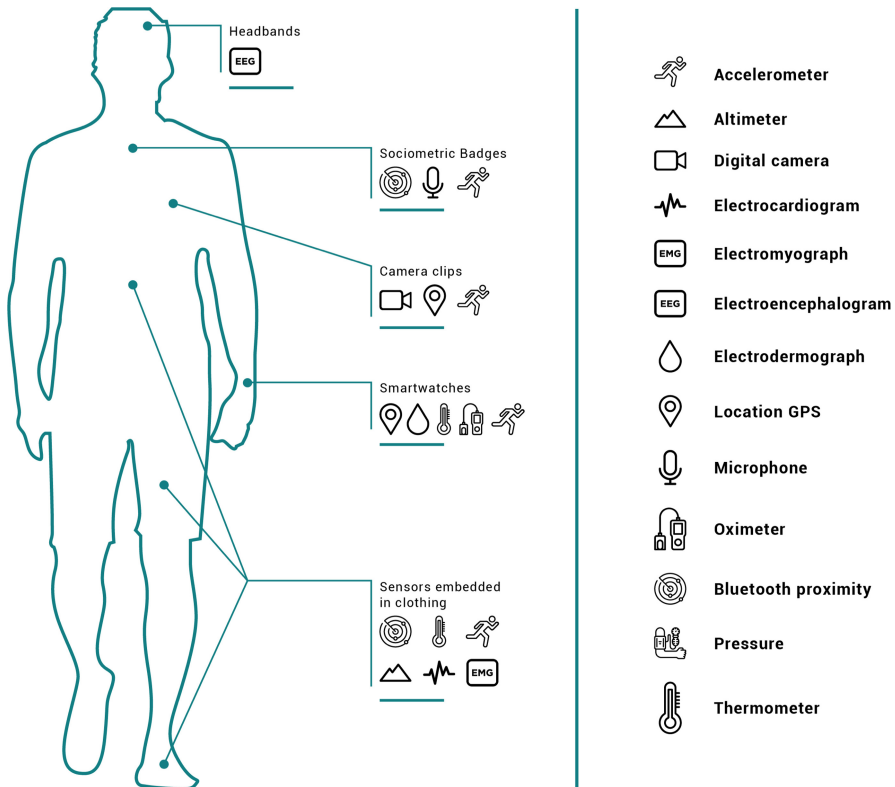


Fig. 1. Infographic of kinds and applications of different sensors integrated in wearable devices (Collecchia 2018).

Similar findings are useful to more accurately assess the effectiveness of therapy with the aim of creating a sort of continuous window on the patient's pathological state, not limited in time and space in clinics and hospitals.

What has been said converges in the design of orthopedic therapeutic devices that integrate detection and monitoring sensors of the treatment, as it is not so important to dwell on the type of diagrammatic representation that you want to adopt, as to go to define a model and structure a matrix through which the *income* data, detected by the sensors, can be processed, translated and displayed, to be made legible and decodable through interaction with the user, no longer just a medical specialist, but increasingly more patient.

5 A Case of Applied Research

Physical and rehabilitative medicine, also known as physiatrics, is a branch of medicine that deals with the prevention, diagnosis, therapy, and rehabilitation of a disability. This paragraph reports the results of an ongoing research, which aims to respond to the need for therapeutic devices for the rehabilitation of the upper limbs, which present a high level of innovation in design and production methods and techniques, an optimal clinical efficacy and high psychological acceptability.

Physiatrics, as a discipline, plays a role of great importance because it is capable of working on patient autonomy, improving it. In particular, it is possible to observe how the integration of digital technologies, for this discipline, is a strategic tool that allows the development of products that intervene directly on the functional recovery of patients, not only promoting dialogue with doctors but also offering studied devices and customized to specific needs and rehabilitation programs that integrate fundamental daily exercises for faster and more efficient recovery.

The field of the pathology considered is limited to the rehabilitative treatment of diseases such as rhizarthrosis, De Quervine Tendonitis, carpal tunnel, hand atrophy, as well as nerve injury, peripheral neuropathy, polyneuropathy, and other incidental injuries, so to all the kind of pathologies that cause the disability of the upper limbs, and more particularly of the hand, that can be caused by various types of nerve injuries or by accidents, all treated through specific therapies for recovery of functional re-education, to be carried out at the hospital facility or home (Caliendo et al. 2018). Similar treatments can be self-administered by the patient, independently, also if the main criticality deduced from the analysis of the state of the art, highlights the difficulty for the user to use this kind of devices independently, as it is difficult to wear and program it – we specified that the therapeutic systems for the physiatric field are worn by patients for a time-limited, to the administration of a specific treatment to be carried out, usually, daily and often for long periods.

With this in mind, it was decided to respond to these pathologies by designing a therapeutic device that is easy to wear and manage, for the performance of rehabilitation exercises, as well as aesthetically pleasing, to help the patient's rehabilitation, increasing compliance and optimizing the overall period of therapy. To do this, the device, designed for home use, integrates specific mechanical and technological components, both for mechanical and electronic therapeutic techniques currently applied separately, for the

rehabilitation of muscle, nerve stimulation, an analgesic therapy (electrostimulation - TENS).

The latter is used in the rehabilitation of the hand, as it allows to improve muscle tone and tropism both following trauma and to speed up the rehabilitation phase. Furthermore, thanks to the TENS mode, it is also possible to use the device for the analgesic treatment for rhizoarthrosis, or rather as a painkiller.

The identification of the most suitable therapy takes place through discussion with the doctor, who examines the case and assigns the use of the device according to the most suitable times and methods. Even the anthropometric data are collected by the doctor who, based on the morphology of the patient's hand, assigns a certain size of the same (S - M - L), in case of special needs there, remains the possibility to further adapt the device and customize it thanks additive manufacturing technology adopted for the realization of the same (Fig. 2 and 3).



Fig. 2. Design model: the patient addresses the doctor who carries out the collection of anthropometric data and assigns the most suitable therapy. The data is used to three-dimensionally tailor-made the device, which is then 3D printed. The components necessary for the operation of the device are then added to the printed object. Once completed, the device is ready to be worn by the user and used.

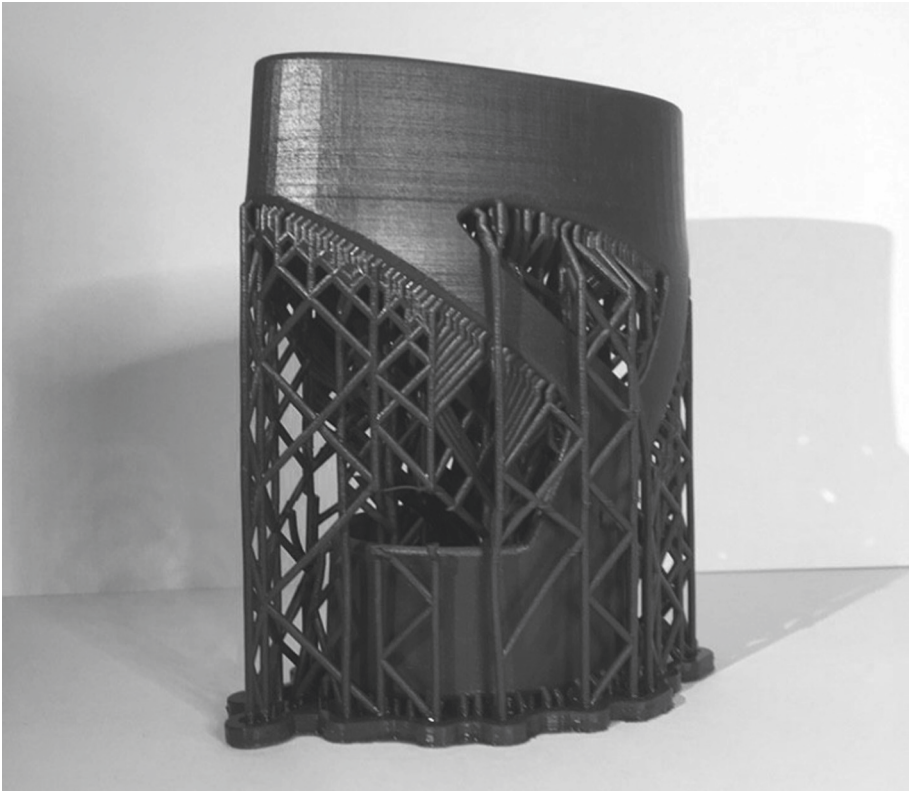


Fig. 3. Prototype of the device made by 3D printing. The prototype, in black resin, was created using the Formlabs SLA Form2 printer, chosen for its high definition and the type of materials that can be used.

The electronic heart of the device, located on the part above the wrist, includes a sensor for detecting movements, as well as the system electronics for the correct functioning of electrodes and sensors and an intuitive user interface for switching the device on and off finally, there is a Bluetooth card, which allows the recording of data and the transmission of the latter to the application for therapeutic tracking (Fig. 4). Once the device is worn and switched on, the patient will have to connect to the appropriate application, to carry out the therapeutic exercises assigned by the doctor and synchronize the course of the therapy in parallel, also through visual feedback.

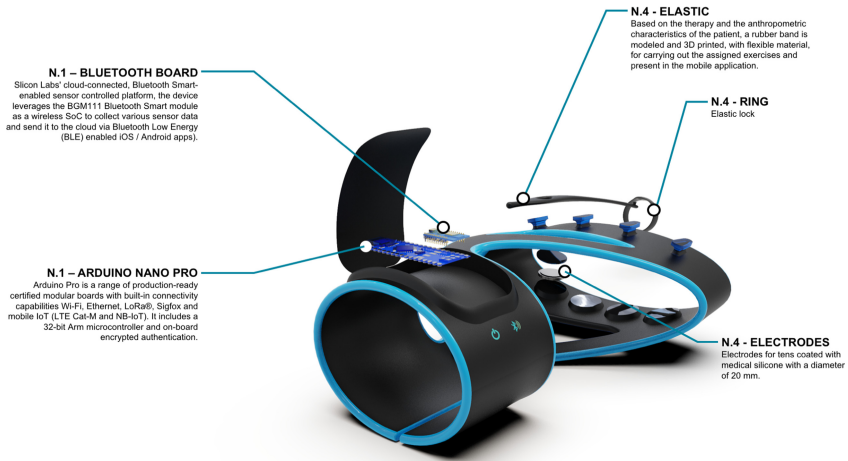


Fig. 4. Datasheet of the electronic components present on the device.

The collected data, through specific computer languages based on MySQL (database) and JavaScript (for the conversion of data into code and consequent display), are converted into mappings studied with a dual language: in fact, both a frontend interface is provided, which offers less medical and more emotional feedback to the patient, linked to gratification and to incentivize the user in carrying out the therapy thanks to the achievement of the required results, and a backend interface dedicated to the doctor, more technical and linked to scientific visualization, to allow him to keep trace of the progress and actual performance of the assigned therapy.

Another innovative feature of the device is wearability, as it is designed for easy application and, as previously mentioned, can be worn independently by patients of all ages without difficulty (Fig. 5 and 6).

What has been described leads to the effect of inserting the designed device, in the broader context of e-health medical products, placing the patient not only in the condition of actively interacting with the therapeutic device/system, but also to improve the efficiency of the therapy, facilitate access to the treatment and management of the same, as well as contribute to the diffusion and dissemination of technical/scientific knowledge thanks to the provision of specific visual tools and interfaces.



Fig. 5. Prototype of the therapeutic device worn. As you can see from the image, the adherence of the device to the user's hand is perfect, this is due also to the use of digital modeling and advanced prototyping techniques.



Fig. 6. Prototype of the therapeutic device worn. In this image it is possible to see the integration of flexible elements necessary for carrying out the therapy.

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