

Orthopedic Device and Data Visualization: A Way to Optimize the Therapeutic Process

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Abstract

Medical design may intervene to improve, prolong and save lives. Many health critical problems can be addressed thanks to the power of design, which solutions, developed in academic and business settings, can answer in an innovative way to the needs of patients. It is in this context that is located the ongoing research presented, which is based on the integration between parametric design and data visualization, whose convergence leads to the realisation of medical devices customized on specific morphologies and needs of users and, as well, - thanks to the integration of IoT - capable to record and return data related to the course of the therapeutic advancements, made readable for both patients and doctors.

As highlighted by the most recent scientific literature, the development of technological medical devices, able to reduce steps and simplify the doctor/patient relationship, is becoming an important field of research, most of all if we consider the condition of endemic fragility that characterises the contemporary society. In this perspective, the aim of the paper is to introduce the concept and design of orthopedic devices, through the description of the methodology and approaches applied and of the protocol outlined during the research.

Keywords: Medical Design; Parametric Design; Information Design; E-health; Personalized medicine

Abbreviations

IoT: Internet of Things

CT: Computed Tomography

MRI: Magnetic Resonance Imaging

3DP: 3D Printing

UCD: User Centered Design

SLA: Stereolithography

FDM: Fused Deposition Modelling

PLA: Polylactic Acid

ABS: Acrylonitrile Butadiene Styrene

TPU: Thermoplastic Polyurethane

PETG: Polyethylene Terephthalate Glycol

Introduction

The field of health increasingly represents a vast and still unexplored field of experimentation for design, capable, through its principles and approaches, of leading to significant advances and innovative solutions that produce significant benefits for society.

This is possible thanks to various factors, including the consistent evolutionary drive that has pervaded technologies and sciences and which has led to the convergence between design and science [1]. This convergence, which takes shape in various design experiences that permeate various spheres of the design culture, becomes particularly relevant for the sphere of health and medicine, as it allows to consolidate the relationship between medical / scientific knowledge and practices and the well-being of individuals, through mediator artifacts, systems and devices that simplify the treatment process, increasing the awareness and compliance of patients through different types of approaches and solutions, tangible or intangible, and that, in this way, can become part of daily life. The ability of designers to give shape to extremely technical artifacts that are actually useful for the reference field, such as devices or interfaces for the medical field, has its roots in the deep understanding of sector methods, contents, as well as performances, knowledge that can only be acquired through dialogue with the scientific community [2]. For this reason, it is possible to affirm that the strategic role of design is triggered by the hybridization of the research and development process with different knowledge and professions, which enable design to translate the complexity of research and scientific practices into technical artifacts - tangible or intangible - which allow people to relate to them [3].

As highlighted by the relevant scientific literature, there are in fact various contexts in which design, and in particular medical design, can help in the improvement of practices at various levels, from those strictly related to training - through the creation of simulations or models of study - up to diagnostic and therapeutic practices, optimizing processes and devices and improving the doctor / patient relationship. The analysis of the scientific literature and the state of the art has in fact made it possible to identify some particularly relevant experiences, useful for understanding the potential offered by the methods and techniques of design in the field of medicine.

The research group coordinated by Ronja Struck of the School of Medicine, Medical Sciences and Nutrition, of the University of Aberdeen, is conducting a careful study on digital detection techniques, in particular on photogrammetry, and on its possible applications in the field of medicine, highlighting the potentialities related to portability, non-invasiveness, accuracy of the survey - avoiding errors that may arise from the traditional survey carried out manually -, and performance in relation to the cost of a technology that is combined with methods such as 3D scanning via laser scanner, computed tomography (CT) or magnetic resonance imaging (MRI) which tend to be significantly more expensive and often larger and heavier than photogrammetry equipment [4-6].

Between the academic / scientific and entrepreneurial fields, more and more collaborations that investigate the potential of 3D printing (3DP) in the field of medical design are being consolidated. In fact, released from some limits that initially limited the use of additive technologies in fablabs, or in any case in laboratory-based contexts, in recent years the 3DP has had an exponential evolution and a contextual ever-increasing diffusion thanks to the possibility of creating easily, in times and with considerably reduced costs compared to the reference state of the art, study models, instruments, prostheses and / or customized wearable and orthotic devices [7-11] - an application that varies according to the available technology and to the function required.

The miniaturization of electronic components, together with the use of information technologies, have opened up important fields of experimentation in the creation of *smart* therapeutic wearable devices, even very small in size, and which can become particularly useful in the survey and monitoring phase of data of a patient, shortening the distance between doctor and patient thanks to specific digital tools that, if on the one hand act as a database, on the other hand can become a visualization tool and relational mediator, increasing patient compliance that in this way does not perceive himself as an external part or excluded from the treatment process, but a proactive part of the latter, as he is always informed of his advances [12, 3].

As revealed by the relevant scientific literature, highlights that for the field of medicine and health in general, the potential of design and its methods and techniques offer an important contribution in terms of process and product innovation and in terms of implementation and interaction with the user. This is even more true if this potential is taken into consideration with respect to the condition of health emergency due to the spread of Covid-19, which has limited mobility and access to hospitals, formalizing the need for medical practices characterized by *perfect* performance, able to keep patients aware and active with respect to their own therapeutic path. A

particularly fitting example in this case, and in a certain sense leading a trend towards home therapy, can be considered the experience conducted at Penn Medicine's Cancer Care, where for the treatment of cancer patients they have been developed domestic treatment plans, in order to minimize the need to move to hospital and therefore the exposure to the risk of contagion [13].

The possibility of improving therapeutic medical treatment thanks to the use of the most advanced techniques of digital design, together with the pressing need to shorten the distance between doctor and patient, while leaving the latter the opportunity to live his daily life in the most natural way possible, are therefore the main themes of this contribution, whose purpose is to outline the methodology used as well as describe some of the results produced by the research activity whose purpose is in any case to arrive at design solutions capable of producing a benefit on the health and the widespread quality of life in society.

Medical Design: an overview on the unsolved needs

The arise of issues related to the widespread quality of life, and more particularly to the health in the society, such as the aging of the population, health disinformation, the growing ineffectiveness of drugs and the inaccessibility of services, increasingly accentuates the need of open opportunities to dialogue and planning, in order to rethink medical care through innovative approaches capable of producing new and better systems and devices [14].

What is outlined in the introductory paragraph highlights the possibility of applying the techniques of advanced digital design, IoT, etc. in the field of medicine, but this opportunity is still limited compared to the potential that design, as a reflective discipline, can offer, reflecting on the various aspects of major changes in order to rethink the relationship of people with objects [15]. Indeed, as Jones states, we need "new ways to learn, think and work quickly, to give a meaning to the human, systemic and organizational problems that co-build the healthcare landscape every day" [16].

For this reason, the role of design must be understood in a more extensive way, investing practices and ways of thinking that can meet current and future health needs, through responsiveness to change and the possibility of extending the scope of reference by overcoming disciplinary boundaries, these identifying characteristics of design, which can act as a means to trigger, expand and consolidate the relationship between the technical / scientific community and society.

To do this, the method used must focus on people, i.e. on the awareness that the central focus of the project consists in the possibility of creating a good, tangible or intangible, useful to others, groups or communities, promoting the quality of life and the well-being of individuals accessing services [17]. With the rapid evolution of technologies and scientific research, in order to produce a designed solution useful to users, design has consolidated some methods that, starting from the centrality of the user - User Centered Design (UCD) - make him more and more proactive part of the design process, participating in the identification of new problems and needs from which to start for the realization of innovative designed solutions - not exclusively in the technological meaning of the term. An example that has become one of the most obvious of all is that of the orthopedic field, in which the need for lighter and more comfortable devices has opened up a vast field of experimentation in which the tools of design, three-dimensional modeling, as well as digital detection techniques and additive manufacturing technologies, have led to the spread of various types of perforated, thinner, washable and customized structures that are revolutionizing the field of orthoses.

As evidenced by the relevant scientific literature, the spread in recent decades of "a practice centered on the user, based on evidence and oriented to results, where the user is whoever is involved" [18] has increased the ability to innovate complex systems, thanks to the analysis of individual needs, values and experiences [19], changing "existing situations into ideal ones" [20].

Although the relationship between design and health, and more specifically between design and medicine, is now evident, there is still a strong need to make the fields converge, integrating ideas, concepts and knowledge in order to develop models, tools, techniques, and artifacts, which can have an improvement both in terms of application and problem solving in real contexts [21].

Personalization, for example, is considered as a key element for the effective adoption of lifestyles or practices related to the medical / health field, as the number of unique situations that require individually developed, tailor-made responses is growing more and more. For this reason, design, capable of driving innovation but also of *humanizing* it [22], is called to play its role as a translator but also as a mediator between science and community, giving value to the experiences and quality of life of patients, to their participation in the care and treatment [23] as well as in the planning process, dealing, rather than with solutions that focus in a reductionist way on disease and treatment, on ways to maintain well-being and on the knowledge and tools useful for individuals to *live well* [17].

Efficacy and acceptance: design as a technical/psychological mediator

The one who has the greatest influence on therapeutic medical treatment is the person himself undergoing the treatment [24]. The lack of psychological acceptance, as well as the lack of compliance, are factors capable of invalidating the course of any therapeutic treatment, as they are closely linked to the way in which the user perceives not only the device / curative service as an end in itself, but the whole system related to it.

This question represents one of the founding themes that then lead to the use of methods such as User Centered Design, in an attempt to balance the more technical and rigorous aspects of the clinical efficacy of the designed device, with the social and psychological implications related to the actual use of the same.

In fact, whatever the designed artifact is, be it physical, virtual or both, the fundamental question on which designers must reflect is linked to the need to relate the technical aspects with the psychological, social, cultural ones, in order to encourage the use of tools designed to improve patient health.

Clinical effectiveness is a central aspect to be taken into consideration because it is also determined by the effective development of the design phases. Devices that fit perfectly on the anatomical part treated, customized, both from a geometric and - possibly - aesthetic point of view, perforated, light, etc. will in fact have a positive influence on clinical efficacy, as the user, in a certain sense encouraged by the characteristics listed above, will wear a rehabilitative - or other type - medical device with more pleasure, and therefore more continuously, by increasing its clinical efficacy.

This aspect well represents the synthesis of the tools and technologies listed in the introductory paragraph, and carriers of innovation in the medical field, as the digital survey, through 3D scanning or photogrammetry, as well as 3D printing, make the phases related to more efficient development and production of a wearable device, while the possible integration of sensors, used for recording and measuring the progress of treatment, and which already represent one of the reasons that led to the spread of e-health medical products, i.e. based on the use of communication and information technologies, can further increase clinical efficacy, as they constantly return to the patient the data related to their therapeutic path, in a logic of democratic access to medical / scientific information.

Natural consequence of what has been described is the close relationship between clinical efficacy and psychological acceptance which, as previously stated, is capable of totally increasing or invalidating the therapy. This highly subjective value of the patient, or in any case of the user who relates to a medical good or service, still needs to be studied and understood, as it is believed that the greater the awareness that users have of the device, the better the response. In terms of use of therapeutic artifacts or for rehabilitation, and consequently the recovery of mobility will be better - in the specific case of an orthopedic device - in the shortest possible time [3], an aspect well described by numerous studies that have shown that the compliance of the patient can have a very strong influence on final results and successful treatment outcome [25, 26].

What is described in this section emphasizes the importance of aspects that make the collaboration between medicine and design particularly significant, as design is able to design, thanks to its methods and techniques, devices such as orthoses and braces, but also wearable devices in a broader sense, which significantly improve many of the aspects related to compliance, such as better wearability, aesthetic appearance, lightness, and developed through greater participation of patients, who in this way acquire greater awareness,

an aspect which is closely linked to a greater rehabilitation capacity and therefore clinical efficacy.

Orthopedic devices and data visualization: the protocol

Based on the above, it is possible to state that the convergence between design and medicine constitutes an important relationship both for the humanization and for the innovation of medical devices, issues that extend to the entire supply chain that goes from diagnosis to treatment.

In particular, the research conducted, and still ongoing, focuses on the field of orthopedic medical devices, highlighting how this category of therapeutic wearables can represent an exemplary case of disciplinary hybridization, but also of the use of more techniques and tools that improve processes, products and services, both from the clinical and experiential point of view of the patient. The aim of this section is therefore to discuss the protocol outlined and used in the project of orthopedic devices that are *increased* by IoT technologies in order to also become tools for the collection, storage and use of data related to the use of the device itself and the patient's adherence to treatment.

To do this, it is necessary to underline how medical design is characterized by tighter constraints mainly due to the need to integrate physical, physiological and psychological factors of the patient, with the more technical and rigorous issues of medical research [3]. This means that in this sector, which is still rapidly expanding, design has a particularly incisive role in all phases of the project, because it offers as final output objects that influence the quality of life of users.

The first aspect to consider is that of diagnosis. Although in fact the field of research is limited to orthopedic devices, it is not certain that the pathology or in any case the diagnosed condition needs to be treated with an orthosis or a brace - just think of the field of rehabilitation in which, sometimes, the treatment is only physiotherapeutic in nature. Similarly, other types of pathologies may exist, for which wearing orthoses or braces, or in any case wearable devices for patient data collection, is a choice determined by the monitoring of the patient and the prevention or treatment of side effects due to other pathologies.

Once the need to use a wearable orthopedic device is established, the real flow that characterizes the outlined protocol is triggered. In the first instance, and as described in the previous paragraphs, a careful analysis of user needs is conducted, in an attempt to identify contextual and subjective needs. To do this, the relationship between design and medicine, together with the participation of the users, leads to the determination of customized processes and products based on the subjective needs expressed: in fact the protocol outlined makes use of the use of digital survey techniques, such as 3D scanning or digital photogrammetry, for the relief of the anatomical part to be treated, this practice is decidedly less invasive and faster than the traditional survey, carried out by hand, or through other digital but more conventional techniques.

The result of the digital survey, both in the case of scanning and photogrammetry, is generally a three-dimensional *image* of the patient's anatomical part, which is therefore analyzed and used in its three-dimensional complexity for the realization of the geometry of the orthopedic device using 3D modeling software. In this case, the research carried out has highlighted how it is possible to model medical devices through different techniques and approaches, dictated by different aspects: production using additive technologies, for example, is in turn linked to the choice of the material considered most suitable for the type of device to be made, this implies that as the material and technology vary, some expedients can be implemented in the modeling that can simplify the production of the device. As regards specifically the question of the approach, 3D modeling is divided into two macro-families, that of manual modeling and that of parametric modeling: in the first case the conformation of the three-dimensional geometry should be understood as a sort of digital art practice, in fact the shape is in a certain sense sculpted by the modeler who *freely* realizes, step by step, the final geometry; parametric modeling, on the other hand, is a more complex practice, which requires specific mathematical and computer skills, as it is based on the concatenation of mathematical functions and parameters, the output of which is the desired geometry. Although manual modeling may be easier, the fundamental difference between the two approaches in managing the modeling process, as manual mod-

eling does not allow you to promptly modify some of the intermediate phases that lead to the final form, while parametric modeling, in particular in the field of medical design, expresses an enormous potential dictated by the possibility of always interacting with all the parameters and intermediate functions, punctually modifying individual values which then allow the geometry to be re-parameterized, based on the modification made. This potential implies that, for example, in the case in which wrist braces are designed, it is possible to modify only the curves that constitute the anatomical part of the specific patient, without having to re-model the whole device from scratch, or again, in the event that electronic components or sensors for data detection are integrated on the device, to maintain these positions and / or volumes as constant, consequently re-conforming the surrounding geometry on the basis of the changes made.

Once the modeling process is completed, also based on the electronic components, the 3D model is then printed using additive technology. As described in the introductory paragraph, 3D printing in the medical field is experiencing a rapid evolution and diffusion in various fields, in fact, depending on the type of device designed, one or the other technology / material is considered more or less suitable. For example, Stereolithography (SLA) is particularly suitable for the creation of bone or dental models, for guides for dental implants or for hearing aids, as this technique stands out for its high resolution and accuracy in the reproduction of very complex and characterized parts from very thin surfaces [9]. Although there are various techniques and materials, an important technology in the field of medical design is Fused Deposition Modeling (FDM) a process that is based on the extrusion of a plastic filament which, level by level, builds the 3D model in height. This technology, which can use various types of plastic materials such as Polylactic Acid (PLA), Acrylonitrile Butadiene Styrene (ABS), Thermoplastic Polyurethane (TPU), Polyethylene Terephthalate Glycol (PETG), etc. has the enormous strength of being an economic technology, in fact there are several machines of this type that are labeled as low-cost, but which thanks to the print settings can achieve remarkable results from the point of view of resolution, as well as resistance. Obviously, as previously reported, the choice of technology is fundamentally dictated by the type of device designed: prosthetic devices, for example, are generally based on a more prolonged use, often in contact with more sensitive parts of the body, and therefore materials certificates printed in turn with specific technologies, are the most appropriate choice. In the case of orthoses or braces for short use - for example for rehabilitation - or of wearable devices of reduced dimensions, the FDM technology and its materials are suitable both for performance and in terms of sustainability of the cycle of product life - PLA for example, which is one of the most used materials in printing using FDM technology, is highly recyclable, and can even be returned to its filament state in order to be printable again.

Once the printing of the orthopedic device has been completed using the chosen technology, it is ready for the assembly of the electronic components, i.e. all those sensors used for recording patient data. Once worn, a device of this type is capable of detecting biometric data, storing it and transferring it via Bluetooth cards to other devices. In particular, the research conducted, and which has as its focus that of reducing the distance between doctor and patient, wanted to focus, in this specific case, on the possibility of making the recorded data accessible to both actors: therefore, to the doctor, through tools management, to view the therapy and adherence to the patient's treatment in a more continuous way, while the user to view, via smartphone app - for example - his progress (Fig. 1).

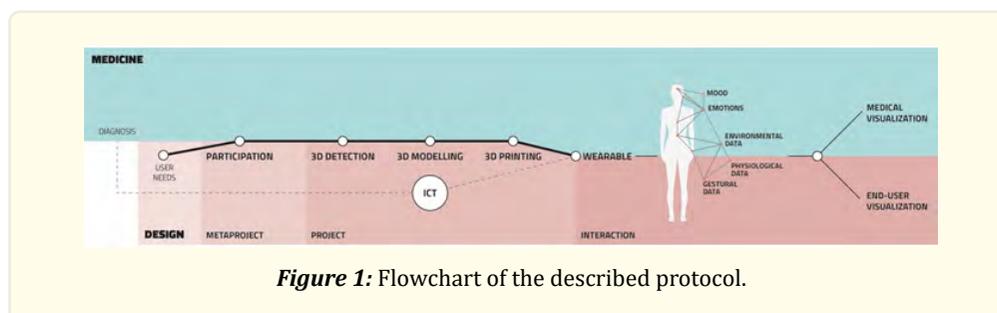


Figure 1: Flowchart of the described protocol.

IoT application in orthopedics

The last phases of the described protocol are fundamentally based on the possibility of integrating IoT components in the design of orthopedic devices, increasing their performance thanks to the recording and display of data deriving from monitoring and interaction with the patient.

Although the IoT is constantly increasing in the industrial sector, as well as in some areas of medicine, in order to have evidence-based results, the integration of this technology in the field of orthopedics is quite recent, with the aim of record and provide adequate processing information. The IoT, in fact, uses sensors to improve the quality of treatment thanks to the measurement, for example, of bone information - an important aspect in the field of post-fracture mobility recovery -, on blood pressure, on brain activity. During the performance of rehabilitation exercises, the IoT is also able to guide patients, in order to instruct them on the correct execution of the exercise. Together these aspects improve patient satisfaction, therefore adherence to treatment and compliance and, consequently, the efficiency of the results [27].

There are several software and IoT applications in the field of orthopedics, ranging from external medical / scientific information - therefore for the patient - to internal training - or for the sharing of research results -, but the great potential of these technologies is to consolidate the communication between doctor and patient leading to better chances of recovery of the latter. In fact, collecting data on the patient's physical activity or daily routine, as well as his biometric data, allows the doctor to access constant monitoring of the patient, especially important in cases where orthopedic treatment is linked to recovery through guided physiotherapy exercises that the patient can perform independently from home, a comfortable environment but in which distractions are high, and therefore provide the user and his family with a tool to quickly check the progress of recovery without any appointment with the doctors, keeps the patient adherence to treatment [28].

There are several IoT technologies useful in the orthopedic field to provide adequate information, these include big data, cloud computing, intelligent sensors, artificial intelligence, actuators and virtual / augmented reality [29], while applications range in different fields, from diagnostics, to the therapeutic one, even to the preventive one [30], and this is the reason why, compared to the analysis of the scientific literature, it is possible to state that this technology will lead to a significant improvement in the management of medical instruments for correct work and efficient, as well as in the design of orthopedic devices, allowing analysis of patient-related data, information and activities.

From the point of view of the protocol described above, the IoT intervenes in the recording, storage and display of data, made accessible for doctors and patients. This operation of translating data into a visual form, typical of information design, is a practice that historically has dealt with the visualization of complexity through diagrams or maps that in the beginning were dedicated to the technical / scientific community of reference, but then, with the advance of emerging issues and the need to make complex information accessible to the community, has spread to society, making information, often abstract as can be those of hard sciences such as mathematics, physics and biology [31], democratic, or decodable for heterogeneous user groups [32-34].

Today this aspect becomes fundamental with respect to the practice of information design, but also of the relationship between design and science and between design and medicine, as especially the health emergency has highlighted the need to make understandable and clear information that are difficult for society to understand, in issue that emerges in a timely manner with respect to the new European Framework Program - Horizon Europe - and the UN Sustainable Development Goals, which had already identified the need to increase the participation of users, and therefore of the community, in the scientific research - think of the Citizen Science strategy.

This framework serves to underline how the possibility of integrating IoT technologies into orthopedic devices, and above all to make information visible through mappings such as bar-chart, flow-chart, etc., but also to make the process of creating participatory data, through interaction with the user, are fundamental issues of the design process and project, as it will help in many aspects mainly

related to the awareness and advancement of the dissemination of medical / scientific research as a common good of society.

Conclusion

Design and medicine, taken individually, are rapidly changing disciplines. The evolution of methods and techniques and the spread of increasingly advanced digital tools and instruments, offers both areas the possibility of developing artifacts characterized by strong system innovation, yet without interdisciplinary commitment the ability to deal with social issues, including the need for patient participation and information: a pertinent example is the Coronavirus pandemic, in response to which the United Nations, in the urgent global call to designers, said that the world is “in a situation without precedents where the normal rules no longer apply. We cannot resort to the usual tools in such unusual times” [35]. United as never before, researchers and professionals in design and medicine have developed new solutions such as digital health applications, technologies for telemedicine, medical devices for disease monitoring, to address previously unknown health challenges and at various levels of scalability. Yet the issues related to the relationship between medicine and design were not unknown to the relevant scientific literature, as well as those of process innovation and access to technical / scientific knowledge. What is described in this paper, thanks also to the analysis of the state of the art, highlights how the relationship between medicine and design is consolidated, in particular as regards the ability of design to offer mechanisms of reciprocity [23] in which the involvement of users in the project is an integral part of the project itself. This participation, transversal to the whole process, as underlined in the section dedicated to the description of the protocol, is fundamental because it equips patients with tools and knowledge useful for psychological acceptance and therefore for the clinical effectiveness of the therapeutic treatments they are subjected to and, in a broader logic, for an improvement in the quality of life.

The intent of the contribution is therefore to be a reference from the point of view of the integrated protocols between design and medicine, but also between different design practices, demonstrating how this is an urgent requirement and not an aesthetic addition, which allows to achieve the actual innovation of an orthopedic device, in line with the expectations of users and with the necessary medical performance, as long as technologies and digital are never understood as the soul of the project, but as a tool to increase its potential, both from the performative and experiential point of view.

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Conflict of interest

None

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