Embodiment Design Process in the Development of Articular Orthosis

Ricardo Duarte, Antonio Ramos, and Michel Mesnard

Abstract—**The development of medical devices entails several challenges in order to obtain adapted and more efficient devices. Orthosis development presents several particularities, such as human-device interaction which requires a human centered design that can achieve a successful device and customer satisfaction. Although the largest and most creative part of product development happens during the conceptual design phase, it is also important to materialize the ideas and considerations. This materialization happens during the embodiment design phase. In the particular domain of orthosis development a design process is needed to organize the prototype structure and gradually extracting the final product architecture.**

The aim of the work presented in this paper is to develop a design process during the embodiment design phase to help in prototype materialization during the orthosis development process.

Index Terms—**Biomedical engineering, design process.**

I. Introduction

The development of medical devices is a difficult task due to the very demanding human interaction requirements. Efficient medical devices start with good planning of each task during the development stages to ensure safety, easy use of the device and effective medical care for the patients [1]. According to the European Medical Device Directive (93/42/EEC), a medical device is "any instrument, apparatus, appliance material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease;
- Diagnosis, monitoring, treatment, alleviation for or compensation for an injury or handicap;
- Investigation, replacement or modification of the anatomy or of a physiological process;
- Control of conception and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means"

Manuscript received November 5, 2016; revised February 12, 2017. This work was funded by ANRT and Lagarrigue S.A.S. Pessac, France.

Ricardo Duarte is with the Université de Bordeaux, Institut I2M-IMC, Talence 33000, France (e-mail: ricardo.duarte@u-bordeaux.fr).

Antonio Ramos is with the University of Aveiro, Department of Mechanical Engineering, Aveiro 3810-193, Portugal (e-mail: a.ramos@ua.pt).

Michel Mesnard is with the Université de Bordeaux, Institut I2M-IMC, Talence 33000, France (e-mail: michel.mesnard@u-bordeaux.fr).

[1]–[3].

On this basis, the orthosis is a class 2 medical device. Additionally, they are a particular case of medical device in which the design process must take into account several human factors as the contact and maneuver since its final role promotes a direct link with the patient [3], [4]. This characteristic in itself creates a physical constraint which must be taken into account in the general design process.

Largely used in mechanical design problems, the Pahl & Beitz sequential vision of the design process, which is divided into several phases (planning and clarification of the task, conceptual design, embodiment design and detailed design) can be transposed for the development of orthosis with curtains considerations in each one [5]–[8]. Also, although these phases are well-defined and differentiated, communication between them is extremely important and the information collected during the first stage may be influential and be used during all the other stages.

Based on the phase division in Pahl and Beitz's design process, a design methodology was implemented for the development of articular orthosis, taking into account the necessary domain specification. One of these adaptations involves the transition between the conceptual design phase and the embodiment design and it's consequently task organization.

During the conceptual design phase, as stated by Duarte et al [2], the term reference was defined. This term designates the body segment that is directly connected to the device and works as an anchorage zone [2]. Consequently, the term support was defined as the regions of the device that are in direct contact with the reference [2]. Finally, the component was defined as an element of the device that enables the references-supports and supports-supports connections to take place [2]. These terms can be observed in the following figure (Fig. 1).

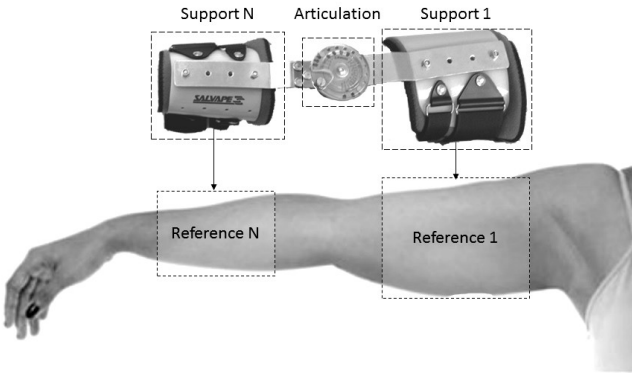

Fig. 1. References, supports and components.

According to Duarte et al [2], at the end of the conceptual

DOI: 10.7763/IJMO.2017.V7.554

design phase, and with this definition in mind, the designer has defined the product concept and its functioning principles. However, the materialization of the chosen concept is not a direct task and may involve further design processes and methods until the prototype can be materialized [9].

According to Baxter, the main difference between the embodiment design phase and the conceptual design phase is the introduction of a significant measure of product testing and evaluation [7]. This phase involves four main principles:

- Idea generation through the exploration of all the possible ways to make the product;
- Idea selection by picking the best of the ideas according to the product specification;
- Failure modes and effects analysis (FMEA) to assess the ways in which the product might fail;
- Prototyping and testing the prototype in order to develop, refine and eventually either accept or reject the preferred design.

This stage represents a very important step for the success of the final product since this is the first time that something testable arises, however, the tasks during this stage remain vague in terms of processes organization and may result in several incongruities in the final product when the orthosis development is considered.

Additionally, the architecture of the product will be closely linked to decisions in other fields, such as marketing strategy, manufacturing capabilities and product development management since the orthosis development entails a great empirical knowledge [9], [10]. Based on this, for the sustainable development of medical devices in general, and the orthosis in particular, a design process is required during the embodiment design phase in order to organize all the principles and the embodiment inputs and outputs [11], [12].

The objective of this work is therefore to present a design process during the embodiment design phase that allows the physical materialization of the concept chosen during the conceptual design phase.

II. Materials and Methods

The embodiment design phase is a transitory phase between the conceptual and the detailed design phases [7], [9], [13]. During this phase the physical device emerges based on the criteria and functioning principles defined during the conceptual design phase. The "translation" between these two phases is not clear and direct and in the case of orthosis it gained an important relevance.

The design process proposed in this work for the embodiment design phase is divided in six stages (support dimensioning, articulation dimensioning, virtual prototype, prototyping techniques, functional prototype and prototype testing) from which it is gradually possible to extract the final prototype (Fig. 2). Additionally, in a more superficial approach, this design process permit to distinguish two important kinds of prototype (virtual and functional prototypes) during the embodiment design phase.

The proposed method will be described during the following sub-sections:

A. Support Dimensioning

Support dimensioning during the embodiment design phase of the orthosis development requires important inputs in order to adapt the orthosis to the human body segment concerned.

It is also important during this stage to take into account the 3D geometry of the human body segment, which was previously obtained during the planning and clarification of the task (first design methodology phase).

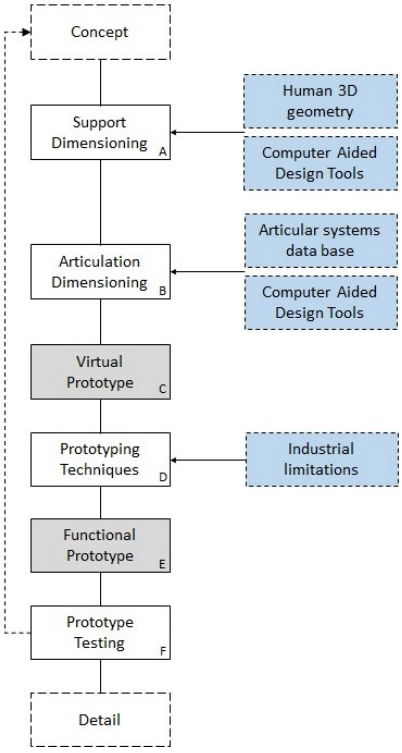

Fig. 2. Design process during the embodiment design stage.

The designer will then have the body segment information (reference information) necessary to project the supports. During the human 3D geometry stage, three different tasks should be evaluated in order to obtain the base geometry used on further computer-aided design tools (CAD) (Fig. 3).

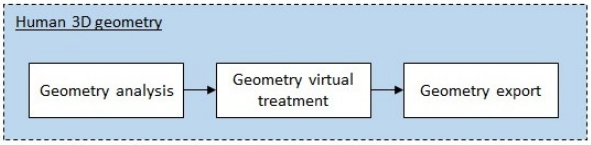

Fig. 3. Human 3D geometry procedure steps.

During this stage, different techniques can be used to treat the 3D geometry of the body segment involved according to the companies' technological limitations (plaster molds, 3D scanning, etc.). Additionally, the result of the human 3D geometry was exported to a CAD tool in which the supports were dimensioned and modelled (figure 4). During this stage, the geometries, the sizes, the materials and the positioning of the supports were assigned respecting the specifications defined during the conceptual phase and the ergonomic principles. Ergonomic principles are also a key factor during this stage. When a medical device is to be in direct contact with the human body, the interface between the device and the

body requires careful attention in order to provide a sensation of comfort [14].

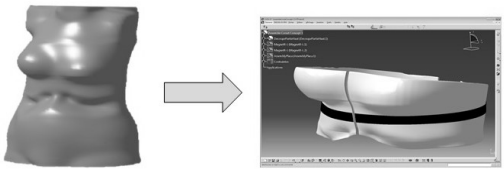

Fig. 4. Support dimensioning stage (brace example).

Thus to provide satisfactory support, ergonomic criteria were evaluated based on three different categories: biomechanical functionalities, emotional and cognitive criteria (Fig. 5) [15]–[17].

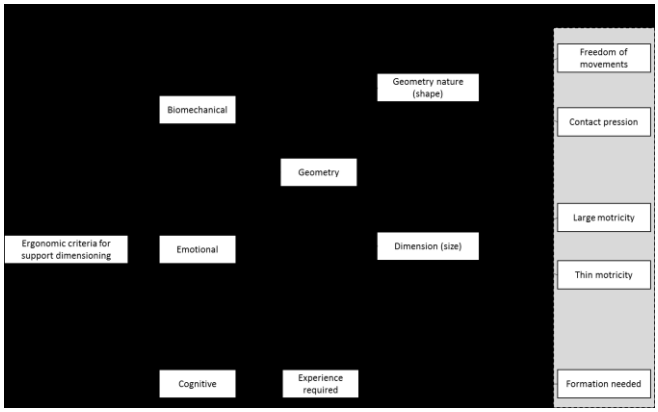

Fig. 5. User/ device interface ergonomic evaluation criteria during the support dimensioning.

The biomechanical functionalities cover motricity as well as freedom of movement. The emotional criteria cover freedom of movement, contact pressure and motricity. At last, the cognitive criteria cover the experience required to maneuver the device.

B. Articulation Dimensioning

The articular dimensioning stage represents the dimensioning of the components that perform the direct connection between the references. This stage was composed of two distinct sub-stages, the articular system database definition and modelling using CAD tools.

The articular system database claimed to present the possible solutions that meet the conceptual functioning behavior requirements of the articular system. This sub-stage may be obtained through a bench-marking and patent evaluation analysis. The articular database was defined through several criteria (Table I).

TABLE I: ARTICULAR DATABASE DEFINITION

No.	Reference	Dimensions	Movement	Applications
1	A_1	B_1	C_1	D_1
2	…	…	…	…
3	A_n	B_n	C_n	D_n

One of the criteria used was the dimension of the system, which, depending on the orthosis concerned, may be larger or smaller in size and have a varying impact during its integration. Also, the type of movement provided by the articulation should be presented in the articular database so that the designer's choice is simplified. Finally, different types of application that may use the same articular system will be described in the application field of the articular database in order to provide extra information about the proposed system for the designer and facilitate the integration of the articulation in the new device. The A_1 - A_n, B_1 - B_n, C_1 – C_n and D_1 - D_n letters observed in the table 1 pretend to generalize and represent the possible values used in each column and introduced by the user during the method usage.

After the evaluation of the systems in the database, CAD tools are used to integrate the chosen system virtually. At this point another task is conducted simultaneously in order to consider ergonomic principles in the component choice. As in the previous stage, an evaluation was conducted in terms of biomechanical functionalities, emotional and cognitive criteria [15]–[17] (Fig. 6).

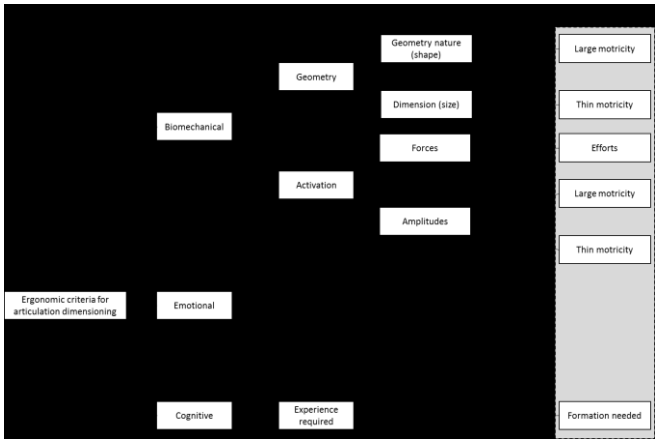

Fig. 6. User/ articulation interface ergonomic evaluation criteria during the support dimensioning.

The biomechanical functionalities cover the motricity as well as the forces involved and the amplitude of movements; the emotional criteria cover the activation requirements of the system and lastly, the cognitive criteria cover the experience required to maneuver the device articulation.

C. Virtual Prototype

The virtual prototype stage marks a point between the virtual project of the device and the start of the physical one. At this point all the supports and articular systems already designed were assembled in their correct position in a single virtual model. This stage may work as a bridge until the functional prototype is achieved in order to guide the designer during the physical realization of the prototype as well as provide indications for production in terms of components and assembly.

D. Prototype Techniques

Although there are several prototype techniques in existence in industry, the development of medical devices has some particular considerations and material restrictions once there are a strict contact with the human body. Additionally, factors such as enterprise limitations should be taken into account when the transition from the virtual prototype to the functional prototype is necessary. Although this may be

controversy, it is important to understand that the orthosis development specific domain rests mainly SMEs and consequently the manufacturing process is not as linear as in a "normal industry". In this case, the manufacturing process required to develop the device depends on the manufacturing techniques available in the enterprise as well as the training and formation of the employees.

E. Functional Prototype

The functional prototype is the penultimate stage of the design process at the embodiment design phase. At this point, the designer has a physical device which may later be subjected to mechanical and medical tests to evaluate and validate the role of the prototype and design process.

F. Prototype Testing

The prototype testing stage is the last stage of the embodiment design phase before the detailed design. At this point mechanical and medical tests will be carried out to evaluate the efficiency of the device based on the previously defined device specifications. These mechanical tests will be based on a failure modes and effects analysis (FMEA) in order to evaluate the desired functions in terms of causes of failure, occurrence and severity [7], [18].

TABLE II: FMEA TABLE

Evaluated criteria	Description
Function	A_1
Potential failure level	B_1
Causes	C_1
Occurrence	D_1
Effect	E_1
Severity	F_1
Design verification	G_1
Detection	H_1
Risk priority number	I_1

The A_1, B_1, C_1, D_1, E_1, F_1, G_1 and H_1 letters observed in the Table II pretend to generalize and represent the criteria description. At the end of this analysis, a risk priority number (I_1) will be achieved with which to compare the most pertinent function failures and consequently those that should be solved first. In addition, a medical evaluation will be required to evaluate the efficiency of the device. At this point, a biomechanical evaluation will be conducted according to the body segment concerned and the orthosis applied. These results will be compared with the expected results to observe the effectiveness of the device that has been developed and possible changes proposed. Although this is the last stage of the embodiment design phase it is important to note that the information generated in prototype testing may provide feedback in order to evaluate either the concept or the prototype, which may result in a few iterations and consequently improvements in the next prototype.

III. Discussion

The new product design process is not an easy task, as it may require different knowledge and expertise in different domains [5]–[7], [19], [20]. During the embodiment design phase the product concept is selected and elaborated, addressing the simultaneous subsystem design [18], [21]. It is also during this phase that the concept acquires a shape, whether virtual or physical [22]–[24]. After this, the definition of the product architecture requires planning and task prioritization. Although few methods are explored in mechanical design, the organization of this phase rest inevitably in four main aspects as functions (F), material (M), geometry (G) and production (P) and considering only the designer, manufacturing and product design as their main branches [22]. However, this still leads some inexactitudes in the domain of medical devices. Also, a more precise method was proposed by Scaravetti et al [23] which proposed a method to perform an analysis of the embodiment design problem which facilitates the search of the indispensable elements and facilitates the structure in the preliminary stages. However, this method does not consider an important factor that is the human interaction. Thus, by dividing the embodiment phase of orthosis design into several different steps it was possible to organize the knowledge and deal with the different problems in different times, and only progressing to the next step when the previous one had been solved which permitted to minimize eventual errors. Additionally, when the functional prototype was established, several tests were performed, although these are not covered in this paper.

IV. Conclusion

Orthosis design is a particular case in medical device development. One of the main problems observed during the orthosis design process was related to the difficulty in passing from the concept to the functional prototype when there is no dedicated method to help the designer to implement the ideas generated during the conceptual design phase in the embodiment phase. Thus the aim of the present work was to propose a method during the embodiment design stage of the orthosis design process in order to help medical device designers to achieve the ideal prototype according to the results obtained during the conceptual design stage.

According to this, the main novelty introduced by this work was a stage structured methodology during the embodiment design phase for the development of articular orthosis.

Acknowledgments

The authors gratefully acknowledge the funding from ANRT and Lagarrigue S.A.S. Pessac, France.

References

[1] L. Martin, B. J. Norris, E. Murphy, and J. A.Crowe, "Medical device development: the challenge for ergonomics.," Appl. Ergon., vol. 39, no. 3, pp. 271–83, May 2008.

[2] R. Duarte, M. Mesnard, and J.-P. Nadeau, "An innovative design approach to develop external articular medical devices.," Int. J. Interact. Des. Manuf., pp. 1–9, 2016.

[3] P. Buckle, P. J. Clarkson, R. Coleman, J. Ward, and J. Anderson, "Patient safety, systems design and ergonomics.," Appl. Ergon., vol. 37, no. 4, pp. 491–500, Jul. 2006.

[4] B. Motyl and S. Filippi, "Integration of creativity enhancement tools in medical device design process," Procedia Eng. vol. 69, pp. 1316–1325, 2014.
[5] G. Pahl, W. Beitz, J. Feldhusen, and K. H. Grote, Engineering Design - A Systematic Approach, 3rd ed. Springer, 2007, p. 629.
[6] D. G. Ullman, The Mechanical Design Process, 4th editio. McGraw-Hill Education, 2005, p. 448.
[7] M. Baxter, "Product design, A pratical guide to systematic methods of new product development," 2nd ed. Chapman & Hall, 1995, p. 308.
[8] S.-W. Hsiao and J.-R. Chou, "A creativity-based design process for innovative product design," Int. J. Ind. Ergon., vol. 34, no. 5, pp. 421–443, Nov. 2004.
[9] K. T. Ulrich and S. D. Eppinger, Product Design and Development, 6th ed. 2015, p. 448.
[10] [D. Rios-Zapata, R. Duarte, J. Pailhès, Méjia-Gutiérrez, and M. Mesnard, "Patent-based creativity method for early design stages: case study in locking systems for medical applications," Int. J. Interact. Des. Manuf., 2016.
[11] K. T. Ulrich and S. D. Eppinger, "Product design and development," in Design for Manufacturing, 2000, p. 10.
[12] S. D. Eppinger, "A model-based method for organizing tasks in roduct development.," Res. Eng. Des., vol. 6, no. 1, pp. 1–13, 1994.
[13] D. Motte, M. Eriksson, and R. Bjärnemo, Mechanical Embodiment Design with Digital Desktops, ACM, 2007, pp. 31–34.
[14] G. Colombo, S. Filippi, C. Rizzi, F. Rotini, and P. Milano, "A computer-assisted methodology to innovate the development process of prosthesis socket," in Proc. Virtual Conncept 2006, 2006, pp. 1–8.
[15] C. James, Y. Li, and A. Blandford, "Integration of human factors and ergonomics during medical device design and development : It ' s all about communication," Appl. Ergon., vol. 45, no. 3, pp. 413–419, 2014.
[16] J. R. Wilson, "Fundamentals of systems ergonomics/human factors.," Appl. Ergon., vol. 45, no. 1, pp. 5–13, Jan. 2014.
[17] L. M. Sáenz, G. Sevilla, and E. Patiño, "Ergonomics/human factors applied in formative research at the faculty of industrial design, universidad pontificia bolivariana," Procedia Manuf., vol. 3, no. Ahfe, pp. 5792–5799, 2015.
[18] E. Lutters, F. J. A. M. Van Houten, A. Bernard, E. Mermoz, and S. L. Schutte, "Technology Tools and techniques for product design," CIRP Ann. - Manuf. Technol., vol. 63, pp. 607–630, 2014.
[19] A. Milton and P. Rodgers, Research methods for product design, 1st ed. London: Laurence King Publishing, 2013, p. 192.
[20] W. ElMaraghy, H. ElMaraghy, T. Tomiyama, and L. Monostori, "Complexity in engineering design and manufacturing," CIRP Ann. - Manuf. Technol., vol. 61, no. 2, pp. 793–814, Jan. 2012.
[21] J. L. Menéndez, F. Mas, J. Servan, R. Arista, and J. Rios, "Implementation of the iDMU for an Aerostructure Industrialization in Airbus.," Procedia Eng., vol. 63, pp. 327–335, 2013.
[22] L. Langeveld, "Product Design with Embodiment Design as a New Perspective," in Industrial design - New frontiers, InTech, 2011, p. 190.
[23] D. Scaravetti, J.-P. Nadeau, J. Pailhes, and P. Sébastian, "Structuring of embodiment design problem based on the product lifecycle.," Int. J. Prod. Dev., vol. 2, no. 1/2, pp. 47–70, 2005.
[24] T. Tomiyama, P. Gu, Y. Jin, D. Lutters, C. Kind, and F. Kimura, "Design methodologies: Industrial and educational applications," CIRP Ann. - Manuf. Technol., vol. 58, no. 2, pp. 543–565, Jan. 2009.

Ricardo Duarte was born in Portimão, Portugal, in 1985. Ms.D at Universidade de Aveiro at 2011; a Ph.D at Université de Bordeaux at 2014 – present. A PhD student in mechanical engineering at Université de Bordeaux, Bordeaux, France

Ricardo worked on the Universidade de Aveiro as a research fellow between 2012 to 2014 and a PhD student at Université de Bordeaux since 2014 till the present. As mentioned the current job is a PhD at the Université de Bordeaux, Bordeaux, France. The author has several international publications as for example: R. Duarte, M. Mesnard, and J. P. Nadeau, "An innovative design approach to develop external articular medical devices," International Journal on Interactive Design and Manufacturing pp. 1-9, 2016; R. J. J. Duarte, A. Ramos, A. Completo, C. Relvas, J. A. Simões, "The importance of femur/acetabulum cartilage in the biomechanics of the intact hip: Experimental and numerical assessment," Computer Methods in Biomechanics and Biomedical Engineering, vol. 18, no. 8, pp. 880-889, 2015; A. Completo, R. Duarte, F. Fonseca, J. Simões, A. Ramos, and C. Relvas, "Biomechanical evaluation of different reconstructive techniques of proximal tibia in revision TKA: An in-vitro and finite element analysis," Clinical Biomechanics, vol. 28, no. 3, 2013, pp. 291-298.

Antonio Manuel Ramos was bron in Aveiro, Portugal. António has worked in mechanical engineering in the computational and experimental biomechanics field since 2001. He graduated in mechanical engineering at the University of Aveiro in 2001.

The basis of his PhD thesis (2002-2005) was to develop a new cemented hip stem, with numerical and experimental techniques correlated with implant success and long-term clinical performance.

A new stem geometry was proposed that reduces the stress in bone cement. This work was awarded the prestigious Professor Carlos Lima Award 2006 by the Portuguese National Associations of Orthopedics and Traumatology.

In 2008, he was appointed as a full-time staff member of the Department of Mechanical Engineering of the University of Aveiro. In Biomechanics his main research interests are biomechanics analysis to predict the mechanical behavior of implants for long-term applications (hip, shoulder, ankle and TMJ joints). In Product Development in recent years he has developed several products and equipment to work in different fields, mainly to clean forests and manage biomass to produce energy.

Antonio has registered four patents and published more than 70 papers in international journals.

A. Ramos et al., "The stock alloplastic TMJ implant can influence the behavior of the opposite native joint," A numerical study / ISSN 1010-5182- Jo. of Cranio-Maxillo-Facial Surgery, vol. 43, no. 8, 2015, pp.1384-1391; A. Ramos et al., "The effect of mechanical properties of bone in the mandible, a numerical case," Advances in Biomechanics and Applications vol. 1, no. 1, 2014, p.67-76; A. Ramos et al., "Numerical and experimental models of the mandible," Experimental Mechanics, vol. 51, no. 7, 2011, p.1053-1059.

Michel Mesnard was bron in Bordeaux, France. He is a professeur Agrégé de Mécanique, "Habilité à diriger des Recherches" at Université de Bordeaux, France.

Michel elaborated and validated an innovative protocol to characterize the biomechanics of the temporomandibular joint (PhD thesis - Bordeaux 2005) and quantified intra and inter-variabilities in a statistical study.

In 2009, he was awarded "Habilitation à Diriger des Recherches," authorizing him to supervise doctoral research and in 2011 created a research structure to develop devices, innovative concepts and methods supervising doctoral theses with a multidisciplinary team and developing a close relationship with industry

His current studies include interactions between experimental characterization, numerical modeling and early prototype in product design. He is also working on the relations between variabilities and manufacturing processes to analyze the opportunity of modular and/or customized technical solutions.

Michel has registered a patent for an innovative temporomandibular prosthesis concept and has published more than 50 papers in international journals

R. Duarte, V. Delos, A. Ramos, M. Teschke, and M. Mesnard, "Development of a relevant image processing method to characterize the distribution of tissue within a bone structure," Jo. of Computer Science & Systems Biology, vol. 8, 2015, p. 199-202; M. Mesnard, A. Ramos, and N. Perry, "Managing the variability of biomechanical characteristics before the preliminary design stage of a medical device," CIRP Annals - Manufacturing Technologies, vol. 63, no. 1, 2014, p. 161-164; M. Mesnard and A. Ramos, "Towards a rigorous approach to designing a temporomandibular joint prosthesis," From Clinical Challenge to Numerical Prototype, vol. 5, 2013, p.141-146.