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ORIGINAL PAPER

Patent-based creativity method for early design stages: case study in locking systems for medical applications

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Abstract Current product design processes are demanding functionality improvements, in order to make the difference in the market. This situation has led designers, engineers and specialist to work together in order to develop new methodologies that might reduce development time and support the quality in the product. In this connection, several tools and methodologies have been proposed over the last decade centred in the combination of industrial design techniques with functional engineering design. Many of these new solutions were based into the treatment of patents in order to reduce the analysis time in terms of existing solutions and how those solutions could be implemented into creation of new products. This article presents the development of a creativity method, based on combination and mutation models, that supports patent search and analysis in the early design stages. The use of this method will be portrayed into the design of the locking system of a medical device used for the treatment of the camptocormia.

Keywords Creativity tools · Early design · Patent search methodology · Camptocormia · Medical devices design

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1 Introduction

Product design processes has been evolving over the last few decades. Even if design approaches continues to be considered as a linear process composed by six major stages (from need identification to manufacturing design), the way the design problem is addressed did change [23]. Under former working approaches, each design stage was developed as an isolated island by isolated discipline, and whole product decisions that were taken at each stage were considered in following stages as unquestionable statements. This lack of challenging decisions normally ended in delays in design processes and lots of rework which costs money to the companies [26]. Designing, as an interdisciplinary task, varies according to the product to be developed, and it requires a collaborative work between different teams that may embrace different domains. According to that, the decisions taken by one of the teams will have an influence on the others. This eventually leads to communication problems between different designing teams, which will be reflected in the final product quality, performance, and cost.

Nevertheless, during the last decades, since the introduction of the concept of concurrent engineering, *collaborative work* in design has started to change. This approach of work invites to all the stakeholders in the product life cycle to work in a collaborative and parallel environment, ensuring the fulfilment of all specifications of the product (structural, functional, manufacture, maintenance, and even considering aesthetics and ergonomics aspects as well) to be considered from the first stages of design [28].

One of these new working methodologies is *interactive design*. This methodology is related to the use of new and more advanced technologies that allows a better overview of the possible solutions and help to obtain a most adequate solution regarding the design problem. Since taking decisions in design process often challenges designers to face to unknown knowledge fields, through the use of graphic models, such as high detailed images, three dimensional models and augmented reality. This allows to a space manipulation and consequently a better comprehension of each possibility solution and also promoting the bases for a most adequate decision [10,11].

Additionally, the success of new methodologies is marked by some key factors, such as collaborative work, which allowed multidisciplinary teams to work in a parallel manner to focus in user centred design and functionality at the same time. These two factors, together and appraised since early design phases, allowed the development of more fitting products.

Many of those working approaches and computer tools that support them, are centred to work in specific design stages, even if is in early design stages where the greatest impact into the solutions can be generated [41]. This triggers that many of the decisions that are made, are taken without the use of any method.

On top of all of this, the evolution of product design processes encouraged product developers to have a wider approach in order to find concept solutions in different fields of knowledge: for instance, searching design solutions in well-stabilised methods, like TRIZ[1], which is centred in a structured search and analysis of patents [31].

However, the resources allocation for solving different sub-problems is unequal and depends on the importance of each sub-system. For example, most of the innovative solutions are centred on the resolution of the main problem over secondary ones [32].

According to that, some of the secondary problems, including several minor features, are relegated to the second plan. Nevertheless, the products' quality and performance are evaluated as their global, dropping responsibility into the minor features as well. According to this, minor features, who are not as important as the main function, are normally not solved using structured methods and may depend on the designer experience. This situation leads the motivation to look forward a more adequate design process in order to ensure the development of more efficient solutions for secondary features [35].

The present work intended to present a method that can be used, whether at need identification or at conceptual design stages, in order to find different solutions to specific subsystems for the development of minor features. Additionally, as the implementation of these new design methods is not restrictive to a single domain it is possible to apply them in different domains as for instance the medical one. Consequently, design methods and their utilisation in the medical domain increased in the past years, redefining design paradigms and knowledge management structures [13].

In this context, this article is centred into the research of a new design method, which may be applied to no matter domain for the development of minor subsystems and its implementation into the preliminary design stages. Based on that an example of its application in the development of medical devices and concretely for the treatment a specific abnormality named camptocormia[2] will be described. This study is being conducted in a partnership between Universit de Bordeaux and Lagarrigue S.A.S.; the development is centred into improving an existing product: within the frame of this article, the locking system will be evaluated in order to develop an innovative solution for replacing the current locking system based in Velcro straps

According to this, the article is structured as follow: Sect. 2 is related to the state of the art and comprises both, design methodologies and creativity relevance in product design. In Sect. 3, the creativity method for patent search and analysis, called RESF, will be presented. Finally Sects. 4 and 5 are related to the application of the design process and method into the development of a medical device subsystem for the treatment of camptocormia.

2 State of the art

The theoretical framework of this research is centred in two main aspects. The first one is related with the design methodologies and how are they used in early development stages. In this context, there will be shown different tools and methods that are suitable to be used in these design stages.

The second part is related to the importance of creativity in early design stages, and how different methods can be used in order to empower finding and analysis of possible solutions in early phases.

2.1 Product development process: early stages

Product design processes are normally based on the adaptation of several design methodologies, which are defined in order to accomplish different goals. Considering methodologies related to collaborative work and centred in user design needs the most relevant authors can be established as Ullman [36], Ulrich and Eppinger [37], Baxter [3] and Pahl and Beitz [25]. These methodologies can be watched in Fig. 1. Under a wider approach, design methodologies can be summarised into 6 linear phases: need identification, product requirements, conceptual design, embodiment design (connection link between functions and shapes), detailed design and manufacturing design.

[1] Theory of the resolution of invention tasks, Russian problem-solving method based in patents.

[2] Medical condition that is characterised by forward flexion of the trunk.

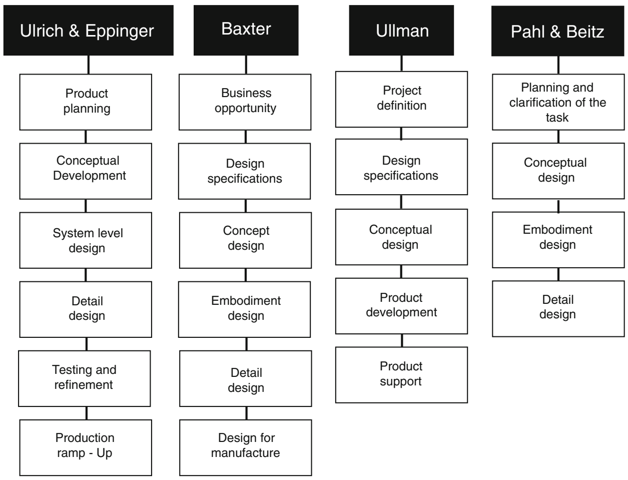

Fig. 1 Principal design methodologies

Analysing in detail the early design stages of these tree authors (Ullman, Ulrich and Eppinger and Baxter), it can be observed that they all make reference to Pahl and Beitz's methodology [25] in terms of how to perform the conceptual design. These conceptual design part and its connection to the other design activities, and within this milestone, these are the goals that must be considered:

1. Essential problem identification
2. Definition of principal function and sub-functions
3. Definition of architectural organisation of the solution
4. Search of solution principles
5. Develop concept alternatives from solution principles
6. Evaluate concepts against design specifications

In the frame of this article, the tools and methods that are going to be developed are centred into the early design stage. In this stage, the requirements are translated from linguistic attributes to variables with solution ranges (i.e. *the glass must be tall*, which is translated in the designing stage to *the glass height must be between 15 and 16 cm*). This major stage includes need identification, product requirements and conceptual design.

2.1.1 Need identification stage

The goal of this stage is to understand the problem, which is also known as the Fuzzy Font End (*FFE*) stage [15]. This stage is performed usually by experts, which might include from marketing professionals or specific actors according to the domain considered.

Before undergoing this stage, five specific goals must be determined: technology development, idea genesis, idea selection, opportunity analysis and opportunity identification [15]. In Table 1 are remarked the main goals of some methods used in this stage.

2.1.2 Product requirements stage

The goal of this stage is to synthesise the FFE information into engineering data. The action that happens in this stage can be considered as the first decision-making processes in the product development that is performed by the design engineering team. All the analysis performed in this stage will allow to settle down the basis for the product development. Table 1 reference two well-known tools used within this stage.

Table 1 Goals at early design stages

Tool/method	Goal
State of the art	Research which are the major trends, legal conditions, market restrictions related to the product. This research should be focus more in patents and article research rather that competitors analysis
Technical state of the art	This task is centred to determine which are the principal competitors in the market and which are the technical specification of their products. The result of this *benchmarking process* is to find performance-gaps that could be introduced and improved in the new product
User identification	In User Centred Design approaches the participation of the users is more active, this allows a better understanding of the problem [30,39]. In order to find tacit and latent needs, it is highly recommended for the design team to conduct interviews, observations and focus groups in order to clarify the those deeper needs of the user [40]
Product Design Specifications (PDS)	Its development allows to the design team to point out the design specifications, considering the product's relationship with the environment and the different situations that will affect the product within its product life cycle [21,27]. The goal is to develop a list that contains the different functions with its desirable metrics value that that the product must accomplish
Quality Function Deployment (QFD)	The first QFD matrix allows to determine the correlation level between the costumer demands (as the result of FFE) into technical requirements (which are results of the PDS). It will allow to determine which are the technical aspects more influential to the user needs [18]

- *Product design specifications (PDS)* This tool allows to the design team to point out the design specifications, considering the product's relationship with the environment and the different situations that will affect the product within its product life cycle [21,27]. The goal is to develop a list that contains the different functions with its desirable metrics value that that the product must accomplish.
- *Quality function deployment (QFD)* The recommendation is using at least QFD matrix #1, which translates costumer demand (as the result of FFE) into technical requirements (which are results of the PDS). This matrix will determine which are the requirements that are more related to the user needs; also it will help to perform a benchmarking in two fronts: how the user see the competence, and how is the relation of the technical behaviour of the competence's product according and the technical specifications of the PDS. Finally, QFD roof can be used for determining designs contradictions that can be solved using TRIZ principles and other creativity tools [18].

2.1.3 Conceptual design stage

The conceptual design strategy must consider the following aspects:

- Perform a hierarchisation of the different functions determined for the product. Determine as well, which are the functions and sub-functions.
- In a parallel manner, develop the construction of the functional structure, which must contain the interaction between the functions-systems and external matter, energy and information fluxes.

The development of these tasks will end with the construction of the functional blocks diagram (FBD) and the architectural distribution of the product. In both of these steps is necessary for the user to understand how the different fluxes interact with the product. Subsequently, the designers must find solutions of each sub-system in order to proceed to the conceptual design and determining the final concept. Some creativity tools, like TRIZ, Heuristics tree are normally implemented in order to solve sub-functions.

2.2 Creativity in design

New product developments are usually related to implement solutions that are conceived as creative ones. Understanding creativity as the ability to respond in an adaptive manner to the needs generated in new products and approaches [2]. Also, creativity can be interpreted as a set of cognitive activities that look forward of new solutions to a specific problem [20]. Additionally can be also interpreted as the tendency to generate or recognise ideas that might be useful in problem solving [12].

It is important to recall that one of the characteristics of creativity as a process of generating ideas, whether randomly or conducted, but always with the goal of harvesting information that can be used to solve problems. In addition, creativity also plays an important role in terms of expectations of success of a product, because it can be used as an element to develop innovative ideas for having prosperous products in the market [29]. Likewise, creativity is also a determining factor in favour of augmenting the quality of the results [42].

In this context, creativity is not only important in order to have new solutions, but it is also important because it can help to achieve innovative solutions as well. Within this idea generation concept, four different models can be discriminated: *combination*, where the idea occurs by the combination from different features into a new idea; *mutation* is when an specific feature is modified in order to create a new one; *analogical thinking* is when the solution of a problem is found in another domain of knowledge; *first principles* is related to developing the design centred in functions and driving it to the form of the product [5].

Connecting with the definition of creativity as a cognitive process, it is important to add that recognition can be also useful as a method that can also lead to new discoveries of immediate solutions, almost implicit or spontaneous [19]. Finally, in this creativity environment, this recognition can also empower several creativity models [9,19].

Linked to models, it is also important to consider how creative ideas can be generated, and unlike brainstorming as a whole, several models propose problem decomposition into different sub-problems in order to achieve better solutions [25]. This decomposition can be made, either explicit or implicit, where the first one is related to the analysis of the function and its structures since the early stages of the design, while implicit one is centred into the experience of the designers team in order to decompose the problem [19].

Altogether, it is also important to remark if the detail of input ideas before a creativity process can affect the result of the solution, that is to say, if the reference model that works as an inspiration is a 3D model or as a 2D image, the creativity process can be dramatically different: 3D models are more useful to understand the functionality, and by allowing dissection, it is easier to assimilate mechanism operation.; on the other hand, by using 2D images as inspiration, the solutions can be more abstract, allowing more creative ideas [33].

Finally, the whole creativity process must end by a proper idea selection process. This process can be whether qualitative or quantitative [22]. Qualitative decisions are made when the designer selects its own idea, and that action is based in three reasons: psychological ownership,

Table 2 Creativity basis

Category	Type
Creativity models	Combination
	Mutation
	Analogical thinking
	First principles
Inspiration models	3D models
	2D Graphics
Idea selection models	Qualitative
	Quantitative

values of the designer and amount of available information.

Quantitative models are related when the best idea is selected and it happens when the team knows better the evaluation criteria, allowing them to take honest decisions centred in the specifications.

To that end, it is important to give designers team enough information, through inspiration models and successful concepts databases, which will allow them to compare several creative ideas, existing concepts, in order to have better discussions and arriving to the best element that will make the product a good one [34].

Summarising, three principal aspects can be used to categorise different creativity features onto a method: creativity models, inspiration models and idea selection models. This can be observed in Table 2.

2.2.1 *Creativity tools centred in information search and analysis*

Different tools are used in order to inspire designers through patent search and analysis. Within the frame of this article, three approaches will be related:

1. The most well-known solution centred patent search and analysis for problem solving
2. Solutions centred in understanding how the problems were solved based in heuristics
3. Solutions centred in patents analysis based in the analysis of the physics phenomena involved

TRIZ is the most well known solution in terms of patent search and analysis. This is a Russian methodology developed during the second half of the XX century and it has been recognised as the most powerful tool used in the concept generation process [24]. It was proposed by Altshuller , and it that helps to find innovative solutions by an extensive patent analysis that was performed by its creator [1].

This method is used to solve design contradiction (i.e. *the product must be strong, must its weight must be low*). The contradictions used as an input of this tool can be obtained by different methods, such as QFD roof, Energy-Material-Signal models and SUH diagrams. The result provided by this tool is a suitable concept-solution to whether physical and technical contradictions, where information is arranged in three different sources: 40 design principles, 76 standard solutions and 4 separation principles.

On the other hand, Heuristics is a practical method of solution finding which allows obtaining a solution to solve a design problem, however that solution obtained by this method may not be the optimal one. Usually, heuristics methods is an alternative solution that can be used when finding an optimal solution is impossible or difficult to reach in order to easily find a satisfactory solution for the existing problem. For instance, an heuristics method may allow to get a feasible solution by the repeatedly inserting proved solutions into a partially constructed feasible solution [7].

Some adaptations of this method can be found as the development of an Heuristics Tree, developed by both, I2M-IMC Laboratory and GRID Research Group, and it is based in the analysis of 78 heuristics rules [4]. This tool is conducted by several steps. The first level asks to *Suppress/reduce/displace/operate the problem*, while on the second level acts on: *By acting on the flow or By acting on the generation / transmission/interaction/system*. The result provided by this tool is a suitable solution by offering solution-examples in three different fields: mechanical solution, commercial product and biomimicry.

Finally, other methods are centred in first make an exhaustive analysis of the function in order to define a set of keywords that connected to the identification of the physical phenomena that governs the problem. A patent search based on finding the gaps and pairing solutions in other physics fields allows designers to find solution by developing analogical solutions. This method, called IMC-G, focuses in identifying relevant physical parameters and link them into physical phenomena. If there is not a corresponding patent related to the physical phenomena, that represents that a corresponding concept does not exist yet [38].

Finally, as the previous methods, the RESF methodology can be included in this stage of the design process and as a creativity tool, which is suitable to be used to find solutions for secondary sub-systems.

3 Proposed method: RESF

Research express solution finder (RESF) is a design method, which may be defined as a creativity method that can be used to find solutions or to orientate the solution in one specific

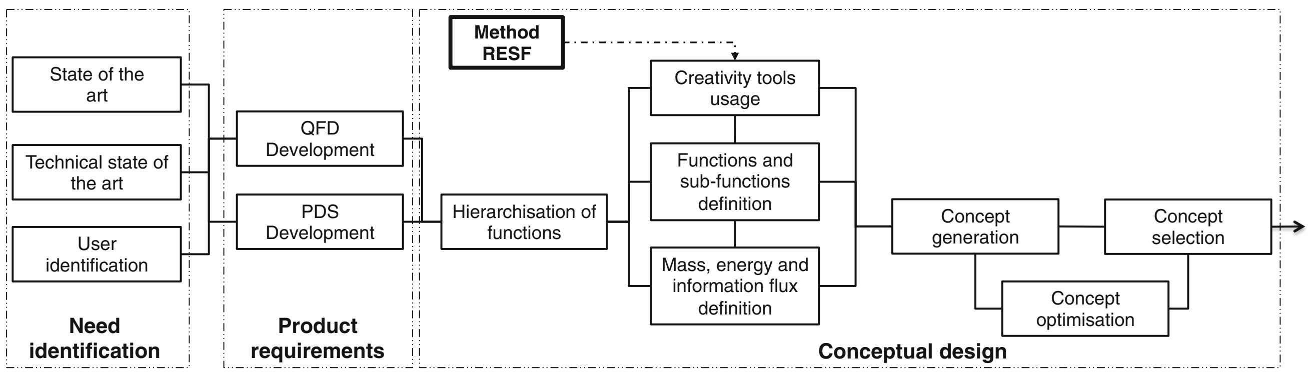

Fig. 2 Preliminary design process

direction for different design problems. This method is based on the search of an adequate solution to solve an expressed problem and on the evaluation of the evolution of one of the possible proposed solutions through the patents analysis. In Fig. 2 are related different tools and methods within a design process, also it is related where the different creativity tools are used.

This method was developed to be used for finding solutions for any subsystem that was declared during architectural design within conceptual design stage. The criteria to use this method recalls on the main goal of the product design.

This method is focused on the subsystems that are not linked to the main function of the product, but nevertheless are necessary to make the product achieving the specifications of the user. Additionally the results of the utilisation of this method can still be used in order to find the solutions for the main function, since it also allows its combination with TRIZ principles or other creativity tools.

The final result of this method is a chronological patent evolution tree that supports decision-making by empowering design teams with valuable information. Also, it is important to remark how the proposed method is different to those explained in Sect. 2.2.1. Unlike other patent search methods, like TRIZ and IMC-G, the way patents are analysed is slightly different. For instance, in TRIZ the patents were analysed before the method is defined, and the solutions offered by the method summarise and categorise several patents. On the other hand in IMC-G, the patents is based in physic phenomena.

Meanwhile, RESF is centred into analysing existing products, and according to those existing product determining feasible solutions to be implemented in product design processes.

Additionally, in order to categorise the tool according the creativity principles of Table 2, several consideration can be declared. For instance, the process suggested by this method is based in the decomposition of the problem, in order to find different solutions for specific problems. In this context, the method can be branded as follows:

- Creativity models: It can be settled the boundaries of combination and mutation models. This is because the not only gives ideas of how to solve problems in terms of functionality and shape, but it also left the door open to mix solutions or evolve them.
- Inspiration model: The tool is centred in 2D, in only handing figures which stimulate creativity, but in providing technical information as well, which will empower designers onto further decision making.
- Idea selection model: The quantitative one is more appropriated, indeed, the tool itself offers information in several steps in order to take the most honest decision.

In this connection, the proposed method presents three stages:

1 Solution preparation
2 Finding benchmarking gap
3 Patents analysis

3.1 Solution preparation

In this stage is very important that designers group all associated information related to the problem, weather it be a new product or a determined subsystem. Two task are related at this point:

- *Extended state of the art* Understand competence, understand how they perform the solution and how they solve the function into a morphological aspect. It is important the development teams perform a deep search, because it is critical for the method to identify the most diverse quantity of commercial products in the market that are used, directly or indirectly, to solve the main problem. In this connection, it is highly recommended to designers to look for products not only in the knowledge field of the product, but searching products in analogical market. For doing so, is important the users nor only look for similar

products in terms of name, but in terms of functionality. This is the reason why this search is made after the definition of sub-systems in the new product development.
- Keywords identification After finding different product that accomplish the same function that it is desired to solve, it is important to identify the technical name of the specific part which solves the function. This will allow a further search of patents.

3.2 Finding benchmarking gap

This stage is essential because it allows to assembly different level knowledge into the same chart. These analyses will allow designers to soak knowledge from existing solutions and will empower them to cross information with the problem specifications.

- Perceptual map definition A perceptual map is a tool that allows to compare several aspects of a product, normally comparing an objective feature with a subjective feature. This allows to compare several products in terms of a very technical and functionality-related aspect with an aspect related to demands that are more centred in meeting users needs.
- *Define the functional core* This selection is made based in the perceptual map analysis. To this end, designers mus first centre in analysing the subjective axis in order to identify which attributes are more related to meet the user expectations. Then, the team must select from the objective axis the solutions that will empower the design to be better. Finally, is in the sector where designers decide to find the solution, is the sector where patents will be searched.

3.3 Patent analysis

This stage is the core of the tool. Here different patents must be searched in order to determine how the evolution happened within the years, and also, to stand knowledge in a deeper level that will be used for the subsequent decision making processes.

- *Identification on international patent classification (IPC)* Before beginning an exhaustive search of several patents, it is very important to designer team to identify the IPC code of the problem-solving patent.
- Patent evolution tree definition In this stage it is not important to search for the entire universe of patents, but seeking every patent when an incremental innovation is identified is required. In this connection, by the identification of whole the major breakthroughs that happen through time, designers will be able to construct a tree where the evolution of the product is the main trunk and the different branches determine the subsequents technological features that have allowed the product to evolve during the time.
- *Analysis the of solution of subsystem* Analyse the solutions and understand which are the key factors of their evolution.

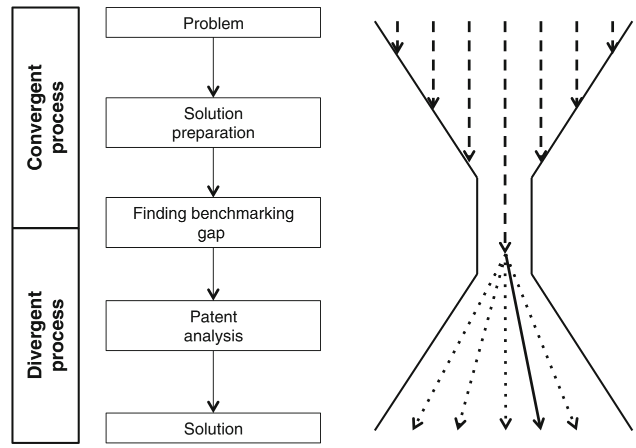

Fig. 3 RESF method

Finally in Fig. 3 is explained how the method can be treated as an hourglass approach. In figure can be seen how the method covers both, convergent and divergent processes. In this connection, within the convergent processes, different ideas are evaluated and filtered in order to find the best idea concept at the *benchmarking gap* stage. Then, the elaboration of the patent evolution tree is supporting the divergent process while it offers several technical solutions that will support the decision making process, for finally selecting and understanding the best solution concept.

4 Case study

4.1 Context

The case study presented in this study lies on a medical device used to treat a postural condition named camptocormia. Camptocormia or bent spine syndrome is a postural disease characterised by the antero-flexion of the trunk during walking gait which worsen with fatigue [8]. Mainly present in population over 60 years old this disease is highly limiting and clearly preclude the patients to have a normal life [16]. According to the present knowledge, the camptocormia origins covers a large spectrum of etiologies since myopathic idiopathic origins to neurological ones. This disease is frequently linked to patients with Parkinson disease, which leads to new challenges into its treatement [17].

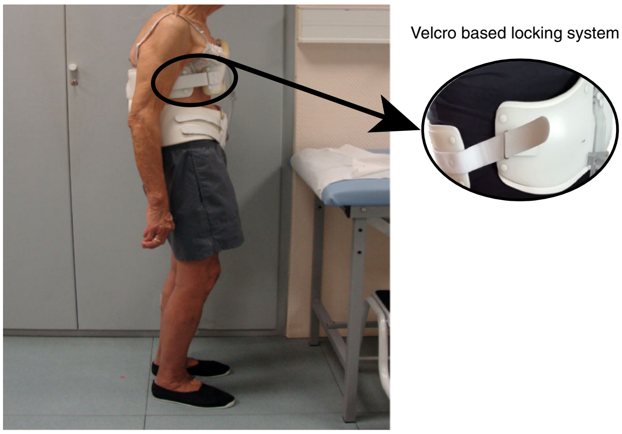

Fig. 4 Locking system of the device: velcro straps

Independently of its origins, presently, the treatment prescribed for the treatment of camptocormia lies on a combined strategy based on physiotherapy sessions combined with a medical brace that allows the redress of the patients trunk [6].

One of the braces used to correct this disease is the TPAD brace (*Thoracic Pelvic Anterior Distractor brace*)[3] This brace is mainly composed by two different annular parts, one at the pelvic level and the other at the thoracic level. This two parts are connected by a distraction system in between, which represents the main function of the product and usually is where most of the time is invested.

Each one of these annular parts are composed by a locking system based on velcro straps which allows the user to lock the device when it is correctly placed. Based on the affected population, there are a several associated problems related with the use of the locking system.

As the major users of this brace are elderly people in some cases they present a reduced mobility, which preclude them to turn their trunk (necessary movement for locking according to the positioning of the existent Velcro system, see Fig. 4) and reduced somesthesie performance, which preclude them to perform precise movements with the fingers. The condition is even more critic when the patient has Parkinson disease, which makes harder the use of the Velcro straps.

These problems should be considered during the planning of the new system in order to develop a more adapted system to the patients needs. According to the most important criteria that should be taken into account during the development of the locking system is listed as:

- Positioning
- Locking efficiency
- Interference with other clothes
- Size
- Stability
- Ergonomics

According to this, the method presented in this work will allow to develop a more suitable system to include a locking system in the TPAD brace considering the patients needs and limitations.

4.2 Conceptual design development

The problem was divided in different sub-functions in order to simplify them in minor and easier problems to solve. According to this, one subsystem (locking system) was selected after a design specification, specification hierarchisation and consequently the definition of the sub-functions.

Based on that, the product is divided in three different sub-functions necessary in the product. According to that, they were hierarchised by order of importance in the product: Distraction of the system through a variable D.O.F. system (which is the products main function); set-up and locking systems and data management through the storage and data transfer system (SDTS). These subsystems are:

- *Variable D.O.F. system* This is the main system of this medical device. It is composed by a linkage chain connected to two different parts of the brace and allows to perform the different required movements respecting the degrees of freedom required.
- *Set-up and locking system* This system as the name indicate is linked to the positioning of the device. This system was developed to allow the correct positioning of the brace in the human trunk. This correct positioning implicates a correct adaptation to the human forms, which is consequently linked to the way that the system is locked when in place. According to this, it is possible to differentiate the two different functions performed by this system and which are considered as complementary. The improvement of this system is going to be developed.
- *Storage and data transfer system* This system allows, in the first stage, to collect and store data related to several criteria necessary to the evaluate the disease evolution during the usage of the brace. After this, the second stage, allows the connectivity to the medical responsible which may analyse the collected data. This allows a personalised treatment and consequently more adapted to the real users needs during the use of the medical device.

Through this decomposition in minor systems it was possible to identify the energy, material and information fluxes. This differentiation allowed to identity the physical phenomenon at the exit of system but also the different type of connections between the different systems which may

[3] Brace developed by Lagarrigue Aquitaine S.A.S.

be consequently taken into account during the development stages.

4.3 RESF implementation

The RESF was implemented during the *Creativity tools usage* activity. This task considers the previous stages results as the input information, which will be processed and structured in order to obtain an efficient result

The following subsections will explain in detail the procedure followed during the RESF use.

4.3.1 Solution preparation

The *solution preparation* subsection include two different stages, the Extended state of the art and the Keyword identification stages. Based on that, this stage of the method pretends to work as a knowledge database for the following stages.

Extended state of the art Based on the present knowledge, in the first stage, the functioning mechanism of the locking systems was evaluated in order to understand and identify the purpose of the mechanism.

Keywords identification In this stage the identification of the subsystem was specified. This process of identification is based on the function that the mechanism should perform i.e. a "function name" and the search of all the related keywords that allows to describe the desired function. According to that, a group of keywords as *lock, close, seal, fasten, occlude, coffin* were evaluated and dissected in terms of its logistical root. That allowed to frame the most useful words in terms of the subsystem function.

4.3.2 Finding benchmarking gap

The *finding benchmarking gap* subsection is composed by two different stages, the Perceptual map definition and the Definition of the functional core. During this subsection the search and the organisation of the solutions were arranged according to predefined criteria which allowed to highlight the solution or group of solutions that fills the requirements.

Perceptual map definition The perceptual map was used to identify the positioning of the different components that perform the required function based on existing solutions and allow to evaluate the most preferable solution. According to that, an exhaustive search of the different existing products/ mechanisms that allow to lock a system was performed. This procedure allowed to obtained a locking system data base composed by twenty five different mechanisms that allow to lock (locking function) a system in many different domains.

Then, the elements were arranged according to objective and subjective criteria. The list of criteria adopted was based on the main functions that the system should perform. According to this, the list comprehend criteria as: regulation, adjustability, size, locking efficiency, resistance, easy to use, ergonomic, known in the daily life, somestesical pleasant, etc. According to the list obtained it was necessary to perform a screening in order to obtain the two most important criteria. Privileging the functionality and the performance the screening was performed through a table of importance in which the criteria were ranked according to the patients and design team voting. According to this, the chosen criteria were the adjustability and easy to use. Which one were divided in objective and subjective criteria as follow:

- *Objective criteria* The adjustability of the solution was considered as the capability of a mechanism to be used in different positions and orientations.
- *Subjective criteria* On the other hand, the subjective criteria is something that can not be measured and consequently depends on the opinion of persons. Based to this, *the easy to use* criteria was considered as the subjective criteria. In this case, as the target population recalls under the elderly persons, over 60 years old, and often with Parkinson disease, the subjective criteria gain an extremely importance since it is directly linked to the users' point of view and their vision of the system.

In this connection those two different features were arranged on the perceptual map respecting the objective criteria on the X-axis and the subjective criteria on the Y-axis, which can be seen on the Fig. 5.

Definition of the functional core Through the analysis of the perceptual map it was possible to observe that the best solution is located when the adjustability and the easy to use criteria obtained the maximum value. It was possible to observe that the solution that best solves that problem recall under the buckle product type. Since this system is usually used attached to a strap or belt it allows one degree of freedom (when the length of the belt is adjusted). Additionally, the setting up process is easy to perform by the user.

4.3.3 Patent analysis

The *patent analysis* subsection is composed by the final stages of this method. During this subsection the patent analysis will be used in order to understand the evolution of the specific mechanism through the identification of the patents under the same IPC, the construction of a patent evolution tree and finally the analysis of the subsystem solution.

Identification on IPC The IPC identification was difficult, because at the beginning the code was not known. The procedure that was followed in order to find the IPC was to search for patents randomly in order to manually find the pattern. It was determined that for this kind of buckles, the code is *A44 B11 - Buckles; Similar fasteners for interconnecting straps*

Fig. 5 Perceptual map of closing system

or the like, e.g. for safety belts. Specifically, the search was conducted using A44 B11/02 and A44 B11/25.

Patent evolution tree definition The search begins by looking at the first patent related with the system on the IPC category. Then, chronological analysis of the patents was made in order to remark those that showed a major breakthrough in this kind of systems. According to that, for the buckling (locking system common word) some breakthroughs were registered along the years.

For instance, at 1960 the system evolved in order to make possible an adjustment of the buckles through the use of straps. Furthermore, at 1977 the metal buckles were replaced by buckles using plastic as material. Later on, at 1979, the buckles' geometry started to change in order to a widely use in different domains. These geometry changes increased specially after 1983. According to IPC it was possible to observe that more six alternative geometries were patented. According to this it was possible to evaluate that since the beginning of this system, the major changes until 2015 were regarding the adaptation of different sizes, materials and geometries. Additionally, at 2016, in order to simplify this buckle, a major alteration was performed. Regarding the patent tree evolution it was possible to observe that at 2016 the idea of a mechanical system to perform the lock changed. According to the evolution of the system, this mechanical way to lock the both sides changed to a magnetic system, which allows a faster and efficient way to lock the buckle. Although, it was observed that in the last decades the geometry represented the main change on this system, it cannot be ignored that a major breakthrough occurred when a magnetic one replaced the mechanical system. The full evolution tree can be seen in Fig. 6.

Analysis and solution definition for the subsystem The uses of this method allowed obtain new knowledge regarding to the characterisation of the buckling systems. At the starting point of the development of the locking system the design team did not have knowledge about the kind of systems were the most suitable to perform the desired function and have no evidences that allowed to select the buckling as a the mechanism to perform the locking.

The creation of the evolution tree facilitated the criteria to determine solutions to specific solution in order to solve the problem. It was also possible to point out the direction of the evolution of this kind of systems. Based on this method it was possible to understand the functional and morphological aspects of this kind of solutions regarding the locking systems and consequently allowing to chose and existing product but also to design a new system to perform the task.

4.4 Proposed locking system evolutionary review

The changing of the locking system in the TPAD brace was a demanding need due to the kind of users of this medical device. As previously stated several criteria should be taken into account in order to improve and facilitate the system usage.

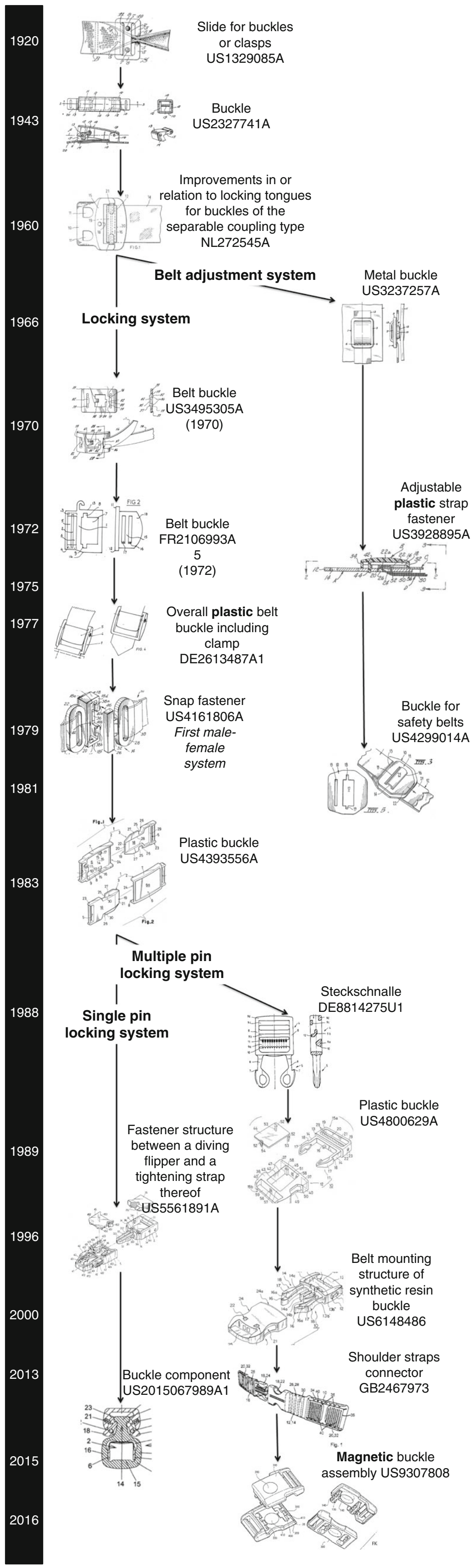

Fig. 6 Evolution tree of locking system

Table 3 Comparison between solutions

Characteristics	Velcro scraps	Buckle
Handedness dependence	–	+
One hand usage	–	+
Interference with clothes	–	+
Blockage efficiency	+	+
Life spam expectancy	–	+
System preparation	–	+
Usage in several orientations	+	+
Size limitation	+	+
System usage apprehension	+	–

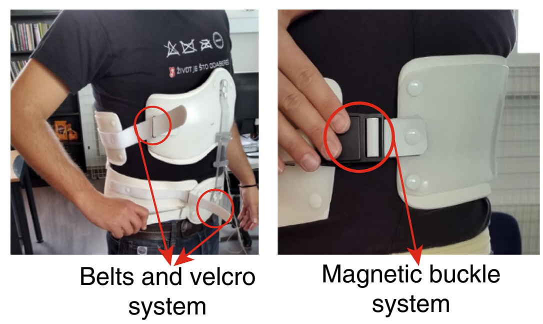

Fig. 7 Comparison of locking system between two models

According to that, the system that budded from the RESF, a magnetic buckle, allowed to be ensure different positioning with the same locking efficiency with a non-significant interaction with clothes. Additionally, the solution proposed by the method allowed to fulfil the criteria linked with size and ergonomics of the system.

Based on the proposed system it is possible to state that the users handedness is not a problem. As the use of this system does not depend on fine motor skills the user may use even right or left hand. Additionally, regarding to the system preparation, that means the actions that are necessary to make it ready to use, which required fine motor skills with the Velcro straps it was suppressed when a buckle was used. The summary of the comparison is observed in Table 3.

Another problem that was solved with this option was the fact of that the Velcro straps has a great influence with user clothes. On the other hand, the magnetic buckle proposed, was a non-roughness component the interference with clothes will be non-existent. This feature will also have an impact in the component life spam expectancy, which is bigger with the proposed component. A comparison between the models can be observed in Fig. 7.

Finally, and regarding to the goals in early design stages, it can be summarised that the RESF method allowed, in terms of the selected sub-function:

- *Essential problem identification* Between the identified sub-functions, it was selected the locking system, specially because it was not linked with the most-added value feature of the final product, but its impact could affect the final performance.
- *Definition of architectural organisation of the solution and search of solution principles* Since it was not know the nature of the final solution, the method was followed in terms of finding well established solutions. This represented the construction of the Perceptual Map (Fig. 5) and the selection of the patents evolution tree.
- *Develop concept alternatives from solution principles and evaluate concepts against design specifications* After analysing the patent evolution tree, it was selected a specific solution, which was the magnetic buckle. This solution embedded a cutting edge solution which assure the usability of the final Brace.

5 Conclusions

The development of new devices requires a large knowledge in different domains which may converge to a common goal. The external medical devices as orthoses[4] represent particular devices in which the adaptation and the interaction with the users gain a particular importance. Usually the development of new orthoses lies under companies' empirical knowledge which preclude in general to obtain an adapted solution.

In general the development of new orthoses may collect, during the planning and clarification phase, a large contents regarding comfort, ergonomics, positioning and size of the different systems. According to that, an orthoses may be divided in several subsystems which one of them have different importance in the final product. According to that the interest of this tool is based on smaller sub-systems in order to allow a relatively faster development steps during the product development.

Based in the importance of achieving good results to each subsystem, the decision of using the RESF method was made, and regarding to its usage, it is very important to say that the major impact of this tool is related with the knowledge that the design team was getting to know the evolution of the locking system.

This argument is centred in two things: the first one is that it allows to understand how different systems are evolving, thus, it gives valuable information that will empower the decision making process for the following design stages. The second one is related in how it helped to reduce time in product design, since the main function of the product is the distraction mechanisms, is in that aspect where most of the resources should be allocated; so the usage of the tool allowed to understand different type of solutions that already exist and are related to locking system.

As respects of this method with interactive design, there is a clear relationship with the proposal and this family of methods: in terms that the solution founded by the use of the RESF was centred in obtaining a quite accurate solution. This was obtained thanks to the use of the information present in the patents and understanding how the evolution of the product developed new topologies and mechanism that perform in a better way the task of locking the product.

Also, it is important to say that the locking system was not selected for a major innovation process, using TRIZ or other innovative techniques, because the nature of the user of the brace. Since the users of this products are elderly persons, usually over 70 years old, it is important to consider into the final solution the adaptive capacity of the user and consequently the direct interaction between user and product. This was consider since the step 3 of the methodology at the perceptual map definition.

About the usage of the innovation method, it is important to say that the tool was born in order to support the design of the different subsystems, specially those subsystems where the knowledge was limited. The problem of having limited knowledge is the lack of criteria in the decision making processes.

In this connection, the method was developed to support in an easiest manner the the definition of which alternatives exist in order to solve a problem, provides criteria of which solution select, and finally allows to make a deeper research in order to gather up the maximum information. Lastly, this tool allowed to search and analyse information that could empower idea generation, and in the end, to meet creative solutions.

Regarding to the results of the analysis of the patent evolution tree, it was found that the geometry was the major change in the last decades, which means that the material and the adjustment allowed are consensual. It was also found the advantages of using a magnetic system to lock the movement, specially because it represented an easier way to elderly persons to perform the action: less force involved in the locking process and less need of fine motricity. It is also possible to state that according to the development stages of the concerned medical device, the solution obtained for the locking system with the proposed method was implemented with success.

According to this, the proposed method allowed to solve a usage problem related with the locking system of a specific brace, which may facilitate the patients manipulation of the system.

[4] An externally applied device used to modify characteristics of the neuromuscular and skeletal system at structural and functional levels [14].

6 Future works

The most essential future works is to apply the method in a different context. As it was mentioned in section 2.2.1, the tool can also be used in Need Identification stage as a decision support aid in patents and state of the art analysis. Also it would be important to verify its usage in other product domains, distant to medical devices.

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