Available online at www.sciencedirect.com
ScienceDirect
Procedia Engineering 69 (2014) 1316 – 1325
Procedia Engineering
www.elsevier.com/locate/procedia

24th DAAAM International Symposium on Intelligent Manufacturing and Automation, 2013

Integration of Creativity Enhancement Tools in Medical Device Design Process

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Abstract

This paper aims at presenting the integration of different creativity enhancement tools, from C-K theory and TRIZ, in medical device design. After the description of the current development process, the paper focuses on the application of C-K mapping and TRIZ tools in a case study concerning the improvement of knee implants for total knee replacement - TKR - surgery. The analysis of this case study highlights that the synergy between TRIZ and C-K theory is possible. As a result, C-K theory represents a good way for structuring design reasoning mostly in the conceptual phases of product innovation and development and it may be also used to explore market information, while TRIZ is suitable for formulating and refining the design problem in a structured way.

Selection and peer-review under responsibility of DAAAM International Vienna

Keywords: TRIZ; C-K theory; creativity in engineering; medical product development; total knee replacement –TKR

1. Introduction

The rapidly changing modern marketplace drives companies to seek competitiveness in product/process development in terms of creativity, innovation, quality, sustainable design, and speed to enter the market. In this time of highly competitive world, innovation and creativity are the fundamental sources of competitive advantage and even a survival necessity. In fact, organizations need a constant flow of ideas while competing through added value factors like emerging technologies or fast new product development. Moreover, they have to create a

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Selection and peer-review under responsibility of DAAAM International Vienna
doi:10.1016/j.proeng.2014.03.124

development environment that promotes systematic creativity and innovation in order to become successful organizations.

At this point, it is important to highlight the concepts of creativity and innovation in an engineering context. Creativity is usually identified with ideas generation and it occurs through a process where an agent uses its ability to generate novel and useful concepts. Innovation refers to the ideas transformation into new products or services. In this sense, innovation is intended as the implementation of creativity results for developing new products, processes or services, while creativity represents the starting point of the whole innovation process [1-3].

As can be imagined, innovation is not easy to achieve. Designing novel and successful industrial products in any field of engineering is a difficult task, from household appliances to medical devices. Current engineering design methods provide help in designing good products, but designers lack tools to create innovative and commercially successful products [4]. Moreover, medical device design is further harder because governed by strict regulations.

The research described in this paper investigates first the application of different innovation and creativity tools belonging to TRIZ and C-K theory in the concept development phase. Then, the authors propose an integration of these tools during the design process and their application to a real case study in medical device development.

The paper is organized as follows. In the next section the medical device design process is illustrated, starting from the analysis of the general product development process - NPD. Then, creativity and innovation tools belonging to TRIZ and C-K theory are presented with a brief description. In section fourth, the activities are illustrated starting from the description of the integration of the creativity enhancement tools in the product design steps and followed by their application in a real case study. Last section highlights the results and conclusions and future developments are set afterwards.

2. **New product development and the medical device design process**

In order to describe the medical device design process it is important to focus the attention on NPD. This will allow understanding better the importance of the introduction of enhancement tools for speeding up creativity, innovation and competitive advantage.

NPD usually implies a strong connection between marketing, R&D and industrial development activities. As stated in [1], there are several factors that influence creativity, innovation and NPD in organizations, such as organization strategy and resource availability, new technologies, R&D intensity, organization culture and communication, organization structure and employee motivation and involvement. For these reasons, it is extremely important to work in multidisciplinary and multisectorial cooperation environments for producing innovative and successful products or services that meet at best customer expectations. As can be found in literature, there is a lot of research concerning the study of NPD processes. The authors decided to base their research on the use of a NPD model adapted from [5-7]. This model is composed by 13 stages, from idea generation to commercialization, as shown in Fig. 1.

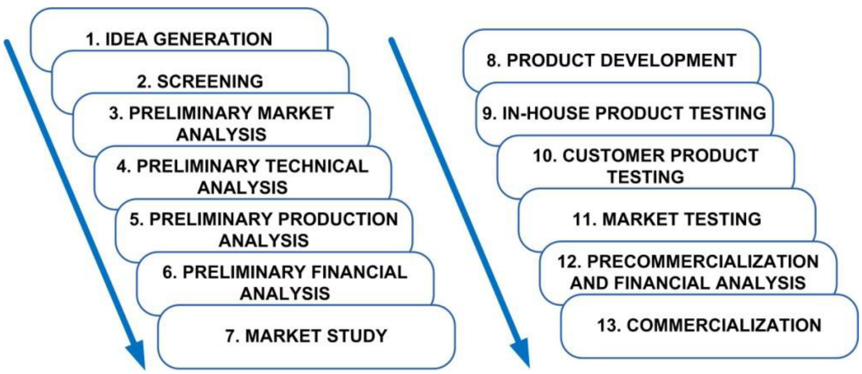

Fig. 1. Stages of the NPD process adapted from [5].

2.1. Characterization of medical device design process

The number of NPD stages may be reduced, depending from industry sector, company dimension, kind of innovative product developed (new to the world or modified), etc. In order to customize the general NPD process for the medical device market, we can consider the stages shown in Fig 2. The design development phase comprises idea generation, concept development and feasibility studies until development. During these stages new ideas for improved medical devices are generated. This phase is followed by clinical evaluation, market launch and high-volume production, which are the pilot program and production phase steps [8-10].

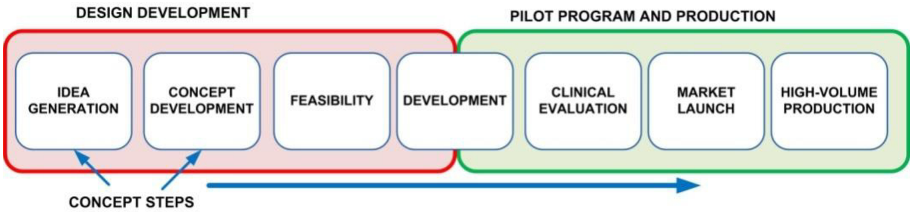

Fig. 2. Medical device design and development process, adapted from [8-10].

More emphasis here is done to the analysis of the NPD process to develop implantable orthopaedic medical devices. The design process of all medical devices is strictly regulated by directives and standards to ensure patients' safety and the healthcare of workers. Also in this case, the concept design is the stage where design solutions are generated to meet all the design requirements. The aim of this step is to generate as many ideas as possible without any kind of judgment. At this point, creativity enhancement methods as brainstorming, TRIZ or other ideas generation methods may be used to help in developing creative concepts [11-14]. After this, the range of concept designs can be systematically rated to determine the most suitable to develop in the specific design stage.

To test the applicability of TRIZ and C-K theory as creativity and innovation improvement tools, the authors, exploiting their previous experience in implantable medical devices development, chose to explore new possibilities for the improvement of knee implants. This case study constitutes an example of the application of some different creativity tools, described in the following sections, during the first steps of the design development phase.

The authors chose this product also because, as reported in some market reports and in literature, the rate of growth for orthopaedic implantable devices is increasing. In fact, as stated in [15], in the last years the knee replacement rates grew 6.7 percent per year. With these premises, orthopaedic implants will remain the largest implantable device segment, both in market value and growth opportunities. For example, US demand for orthopaedic implants is forecast to increase 8.8 percent annually, to 29.4 billion dollars in 2015, spurred by technological advances and safety enhancements. It will also reflect the growing prevalence of degenerative musculoskeletal disorders, together with lifestyle changes that place people at risk for sports and exercise injuries. Improved orthopaedic product design allows less invasive surgeries. At the same time, as products become more durable and long-lived, demand will come from an enlarged patient base for new surgeries rather than for replacements. So it is extremely important to analyze every possible idea for the improvement of the product and to forecast the market evolution.

3. **Creativity and innovation enhancement tools from TRIZ and C-K theory**

3.1. TRIZ and tools

TRIZ was originally proposed by Altshuller in 1946. This theory comes from the idea that every engineer or people in general, can become an inventor and solve very difficult technical problems by proposing innovative solutions in a systematic way. The TRIZ systematic approach guides people during problem solving activities avoiding a random exploration of the space of solutions. TRIZ gives directions to explore a restricted space for finding innovative solutions; it also guides problem solvers towards solutions or strategies that have demonstrated their efficiency and effectiveness in similar situations in the past, in the same or in completely different application domains [11-14]. TRIZ does not give solutions directly applicable; it suggests only research directions to find solutions, then leaving place to the designers' creativity. With TRIZ, inventors can generate more ideas than before, faster than before, and select the best ones in an automatic way.

The most important source of TRIZ is the knowledge base generated by the analysis of thousands of patents and pieces of technical information. This theory is also based on the analysis of scientific literature, on the psychological behaviour of inventors, and, of course, on the analysis of existing methods and tools for product innovation. As explained in [13,14], the three primary findings of this analysis are: problems and solutions are repeated across different domains (industries and sciences); patterns of technical evolution are also repeated across different domains; innovations use scientific effects outside the field where they are developed. This huge work generates the knowledge base used in the heuristics and tools of TRIZ. This way, TRIZ theory has a lot of interesting tools to work on problem solving. They can be classified in three categories: tools to model the problem (for example, Substance-Field Analysis), tools to break psychological inertia during problem formulation and interpretation tasks (Ideal Final Result, Multi screens or Nine box approach), and tools to solve generic problems (Scientific effects, Principle separation, Contradiction Matrix) [11-14,16,17].

The main TRIZ tools, candidate for the integration in the medical device design process, are briefly described hereafter.

- Functional Analysis. This is a basic tool for preliminary problem definition. Each system has its main, overall function, and all its components have to contribute to this function in the most effective way. Otherwise there could be some underuse and/or conflicts. Functional Analysis highlights not only the useful but also the harmful functional relationships existing inside a system. To solve efficiently the problem it needs to define innovative relationships of cause and effect among the associated problems. Once established these cause-effect relationships, it is likely that it is sufficient to solve even one of the minor problems to completely solve the main problem.
- Contradictions and Inventive Principles. In TRIZ, problems can be described in terms of Contradictions. An inventive problem contains at least one Contradiction, and an inventive solution overcomes totally or partially this Contradiction. A Contradiction is a conflict in the system and it arises when two requirements or needs for a system are mutually exclusive but both are required by the overall function or, in other words, to reach the system goal. Inventive Principles come from the Altshuller's analysis of patents. They have been derived from the study of the principles used in the top few percents of the global patent literature, where a breakthrough invention had actually occurred. Principles are used to guide the TRIZ practitioners in developing useful concepts of solution for inventive situations. Each solution is a recommendation on how to make a specific change to a system for eliminating a technical Contradiction.
- Ideality and Ideal Final Result. Ideality refers to a psychological concept that allows finding the best solution for a complex problem without taking into account cost, time, space or any problem constraints. Ideality is defined by the ratio between the positive and useful functions of the system and the negative and harmful ones. It defines a sort of virtual goal. In TRIZ, Ideality is a goal. All systems evolve towards the increase of their degree of Ideality. The perfect system, called Ideal Final Result, has all the benefits the customer wants, with no harmful effects. The ideal system is often a utopia but it could guide toward seldom-explored directions.
- Laws and Evolutionary Trends. During its lifecycle, a system is always evolving and this evolution is governed by objective Laws. This concept allows anticipating future ways of evolution of systems that show some sort of similarities. If the target is to generate a competitive advantage through a radical innovation compared to existing products, then the most effective tool to be used are the Evolutionary Trends. At a certain level of abstraction, system evolution can be described by universal laws and, thus, prediction potential future development of the system can be done. Trends have a level of abstraction which allows their effective use even in non-technical fields. Evolutionary models of product / technology may open a

window on the future of other products, placing the current product to inside of a trend in which is possible to predict future steps.

3.2. C-K theory and tools

C-K theory is a unified design theory introduced by Hatchuel et al. [18-20]. The name reflects the assumption that design can be modelled and analyzed as the interplay between two interdependent spaces: the space of concepts (C) and the space of knowledge (K).

In this theory, the starting point of a design project (or research) is the formulation of an idea, a specification, a concept, which is an incomplete or ambiguous set of desired properties qualifying the object to be designed. The theory assumes a space of knowledge (K), which is the established knowledge available to a designer and contains propositions of partly known objects as well as relations between these objects. Propositions have a logical status (true or false). Knowledge is expandable since its content changes over time. A concept is a proposition implying that an object verifies a group of properties. A concept has no logical status in the space of knowledge (K). In fact, when a concept is proposed, it is not possible to prove that it is a proposition of K. Concepts are considered as sets that can only be partitioned or included (not searched). If a property is added, the set is partitioned in subsets. If a property is removed, the set is included in a set that contains it. The process of adding and removing properties to or from concepts is the central mechanism for the design reasoning activity. The space of concepts (C) has a logical tree structure based on concepts partitions and inclusions, while the space of knowledge (K) has a categories structure and it is a space made of propositions with a logical status, as shown in Fig. 3.

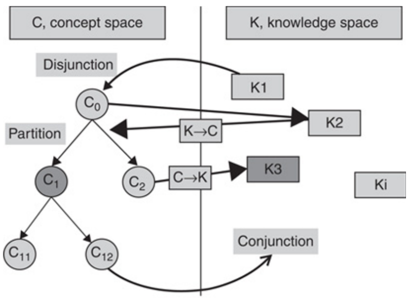

Fig. 3. Concept and knowledge space expansion dynamics adapted from [20].

Four operators have been defined to model these spaces. These operators are represented in the so-called design square (see Fig. 4):

- K → C operator: this operator adds or removes properties from K to concepts in C. It creates disjunctions when it transforms a proposition into a concept. This corresponds to the generation of alternatives. It expands the space C with elements from K.
- C → K operator: this operator seeks for properties in K that could be added or removed to reach propositions with a logical status. It creates conjunctions which could be accepted as finished design. This corresponds to evaluation using an experimental plan, a prototype, or testing. It expands knowledge with the help of concepts.
- C → C operator: this operator controls the expansion of the space or tree of concepts, by partition or inclusion.
- K → K operator: this operator allows expanding the space of knowledge using logic and proving new theorems. The expansion mechanisms help to define design as the reasoning activity which starts with a concept about a partially unknown object and attempts to expand it into other concepts and/or to generate new knowledge. Design generates the co-expansion of the two spaces: design is the process by which K → C disjunctions are generated, and then expanded by partition or inclusion, to reach C - K conjunctions.

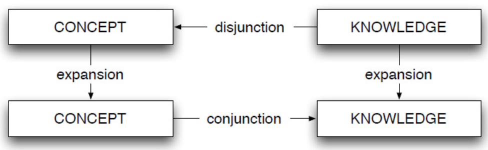

Fig. 4. C-K theory operators.

C-K mapping represent the most effective tool for applying C-K theory to design rationale and to figure out concept and knowledge expansions.

To explain how C-K theory works an example of new product concept development is reported from [20], where Hatchuel et al. describe the development of an innovative product. In Fig. 5 are reported two examples of C-K mapping for this product: a nail holder for safe hammering (after commercialized under the name "Avanti"). In this case C-K theory helped to structure the great quantity of ideas and also the connected amount of knowledge. The initial concept C0 considered is "safe hammering with hammer in right and the left hand doesn't hold the nail" (Fig. 5a). The C-K map in this case served to structure this apparently simple exploration.

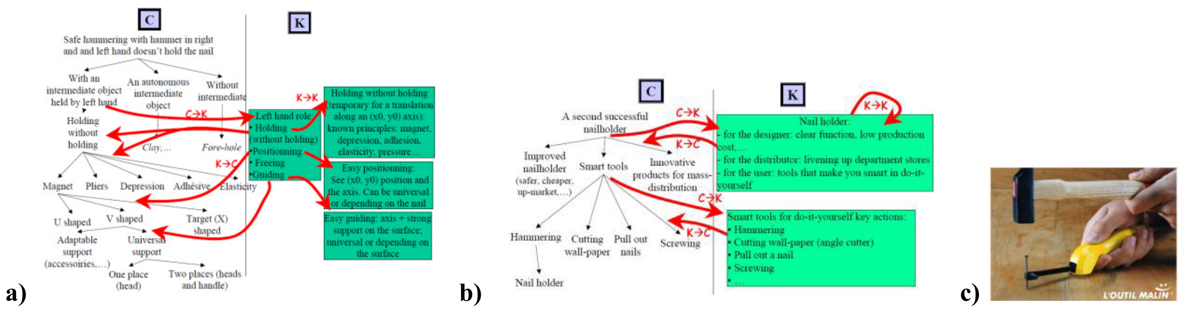

Fig. 5. a) C-K mapping for a nail holder; b) C-K mapping for market exploration; c) the design result: Avanti [20].

In this case, the option explored is "left hand does not hold the nail" and it aims to model the role of the left hand. This way, this concept allows a major expansive partition of the concept space and the modelling helped to study this partition. The aim was to find possible means for holding the nail: with or without an intermediate object. These different levels of exploration of C space gradually helped to define the nail holder innovative concept. At the end of the exploration a great number of concepts were found and, in opposite to brainstorming, ideas were not only produced but also new solutions were elaborated. In Fig. 5b another example of C-K mapping also relative to the innovative nail holder "Avanti" (Fig. 5c) from [20] were reported to clarify also the possibility of use C.K theory and mapping for interpreting market information. In this case, starting from the Avanti nail holder concept, a new class of "smart tools" was designed as a class of tools being still easy to use, cheap to produce and smart in design.

4. **Activities**

4.1. Integration of creativity tools into the medical device design process

In this section, an integration of the creativity tools along the product development process is proposed.. The integration started from a literature review to search the most used TRIZ and C-K theory tools. As a result, in the most of the literature cases the application of more than one of these tools is not efficiently addressed and developed. There are many examples of application of single TRIZ tools as the Inventive Principles or the Contradictions. Moreover, the schematic model of the problem is missing and the application of Inventive Principles is not sufficiently structured. The conscious use of the tools for the acquisition and the management of knowledge is missing too [17,21,22]. As observed in [17,22], literature is oriented toward using TRIZ for mere problem solving, neglecting the potentiality of tools for knowledge acquisition and coding and for strategic analysis of the evolution of technology. Laws and Evolutionary Trends are less present than other tools even if they may provide concrete help in several steps. At last, the concept of Ideality and the Ideal Final Result are used for evaluation purposes of solutions and design, but not to define the goal or to establish a direction of development.

Table 1 reports the proposal of integration of tools into the first product development process steps.

Table 1. Creativity tools vs. product development phases.

Tools		Idea generation	Concept development	Feasibility	Development
TRIZ	Functional analysis	X	X	X	X
	Contradictions/Inventive Principles		X	X	X
	Ideality and Ideal Final Result		X	X	X
	Laws and Evolutionary trends		X	X	X
C-K	C-K mapping	X	X	X	

4.2. C-K mapping for structuring concept development in a creative way

As a result, Functional Analysis of TRIZ and C-K mapping represent the creativity enhancement tools that can be used to mange in an effective way the idea generation and concept development steps of the medical device design process, as suggested in the integration approach presented in Table 1. In the following paragraph, the application of C-K mapping is illustrated as the beginning of the creativity enhancement process.

Moreover, C-K map represents, as stated in C-K theory fundamentals, an important starting point to construct a structured space of concepts and knowledge for considering all the possibilities [18-20,23].

Starting from these premises, an initial brainstorming session was done to focus on the case study object: to explore the improvement or innovation possibilities for a knee implant design. This brainstorming session, connected to the analysis of the state of the art in knee prosthesis design, gave some interesting observations such as: the necessity of developing implants for different genders or for different anthropometric types (in fact, the diffusion of the global market has extended the use of knee implants also in the emergent and developing countries where people do not belong to Caucasian type but for example to Asian). Moreover, another frequent requirement for TKR surgery is the design of implants allowing more possibility of movement to answer to the demand of more active lifestyles of young patients or to new request connected to cultural habits (such as squatting, religious practices, kneeling and sitting cross-legged habits for North Africans population) [24-26].

Starting from these considerations a C-K map for the concept C0 “a more natural knee implant” was realized. First, the concept space was explored using a depth first strategy and then, in parallel, the knowledge space was built. This way, the concept and knowledge space exploration were also used to interpret possible market information. In Fig. 6 the resulting map is illustrated.

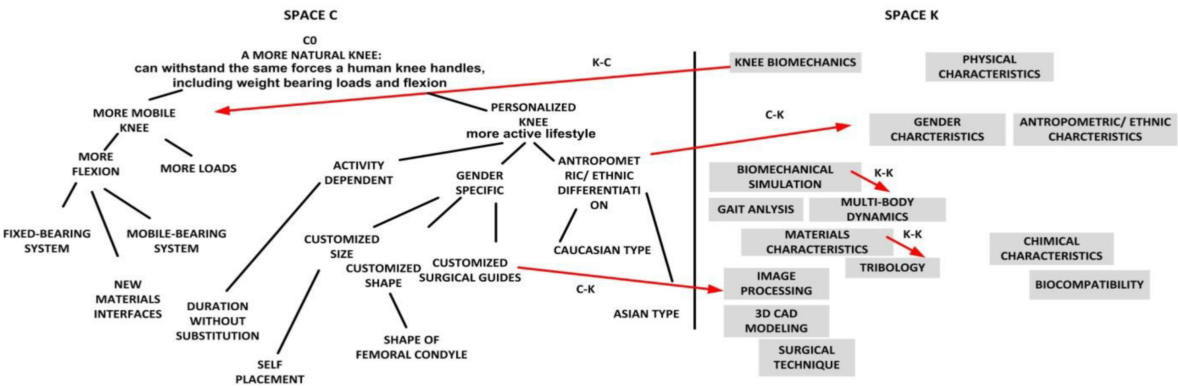

Fig. 6. C-K map for the concept “a more natural knee implant”.

4.3. Problem analysis with TRIZ tools

Once realized the C-K map, it has been possible to analyze some specific concepts/problems by using TRIZ tools such as Functional Analysis or Inventive Principles (concept development and feasibility steps in Table 1). Starting from the ideas collected with the C-K mapping, some possible concepts/problems to consider may be the design of a knee implant (Fig. 7a) which allows more possibilities of movement or the development of a self positioning implant that guides the surgeon during the insertion.

Since this analysis is also under development, only the preliminary steps are reported here. For instance, in the case of the development of a more "natural" knee the attention is pointed on the widening of the motion range (more flexion, rollback effect, etc.) by using the Functional Analysis. This way, the problem concerns the improvement of the function related to the movements (for example internal/external - I/E rotation, flexion/extension - F/E rotation, etc.) in contradiction with the function "fix". An example of functional scheme for a TKR implant is illustrated in Fig. 7b.

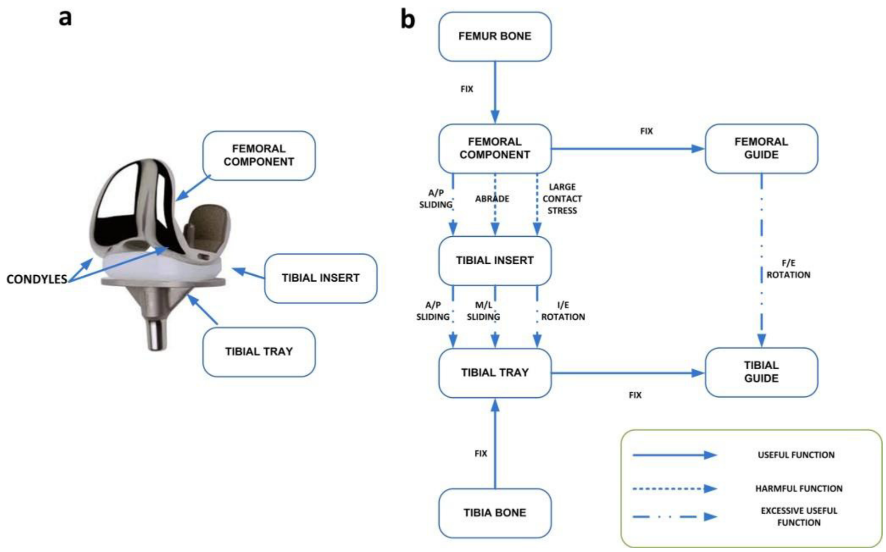

Fig. 7. a) TKR implant components; b) TKR functional scheme.

The functional scheme allows highlighting two possible problems to be solved, connected to the presence of harmful functions. Possible solutions may arise from the redefinition of the shape of femoral condyle into the femoral component of the implant or from the use of innovative materials (Fig. 7a). This way, eliminating possible sources of wear problems or incorrect or limited movements may allow a more natural implant motion and a better condition of contact in knee surfaces with the decreasing of component wear [24-28].

At this point, an important observation may be done considering also TRIZ Evolutionary Trends. The shape of the femoral condyles has changed and evolved in the history of TKR implants. In particular, the geometry of the femoral condyle in the sagittal plane evolved from single curvature radius to two, three-segment radius and now it is oriented on multiple-segment radius (see Fig. 8). This way, a possible evolution, considering the Trend of increasing Ideality of the system, is toward a complex-curvature curve which allows considering multiple curvature centres to simulate the real rollback movement of a normal knee. Another Evolutionary Trend to study may be the use of asymmetric shapes, for example the asymmetric shapes of lateral and medial compartments of the knee, represented in the sagittal plane [26-28].

The analysis of Evolutionary Trends may be also use as a potential in concept development to evaluate the overall degree of evolution of the system and to suggest how the particular problem may evolve.

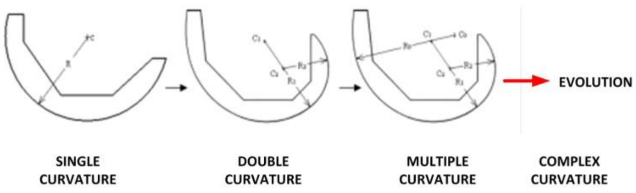

Fig. 8. Femoral condyle curvature Evolutionary Trends [25].

5. **Conclusion and future developments**

This paper described the integrated application of TRIZ and C-K as creativity enhancement tools in product design. In particular, the analysis of the case study highlighted the possibility of exploring the design space in a more structured way, mainly at the concept development level, also considering the knowledge requirements. This link, between knowledge and concepts, is obtained by the introduction of C-K mapping that put to evidence the feasibility of developed concepts. Moreover, this tool allows a more precise characterization of the design problem under consideration and the aware introduction of the TRIZ tools.

The structured application of C-K theory and TRIZ highlighted their potentiality as creativity enhancement tools, allowing to structure the design space and also to explore and interpret market information or to manage technology forecasting.

Future developments may consider the application of these tools to different industrial sectors also for product and service design, and the extension of the application of the less used TRIZ tools such as Evolutionary Trends as a strategic leverage in product development. In addition, the definition of a general approach based on these tools may be used as a framework for product development in different domains.

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