

# HORA AND TEMPUS IN THE MAKING: AN HISTORICAL APPROACH TO TECHNOLOGICAL COMPLEXITY

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## Abstract

Evolutionary approaches to technological complexity tend to ignore the role of invention. In this paper, we follow the theory of invention developed by Brian Arthur to trace the emergence of complexity. The notion of *structural deepening* helps us to understand the emergence of complexity –in the form of designed and unexpected relationships between elements- during the invention process. Structural deepening describes the growth of complexity as a consequence of the “crude” nature of the original concept of the new technology (the base principle), which needs more design sophistication to enhance basic performance. The history of the artificial intervertebral disc -a surgical prosthesis used in the treatment of spinal pain- offers an excellent context for investigating structural deepening. We find that one factor is influential in the extent of structural deepening is the success or failure of the “technological neighbors” of the artificial disc. This “neighborhood effect” consists of a reduction in complexity “borrowed” from the technological neighbors. We call this process “architectural stabilization”.

## 1. Introduction

Let us begin with a fable related by Herbert Simon to illustrate his influential theory of the evolution of complex systems (1962). Hora and Tempus were two mythological watchmakers in Simon’s fable, and complexity had two sides to it. Complexity refers to the number of parts in the system: in the fable Hora and Tempus manufactured identical watches. Complexity is also the number of relationships among the parts of the system: Hora and Tempus’s success at watchmaking depended inversely on the complexity of the design of the watches they had manufactured. The more complex design failed because its high level of complexity imposed too many conflicting constraints and

technological trade-offs among the watch's elements, and made its manufacture more difficult. The greater the complexity, the more the probabilities of "complexity catastrophe". This last sense of complexity is the one we will use in this work.

Simon's work has been used to understand technological complexity (Murmann and Frenken, 2006). However, he says nothing about the origins of complexity; he saw the emergence of complexity as a random process<sup>1</sup>. Since then, evolutionary approaches to technological complexity tend to ignore the role of "invention".

In this paper, we follow the recent theory of invention developed by Brian Arthur (2007) to trace the emergence of complexity. The notion of *structural deepening* (Arthur, 1993, 1994, 2009) helps us to understand the emergence of complexity during the invention process. Structural deepening describes the growth of complexity as a consequence of the "crude" nature of the original concept of the new technology (the base principle), which needs more design sophistication to enhance basic performance. This process leads to the addition of components and of –designed and unexpected–relationships among the components.

There is a lack of empirical work on this phenomenon of technological structural deepening: to the best of our knowledge, the only empirical illustrations are the examples of turbine technology used by Arthur (1993, 1994, 2009). The history of the artificial intervertebral disc -a surgical prosthesis used in the treatment of spinal pain- offers an excellent context for investigating structural deepening and, at the same time, reconstructing the Hora and Tempus approach to complexity to include invention of complexity. As in the Simon's fable, there were two different designs of artificial disc, of different complexity, and the one with fewer interactions among its components proved more successful.

But our empirical case shows also that the invention processes designs were different. These differences affected the complexity of the two designs of artificial disc, and therefore their success. The case provides a better understanding of structural deepening by studying the factors that influence the differential "depth" of the complexity in these cases. We find that one factor is influential in the degree of technological complexity of the two designs: the success or failure of other two medical devices (the hip prosthesis

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<sup>1</sup> "The complex forms can arise from the simple ones by purely random process" (Simon, 1962:471).

and the silicone implants), which were “technological neighbors” of the two designs of disc. This “neighborhood effect” consists of a reduction in complexity “borrowed” from the technological neighbors. We call this process “architectural stabilization”.

Complexity approaches to technological change use computer simulations (Frenken, 2006; Frenken et al., 1999a) or treat statistically quantitative data on technological characteristics from technical encyclopedias (Castaldi et al., 2009, Frenken and Nuvolari, 2004; Frenken and Leyesdorff, 2000; Frenken et al., 1999b). Here, we provide a “qualitative” and historical discussion of the origins of a technology in terms of complexity. Staudenmaier (1985:8) divided the history of technology into externalist and internalist accounts. Internalist accounts are focused on “technical design”; externalist accounts are focused on the “contextual history”. Arthur (2009:198-205) has claimed that there is a lack of a theory capable to frame an internalist history that could account for the great diversity of actual cases: “we know a great deal about technologies in their individual sense, but much less about technology in the way of general understandings”. We believe complexity theory can provide a general framework for covering the internalist history of the invention of technologies.

## **2. Theoretical framework**

### ***2.1 Complexity and Invention: an under-analyzed question***

A theory which understands the physical configuration of artifacts as complex systems should explain also how the current complexity of artifacts was *invented*<sup>2</sup>. In fact, the dynamics of complex systems are highly dependent on initial conditions (Ruelle, 1991; Bonaccorsi, 2008). Besides, theories of path-dependence show that the physical configuration of current artifacts depends critically on the contingencies in the initial phases of their development (David, 1985).

However, invention has become forgotten in complexity approaches to technology, even those within an evolutionary framework<sup>3</sup>. Take the case for example of

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<sup>2</sup> The typical complexity question should be “how did the current complexity *emerge*?” (Waldrop, 1992). We use emergence and invention alternately in this work, although invention suggest the presence of a particular agency (invented *by*) and emergence refers to the self-organization of multiple agents.

<sup>3</sup> We do not review approaches where the absence of a reference to invention is somehow assumed. We refer to the “mirror hypothesis”, which considers technological complexity as a “reflection” of the

technological complexity in Product Life Cycle Theory which distinguishes between complexity of the core of the artifact –i.e., the components related by a higher number of functions- and the periphery –the remaining components, and proposes that in the early phases of development technological change affects only the core elements, and in later phases changes are concentrated in peripheral components only (Murmann and Frenken, 2006; Tushman and Murmann, 1998). However, these approaches do not explain the *origins* of the core-periphery structure, which renders the source of technological complexity exogenous. There may be two explanations for this oversight.

First, due to their biological inspirations, many evolutionary models explicitly assume the complexity of artefacts to be “given by nature” (Kaufmann et al., 2000:145, in Frenken, 2006:39). The underlying argument is that the laws of chemistry and physics determine the relations between technological elements, analogous to the fixed nature of the relations among an organism’s genes. However, as Frenken (2001:101) put it, “even when one accepts the assumption of a fixed law-governed set of ... relations in biological organisms, the assumption is not justified in the context of technological evolution”, where the emergence of technological complexity can be explained by studying the invention process (Arthur, 2007).

The second reason may be that Product Life Cycle Theory is intended ultimately to explain how technological change is related to changes in market structures (Murmann and Frenken, 2006), in the form of firm entry, exit and survival in a new manufacturing sector (Klepper, 1997). The manufacturing firm, as is the norm in neo-Schumpeterian approaches to technological evolution, is the fundamental unit of analysis (Nelson and Consoli, 2010). The empirical data in these works begins typically with the introduction of a product into the market, i.e., the first innovation (Schumpeter, 1957; Abernathy and Utterback, 1975), which excludes the phase of invention defined in the neo-Schumpeterian framework as the formulation of the new idea prior to its introduction to the market. Even some of the more technological oriented works in this tradition, such as Kim Clark’s (1985) paper about changes in complexity in the automobile industry, deal only with changes in complexity from 1895, when the first US manufacturing companies emerged, and ignore the influence of developments in the 19<sup>th</sup> century related to the complexity in automobile structures.

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complexity of the organization and/or industry that develop the technology (MacCormack, 2008; Henderson and Clark, 1990).

## ***2.2 A theory of complexity changes during the invention process***

### *2.2.1 Design and service spaces.*

Our theoretical framework of invention is based on the work of Brian Arthur (2009, 2007, 1994, 1993). For Arthur (2007:285), “invention is not an event signaled by some striking breakthrough. It is a process – usually a lengthy and untidy one-” of linking an “effect” with an unmet “need”. The notion of invention as a relationship between an effect and a need resonates with other definitions of the concept of technological novelty in the literature. For Alexander (1964) and Clark (1985), the linkage is between a “form” and its “context”. For Ulrich (1995), it is between a “physical element” and a “functional element”. Finally, there is a tradition that began with Saviotti and Metcalfe (1984) which considers technology as the relationship between a “design space” and a “service space”.

We adopt this latter formulation as being the most closely associated to design-service maps, the instrument we use to represent technological complexity (Fig. 1). As Castaldi et al. (2009:550) state: “Technical characteristics represent the internal structure of the artefact and, in most cases, are the dimensions that designers take into consideration (e.g., in the case of the car, type of engine, type of suspensions, weight, etc.). Service characteristics, instead, are the “services” actually delivered by the artefact in which users are interested (in the case of the car, speed, reliability, comfort, etc.)”. We define complexity as the number of relationships between the design and the service space. In a complex design, one service characteristic may be influenced by several technical characteristics. For instance, in the tank example (see Figure 1), better battlefield capability (i.e. better protection) achieved through thicker armor leads to an increase in the weight of the tank and a decrease in road speed. High technological complexity is associated with these kinds of trade-offs.

It is useful to distinguish between ‘designed’ and ‘unexpected’ relationships between technical and service elements<sup>4</sup>. For *designed* interactions, Baldwin and Clark (2000:23) used the example of a plastic coffee mug and its plastic cap. The mug has to hold liquid,

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<sup>4</sup> We are grateful to Paul David for pointing this out during a session of the 2011 Stanford Science, Technology and Society Seminar Series.

the cap has to avoid the liquid to be poured. The dimensions of the cap have to be designed to fit snugly into the top of the vessel, and thus providing the required services. One of the most known examples of *unexpected* interactions can be found in the evolution of machine tools during the first decade of 20<sup>th</sup> century (Rosenberg, 1969). The introduction of new steel alloys for the cutting tools of the machines allowed the operation at dramatically higher speeds. But it turned out that the structural and frame elements of the existing machines could not withstand the stresses and strains created by those higher speeds.

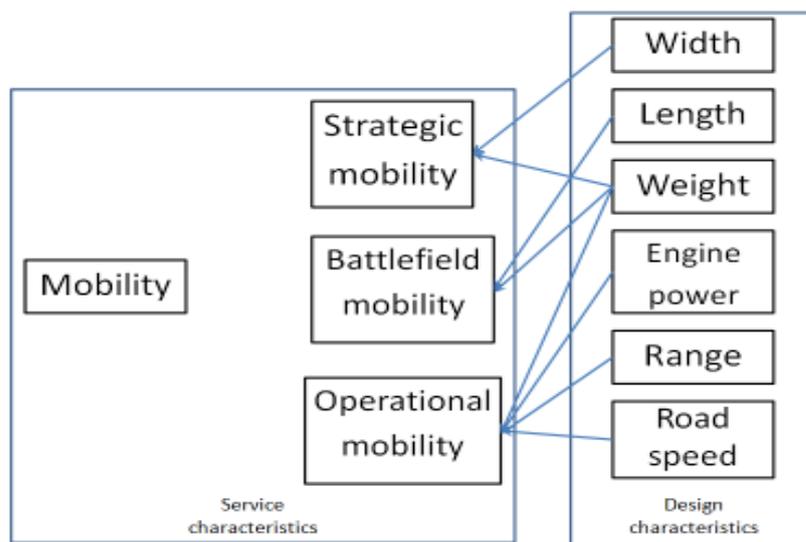


Figure 1. Mapping of the design and service spaces for tank mobility (source: Castaldi et al., 2009).

### 2.2.2 The base principle

This original idea, which first linked the design and service space, is called the *base principle* (Arthur, 2007) or the *operational principle* (Polanyi, 1962; Vincenti, 1990). For example, the base principle of the first successful human flight was proposed by Cawley in 1809 to: “separate lift from propulsion by using a fixed wing and propelling it forward with motor power. The central idea was that moving a rigid surface through resisting air would provide the upward force countering gravity” (Murmman and Frenken, 2006:939). The main means of generating a new base principle is to combine<sup>5</sup>

<sup>5</sup> Combination has been proposed as the source of novelty by Schumpeter, Einstein, Poncairé or Usher. For an excellent review of combinatorial perspectives on technological novelty see Operti (2009).

bits of the inventor's pre-existing knowledge<sup>6 7</sup>. The complexity of the original principle is constituted by the new relationships imposed on these pre-existing bits of knowledge in the act of combining it to form a new base principle.

### *2.2.3 Structural deepening*

As we have said, invention is a process, not an event. Maybe the core of the Arthur's theory is the idea that the original insight of the base principle creates<sup>8</sup> new sub-problems, the solutions to which may raise further challenges. The process nature of invention is explained because the inevitable "misfit" (Alexander, 1964) between the original design and service elements of the base principle "involve[s] an almost compulsive formulation" (Rosenberg 1969 [1976]: 111) of new problems which promotes a "problem-sequence" (Metcalf et al., 2005).

This problem-sequence implies a growing degree of complexity in the artifact's structures. "Additional components and assemblies are added to it to work around its limitation" (Arthur, 2009:2024-2030). "[Developers] add depth or design sophistication to their structures. They become more complex" (Arthur, 2009: 2030-2037). Arthur calls this process "structural deepening" and cites turbine technology as an example. "Modern aircraft engines are 30 to 50 times more powerful than Whittle's original jet engine, but there are considerably more complicated. Whittle's turbojet prototype of 1936 had one moving compressor-turbine combination and a few hundred parts; its modern equivalent has upwards of 22000 parts".

Although structural deepening as described by Arthur, can happen throughout the life of the technology, we are interested only in the invention process, following the original conception of the base principle and before introduction of the product to the market. In

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<sup>6</sup> "Building blocks", in Arthur's terminology. The insight of the original combination of pre-existing building block "comes to an individual person, not to a team, for it wells always from an individual subconscious. And it arrives not in the midst of activities or in frenzied thought, but in moments of stillness" (Arthur, 2007:280).

<sup>7</sup> Arthur (2009:1666-1673) prefers the word "originator" to "inventor", to avoid connotations of "lone eccentrics at work". Fn 4 implies that to generate a new combination of pre-existing bits of knowledge requires the effort of these lone individuals.

<sup>8</sup> It could be argued that the micro-process of combining pre-existing knowledge, in the mind of originator, which precedes the original insight of the base principle (see Note 4), is the real beginning of the invention process.

this context, structural deepening enhances the basic performance of the technology<sup>9</sup>. Structural deepening essentially has two properties:

- first, it is *recursive*, as it uses the same logic of problem solving through the whole process: the original misfit between design and service in the original base principle raises new sub-problems whose resolution raises yet other sub-problems;
- second, it implies additional components and relationships among components, which increases the complexity of the artifact.

These new components and interdependencies are the cause of the fundamental problem of complexity: too many relationships in the technical-service characteristics map impose “too many conflicting constraints and trade-offs between elements” (Frenken, 2001:65), as illustrated by the story of Hora and Tempus. Structural deepening is a process of navigating between Scylla and Charybdis -or, in complexity terms, at “the edge of chaos” (Waldrop, 1992). On the one side, the addition of new components is necessary to resolve the sub-problems generated by the base principle. On the other side, their addition increases the relationships between elements and the potential negative trade-offs and unexpected interactions, which can result in a “complexity catastrophe”. Figure 2 show the increasing complexity of the base principle during the invention process, distinguishing between designed and unexpected (dotted arrows) relationships.

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<sup>9</sup> Through the life cycle of the technology other circumstances lead to the structural deepening of an artifact (Arthur, 2009:2031-2038): a) monitoring of and reacting to changed or exceptional circumstances; b) adaptation to a wider range of tasks; c) enhancement of safety and reliability.

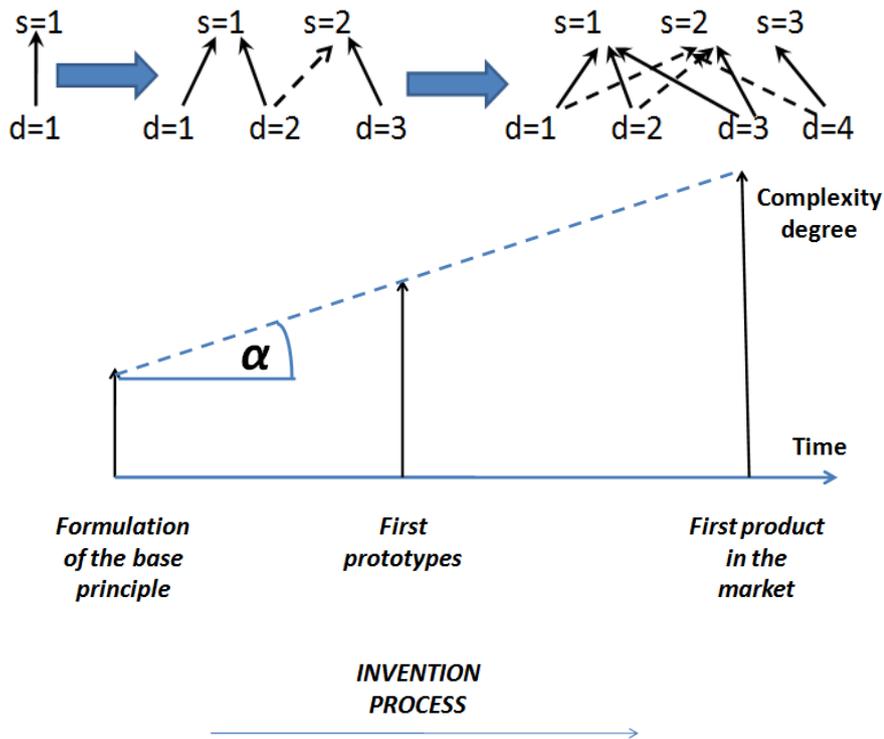


Figure 2. Structural deepening through the invention process

#### 2.2.4 Neighbor technologies.

In Figure 2, the slope (alpha) represents the growth of complexity during the invention process, which ends with the introduction of the first innovation in the market. Computer simulations of technological evolution have shown (Silverberg and Verspagen, 2005:199) that one decisive factor in an artifact's transition from "1 to 2, i.e., from discovered to viable (invented to innovated)" depends on the degree of development of its neighbor technologies in the broader technological space. The design space of one artifact can be conceived as belonging to a broader technological space of all the possible artifacts (Kaufmann, 1993; Dennet, 1995). In this broader technological space, the proximity between artifacts is defined by the presence of a common repertoire of design elements (Stankewitz, 2000). One of the main objectives of our empirical research is to explore the relationship between the structural deepening during the invention process of a particular artifact and the degree of development of its technological neighborhood. We will show that the rate of complexity growth –in the form of designed and unexpected relationships between elements- depends of this neighbor degree of technological development.

#### 2.2.5 Other theoretical issues.

Let us include here some comments about our framework. In Figure 2 the original complexity depends on the combination of bits of pre-existing knowledge in the mind of the inventor, as a single relationship between a single design element and a single service characteristic. This is a convention, as “the [original base] principle need not be simple” (Arthur, 2007: 276). However, the number of characteristics depends on the level of abstraction (Ulrich, 1995; Fowler, 1990), so, theoretically any original base principle could be depicted as in Figure 1. In the next section, we deal with the concrete level of abstraction adopted for our empirical case.

Figure 2 also depicts the relationship between complexity and the criterion of evolutionary fitness. Complexity, in the form of both new components and relationships in the design-service space, grows as more components are needed to improve performance until it is good enough for the product to be introduced into the market. This kind of selection can be understood in an evolutionary framework as based on a fitness level. In our case, the fitness levels are determined by entry to the market: for our analysis, the invention process ends when the artifact is introduced into the market as an innovation. We are aware that many important improvements are made after this first introduction, and that other fitness criteria can be conceived; however, here we focus on the often neglected process of technological change that precedes innovation (i.e., invention).

### **3. The history of the artificial disc.**

#### ***3.1. Hora and Tempus in the making: the importance of this case***

The histories of the two competing designs for artificial vertebral discs -a surgical prosthesis used in the treatment of spinal pain- provide an excellent example that increases our understanding of the factors influencing the depth of complexity during the invention process. Our work makes a substantial contribution since, to the best of our knowledge, the only empirical illustration of structural deepening so far is the example of the turbine technology in Arthur<sup>10</sup> (1993, 1994, 2009).

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<sup>10</sup> Arthur’s other examples refer not to the history of technology, but to computer simulations, the history of scientific ideas or the evolution of institutions.

The story of the two disc designs is appropriate for a comparative study because of their striking similarities. First, the processes were contemporaneous. The original base principles for the designs of the two artificial discs were formulated in the late 1950s and the first industrial prototypes were manufactured in mid-1980s also in both cases. Second, similar amounts of resources were invested in these processes of invention. In their work on the history of the artificial disc, which extends from the early 1960s to the early 2000, Bono and Garfin (2004) identify four relevant projects for one of these designs and six for the other. We also have data from Engelhardt (2004a, 2004b, 2006), showing that in the period 2000-2006 (following growth in the industry after FDA approval for the first artificial disc in the US) the numbers of projects during that period were respectively eight and eleven. Finally, we will show that similar typologies of agents -surgeons-inventors, university hospitals and small companies already established in the orthopaedic implant industry- participated in the development of the most important projects of the two designs.

### ***3.2 The case***

The condition we are interested in is the pain related to spinal disorders, which is the main factor in cases of pain and disability in the US. In the 1990s, health costs in the US associated with this spinal disorders accounted for an average yearly spend of \$34,000 million, not including the \$16,000 million from lost productivity (Errico, 2005).

Spinal pain is most commonly associated with Degenerative Disc Disease (DDD), which includes the natural ageing processes related to the discs forming the vertebral column. Surgical treatment of DDD consists of extraction of the diseased and painful disc. The artificial disc procedure (or arthroplasty) consists of substituting the articulation of the anatomical disc with an implantable artifact (Figure 3).

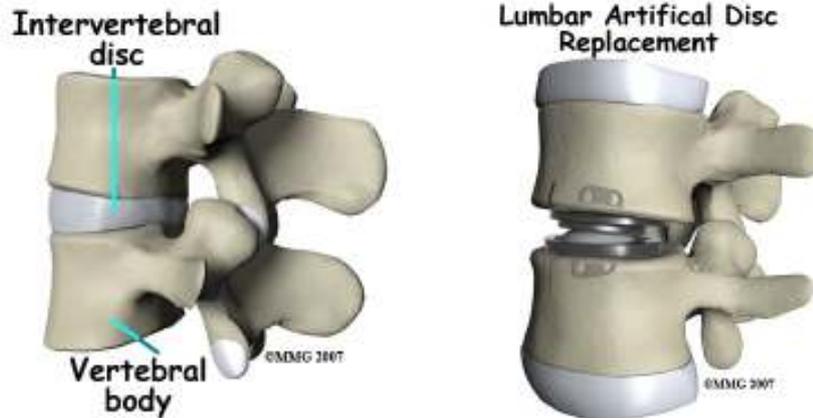


Figure 3. The anatomic intervertebral disc (on the left) and the artificial prosthesis (on the right)

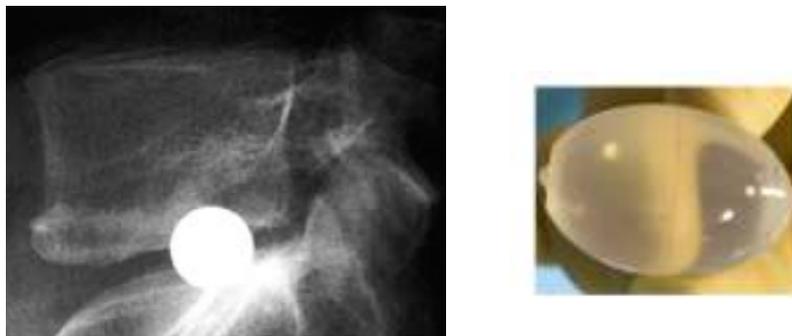
### 3.2.1 The base principles.

Two different base principles have been proposed for this kind of artifact<sup>11</sup>. They emerged contemporaneously (early 1960s). The inventors were two physicians (Alf Nachemson and Ulf Fernström), as is usual in medical technologies where lead users are often the sources of new ideas (Von Hippel, 1986; Metcalfe et al., 2005). The complexity of each idea was dependent on the personal knowledge bases of the two physicians. Nachemson was more science-oriented, with deep knowledge about the elastic properties of the anatomic disc. His doctoral thesis is a landmark work, and researches the loads of the spinal column using cadaveric specimens (Rydevik et al., 2007). Nachemson is considered a pioneer in modern scientific inquiry into the biomechanical behavior of the spinal column, and throughout his career his opinion was very influential<sup>12</sup>. Fernström was more surgery oriented and was less interested in the biomechanical sources of disc pain and more interested in finding a chemical explanation (Bono and Garfin, 2004; Naveira, 2008; Young, 2007). His idea was to use a solid-rigid sphere (made of stainless steel) to substitute for the damaged disc. The solid-rigid sphere would give mobility to the disc articulation. Nachemson, based on his

<sup>11</sup> Similar classifications of two base principles can be found in work on the technological history of the artificial disc (Spalzski et al., 2002; Bono and Garfin, 2004; Lee and Goel, 2004).

<sup>12</sup> “It is rare, in a lifetime, to have had such a profound impact on so many people and, in fact, on a whole medical specialty” (Rydevik et al., 2007:303)

biomechanical knowledge<sup>13</sup>, focused more on the elastic properties of the anatomic disc (such as shock absorption), which cannot be mimicked using a solid-rigid ball such as Fenström's. Instead of a solid-rigid artifact, Nachemson used a silicone ball and developed his idea in elastic prototypes, which were tested on cadaveric specimens, and which failed after a few simulated iterations of walking (Szpalski et al., 2002). Fenström's idea was much better developed: more than 100 human subjects<sup>14</sup> were fitted with the stainless steel prosthesis, with very poor results in the 3-4 years of follow-up (Bono and Garfin, 2004). The failures were caused by the sphere's geometry, which could not reproduce the properties of cylindrical discs to support adjacent vertebrae (Figure 4).



*Figure 4. On the left: a radiography of a Fenstrom ball 3 years after surgery. The steel ball has become encrusted in the bones because of the high pressure exerted in the original one-point contact between vertebrae and ball (source: Bono and Garfin, 2004). On the right: a silicone prosthesis similar to the ones Nachemson used in the cadaveric trials (source: Bodiwala et al., 2007)*

We will discuss the origins of these two operational principles in terms of technical and service characteristics. In Fenström's case (left in the Figure 5), the only service to which the sphere is related is mobility of the intervertebral space. In Nachemson's case, other services related to elasticity are present, namely the shock absorbing properties of the anatomic disc.

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<sup>13</sup>Nachemson was very critical of Fenstrom's procedure. Their different approaches not only caused different base principle complexity, but also an angry professional dispute, with Nachemson referring to Fenström's prosthesis as "the rape of the spine".

<sup>14</sup>Young (2007) affirms that "probably" this series of patients intervened with Fenström's spheres included President JF Kennedy.

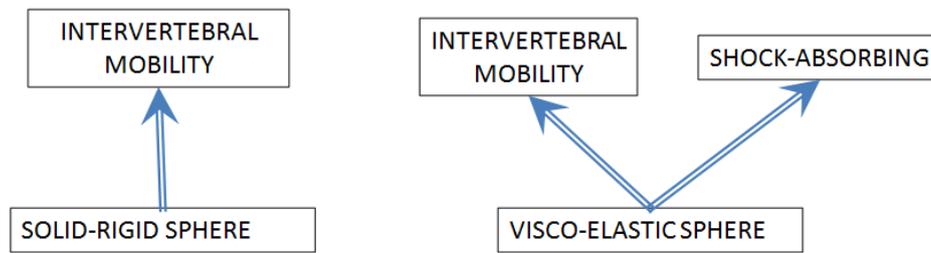


Figure 5. Technical-service characteristics of the Nachemson (right) and Fenström (left) spheres

In terms of the level of analysis selected for the design-service characteristics map, we showed in Section 2.2.2 that the number of characteristics in the design-service spaces depends on the level of abstraction chosen. For the design characteristics, we chose what Ulrich (1995) describes as the “iota level”, the level of individual pieces. For example, in the automobile industry, the iota level in a General Motors vehicle is the parts resulting from a complete disassembly of a vehicle, including the last nut, bolt or washer (Ulrich, 1995:423). The simplicity of Nachemson’s and Fenstrom’s spheres helps us to maintain a level of complexity of the design space which is easily understandable through our narrative approach<sup>15</sup>. The service space of the Fenstrom and Nachemson implants follows the classification of Lee and Goel between two “subgroups”: “disc prosthesis for motion and shock absorption” and “disc prosthesis for motion” (Lee and Goel, 2004: 211-213S).

### 3.2.2 Structural deepening (mid 1980s-early 2000s)

Bono and Garfin (2004:147S) explicitly consider the notable clinical failures of the Fenström early prostheses as lessons learned for new developments carried out in the early 1980s, which added new components and complexity to the original base principle; we have characterized this phenomenon of growth of complexity as structural deepening to enhance basic performance. Nachemson’s and Fenstrom’s early prototypes needed the addition of two surfaces acting as intervertebral plates between the ball and the adjacent vertebrae (Bono and Garfin, 2004). The silicone prosthesis was attached to two metallic vertebral plates, forming a sandwich structure (Figure 6). Fenstrom’s solid

<sup>15</sup> Theories of technological complexity often uses relatively simple artifacts to illustrate their concepts. Alexander (1964) illustrates his theory with the example of a coffeepot. Baldwin and Clarck (2000) use the example of a coffee mug.



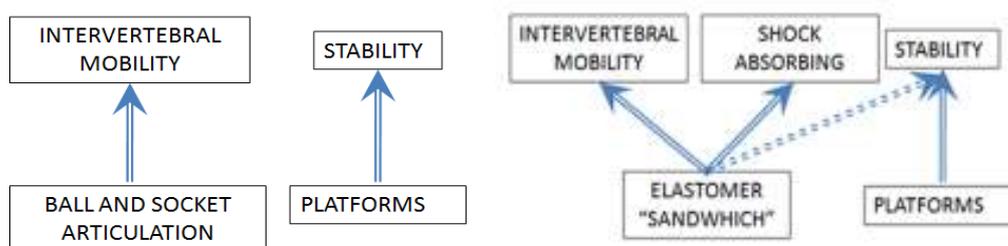
kinds of designs (“hip-like” and “mimetic”) were very different. The first important hip-like project began in 1982 in Charité Hospital in the University of East Berlin, when the surgeons Kurt Schelznack and Karin Buttner-Janz started the design of the SB Charité, the first artificial disc to be implanted commercially in France in 1989. In 1986, Waldemar Link, a West Germany orthopaedic implants company, joined the project. The hip-like design was in regular clinical use in Europe in 1989, and in the US in 2004. Since then 10 hip-like designs emerged and have been used in Europe up to 2006 and 3 have been used in the US up to 2007 (Barberá et al., 2010; FDA, 2007).

Mimetic disc have failed to reach regular clinical use until recent years, when this type of disc have experimented a renaissance: 3 of them were approved for its use in Europe in the last 4 years and are currently performing pre-approval experimental trials in the US. But, during the 1980s and the 1990s, there were several mimetic artificial disc projects which had to be aborted after the failure of important design and testing efforts. One important mimetic project was developed by Acromed, an orthopaedic implant company. Led by the surgeon Arthur Steefe, the so-called Acroflex disc project during in pre-FDA approval conducted experimental human trials, in 1988-1989, 1993-1994 and 1998-2000, but all failed. Another major mimetic project was led by Dr. Casey Lee, and several collaborators including Ethicon (a Johnson&Johnson company) and the University of Medicine and Dentistry of New Jersey. Although this project did not arrive at experimental human trials, it was thoroughly tested in the laboratory, in at least two different series, involving more than 100 prototypes of the disc (Lee et al., 1991; Vuono and Hawkings, 1995).

In section 2.2.2 we showed that for an invention to become an innovation (i.e., to be introduced into the market) it can be understood as having achieved a fitness level within an evolutionary framework. In our case, this kind of market selection is easily identified because medical technologies have to be approved prior to their introduction in the market, by institutions such as the US Food and Drug Administration (FDA), and the European Commission’s Notified Bodies. It is important to state that this fitness criterion does not necessarily represent an “objective” statement about the differential performance of the operational principle. In fact, there is no scientific unanimity about the theoretical performance of the mimetic disc as opposed to the performance of the hip-like prosthesis since there is still significant uncertainty about the existence of the

shock absorption characteristics of the anatomic disc (Le Huec et al., 2003). For advocates of the hip-like disc, the elasticity of the anatomical disc (if it exists) is irrelevant, and the prosthetic restoration of movement is sufficient (Mayer, 2005). For advocates of the mimetic disc, artificial discs that do not absorb load will have poor long term results (Van Ooij et al., 2003).

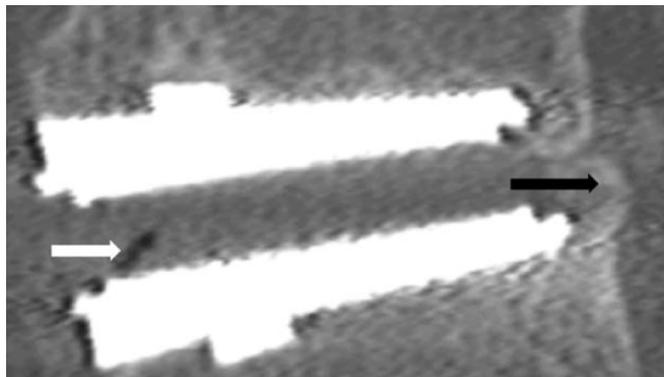
The FDA gives approval only when it considers that the “safety” and the “efficacy” of the device being considered is proven. The European Commission bodies are concerned only with “safety”. Proof of the relevance of institutions in building selection criteria is expressed in this difference, cited as the reason for the “slowdown of translation of those technologies into treatments” in the USA compared to Europe (Miller, 2004: 2).



*Figure 8. On the left, a technical-service characteristics representation of a hip-like disc prosthesis: on the right, a representation of the mimetic principle*

However, although socially constructed, our point is that this institutionally sanctioned safety and/or efficacy can be interpreted as a fitness value that can be used to calibrate chronologically the success of different artifacts, and to relate this success with their degree of complexity, as in Simon’s fable. Our interpretation is that the different success of the two operational principles in achieving this fitness criterion (i.e., in arriving on the market) was due to the more complex structure of the mimetic design. Figure 8 depicts the technical and service characteristics of the two operational principles in the 1980s and 1990s. The hip-like principle is represented on the left. The “ball-and-socket” technical characteristic assures the “mobility” service. The “platforms” are responsible for the “stability” of the construct, which is added as a service characteristic after the stability failures of Fenström’s sphere (Bono and Garfin, 2004; Lee and Goel, 2004).

The representation of the mimetic design which failed in the 1980s and 1990s is more complex (Figure 8, right). There are more services (“shock absorbing” is added), and moreover the elastic layer (or “elastomer”) has an unexpected influence on “stability” (dotted arrow in Figure 8)<sup>16</sup>. This influence is evident in the failures of the most sophisticated of the Acroflex mimetic prototypes, tested in a multiclinical and multinational trial effort (Fraser et al., 2004) conducted by Acromed. The mechanical failures of the elastomer, which occurred in ten out of twenty-eight cases, compromised the stability of the entire construct (Figure 9). The failures had a typical pattern: “anteroinferior peripheral tears” (Fraser, 2004:248S). It has to be highlighted that the failures were “unexpected given that the device was extensively tested in the laboratory and had easily withstood the range of described normal in vivo loads on the lumbar intervertebral disc” (Fraser, 2004:250S). Thus, the deleterious effect of the in vivo constraining loads on the elastomer integrity could not have been predicted with existing knowledge.



*Figure 9. A failed mimetic in disc during a clinical trial. The white arrow indicates the failure in the interface between the elastic part and the metallic plates. The black arrow indicates the displacement and instability of the prosthesis (source: Fraser, 2004).*

### **3.2.3. Neighbor technologies**

The higher complexity of the mimetic disc was due first to the different knowledge base of the inventors. This resulted in the original service requirements of the elastic design

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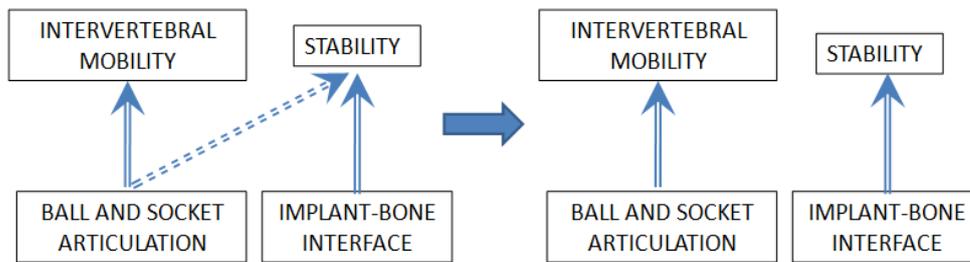
<sup>16</sup> Referring to these discs, Lee and Goel (2004:211S) give a very similar service description: “Total disc prostheses restore the function of the disc for motion, stiffness and stability”.

being more numerous than those of the solid-rigid design: elasticity as well as mobility was required.

We argue that the second reason for the less complex hip-like disc design stems precisely from this neighborhood between the implant and the hip prosthesis in the broader technological space. In 1962 Sir John Charnley began to experiment with a plastic material, UHMWPE (Ultra High Molecular Weight Poly Ethylene) in a ball-and-socket articulation. Charnley discovered that UHMWPE particles, which were the result of friction in the articulation, did not provoke the dramatic allergic reactions in the bone-implant interface caused by the plastic materials formerly used. The migration of these particles to the contact surface between the bone and the implant caused systematic loss of stability of the prostheses; but UHMWPE particles in this immunologic sense were almost harmless. In a technical-service framework, it could be said that UHMWPE broke the initially unexpected influence of the ball-and-socket articulation in the stability of the implant (dotted arrow in Figure 10), since the particles did not cause the allergic reaction that had caused the previous failures of the hip prosthesis. The introduction of UHMWPE transformed hip surgery: during the 1960s, some 100 experimental hip prostheses were implanted annually, worldwide. In 1972, surgeons were performing up to 50,000 hip surgeries<sup>17</sup>. The number of these surgeries in the US in 2003 was 300,000 (Gómez and Morcuende, 2005). Even more important, UHMWPE began to be used in other prostheses, such as knee and shoulder (Crowninshield, 2000). The knee prosthesis case was especially important and have resulted in more knee than hip replacements during late 1990's (Mendenhall, 2000). The success of UHMWPE has focused research in the industry on this type of biomaterial, to optimize friction behavior (Miller, 2002).

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<sup>17</sup> In 1972, in the keynote speech at an orthopaedic congress, Professor J.E Dunphy said: "Orthopaedic surgery was on the verge of one of its finest eras. The triumphs of joint replacement had been made possible by Dr. Charnley of Manchester" (in Anderson, 2007:156).



*Figure 10. The technical-service characteristics map of the hip prosthesis, before and after the introduction of UHMWPE in the ball-and-socket articulation. The no influence of UHMWPE particles on the stability of the implant is the reason for less complexity in the map of the right.*

Unlike the hip-like principle, mimetic discs had no neighbor technology and no source of R&D “spillover”. In the former case, spillovers from hip prosthesis technology helped the artificial disc to achieve a satisficing degree of complexity more quickly. The materials used in the mimetic prosthesis were also used in finger joint prostheses (Engelhardt, 2003), but the load is much smaller than in the case of an intervertebral discs, and the metal plates interfacing with the elastic components were not required. These were causing big problems in the mimetic projects of the 1980s and 1990s.

Furthermore, litigation against Dow Corning for failed breast implants provoked some big companies to abandon the market for elastic biomaterials, as silicones, which had been used in the mimetic projects; research on plastic biomaterials experimented a “crash” due to this litigation during the 1990s (Reisch, 2007)<sup>18</sup>.

“Arrogantly judging our forebears in the light of modern knowledge perforce unavailable to them” is, according to Stephen Jay Gould, the greatest of all historical errors<sup>19</sup>. Although retrospectively it might seem obvious to take advantage of the development of the hip prosthesis, at the time the outcomes were not clear. As Engelhardt (2003:7) said, “it became part of the AcroMed culture to ridicule” SB

<sup>18</sup> Robert Ward, founder of the Polymer Technology Group, a Berkeley based company devoted to research on plastic biomaterials, said that the departure of big suppliers such as DuPont and Dow Corning in the 90’s left the field wide open to small companies such as his. Ward participated as consultant and supplier to Medtronic and Axionmed in the development of artificial disc projects during the early 2000s (Reisch, 2007).

<sup>19</sup> Quoted in Gaddis (2002:140).

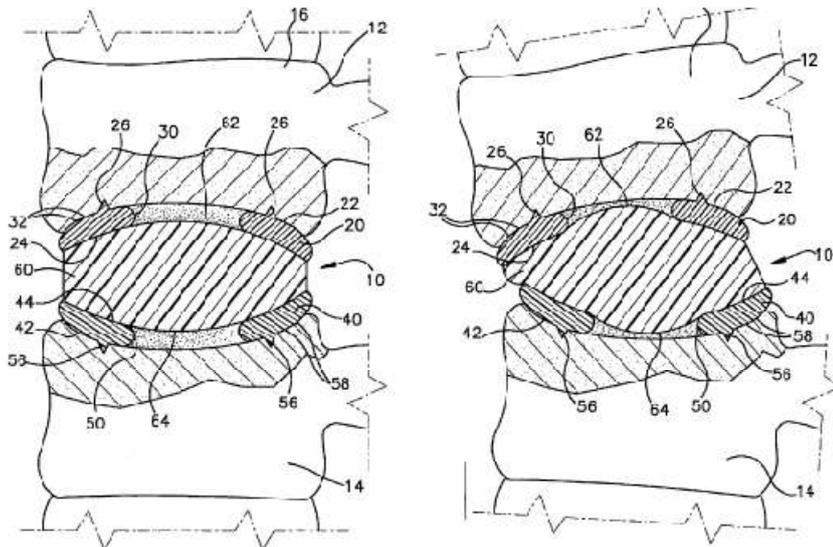
Charité for its inability to reproduce the viscoelastic behavior of the anatomic disc. For Acromed engineers it was clear that “Acroflex technology would easily eclipse it, and relegate it to the museum of things that didn’t work”.

There is some irony in the conclusion of the Acroflex-SB Charité rivalry. In 1998, when the last series of the Acroflex experimental clinical trials was launched, Depuy Orthopaedics bought Acromed (New York Times, 1998a). Depuy, which was founded in 1895, was the oldest company in the orthopaedics sector. A few months later, Johnson&Johnson bought Depuy (New York Times, 1998b). “Although the [Acroflex] project continued, it was ultimately shut down, and along with it, the corporate legacy” (Engelhardt, 2003:7) of the mimetic design. Finally, in 2003 Depuy Acromed, the Johnson&Johnson company, bought Link Spine Group, a subsidiary of Waldemar Link devoted to the development and commercialization of the SB Charité artificial disc for 325 million \$ (New York Times, 2003).

#### ***3.2.4 Architectural stabilization***

The mimetic design did not receive the same “help” from neighbor technologies as the hip-like design, which had previously solved the unexpected interactions between the ball-and-socket articulation and the stability of the implant. The industry required to carry this help in the mimetic case, the plastic biomaterial industry, crashed as a result of litigation. Thus, to overcome problems with the sandwich elastomer which had a negative and unexpected influence on the stability of the design, the mimetic projects had to achieve better results through the operation of what we call “architectural stabilization”.

One of these projects was conducted by someone previously involved in the failed Acroflex project. Axiomed was founded in 2001 by James Kuras, a former employee of Acromed (PR Newswire, 2003). Kuras was one of the engineers in charge of development of the Acroflex disc, and is named as an inventor on at least two patents associated with this device (US5824094 and US6162252).



*Figure 11. Freedom disc design. An opening in the plates limit the amount of stress in the elastomer. Source: US6607558*

Axiomed is a one-product-company which develops a mimetic artificial disc design, the so-called Freedom disc. The designs of the Freedom disc and the Acromed device are similar: two metal platforms and an interposed elastomer core which form a sandwich structure. But the platforms have two openings to avoid failures of the constrained elastomer, which happened in the Acroflex case: “the core expands energy when the core deflects into the opening to limit the amount of stress in the core” (Figure 11). The Freedom disc was finally approved for clinical use in Europe in 2009 (Axiomed, 2009).

A similar operation has been carried in other improvement of the failed mimetic projects of the 1980s. This was the project led by Dr. Casey Lee. Lee and Alastair Clemow (a former Ethicon employee, who was involved in Lee’s 1980s-1990s projects) in 2004 founded Nexgen, a start-up devoted to the development of a mimetic artificial disc, the so-called “Physio” disc. This new design is a typical elastomer-metal sandwich configuration, but as in the Freedom case, the research concentrated on improving the design architecture. Systematic laboratory research was conducted to calculate empirically the optimal proportions between the height and the width of the elastic component to optimize its behavior under load constraints (Figure 12). The rationale for

the final proportions (3 times wider than its height) is detailed in patent application US20070032874.

We describe the Physio and Freedom efforts to eliminate the negative and unexpected relationship between the elastic component and the stability of the implant in the mimetic principle, which caused the failure of the Acromed project (see Figure 13). This resonates strongly with the definition of “architectural innovation”, a very closely studied concept in the management of technological change (Operti, 2009). Architectural innovation consists of changing “ the way components are linked together...while leaving the core design concepts ... untouched” (Henderson and Clark, 1990:12).

But the term architectural innovation is usually employed to describe a strategy to create a modular design (Operti, 2009). A typical example of such an architectural innovation aimed at modularization was the development in the IBM/360 project in the late 1960s described by Baldwin and Clark (2000), which created the modular architecture of modern personal computers. We prefer the term “architectural stabilization”, which is formally identical to Henderson and Clark’s definition, but refers to a much earlier phase in the evolution of the technology, namely the invention process. Following the example of the history of computers, architectural stabilization is more related to what Baldwin and Clark (2000) call the “fragmentation” of the ENIAC computer in a less integrated design in late 1940s. Charnley’s idea of using UHMWPE to avoid the influence of the ball-and-socket articulation in the stability of the hip implant can be interpreted as “architectural stabilization” (Figure 10). It was the absence of this stabilization in the mimetic principle that forced the improvements described in the Physio and Freedom projects. To sum up, architectural stabilization is not a conscious modularization strategy, but is a way to deal with the complexity related to structural deepening in the early phases of technology development.

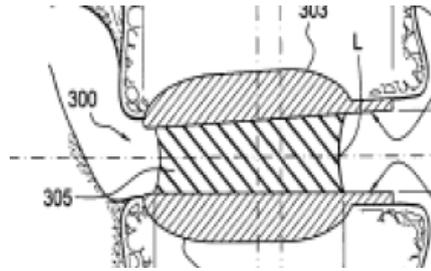


Figure 12. The Physio disc. The relationship between the height and width of elastic component (US20070032874).

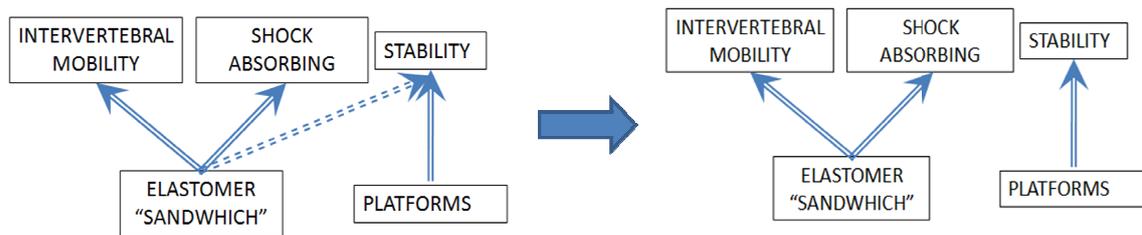


Figure 13. The improvements of the Physio and Freedom discs eliminated the deleterious relationship between the elastic component and the stability of the implant in the mimetic principle.

#### 4. Conclusion.

Figures 14 and 15 summarize our story in complexity terms. Figure 14 shows that the mimetic project had to deal with greater technological complexity since the original complexity of the base principle was higher in the case of the Nachemson viscoelastic sphere, which was conceived to achieve both mobility and shock absorption. Also, the “depth” of the mimetic structural deepening process (Beta) was higher in the mimetic case. Architectural stabilization was necessary to eliminate the unexpected relationships between elements which appear during this mimetic structural deepening process, which in turn meant a considerable delay compared to the hip-like principle, which borrowed its architectural stabilization from Charnley’s research. Figure 15 (at the end of the paper) represents this dynamics in terms of the evolution of the design-service maps.

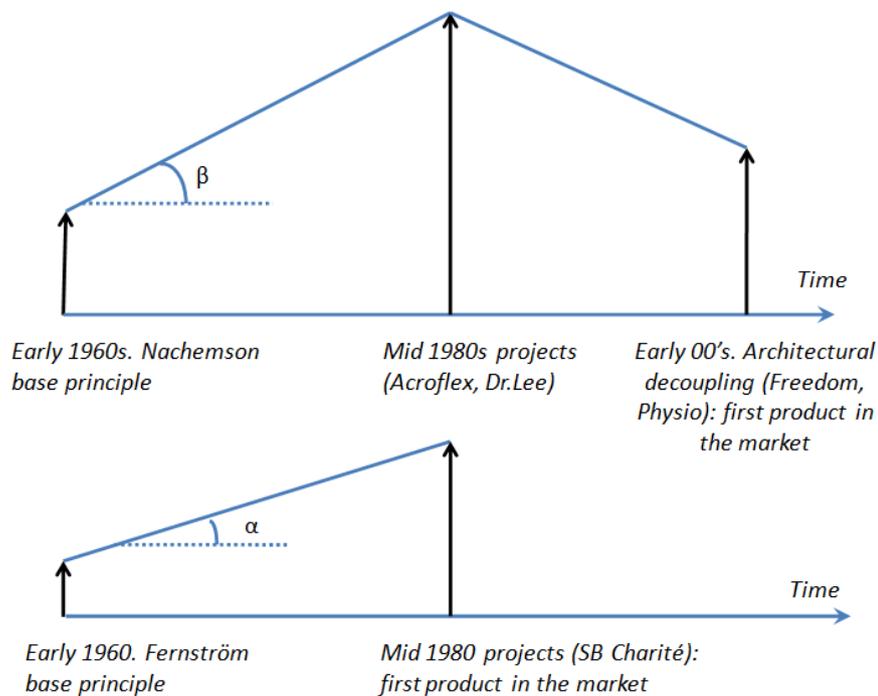


Figure 14. Complexity degree during the invention process in the mimetic (above) and hip-lile (below) principles.

This study describes the (invention) process of emergence of complexity in two artificial disc designs. In his study about the historical method, John Lewis Gaddis pointed out that (2002:62) “the distinction between structure and process corresponds to the one between present, where structures exist, and the past, where processes produced them”. We have tried to explain the degree of complexity of present structures/designs describing the past processes and contingencies involved in producing them.

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## HIP LIKE PRINCIPLE

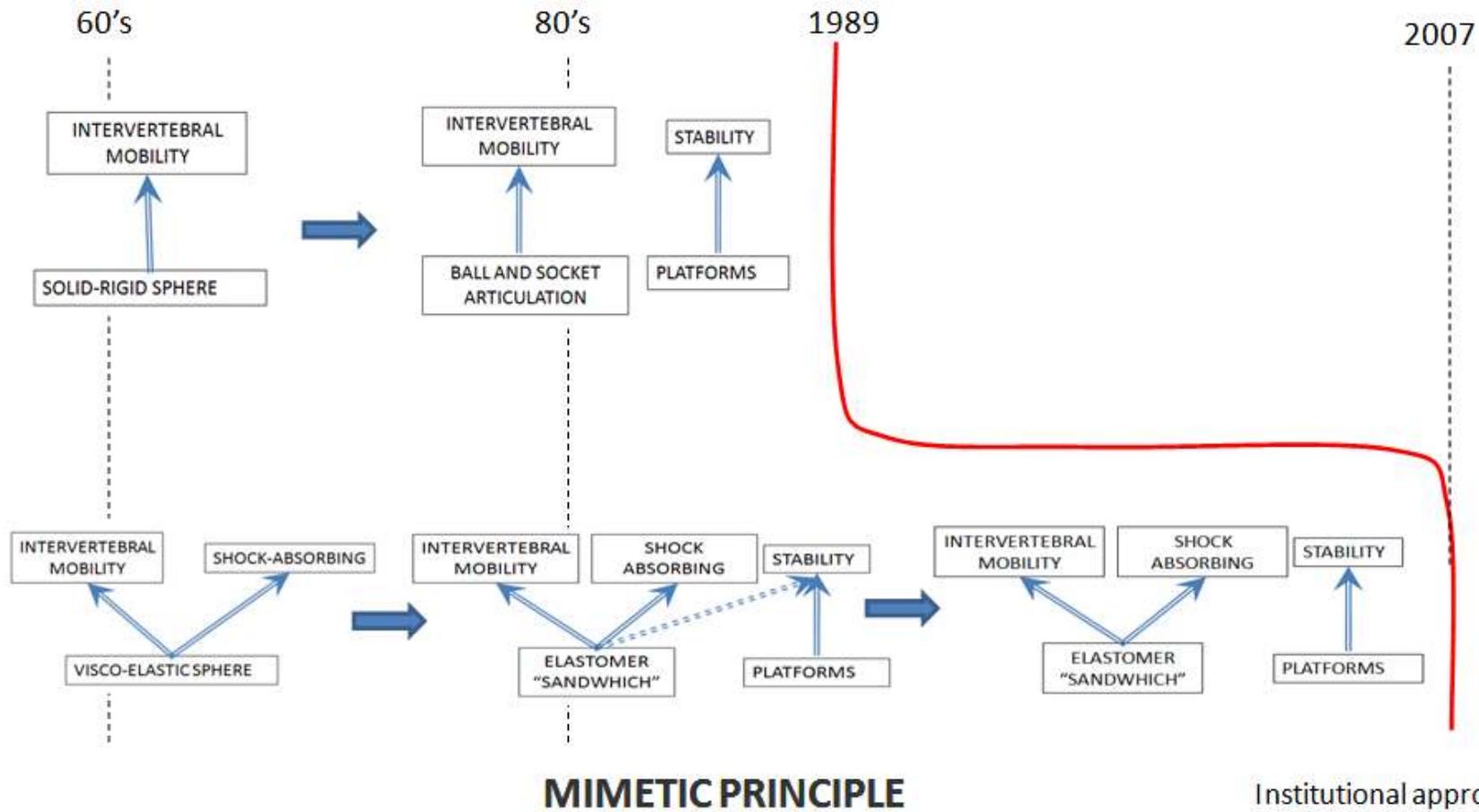


Figure 15. Evolution of the design-service maps.