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IDENTIFYING RECENT DEVELOPMENTS IN KNEE PROSTHESES THROUGH A PATENT ANALYSIS

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ABSTRACT

Artificial knees represent an important issue for a global technology trends analysis. On average, the growth rate of knee replacement surgeries increased by nearly 50% over the past decade in Organization for Economic Cooperation and Development (OECD) countries. This study focuses on a patent analysis as a part of a Competitive Technical Intelligence methodology. The aim is to provide organizations in this industry with insights on knee prostheses research, particularly to determine the most active patenting entities as well as their focus of research. The topmost in each category: inventors, organisations, technology classifications, advanced materials and top keywords were determined.

Keywords: patent analysis; international patent classification; knee prosthesis; knee replacement; competitive technical intelligence.

1. INTRODUCTION

Knee replacement through prosthesis is considered the most effective intervention for severe osteoarthritis and other bone diseases. On average, the growth rate of knee replacement surgeries increased by nearly 50% over the past decade in the 34 Organisation for Economic Co-operation and Development (OECD) countries. According to OECD, the United States had the highest rate of knee replacement, followed by Austria, Germany and Switzerland. The United States by itself had the highest rate of knee replacement in 2013, with 226 knee replacement surgeries per 100 000 population [1].

Knee replacement surgeries are increasing swiftly every year around the world. According to the American Academy of Orthopaedic Surgeons, in the United States, approximately 270, 000 of these operations were performed in 2009 and over 721, 000 in 2010 [2].

More than 4.5 million people in the United States are currently living with at least one knee prosthesis. In 2009, knee replacement represented the 14th most common surgical procedure in the United States [3]. This surgical procedure consists of replacing damaged parts of the knee joint with artificial parts; the part between the knee joint and the knee-cap is filled with metal and plastic to cap the ends of the bones [4].

Knee prosthesis specialists place emphasis on the design and resistance of the prosthesis, as it should support the body weight. The forces exerted by the tibiofemoral joint may cause polyethylene wear and excess stress distribution on the implant, on the bone interface and on the underlying bone, thus affecting the longevity of the knee implant [5].

Through patent analysis, we intend to detect main trends in the technologies used in knee prosthesis development. The main technology standard classifications, inventors and companies involved are identified in this approach.

2. PROSTHESIS CHARACTERISTICS

Materials used in prostheses are deeply studied by surgeons and researchers. One of the major factors restricting the longevity of knee implants is the wear on ultra-high-molecular-weight polyethylene in knee and hip prostheses. In fact, knee prosthesis materials may suffer from wear or scratches. This condition is commonly observed in the metallic femoral components of retrieved knee prostheses that have anatomical designs [6].

Fixed-bearing and mobile-bearing are the two main types of prostheses. Although both types provide a relatively natural joint, they differ in the design of the polyethylene insert. In a mobile-bearing prosthesis, the polyethylene “can rotate short distances inside the metal tibial tray" [7], while in a fixed-bearing prosthesis, the “polyethylene of the tibial component is attached firmly to the metal implant beneath” [7]. Therefore, fixed-bearing prostheses are mainly used when the condition of the patient's soft tissue does not allow for the use of a mobile-bearing prosthesis.

3. METHOD

3.1. Competitive technical intelligence

Competitive Intelligence (CI) is “the process of ethically gathering and refining sufficient information to make a strategic business decision” [8]. Although, CI can contribute in both strategic and operational contexts, the strategic context is crucial for the achievement of long-term goals [9].

Some of the key areas in which competitive action can have a profound effect on a company’s performance include technology, finances, distribution, market and suppliers, among others [10]. Therefore, a company should focus on technological areas to gain insights from competitors’ products, manufacturing processes, technologies, etc. Thus, including the technological aspect in the CI concept is mandatory in this approach. As a result, Competitive Technical Intelligence (CTI) is conceived. CTI is defined as “the analytical process that transforms disaggregated competitor technology data into relevant and usable strategic technology knowledge about competitors’ positions, sizes of efforts and trends” [11].

3.2. Patent analysis

One of the most valuable tools in the CTI area is patent data analysis, as established in several research studies [12, 13, 14, 15, 16]. Patents represent an important source for monitoring an organization, as they embody technological novelty, which translates to strategic advantages [17]. Technology monitoring is an important process since is often used to identify and evaluate the critical technological advances that can have a significant impact on a company's competitive positioning [18]. Patents constitute a powerful tool in technology monitoring for identifying developments in technology, determining state of the art and foreseeing future advancements [19]. Moreover, through a patent analysis, it is possible to create technology maps, identify main organisations and inventors involved and detect main research areas. Similarly, patent analysis could help organisations to develop innovation roadmaps, in order to maintain competitive in fast-paced industries [20].

Patent trends in an industry could influence the research and development (R+D) strategies of all involved actors [16]. In fact, the level and quality of a company's overall R+D activities can be benchmarked against its relevant competitors using patent portfolios. [21].

Several worldwide databases contain patents, such as:

- USPTO - Patent database of the United States with full text and images.
- Espacenet - Patent database of the EPO (European Patent Office), with more than 80 million patent documents from over 90 patent-granting authorities worldwide.
- WIPO PATENTSCOPE - Patent database of the World Intellectual Property Organization.
- JPO - Patent database of the Japan Patent Office.

For this research, we applied Patent Insight Pro, a patent research, analysis, mapping and visualisation software program. Developed in India in 2004, this software provides decision support solutions, information analysis and technology monitoring. Patent Insight Pro provides global services to industries such as energy, electronics, medical devices, etc. [22]

3.3. Competitive technical intelligence through patent analysis

Figure-1 shows the 6-step methodology, developed by Escorsa and Rodriguez [23], that was used in this research.

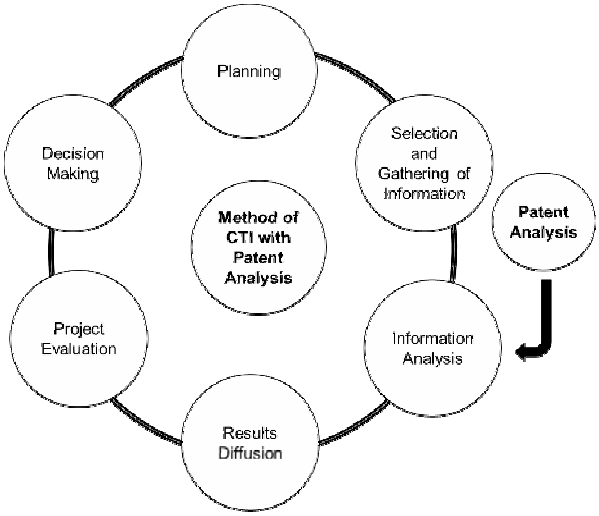

Figure-1. Escorsa and Rodriguez CTI Six-Step Methodology [23].

The six steps from Figure-1 are described as follows:

a) **Planning:** This step refers to the statement of objectives, scope and limitations and involves the allocation of resources and responsibilities.
b) **Selection and gathering of information:** Primary and/or secondary sources of information are chosen and gathered. In our case, we used patents as the source of information.
c) **Information analysis:** Different methods could be used. In this case, we developed a patent statistical analysis.
d) **Diffusion of results:** In this step, information is disseminated to stakeholders.
e) **Project evaluation**.
f) **Decision making**.

3.3.1. Planning

In this phase, we established the scope, objectives and participants of the project. The research focused on patents published in the last 5 years. The objective was to identify top companies, inventors and trend technologies developed in the biomedical field of knee prostheses.

3.3.2. Selection and gathering of information

The collection and analysis of patent data were performed using the Patent Insight Pro software program. We selected the time period from 2009 up to March 21, 2014. This search was conducted on the Espacenet Database to retrieve a high number of patents worldwide, which would provide an accurate perception of the latest progress in this field.

We first performed the search in the abstract and claims sections of the patent documents using (knee AND prosthesis) as keywords and obtained 13, 902 results. However, some results were not within the scope of our research because in some cases, the main keywords were not listed as the patent's central invention. We then

modified our search to the title and abstract of the patent documents using the same search string and obtained 775 results.

Upon analysing the obtained results, we added the term "joint" to the search string to delimit the results to a more specific research area.

Finally, to perform the search, we used the terms (knee/"knee joint" AND prosthesis) as the main keywords. The established keywords provided accurate results according to the scope of our analysis.

To perform the search in Espacenet, we used Boolean terms to transform our keywords into a search string. Through the patent search in Espacenet, we obtained the following results:

- 567 published patents (224 patent families and 343 individual issued patents), 268 assignees, 561 inventors, 20 IPC (International Patent Classification) main groups, 19 CPC (Cooperative Patent Classification) main groups and 9 USPC (United States Patent Classification) main groups.

Figure-2 presents the patenting trend by year. The X-axis in the graph indicates the years, while the Y-axis indicates the number of patents. As we can see, prior to 2012, there was little, but stable, growth; however, between 2011 and 2012, there was a marked increase of 73% in the number of patents.

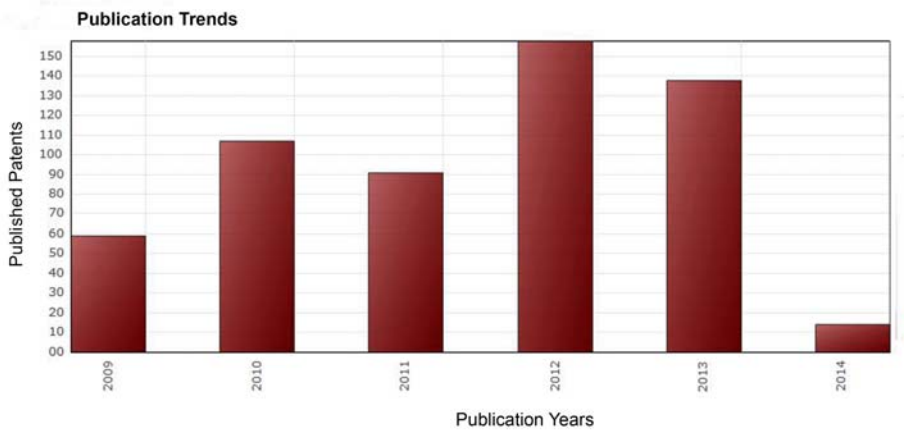

Figure-2. Patenting trend. Data from Espacenet through Insight Pro.

4 RESULTS AND DISCUSSIONS

4.1. Processing

Once we obtained all of the patent documents, we proceeded to filter and clean up the 'Assignees' and the 'Inventors' fields. This task is useful for merging similar inventor names, updating patent information to the latest assignees, avoiding repeated information, etc. In fact, in this stage, internal keywords were identified (453 different keywords in total) among the most repeated words in the Title, Abstract and Claims sections of the 567 patents. These keywords were later used for further analysis stages. From the 561 inventors detected from the total patent documents, we identified the Top 5, as shown in Table-1.

Table-1. Top 5 Inventors. Data from Espacenet through Insight Pro.

Inventors	Patents
Wagner Christel	41
Wyss Joseph	36
Deffenbaugh Daren	35
Azerbrouck Stephen	33
Gomaa Said	31

Organizations with the highest numbers of patents were also identified and are shown in Table-2.

Table-2. Top 5 Assignees. Data from Espacenet through insight Pro.

Assignees	Patents	Country
DePuy Products Inc.	109	US
Zimmer Inc.	65	US
Biomet Manufacturing LLC	48	US
Smith and Nephew Inc.	21	GB
Exactech Inc.	19	US

We also determined the patenting trend for the Top 5 Assignees during the past five years, as shown in Figure-3. This graph shows that both DePuy Products Inc. and Zimmer Inc. have been experiencing significant increases in their patent activities since 2011.

The International Patent Classification (IPC) is described as a hierarchical system of language-independent symbols for the classification of patents and utility models according to the different areas of technology to which they pertain [24].

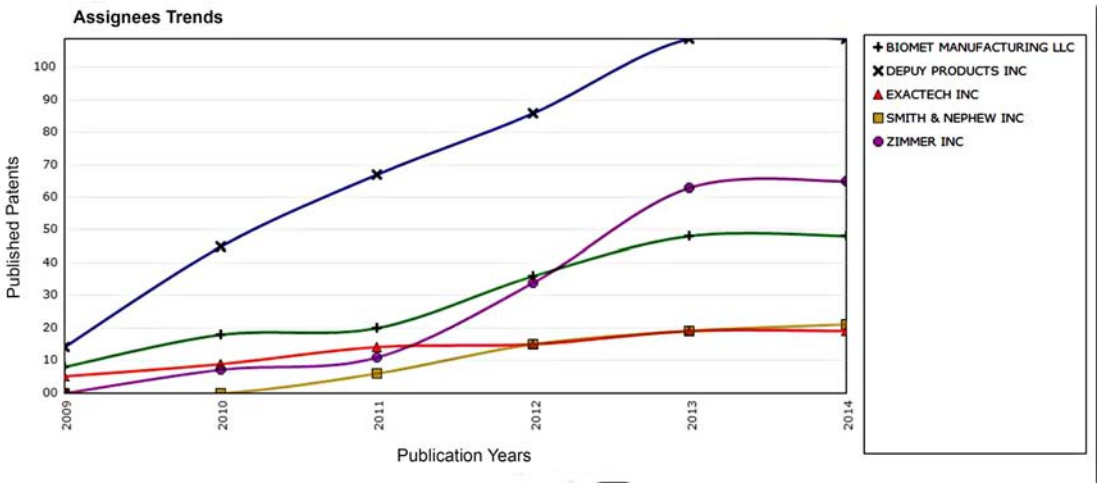

Figure 3. Top 5 Assignees' Patenting Trends. Data from Espacenet through Insight Pro.

To identify the main research areas in the knee prosthesis field, we analysed the main International Patent Classification codes from two groups: 4-Digits and Full Digits. The IPC 4-Digits group refers to more general technological classifications, i.e., class and subclass, while IPC Full Digits considers class, subclass, group and subgroup.

4.2. International patent classification 4-digits

Table-3 shows the Top 4 IPC 4-Digits obtained in our research. We present their technical areas based on the World Intellectual Property Organization [25].

Table-3. Top 4 IPC 4-Digits. Data from Espacenet through insight Pro.

IPC 4-Digits	Patents	Technical area
A61F	523	Filters implantable into blood vessels; prostheses; devices providing patency to, or preventing collapsing of, tubular body structures, e.g., stents; orthopaedic, nursing or contraceptive devices; fomentation; treatment or protection of eyes or ears; bandages, dressings or absorbent pads; first-aid kits.
A61B	75	Diagnosis; surgery; identification (analysis of biological material).
A61L	9	Methods or apparatus for general sterilisation of materials or objects; disinfection, sterilisation, or deodorisation of air; chemical aspects of bandages, dressings, absorbent pads or surgical articles; materials for bandages, dressings, absorbent pads or surgical articles.
G01N	4	Investigation or analysis of materials by determining their chemical or physical properties.

As we can see, both A61F and A61B are the leading 4-Digit International Patent Classification classes. The incidence of the patents in these classes is considerably higher than the next two IPC classes: A61L and G01N.

IPC G01N (Investigating or analysing materials by determining their chemical or physical properties) represents a recent research area, as it only emerged in 2012 and 2013. Nevertheless, it contains 4 patents, each with a very specific invention focus. These patents are:

a) CN101561358. Artificial knee joint prosthesis simulated motion tester.
b) CN102680344. Six-degrees-of-freedom parallel and oscillating guide bar mechanism combined knee-replacing prosthesis abrasion tester.
c) CN202355480. Two-stage transition and two-stage shift motion synthesis knee displacement prosthesis tibiofemoral joint abrasion tester.
d) CN202676561. Six-degrees-of-freedom paralleled and swinging guide rod mechanism combination knee replacement prosthesis abrasion machine.

The main inventions of these four patents are simulation testers for knee joints. These knee joint simulation testers can perform knee prosthesis abrasion tests, which can simulate the motion characteristics of the

knee joint of the human body, providing data for total knee replacement surgeries. Testers have high practical value and broad application prospects in the fields of biomedicine and medical equipment manufacturing because mechanical testing is an important step in the manufacturing and design of total knee replacement components [26].

4.3. Advanced materials search

An advanced materials search was conducted within the group of the 567 world patents analysed, in the Title, Abstract and Claims sections. These materials were first identified using search terms such as alloys, materials, metals, ceramic, etc. They were then categorised into 2 main groups: metals and non-metals. The identified materials are presented in Tables 4 and 5 in descending order according to the incidence of their patents.

Table-4. Metals used in knee prostheses. Data from Espacenet through Insight Pro.

Metals	Patents incidence	Percentage of total
Titanium alloys	110	19.40%
Stainless steel	51	8.99%
Cobalt-chrome alloys	44	7.76%
Tantalum	37	6.53%
Niobium	33	5.82%
Zirconium	18	3.17%
Cobalt-chromium-molybdenum	8	1.41%

Table-5. Non-metals used in knee prostheses. Data from Espacenet through insight Pro.

Non-metals	Patents incidence	Percentage of total
Ultra-high-molecular-weight polyethylene (UHMWPE)	106	18.69%
Ceramic	84	14.81%
PEEK (polyetheretherketone)	43	7.58%
Elastomers	17	3.00%
Polypropylene	16	2.82%
Nylon	12	2.12%
PVA hydrogel	9	1.59%

From the results obtained, we observe that titanium alloys, stainless steel and cobalt-chromium are among the main three metals. Each of these metals has different characteristics, such as hardness and wear, among others. Titanium alloys provide more biocompatibility with the surrounding tissue. Meanwhile, stainless steel alloys and cobalt-chromium provide higher hardness and are more resistant to wear [27].

The three most used non-metals in knee prostheses are: Ultra-High-Molecular-Weight Polyethylene (UHMWPE), ceramic and PEEK (polyetheretherketone). The leading non-metal, UHMWPE, has been highly used in knee prostheses since 1962; however, UHMWPE implants have only a finite lifetime. Wear and damage of these components is one of the factors limiting implant longevity [28].

4.4. Cooperative patent classification analysis

The CPC is a classification system jointly developed by the European Patent Office and the United States Trademark Patent Office. While the IPC has 70, 000 entries and ECLA (European Classification System) has 160, 000, the CPC has more than 250,000, making it much more precise [29]. Figure-4 shows the Top 5 CPC Full-Digits Patenting Trend obtained in our research.

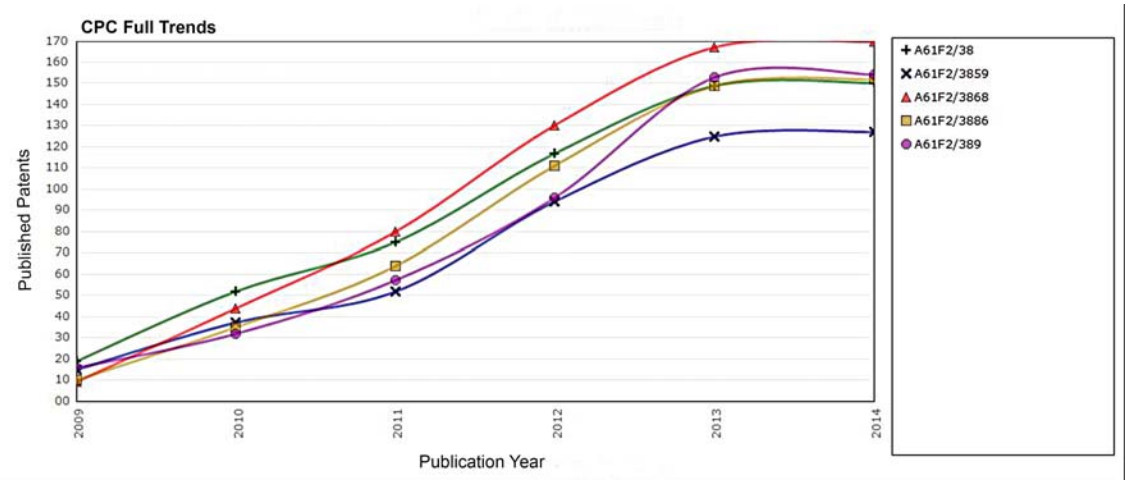

Figure 4. Top 5 CPC full digits patenting trend. Data from Espacenet through insight Pro.

To strength the previous results, Table-6 shows the Top 5 CPC Full-Digits obtained in our research, in descending order according to the incidence of their patents. We present their technical areas based on the World Intellectual Property Organization [29].

Table-6. Top 5 CPC full-digits. Data from Espacenet through insight Pro.

CPC Full-Digits	Patents	Technical Area
A61F2/3868	170	Filters implantable into blood vessels; Prostheses, i.e., artificial substitutes or replacements for body parts; Appliances for connecting the prosthesis with the body / With sliding tibial bearing.
A61F2/389	154	Prostheses […] / Tibial components.
A61F2/3886	152	Prostheses […] / For stabilising knees against anterior or lateral dislocations.
A61F2/38	150	Prostheses […] / Joints for elbows or knees.
A61F2/3859	127	Prostheses […] / Femoral components.

Within the group of CPC Full Top 5 Digits, A61F2/3859 (Prostheses, i.e., artificial substitutes or replacements for body parts; Appliances for connecting the prosthesis with the body/with sliding tibial bearing) remains the most cited.

4.5. Top keywords

We also analysed the internal keywords that are the most repeated words extracted from the Title, Abstract and Claims sections of the 567 patents. Figure-5 shows the top keywords based on their correlations with patents, including those keywords that are shared among the patents. These insights, similar to the previous ones, were very important in understanding the main directions of inventions in our research.

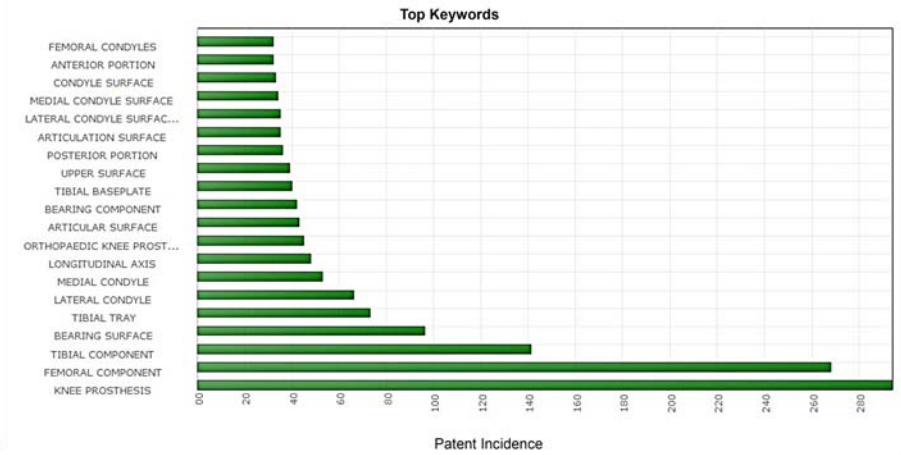

Figure-5. Internal keywords and their patent incidences. Data from Espacenet through insight Pro.

5. CONCLUSIONS

The CTI methodology provided valuable insights for detecting the main trends present in the biomedical field of knee prostheses. Using this approach, we identified key inventors, companies, materials, IPC main classes and CPC full digits.

The information presented here could help companies to identify their main competitors and the foci of research on knee prostheses for the last years. It is important to note that the top four companies come from the United States. Moreover, the Top 3 companies, which are located in Warsaw, Indiana, belong to an Orthopaedic-Biomedical Cluster that leads the global market in knee prostheses, among other orthopaedic products. With $11 billion in annual sales, this cluster represents nearly one-third of the world's orthopaedic sales volume [30].

Information coming from our patent analysis could add value to the strategic decision process, not only for biomedical companies but also for research institutes and other stakeholders. Trending areas of research were identified in this study. In this context, we detected the Top four IPC 4-Digits and the Top 5 CPC Full Digits. For a larger and more complete investigation, it would be convenient to analyze detailed technical issues, such as processes and applications, to obtain more specific insights for innovation research areas.

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