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Major advances in ophthalmology: emergence of bio-additive manufacturing

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ABSTRACT Important efforts to discover new ways to combat illnesses are being carried out worldwide. In this sense, bio-additive manufacturing is an innovative technology that will revolutionize the health industry, as it provides the possibility to develop three-dimensional bio devices, such as body tissues and even organs. This research explores the most novel inventions of bio-additive manufacturing in ophthalmology. The main aim is to support the decision making of the research community and the organizations involved in this industry. The major advances, organizations, research focuses and main countries involved in the ophthalmology field were identified. To accomplish this, a scientometric patent analysis was carried out using advanced data mining software and consultations with experts. Insights show a global research trend toward the development of lenses, followed by prosthesis and implants. Bio-additive manufacturing is now in a nascent S-curve phase; however, important advances are being carried out.

KEYWORDS 3D bioprinting, 3D printing, additive manufacturing, bio-additive manufacturing, biomedical devices, bioprinting, health, ophthalmic devices, ophthalmology, sientometrics, patent analysis

1. INTRODUCTION

Additive manufacturing, also known as 3D printing and rapid prototyping, is an innovative technology that enables the development of products in an additive way by fusing or depositing materials in layers to produce a three-dimensional physical object (Delgado, Ciurana, and Rodríguez 2012). The first technique was developed by Charles Hull in the early 1980s (Schubert, van Langeveld, and Donoso 2014). Since then, the industry has grown, and as a consequence, the number of patents has increased (Rodríguez et al. 2014).

High value products can be developed with this technology, including artwork, automotive parts, architectural models, dental bridges, jewellery and ductwork for mobile hospitals. Versatility is one of the core advantages that 3D printing offers (Conner et al. 2014). In addition, it allows for customized designs (Euromonitor 2013) and product manufacturing with complex geometries and superior quality (Campbell et al. 2011). A wide range of sectors could benefit from this technology, particularly the health industry, which presently needs to develop more innovative processes to face global changes in sustainability. Worldwide markets demand high quality services and products at affordable prices (Kivisaari et al. 2013). Bio-additive manufacturing applications are growing rapidly and are expected to revolutionize the entire industry (Schubert, van Langeveld, and Donoso 2014) with tools that facilitate education, surgical planning and organ transplantation research (Huang and Zhang 2014).

The purpose of this research was to identify the main organizations, their research focus, the major advances and the main countries involved in bio-additive manufacturing applied to ophthalmology. For this aim, a scientometric patent analysis was developed. The insights obtained could be useful to key players in the healthcare industry, particularly those who focus on researching emerging technologies to enhance innovative applications in ophthalmology.

This paper is organized as follows. First, a review of additive manufacturing applied to health care is presented. Second, current applications of this technology in the ophthalmology field are explored. Third, an overview of the scientometric patent analysis is provided. Fourth, the methodology applied is explained. Lastly, the results are analyzed, and the conclusions are presented.

2. LITERATURE REVIEW

2.1 Additive manufacturing: applications in the health care industry

Additive manufacturing has been used for decades, mainly in the manufacturing industry to produce prototypes (Schubert, van Langeveld, and Donoso 2014). A wider adoption of this innovative technology is expected in the next two to five years due to its rapid diffusion into other industries. Currently, its application has been extended to accessories, assembly parts and medical devices, including prosthesis (Wohlers Associates 2013), eye glasses and implants (Schubert, van Langeveld, and Donoso 2014). As an example of its applications in health care, this technology is used to produce customized dental braces. The dental impression is converted into an stereolithography (STL) file, and then the braces are printed to fit the patient's anatomy (Conner et al. 2014). 3D printing offers valuable solutions for bone implant production. Novel materials, such as Cobalt–chromium–molybdenum alloy, can be used with this technology, allowing for the integration of a prosthetic component with a surrounding bone, which increases surgery success (Stenlund et al. 2015). Bio-additive manufacturing will play a determinant role in the health sector, considering the growing interest in developing breakthrough products that could change people's lives, resulting in its global use (Basiliere and Shanler 2015).

The use of bio-additive manufacturing in the health industry began with the production of medical devices that could repair, replace or control body functions. Currently, it also includes the development of pre-surgery planning tools, surgical cutting templates (Burton and Shanler 2014) and custom-made products, providing patients and doctors with significant benefits that range from reduced time invested in surgery, to expedited patient recovery, to a higher likelihood of successful interventions. Additive manufacturing also provides the possibility of printing tissue and organs directly, and it has enabled researchers to develop heart valves and cartilage tissue, among other body components. As the technology advances, the probability of developing functional tissues and organs using additive manufacturing will increase. In 20 years, it is expected that this technology will also offer the possibility of developing organs, such as eyes, hearts, livers and kidneys (Ventola 2014).

2.2 Bio-additive manufacturing in ophthalmology

The potential uses of bio-additive manufacturing in ophthalmology are promising. Complex three-dimensional models for ophthalmologists' training are expected to be developed in the near future, enhancing the learning experience. Moreover, advanced models of a patient's eye anatomy could be reproduced and as a result, surgeons would be able to practice before an intervention, increasing precision and success (Huang and Zhang 2014). Although more research is needed, there are significant advances in this area. Along these lines, a 3D hollow eye model was fabricated almost 10 years ago using a rapid prototyping machine in which the purpose was to test a novel cleaner for healing complications in retinal diseases treatments. The inner walls of the model were coated with 5% bovine serum albumin to mimic the surface properties of the human retina (Chan et al. 2015). Important research has also been carried out for developing ophthalmological surgical instruments. For example, an ophthalmic speculum and a customized spatula have been developed using bio-additive manufacturing technology. They are currently undergoing prototype testing and a computer aided design (CAD) development stage, respectively (Lupeanu et al. 2014).

By means of bio-additive manufacturing, the development of a printed cornea is a real

possibility. For example, a research group from Massey University and Auckland University have discovered how to print cornea replacements using collagen (Mechatronics and Robotics Research Group of Massey University 2015). This development is in the proof of concept stage.

Although the use of bio-additive manufacturing in ophthalmology is still limited, there is a significant potential for the development of ocular tissues, such as conjunctiva, sclera and corneas. Also, the printing of artificial lenses, glaucoma valves and a variety of medical implants developed in customized processes will be a reality in the future (Huang and Zhang 2014). Moreover, the use of additive manufacturing in the development of flexible optical lenses for smartphones has been reported as well (Sung et al. 2015). With additional research, this progress allows for the possibility of producing high-quality ophthalmic lenses for human use. Ophthalmology is expected to be an important industry for future developments and innovations in bio-additive manufacturing (Huang and Zhang 2014).

2.3 Scientometric patent analysis

Important studies have applied quantitative methods of analysis to evaluate scientific and technological literature production in the health domain. They have shown how research trends could improve the management and establishment of new strategies. One example is the investigation developed by Zhang et al. (2013), who analyzed research papers on health management with the purpose of identifying the current status of collaborative activities and research topics in the field. Their main objective was to develop insights for policy makers to allocate health research funds in a more precise manner; however, when analyzing technologies, patents emerge as an important source for developing valuable insights, in addition to scientific production.

Patents are highly valuable mechanisms for protecting innovations. They provide important competitive advantages, such as the invention right of for twenty years (Weenen et al. 2013). In addition, patents are considered good indicators of the technological innovation process (Hidalgo-Nuchera, Iglesias-Pradas, and Hernández-García 2009; Rodríguez and Tello 2012 utilization). In fact, they are frequently seen as a level of R&D activities and are widely used to determine research trends as well as development profiles (Tsuji 2012). Moreover, 90% of all available technological information can be found in patent publications (Blackman 1995). They represent an accessible, reliable, updated and standardized source of information (de Souza Antunes et al. 2012). Most importantly, they provide a way to envisage technology trajectories and to identify ongoing developments of organizations (companies, government agencies, centers, universities, etc.) (Rodríguez et al. 2014). Patents are used frequently as an indicator of technology research; its statistical analysis offers valuable insights (Huang and Yang 2013), as is the case for scientometrics applications, which involves the statistical analysis of technological literature.

Since the 1980s, extensive literature regarding patent analysis has been produced, causing a large growth in the early 2000s (Ranaei et al. 2014). However, for additive manufacturing technology, there is still scarce patent analysis research. Previous studies (Rodríguez et al. 2014; UK Intellectual Property Office Patent Informatics Team 2013; Gridlogics Technologies 2014; Tsuji 2014) have focused on determining patent activity from a general perspective rather than in regards to a specific sector or application. In this research, a scientometric patent analysis on additive manufacturing applied in the ophthalmology field was developed.

3. METHOD

A scientometric patent analysis was developed during this study. The research began with a broad analysis of the field and included the application of Patseer software and consultation with experts. Patseer is a global patent database and research platform with integrated analytic tools covering more than 92 million records from the main authorities worldwide (Sinha and Pandurangi 2015). Patents were retrieved from 19 patent authorities. The time period covered in this research depended on the authority coverage, which ranged from 1782 to 2015 (April 29).

The “title” and “abstract” fields as well as the following queries were considered: (3D print* OR additive manufactur* OR bioprint* OR rapid prototyp* OR rapid manufactur*) AND (eye* OR ophthalm*).

Table 1 Research focuses and recent inventions of organizations, ordered by family patents. Family patent refers to the same patent application or the publication of a single invention protected by different authorities by a common owner.

Family Patent No.	Patent Publication Number	Application Date	Invention Description	Organization
RESEARCH FOCUS: LENSES				
1	WO2015014381A1 (Single patent)	July 31, 2013	A method for ophthalmic lens using additive manufacturing. It includes constituting voxels of one or more compositions, wherein manufacturing a three-dimensional at least one of the compositions comprises one or more pre-polymers or polymers.	Essilor International SA (France)
2	WO2015014380A1 (Single patent)	July 31, 2013	A method using additive manufacturing technologies and processes to manufacture a three-dimensional ophthalmic lens with a high management level of the homogeneity during the construction.	Essilor International SA (France)
3	FR3006622A1 Family patent: WO2014195654A1	June 7, 2013	A process for manufacturing an ophthalmic lens having at least one optical function. It comprises the step of additively manufacturing an intermediate optical element.	Essilor International SA (France)
4	FR3006623A1 Family patent: WO2014195653A1	June 7, 2013	A process for manufacturing an ophthalmic lens having at least one optical function characterized by comprising a step of additively manufacturing the ophthalmic lens.	Essilor International SA (France)
5	FR3008196A1 (Single patent)	July 8, 2013	A method for manufacturing an ophthalmic lens having at least one optical function, comprising the step of providing a starting optical system of the lens with a basic optical function and the step of additively manufacturing an additional optical element of the lens.	Essilor International SA (France)
6	CA2884801A1 Family patent: WO2014049284A1	Sept 26, 2013	A method for manufacturing an ophthalmic lens comprising a marking step for producing permanent technical marks. It comprises a step of additive manufacturing of a body and first and second surfaces.	Essilor International SA (France)
7	FR2985214B1 Family patent: WO2013098511A1	Dec 29, 2011	A template for an ophthalmic lens produced by additive rapid prototyping.	Essilor International SA (France)
8	CN102854639A (Single patent)	Sept 21, 2012	A manufacturing process of photosensitive resin eyeglasses. With the adoption of the manufacturing process, optometry prescription data can be directly input into rapid prototyping equipment in a factory or eyeglass store.	Jiangsu Wanxin Optical Co. Ltd. (China)
RESEARCH FOCUS: PROSTHESIS				
9	CN104091506A (Single patent)	July 24, 2014	The invention discloses a novel three-dimensional simulation eye. According to the novel three-dimensional simulation eye, the 3D printing technology is adopted.	Liu Qinghuai (Individual) (China)
10	GB2504665A Family patent: GB201211903D0	July 4, 2012	A method of manufacturing an artificial eye is presented. A digital image of an iris may be acquired and transferred to a substrate either by 3D printing or a transfer material, such as a dye sublimation film.	Manchester Metropolitan University (UK)
11	GB2487055A (Single patent)	Jan 5, 2011	A method of manufacturing an artificial eye is presented. In one embodiment, the image of the iris is CAD modelled, and the substrate may be formed as an inherent part of the transfer step by a 3D printer using silica powder and then bound using cyanoacrylate.	Fripp Design Ltd. (UK)
RESEARCH FOCUS: IMPLANTS				
12	DE102012011311A1 (Single patent)	June 10, 2012	The invention relates to an intraocular lens that has a front side at which light occurs and a back side at which the light emerges. The lens is manufactured by an injection molding process, rapid prototyping or laser sintering.	Becker Hartwig (Individual) (Germany)

4. RESULTS AND DISCUSSION

Additive manufacturing applications in ophthalmology are in a nascent stage; only 33 patents were initially identified. A data cleaning process known as standardization (Randall et al. 2013) was conducted manually to remove irrelevant information and to homogenize organizations' names. After this process, a total of 17 patents were analyzed. This information was organized and categorized, resulting in 12 family patents (the same patent application or the publication of a single invention protected by different authorities by a common owner), which are shown in Table 1.

The results obtained show that the main research focus of Bio 3D printing in ophthalmology is on the development of ophthalmic lenses. Essilor International SA has 7 families in this area. For example, this company patented the process development of ophthalmic lenses and its intermediate or additional elements. Incremental innovations of root patents have been developed through the application of additive manufacturing technology. Additionally, Jiangsu Wanxin Optical Co. Ltd. has patented an invention for producing photosensitive resin eyeglasses.

Prosthesis advances emerge as the second main research focus, which include 3 families. Liu Qinghuai (individual), Manchester Metropolitan University and Fripp Design Ltd. have patented the development of artificial eyes.

The third research focus is on implants. Becker Hartwig (individual) patented the creation of an intraocular lens.

Figure 1 shows that the top country in patenting these innovations is France (FR: 5 families), followed by the United Kingdom (GB: 2 families), China (CN: 2 families) and Germany (DE: 1 family). In addition, 2 families were first filed to be protected in all European Union countries at the same time (EP: 2 families).

The identification and analysis of the inventions presented show the first efforts devoted to the application of bio-additive manufacturing in the field of ophthalmology. Industry and academy are attempting to identify superior solutions to manage eye illnesses. This technology is in a nascent stage; however, the results show promising advances. Bio-additive manufacturing provides the possibility to develop breakthrough innovations to improve patients' conditions.

5. CONCLUSIONS

Valuable insights were obtained through the scientometric patent analysis developed. The application of bio-additive manufacturing in the field of ophthalmology is still in its infancy. The majority of inventions found correspond to products developed to be used outside the human body, which represents the lowest risk for patients. This fact could be related to the novelty of the technology.

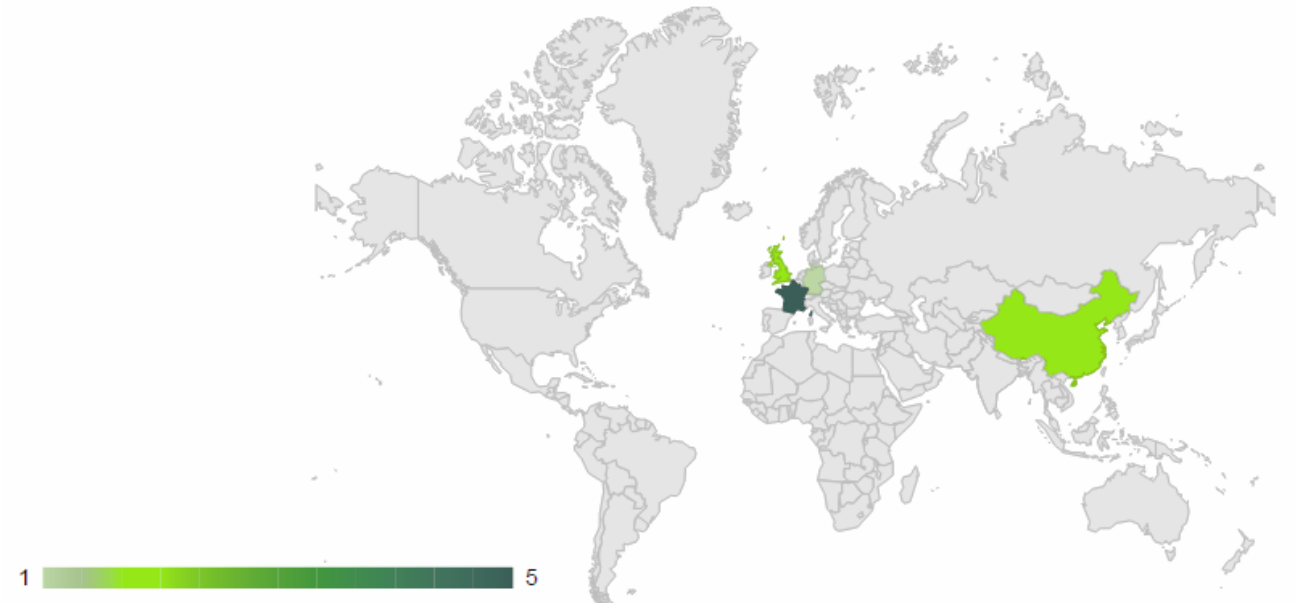

Figure 1 Top countries for the development of ophthalmic inventions, determined by family patents.

The findings of this study show that the main research focus is on the development of lenses due primarily to the invention activity of Essilor International SA. The second focus is related to the development of prosthesis, such as artificial eyes. In this sense, bio 3D additive manufacturing technology is mainly used to simplify the manufacturing processes and to create additional realism in the devices. Only one invention belongs to the research focus group of implants, and this corresponds to the development of an intraocular lens.

Regarding the top country of protection, France occupies the leader position, particularly as a consequence of the patent activity of one company (Essilor International SA). The results of this research offer valuable knowledge on emerging technologies and breakthrough innovations in ophthalmology.

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