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TECHNOLOGICAL STUDY AND MONITORING OF THE SURFACE FUNCTIONALIZATION OF THE Ni–Ti SHAPE MEMORY ALLOY WITH POLYMERIC COATING

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ABSTRACT

Ni–Ti shape memory alloys are generally applied to produce orthodontic and orthopedic implants. However, it is essential to highlight that implants may fail due to local inflammation caused by the accumulation of bacteria. Therefore, functionalizing the metal surface with biocompatible polymeric coatings is generally used to avoid implant failure. This article addresses a technological monitoring study of Ni–Ti shape memory alloys with surface functionalized with polymeric coatings, using patents as sources of information. The Questel Orbit® platform was used to collect the information, applying the following keywords as previous search terms: "nickel–titanium", "Ni–Ti", "Nitinol", "Coated", and "Polymer". Among the areas of technologies related to the topic, the ones that stood out the most were the systems used to produce advanced biomedical devices for use in medicine, such as stents, plates, pins, and wires applied to orthodontic and orthopedic devices. Therefore, the results of this research show a general overview of the main innovations developed in the area and, therefore, can guide future research focused on developing systems formed by Ni–Ti alloys coated with polymers applied in different technological sectors.

Keywords: Nickel–Titanium; Nitinol; Polymer.

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INTRODUCTION

Ni–Ti alloys, commercially known as Nitinol, present the phenomenon of shape memory, that is, the restoration of the structural shape of the material after a disturbance (heating) can occur through two different routes: superelasticity (SE) phenomenon, process characterized by an isothermal loading and unloading cycle that will cause a pseudo-elastic deformation to the system; or the phenomenon of shape memory effect (SME), which occurs due to heating applied after pseudoplastic deformation. The two SE and EMF phenomena are related to energy dissipation processes through an observable mechanical hysteresis between the charge/discharge curves, and these phenomena are caused by transformations that occur in the solid state and that are reversible between the two crystallographic phases Austenite (A) and Martensite (M). It is important to highlight that, as commonly occurs in all phase changes, the phase transition that occurs in shape memory alloys is directly related to the release of latent heat, being an exothermic process in the direct transformation, that is, Austenite → Martensite and endothermic during the inverse transformation (Martensite → Austenite) (MONTENEGRO *et al*., 2020; CRUZ GOMES, DA *et al*., 2021; SOUZA, DE *et al*., 2021).

Due to their chemical and mechanical biocompatibility, one of the main applications of Ni–Ti alloys is in producing biomaterials, such as orthopedic and orthodontic plates, wires, and pins. However, local inflammation caused by releasing Ni^{2+} ions can cause implant failure in allergic people. Therefore, a commonly adopted strategy to avoid this problem is based on functionalizing the Ni–Ti alloy's surface with thermal treatments or applying protective coatings. Among the coatings used, polymeric coatings stand out due to their ease of application and the intrinsic biocompatibility presented by some polymers, such as natural polymers, such as polysaccharides, proteins, and polyphenols (LIA FOOK *et al*., 2019; GOMES DA SILVA *et al*., 2021; DUDEK *et al*., 2023).

Due to these favorable functional characteristics and the wide application in producing biomaterials in the medicinal area, systems formed by Ni–Ti alloys act as a source of innovation, driving medical advances. In order to understand technological development around this topic, we highlight technological prospecting as a way of mapping and identifying emerging trends and innovations. Since this study is considered an intelligence tool, it provides valuable information for prospective technology studies. (FERNANDES *et al*., 2022).

Technological monitoring is part of the technological prospecting study, which allows providing information and indications of the main technological trends in the global context (PORTER *et al*., 2004). Furthermore, these studies help to identify the state of the art of technology, its developments, and trends according to the needs of society. Patent analysis is one of the leading official indicators recognized worldwide to map technological advances in a given sector or area of knowledge (VINCENT *et al*., 2017).

Patent databases store vast documents, and text mining tools make it easier to analyze large datasets of information about a technological domain. These tools also help in making decisions about the main assignees, inventors, companies, and countries involved in the respective technological field (SINGH; CHAKRABORTY; VINCENT, 2016). One of the prominent tools in this context is the Questel Orbit. Questel Orbit is an advanced patent intelligence platform that offers a comprehensive range of capabilities for analyzing and managing patent information. This tool covers patent offices that represent more than 99.7% of the world's patent applications, including the five most prominent intellectual property offices (China, Estados Unidos, Japão, Coreia do Sul, Escritório Europeu de Patentes) (CHAVES *et al*., 2023).

Given the above, this article aims to carry out a study of the current state of the art in the development of systems formed by Ni–Ti (Nitinol) alloys coated with polymers based on the systematic application of patent monitoring to verify the technological development using the Questel Orbit® platform.

METHODOLOGY

The technological monitoring method used in this study uses information from patent documents, using the Questel Orbit® platform as the primary search tool, which accesses patents in several internationally renowned databases, including Espacenet, United States Patent and Trademark Office (USPTO), European Patent Office

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(EPO), World Intellectual Property Organization (WIPO), Japan Patent Office (JPO), Korean Intellectual Property Office (KIPO), Canadian Intellectual Property Office (CIPO), Intellectual Property Office (IPO), China National Intellectual Property Administration (SIPO) and National Institute of Industrial Property (INPI).

The research methodology, used to map patents in the context of the development of polymeric coatings applied to functionalize the surface of Ni–Ti (Nitinol) shape memory alloys, consisted of a previous search using keywords and/or international patent classification (International Patent Classification – IPC) as input for the Questel Orbit® tool. Initially, a macro analysis was carried out, which was done using the keywords "nickel–titanium", "Ni–Ti", "Nitinol" and "Coated". The Boolean operators AND, OR, and trickery (+) were used in the research, which allows for finding possible derivations in the title and summary fields to obtain the largest possible number of documents between 2004 and July 2024. This time interval proposed was considering the technological development of the last 20 years, a period in which patented knowledge generally remains protected (SINGH *et al*., 2016).

After analyzing 899 documents retrieved and considered relevant to the study, searches were carried out at a more specific level, adding the keyword "Polymer", considering the patents that presented the nickel–titanium alloy with polymeric coating as the focus of the study, finding a total of 99 patents. The selected patent documents were read, and the relevant information found in the texts was evaluated and presented as figures and graphs to show the trends and main applications involved in studies of the prospected topic and, thus, guiding future research in the area.

RESULTS AND DISCUSSION

After carrying out the searches and reading the content of the patent documents selected based on the applied methodology, the information extracted was analyzed and discussed in detail.

Patent distribution

In this research, the Questel Orbit® platform was used as the primary search tool, which accesses patents in several internationally renowned databases, including Espacenet, USPTO, EPO, WIPO, JPO, KIPO, CIPO, INPI, SIPO and IPO. The keywords used were: (nickel–titanium OR Ni–Ti OR nitinol) AND +coat+ AND +polym+. The use of trickery tools (+) made it possible to find possible derivations of keywords, while the Boolean operators AND and OR helped to refine and specify the desired technologies. As a result of the search, 99 patent registrations on the proposed topic were selected.

The first analysis is related to the evolution of technological production in terms of the number of patents by country. When analyzing the graph (Figure 1) of the panorama of patents filed by countries, we observe that China (CN) dominates the ranking of filings related to the topic studied, with 19 patent registrations. The European Patent Organization (EP) and the United States (US) continue with 8 patents each. Greece (GB) and the Republic of Korea (KR) have 6 patents, each one. Germany (DE) and Ireland have 4 patents, while France (FR), India (IN) and the Russian Federation (RU) each have 3 patents.

China is among the most depositing countries due to intense investment in innovation, research, and development (R&D), reaching 12th position in the 2023 Global Innovation Index and leads the world in the number of clusters and technological innovation centers among those listed as top 100 (WIPO, 2023). Furthermore, China has government policies that actively encourage patent registration as a strategy to protect intellectual property and strengthen global competitiveness (CARTA IEDI, 2011).

Then, there is the European Patent Organization (EP), which is an institution responsible for examining and granting patents in Europe and in the United States (US), a country traditionally known for standing out for its innovation ecosystem, driven by renowned universities, private investments and a strong presence of technology-based companies. Both regions have shown great interest in protecting polymer-coated nickel-titanium alloy technologies. The main purpose of these technologies is the development of advanced medical devices and biomaterials, mainly focused on the area of cardiovascular

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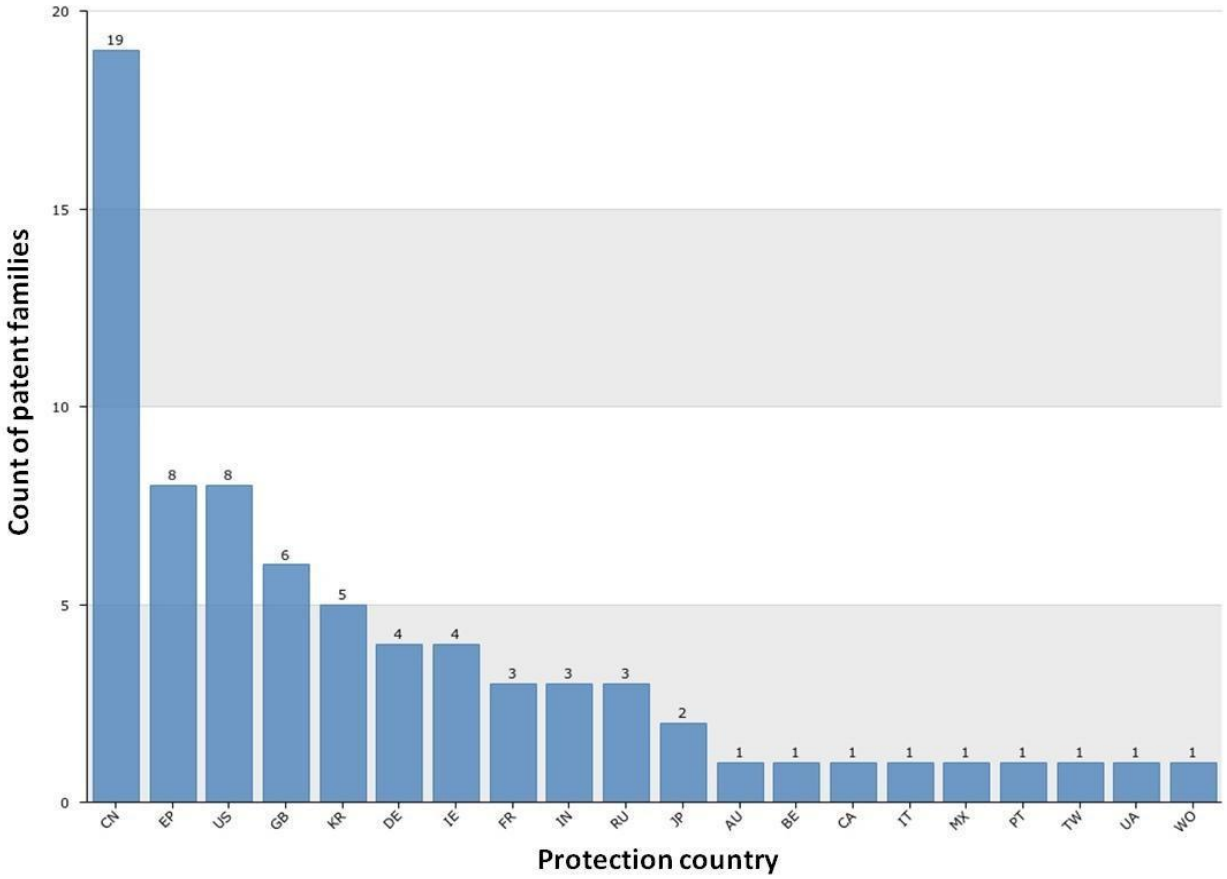
health and functional biomaterials. Despite its position in the specific ranking of this study, the United States continues to be one of the global leaders in technological innovation, occupying 3rd place in the 2023 Global Innovation Index (WIPO, 2023).

Another country that stands out is Greece (GB), with 6 patent registrations in the area investigated, which shows an impressive performance considering its smaller economy compared to other nations in the ranking. This result may be associated with strategic investments in specific areas of innovation. Among the patents filed by the country, we can mention a device coated with a layer of biodegradable polymer containing a pharmacological agent, aiming at the controlled release of medicines. Finally, the Republic of Korea (KR), with 5 patent registrations, is a country with innovation in the technology industry, especially in the semiconductor, electronics and telecommunications sectors. The country stands out for its high patent density in relation to GDP and population, and ranks 10th in the 2023 Global Innovation Index (WIPO, 2023).

Figure 1. Patent distribution by country.



Source: Questel Orbit® (2024).

Figure 2 shows the graph showing the evolution of patent filings over time. The most significant quantities of patents were filed in 2011, 2015, and 2019, such as 8, 8 and 9, respectively. It is also noted that in other years, the number of patents varied from 1 to 4 filings per year, consistent with the number of patent registrations on the

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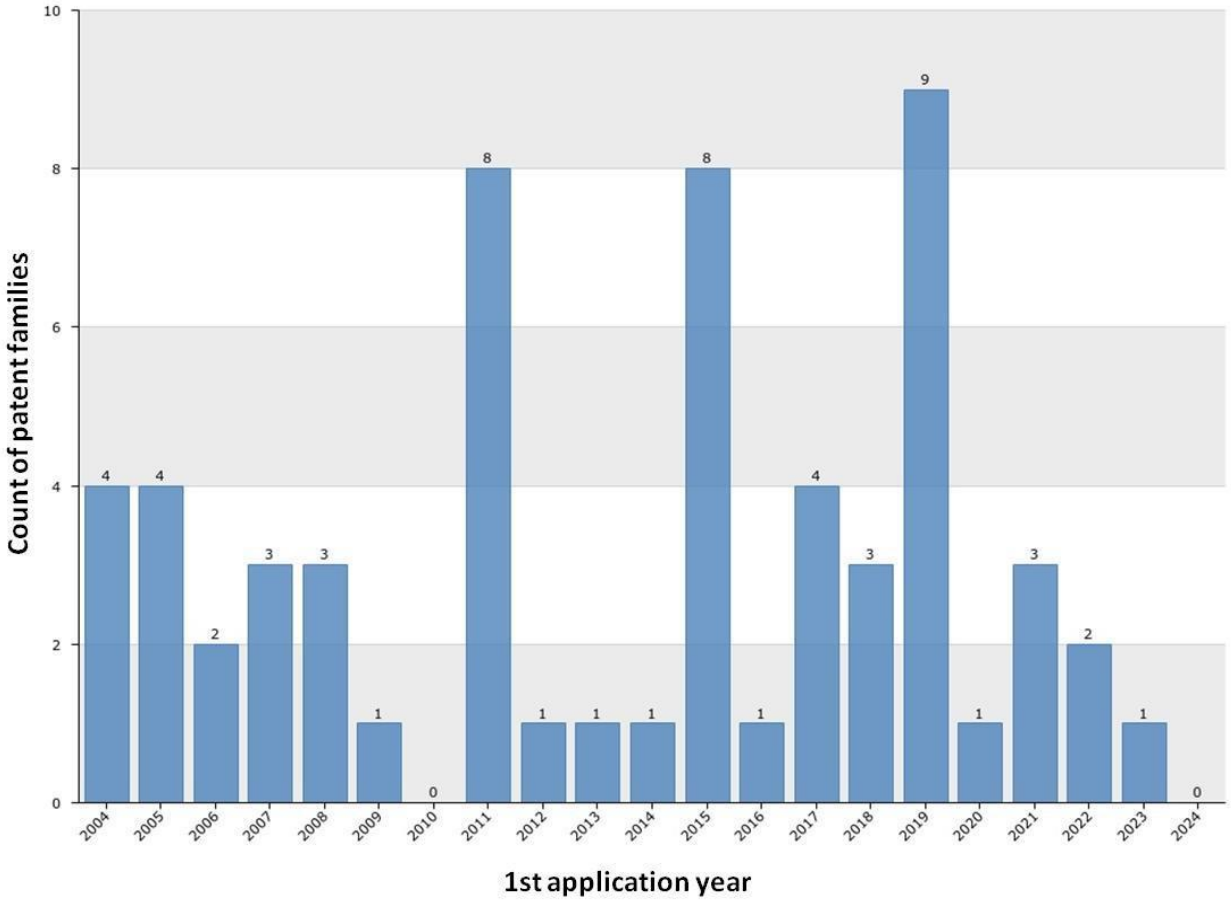
prospected topic. Only in 2010 and 2024 (until the date of the search) no record of patent filing was observed.

When analyzing the graph (Figure 2), it is not possible to observe a significant trend over the last 20 years. However, the significant increase in the number of patents in 2011, 2015, and 2019 may indicate periods of technological advancement or increased investment in research and development in this area of research. On the other hand, years with lower numbers of deposits may reflect slower development cycles or redirection of efforts/investments to other technological areas (NAGAOKA; MOTOHASHI; GOTO, 2010).

Figure 2. Patent distribution by year.



Source: Questel Orbit® (2024).

Figure 3 presents the graph that lists the technology domains related to the research topic. It is noted that the records found refer predominantly to research carried out by companies and institutions specialized in the development and manufacture of devices applied in medicine. Companies and research institutions such as Target Therapeutics, with 6 patents, and Cook Medical Technologies, with 4 patents stand out, which lead the sector by registering advanced medical devices for biomedical use, such as stents, plates, pins, and wires, reflecting the ability of these organizations to drive significant advances in healthcare. The application for the production of materials used in medicine was already expected for Ni–Ti alloys due to their biocompatibility in physiological environments, thanks to their mechanical and corrosion resistance properties (NAVARRO *et al.*,

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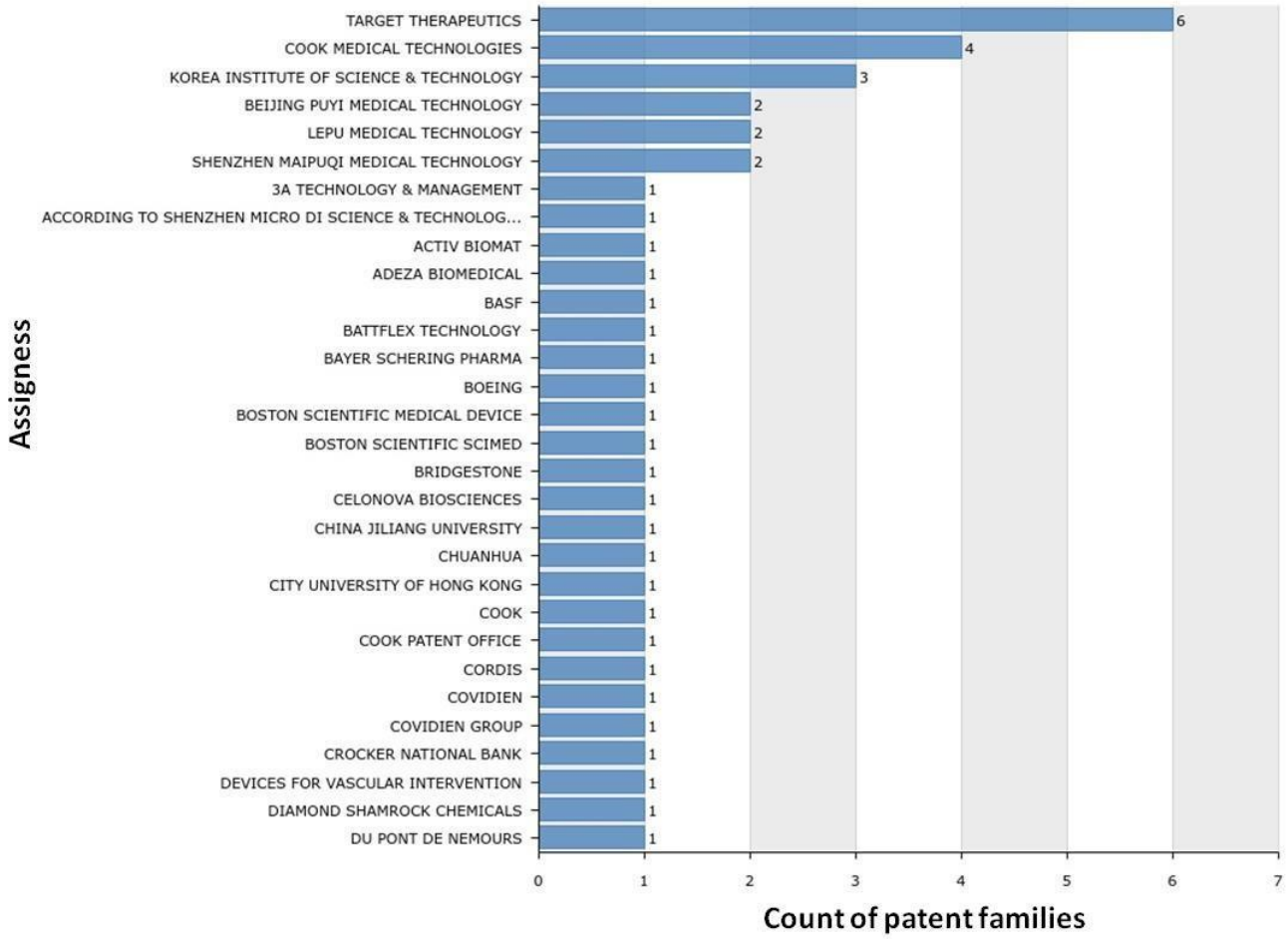
2008; SHABALOVSKAYA; RONDELLI; RETTENMAYR, 2009; MANIVASAGAM; DHINASEKARAN; RAJAMANICKAM, 2010; PATEL *et al*., 2020). Furthermore, the strategy of functionalizing the surface of Ni–Ti alloys with protective polymeric coatings is commonly adopted in order to improve the biocompatibility of the system formed and, thus, improve the performance of the device, ensuring adequate integration into the biological tissue or improving the patient's surgical recovery process (NATHANAEL; OH, 2020; DUDEK *et al*., 2023).

Figure 3. Patent distribution by applicants.



Source: Questel Orbit® (2024).

Figure 4 shows the codes of the International Patent Classification (IPC), which groups patents into 35 distinct technological fields, making it possible to identify the diversity or specificity of an applicant's patent portfolio based on a color scale, with the most intense colors (red) related to the largest quantities of records. Note (Figure 4) that the area that showed the greatest prominence (in red) was the medical technology sector. Such information highlights the strong performance of companies and research institutions in developing innovative systems in biomedicine using the Ni–Ti alloy with polymeric coatings. Also highlighted (in orange) are

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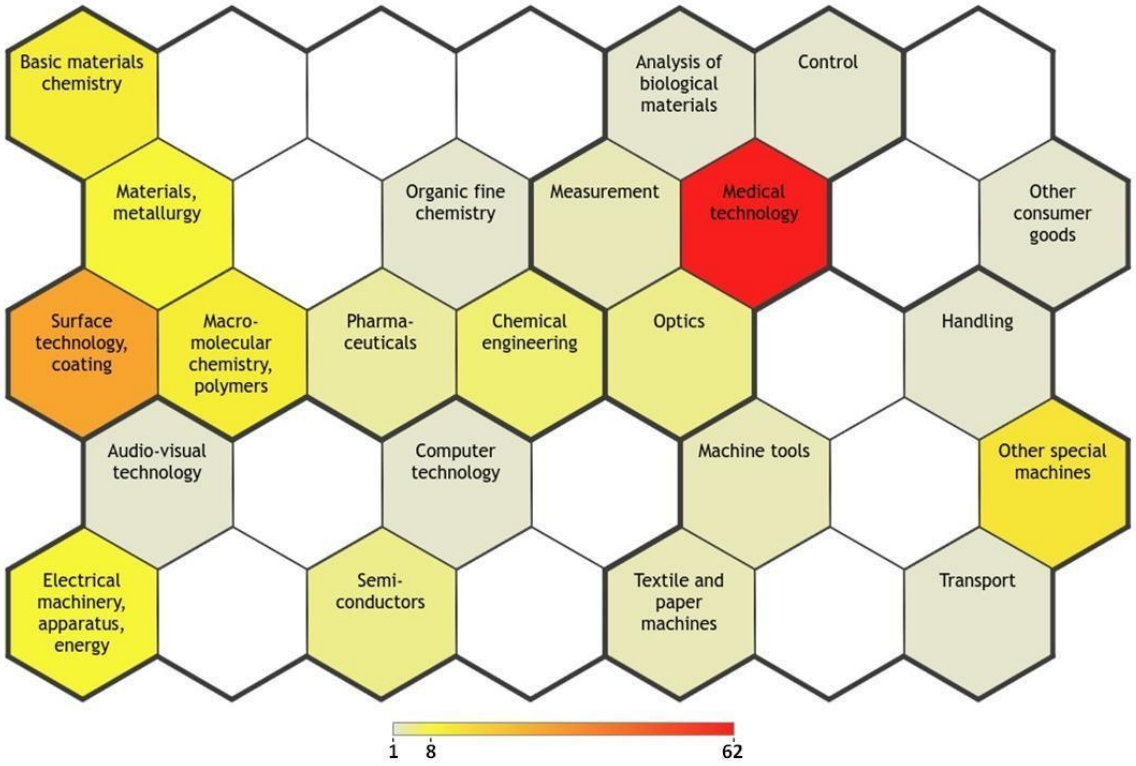
surface treatment and coating technologies that showed a significant presence of records, indicating considerable interest in these research areas. Furthermore, the categories least represented in the distribution (in yellow and shades of gray) point to other potential applications of patents, opening up new opportunities for exploration and development, such as in the energy, analysis, transport, and computing sectors, among others.

Figure 4. Patent distribution by technological fields.



Source: Questel Orbit® (2024).

For a given material to be considered biocompatible, its interaction with biological tissue must not cause side effects such as, for example, local inflammation, mutagenic or carcinogenic allergy, toxicity, or irritability. If the material causes undesirable effects, it is considered toxic to the biological environment. In the case of disorders caused by excessive immune responses, causing lesions located close to the implant (in the body's tissue cells), we have the effect of hypersensitivity or specific allergy reactions that the immune system can acquire to certain materials (MENEZES; FREITAS; GONÇALVES, 2009; PIRES; BIERHALZ; MORAES, 2015). However, as most materials used in the manufacture of implants, especially metallic materials, have some toxicity to biological systems (as they are "foreign bodies" to biological systems), the choice of materials used in the manufacture of implants must be based on the possible benefits and the possible inevitable need to use the material as opposed to the biological risks inherent to the implant (SHABALOVSKAYA *et al*., 2009). Thus, the number of studies focused on the development of biocompatible and protective polymeric coatings applied to functionalize the surface of the Ni–Ti alloy for biomedical applications is justified (NAVARRO *et al*., 2008; SUN *et al*., 2008; MANIVASAGAM *et al*., 2010).

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The use of natural or synthetic polymers, such as chitosan, gelatin, heparin (natural) (DONG *et al*., 2009; AVCU *et al*., 2019) and silicone, polypropylene, Polyethylene (synthetic) (THOMÉ *et al*., 2012; MAO *et al*., 2021; SILVA, DA *et al*., 2021), for surface functionalization of Ni–Ti shape memory alloys, due to the ease of handling and application of these polymers in the form of films, coatings, wires, among others. They are combined with the low processing cost and abundance of raw materials, especially polymers of natural origin. Therefore, biopolymers obtained from renewable and abundant sources, such as polysaccharides, can be used to improve the biocompatibility of the Ni–Ti alloy surface for various applications in biomedicine. What makes this line of research attractive to the technological innovation field (NATHANAEL; OH, 2020; SU *et al*., 2021; ÖSTERBERG *et al*., 2023).

Challenges and future perspectives

To date, the results show great interest in the development of polymeric coatings used to functionalize the surface of NiTi alloys for biomedical applications. However, further research efforts are still needed to overcome the difficulties of clinical implementation of technologies developed in the laboratory, given that most of the tests are still predominantly in vitro, i.e., it is noted that most of the research is still at a fundamental level. One possible explanation for this finding is the difficulty faced in developing biomedical devices that can be applied and made available for clinical use, given the complexity of factors that must be investigated until the material is fully developed for safe applications, such as the high financial investment required for clinical studies, the various factors that must be investigated to ensure adequate biocompatibility, the challenges faced in conducting in vivo tests, among other challenges. Thus, there is a need for advances in research aimed at evaluating and avoiding possible undesirable interactions such as cellular toxicity, mechanical incompatibilities, control of the release of therapeutic species (drugs impregnated in composite coatings), surface physical-chemical interactions between coatings and bone tissue, a greater understanding of the biological mechanisms of cellular interaction involved in tissue regeneration, among other clinical challenges involved in the development of materials applied as biomaterials. Finally, some materials stand out as promising for future studies, such as the use of biopolymers as a coating to functionalize the surface of the NiTi alloy, with special emphasis on composite coatings formed by the natural polymer chitosan, due to its excellent biocompatibility (INTRAVAIA *et al*., 2023; ÖSTERBERG *et al*., 2023; YADAV *et al*., 2023).

CONCLUSIONS

Through a detailed analysis of patent documents published between the years 2004 and July 2024, the following conclusions can be obtained:

- China leads the number of patent filings related to the topic, with 19 registrations, reflecting its intense investment in innovation and research and development (R&D).
- Over the last 20 years, significant variations have been observed in the number of patents filed yearly. Years like 2011, 2015, and 2019 showed spikes in deposits, indicating possible technological advances or increases in R&D investments.
- Patents are primarily concentrated in medical technologies, especially in developing medical devices such as stents and guide wires that use Ni–Ti alloys coated with polymeric materials. The biocompatibility of these alloys makes them particularly suitable for medical applications.
- Analysis of IPC codes reveal that medical technology is the most prominent domain among the analyzed patents. Surface treatment and coatings technology also stand out, indicating continued interest and development.

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