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A Review of the Medical Capsule Robot Development Process

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Abstract. With the commercial application of wireless capsule endoscopes in the new millennium, this field has rapidly expanded to endoscopic examination, biopsy and targeted drug delivery. However, capsule robots still face key challenges such as a lack of durability, inaccurate positioning and active movement ability, which limit their wide application in clinical practice. This article reviews the development process and main difficulties of capsule robots. It focuses on the recent progress in research on magnetic drive power supply, micro electrochemical batteries, and multi-modal positioning technology. These emerging technologies provide a feasible path to break through the existing bottlenecks. The research findings suggest that the forthcoming capsule robot is poised to transition from a single-use, passive diagnostic instrument to a controllable, long-duration, and intelligent diagnostic and therapeutic platform, thereby revolutionizing the precision diagnosis and treatment of gastrointestinal disorders.

Keywords: Capsule Robots, Magnetic Drive Technology, Diagnosis and Treatment

1. Introduction

In the early 20th century, Paul Ehrlich conceptualized the "magic bullet" concept, envisioning a therapeutic agent capable of selectively targeting afflicted tissues within the body [1]. Since then, scientists worldwide have worked tirelessly to make this dream a reality. In the early 2000s, Given Imaging (now Medtronic) pioneered wireless capsule endoscopy, a minimally invasive technique for visualizing the gastrointestinal tract. This innovation largely mitigated the infection risks inherent in conventional endoscopy and addressed the limitations of relying solely on peristaltic action. This advancement heralded the emergence of medical capsule robotics [2]. The function of medical capsule robots is extensive; this paper focuses on the history of medical capsule robots, the difficulties encountered, and the outlook of the mechanical capsule robot.

2. Categories of medical capsule robots

This article focuses on three types of medical capsule robots: endoscopic capsule robots, capsule robots with biopsy function, and capsule robots for obesity treatment.

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2.1. Endoscopic capsule robots

Endoscopic capsule robots, or wireless capsule endoscopes (WCE), are diagnostic procedures that use a miniature wireless camera in a capsule endoscope to capture images of a patient's digestive tract. Given its straightforwardness and non-invasive nature, this approach circumvents the risks of infection, perforation, and laceration associated with traditional endoscopic procedures. More importantly, WCE solves the biggest problem of traditional endoscopes: the inconvenience of handling, due to its non-invasiveness, lack of need for sedation, and ability to be moved passively or actively in the intestinal tract. Post-COVID-19, this technology has been employed to capture patient anatomical images, facilitating the identification and diagnosis of potential anomalies by medical practitioners [3]. The advent of endoscopic capsule robots has revolutionized the field, overcoming limitations inherent in conventional endoscopes and demonstrating significant promise in diagnostics, targeted drug delivery, and minimally invasive surgical interventions [1].

2.2. Capsule robot for biopsy function

Capsule robots for biopsy are also known as biopsy capsule robots (BCR). Although external magnetic fields and internal actuators can actively move today's CRs, they can also transmit images for real-time monitoring. However, imaging modalities alone are insufficient for definitive diagnosis, necessitating tissue characterization via biopsy. BCRs offer a minimally invasive approach to perform in vivo biopsies, thereby addressing a critical unmet need in the field of capsule endoscopy for the identification of suspicious lesions [4]. Currently, BCRs are fitted with different building blocks to meet the pathological determination of the location of a suspicious lesion, of which three are described below: The initial design incorporates a biopsy needle-equipped BCR, facilitating the acquisition of deep tissue specimens to enhance the detection sensitivity for submucosal neoplasms [5]. The second type is equipped with pincers, where an external rotating magnetic field drives a gear set inside the BCR to drive the pincers to hold the target. The third configuration incorporates a rotating blade BCR. This design utilizes a high-speed, rotating, sharp blade to abrade soft tissues, thereby mitigating tissue tearing [4].

2.3. Capsule robots for gastrointestinal drug delivery

Upon drug administration into the gastrointestinal tract, the efficacy of certain macromolecular drugs may be compromised or nullified prior to reaching the target site due to enzymatic degradation and the acidic gastric environment [5]. Coupled with the differences in the gastrointestinal physiological or physical environments of the same patient from one patient to the next or from one physiological state to another, gastrointestinal drug delivery robots have emerged. Stimulus-responsive materials enable gastrointestinal drug transport robots to achieve high-precision, targeted delivery within a specific gastrointestinal pH microenvironment [6].

3. History of capsule robotics

3.1. Conceptualization of capsule robotics

The genesis of capsule robotics can be attributed to the early 20th century, specifically to Nobel laureate Paul Ehrlich's proposition of "magic bullets" within his investigations into therapeutic interventions for infectious diseases [1].In the late 1980s and early 1990s, although the technological development of conventional endoscopy was already very mature, it was hampered by the side

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effects and the lack of a reliable endoscopy system. In the late 1980s and early 1990s, although the technology of traditional endoscopy was already very mature, due to the side effects of conventional endoscopy and the lack of an effective means of examining the curved and complex small intestine, scientists were committed to developing a means of non-invasive and thorough examination of the human intestinal tract until the end of the twentieth century, when Dr. In his investigation of guidance and reconnaissance technology for micro-missiles, Gavriel Iddan determined that the integration of a micro-camera and wireless transmission device within the confines of a missile's architecture was insufficient for the intended purpose. Subsequently, in 1998, Dr. Gift and Dr. Paul Swain co-founded Given Imaging, pioneering the development of the wireless capsule endoscope (WCE) at the turn of the century [2], which formally kicked off the medical capsule robotics. It also officially kicked off the medical capsule robotics.

3.2. Capsule robot fabrication

The fabrication of a medical capsule robot is a highly complex and sophisticated process, and we can use the most common wireless capsule endoscopes on the market today as an introduction to the general fabrication process of medical capsule robots.

The first step is to customise and integrate the core components.The fundamental elements of wireless capsule endoscopes encompass image sensors, an illumination system, a power source, a wireless communication module, and a central processing unit. Each core component is miniaturized because it needs to be integrated into the WCE. The image sensor, as the "eyes" of the WCE, needs to be selected and customized as a miniaturized CMOS image sensor. Still, it also needs to have high resolution and low power consumption characteristics and be able to be achieved in a tiny size, under the function of stable image acquisition and a micro-LED light source, with the realization of a small size and insufficient light to complete the task of capturing images of the human body. Capture the task of the image of the human body; the power system is currently used in the medical-grade microbattery and needs to provide eight to twelve hours of endurance power. The miniature radio frequency transmitter and antenna, composed of a wireless transmission module, are responsible for the image data from the capsule to the receiver outside the patient's body; the central processor coordinates the work of all the miniature components.

Following micro-component fabrication, the subsequent phase involves integration and encapsulation, wherein the bespoke micro-components are incorporated into the capsule shell. All miniaturized electronic constituents are assembled on fully or semi-automated production lines within a controlled cleanroom environment to mitigate the impact of particulate matter and other contaminants, thereby ensuring component efficacy and patient safety. Next, the capsule is encapsulated in a medical-grade, biocompatible polymer (e.g. polycarbonate or acrylic) that protects the electronics inside from digestive juices and makes it easy for the patient to swallow and move through the digestive tract. Finally, a hermeticity test ensures the capsule does not pass through the digestive tract without penetrating and damaging the internal circuitry or leaking hazardous substances.

Next, Seiko's wireless capsule endoscopes undergo rigorous product tests before leaving the factory. To guarantee the capsule's capacity for capturing high-resolution images, optical performance is rigorously evaluated. Wireless transmission assays are performed to ensure dependable data transfer to the receiving unit. Biocompatibility assessments are carried out to confirm the absence of allergic or toxic responses within the human body. Finally, battery longevity and functionality are tested to verify that the wireless capsule endoscope (WCE) executes its designated functions effectively.

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Finally, it is medically sterilized and individually packaged to produce a complete wireless capsule endoscope.

3.3. Commercialization of capsule robotics

In 2001, Given Imaging marked a pivotal moment in the advancement of medical capsule robots with the launch of the PillCam SB, which was the first capsule endoscope to be successfully commercialized on a global scale [1]. The PillCam SB directly addressed the huge clinical need for small bowel examinations. It was approved by stringent regulatory agencies, such as the FDA, which proved the safety and efficacy of the commercially available capsule robots it produced—the safety and effectiveness of the commercial capsule robot it produces.

PillCam SB's success has attracted companies worldwide to join, including many industry giants such as Japan's Olympus, which launched its capsule endoscopy products. Although China started in this field late, it is developing rapidly. Chinese companies represented by AHAN Technology and Kingsoft Technology have broken through the foreign technological blockade and monopoly through technological innovation. More enterprises joining, on the one hand, brings stronger R&D strength and marketing ability for medical capsule robots; on the other hand, it also intensifies the market competition.

So far, the most significant development trend of capsule robots is from "passive observation" to "active control," the development of magnetic control technology, so that capsule robots have five degrees of freedom, with a more flexible mode of movement [5]. Concurrently, advancements in artificial intelligence for diagnostic capsule robots and AI-driven diagnostic support have spurred significant software innovations in wireless capsule endoscopy imaging [7].

Although capsule endoscopes are currently a huge commercial success, due to their single-function limitations, the market is calling for more medical capsule robots to complete their development and enter the market to seek the well-being of the lives and health of all humanity.

4. The predicament encountered by capsule robots is the introduction of new technologies

Capsule robots face many challenges in clinical applications, among which precise positioning, durability and active movement are the key factors that limit their wide application and functional expansion. Although many functions have not yet been realized in the commercialized capsule robot, the previous difficulties have been solved with the introduction of new technologies.

4.1. The dilemma faced by capsule robots

Although capsule robots have great prospects in the non-invasive diagnosis and potential treatment of digestive tract diseases, there are still significant bottlenecks in their clinical applications, mainly focusing on precise positioning, insufficient durability and lack of active movement ability. First, the complex and changeable digestive tract environment makes predicting the capsule's location difficult. Its limited volume space limits the integration of sensors and batteries, so the existing technologies, such as magnetic positioning, radio frequency positioning, and image recognition, are limited. It isn't easy to meet the clinical needs of high accuracy and stability. Secondly, capsule robots generally adopt a disposable design and rely on micro batteries with limited capacity for power supply. The traditional silver oxide batteries (3 V, 20 mW) currently used on the market also impose significant restrictions on the size [8]. Under the long-term action of acidic digestive juice and peristaltic extrusion, the shell is easy to corrode or wear, thus shortening its working life and

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making it difficult to achieve complex tasks such as continuous monitoring, targeted drug delivery, and biopsy. Finally, most commercial capsules still rely on intestinal peristalsis for passive movement, and the movement trajectory and observation field of view are uncontrollable. Staying in the focal area for delicate operation is difficult, and accurate treatment functions cannot be achieved. These difficulties have largely constrained the transformation of capsule robots from a single diagnostic tool to a multifunctional clinical platform.

4.2. New technology introduction and solutions

To break through the above bottlenecks, researchers are constantly exploring new technologies to promote the intelligent and multifunctional development of capsule robots. Introducing magnetic drive technology has become a vital breakthrough in energy supply. The novel dual-layer Helmholtz coil notably boosts radio power transfer efficiency by amplifying magnetic field energy concentration, thereby enabling capsule robots to secure more sustained and reliable power within the body [9]; magnetic field localization technology leverages the magnetic field.. It penetrates the characteristics of the human body and realizes accurate three-dimensional tracking of centimeters or even millimeters through external magnetic field sources or internal magnetometers.Its merits encompass elevated accuracy and the absence of radiation emissions; conversely, its limitations include substantial peripheral instrumentation and vulnerability to metallic impediments [9,10]. Radio frequency signal positioning technology uses parameters such as signal strength and arrival time difference to locate the capsule by measuring the radio frequency signal emitted by the capsule. Hany U., Hye N.M., Akter L. The scientific team used two smoothing techniques (LLRMA and LWLR) to process data and used the processed and raw data as input features of five machine learning models (DT, RF, **XGB, LR and KNN). The method is optimized through data operation, feature selection and k-fold cross-verification, and achieves a positioning accuracy of less than 0.22 mm in the case of 48 sensors. Currently, the methodology has undergone simulation within both the ultra-wideband (3.1–6 GHz) and medical implant communication service (402–405 MHz) frequency bands [11]. The advantage of this method is that the device is lightweight and easy to wear. However, the signal's serious attenuation and multipath effect in human tissue led to its lack of accuracy and stability, and it is usually only used for rough positioning. To overcome the limitations of a single technology, researchers are actively exploring hybrid positioning schemes to integrate the advantages of different technologies to improve the accuracy and usability of positioning significantly. Looking to the future, this field will continue to develop, and eventually the capsule robot will be built into an intelligent medical platform integrating diagnosis and treatment.

5. Conclusion

In summary, as an important innovation in minimally invasive diagnosis and treatment, medical capsule robots are continuously breaking through the limitations of traditional endoscopes and showing broad prospects in biopsy, targeted drug delivery, and long-term monitoring. Despite this, its enduring lifespan, precise targeting, and adaptable functionality remain critical challenges that hinder its extensive clinical application. With the continuous maturation of magnetic drive energy supply, miniature electrochemical batteries, and multimodal localization technology, capsule robots are expected to gradually eliminate dependence on limited battery capacity and passive motion and transform into a controllable, long-lasting, intelligent diagnostic and therapeutic platform. It is foreseeable that the capsule robot will become a key tool for accurately diagnosing and treating digestive diseases under the synergistic promotion of artificial intelligence, material science, and

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biomedical engineering, laying a solid foundation for developing individualized medical treatment and telemedicine. As these advancements unfold, integrating real-time data analysis and patient monitoring will enhance the efficacy of treatments. This evolution not only promises improved patient outcomes but also paves the way for more personalized healthcare solutions that can adapt to individual needs.

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