TEAM 2
PROJECT REPORT

Course	CMPS1211 - Hardware Fundamentals
Section	1 (Tuesday & Thursday 2:00 PM - 3:15 PM)
Instructor	David Garcia, MSc.
Semester	2023-2
Date Due	2024/05/02

Biocompatible Electronics

SIGNATURE BLOCK				
Statement	I did my share of the work, and I have a general understanding of the contents of the assignment.			
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Table of Contents

Abstract

Biocompatible electronics are devices and computers that integrate with the body and are exceptional in sensing. They come in three primary forms: wearable, ingestible, and implantable. With their relevance in information technology and biology, these devices have great applicability in healthcare and show even greater potential as the technology develops. We discuss implantable biocompatible electronics further in terms of the current state of development with PEDOT: PSS and PEDOT: CTPR. We also contemplate the emergence of Neuralink and the ethical concerns these electronics have and will have in the future.

Introduction

Biocompatible electronics refer to electronic devices that are able to harmonize with the human body. Biocompatibility is defined as the ability to cause appropriate reactions in specific parts of the body [1]. It is also interpreted by the International Standards Organization (ISO) as the ability of living organisms to interact compatibly with inactive materials. On the most basic level, biocompatible electronics are computers that can not only function in the environment of the human body but also interface with it. Conducting signals can be sent and received between the electronic device and the human tissue. The most widely used purpose for the research and use of these electronics is for advanced biosensors that can interpret and analyze the intricate complexities of the human body and its systems. Many terms synonymously describe biocompatible electronics or fall under its purview, such as biosensors, biocompatible devices, and biocompatible technology. The most defining aspect of all of those terms is biocompatibility, and in this report, biocompatible electronics will be discussed in the context of sensors.

Biocompatible electronics in the form of biosensors have three primary forms: wearable sensors, ingestible sensors, and implantable sensors. These forms' developmental considerations, use cases, and technical challenges are discussed in Tian Lu et al.'s [2023] review [2]. Wearable biosensors typically function on the skin, ingestible biosensors work by traversing through the gastrointestinal tract (GI) (i.e., stomach and intestines), and implantable biosensors are typically in direct contact with tissue for direct sensing. In the following subsections, each type is described in further detail.

Wearable Biosensors

Wearable biosensors are typically lightweight, portable, and reliable devices and systems with high monitoring performance. Although they don't have as intricate contact with human tissues as the other types of biosensors, they still work closely with the body and are the most developed of the three. The mechanical design of these biocompatible sensors involves considerations of flexibility and weight so as not to constrict body movements in both active (running) and passive (breathing) ways. Ideally, these types of devices will not cause any additional health threats to the body by using biocompatible materials. In terms of sensing, wearable biosensors can record and analyze various health parameters depending on the device's location on the body. Tian Lu et al. [2023] describe categorical modalities from which parameters such as electrocardiograms, electroencephalograms, blood pressure, and glucose can be measured. Modalities can be combined for more specialized sensing. Figure 1 shows the various parameters that wearable biosensors can detect. Wearable biosensors work great as a non-invasive form of detection, as challenging as the design development in that direction requires. Recent advances continue to improve these devices. Synthesized markers will allow advanced detection of diseases, even.

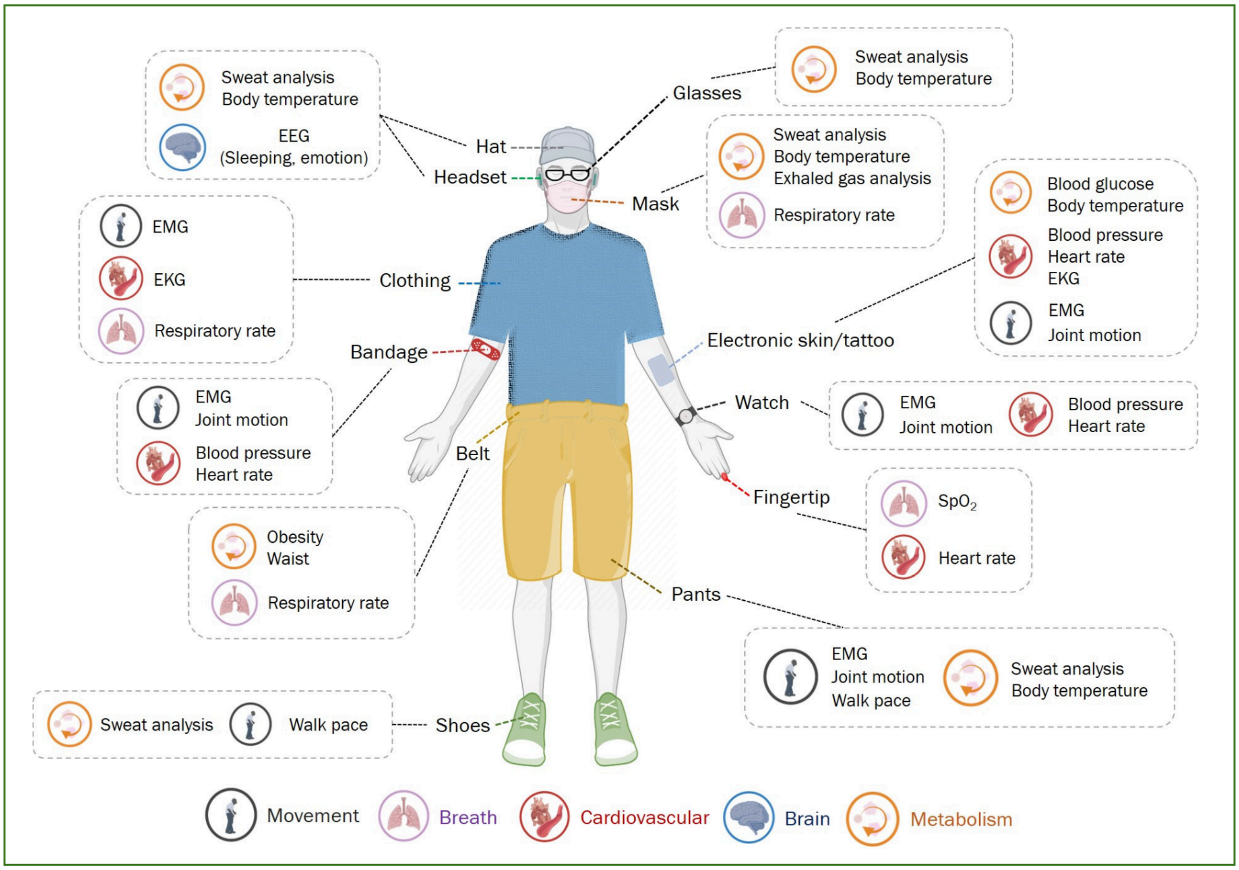

Figure 1 - Wearable biosensors can detect various health parameters from different body systems. Image credit to Tian Lu et al. [1]

Ingestible Biosensors

Ingestible biosensors come in the form of capsules (ingestible biosensing capsules or IBCs) that can monitor biomarkers, be used as diagnostic tools, and provide surgical procedures or pharmaceutical therapy. While commercial and mainstream capsules (such as PillCam and VitalSense) exist now, research continues with the aim of improving technical and design features. The design considerations include the power source (risk when IBC shell breaks), locomotion (passive by following intestine peristalsis or active by magnetic fields or physical protrusions), localization (area of effective therapy), and safety (device retention and risk of GI tract blockage). Ingestible biosensors can also detect a wide range of indicators, like wearable biosensors, with the specific addition of observing the optical appearance of tissue and the GI tract microbiome. Sensing and diagnosis in these devices extend to ultrasound imaging, spectroscopy, and odometry. Operational procedures involve stomach ulcer patching and painless targeted drug administration, which is of great interest for on-demand drug delivery. Figure 2 shows a representation of ingestible biosensors and their capabilities.

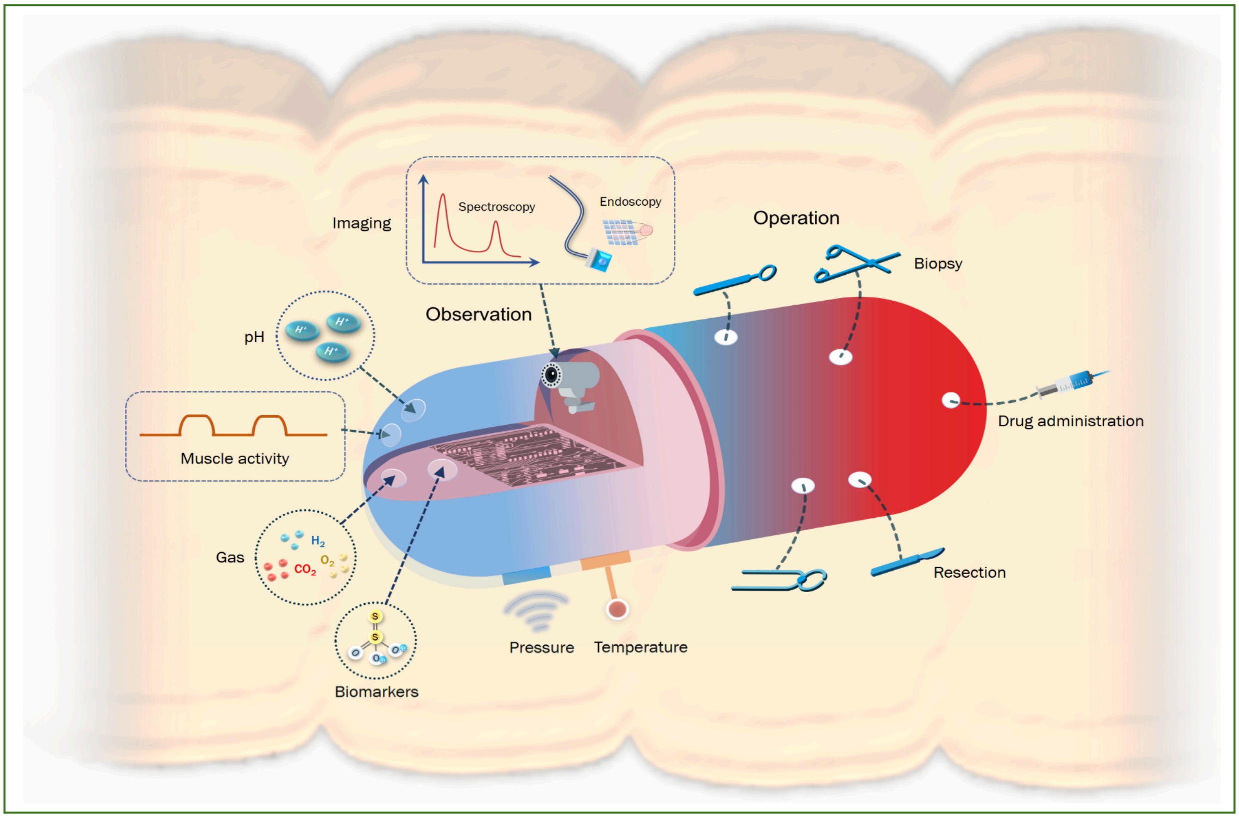

Figure 2 - An ingestible biosensor in the form of a pill inside the GI tract and the various health parameters and operations in its capability. Image credit to Tian Lu et al. [1]

Implantable Biosensors

Research in implantable biosensors aims to provide high-quality detections and monitoring in vivo. However, this type of biosensor is the least developed of the three. This underdevelopment is due to the incredibly complex mechanisms of how the body responds to foreign objects. Biosensors implanted in blood environments almost always have protein adsorption, where molecules stick to the surface, and cause decreased sensibility, signal interference, and cascading biochemical implications. The nervous system also enacts a foreign body response (FBR), which results in the same downsides. The development of these biosensors focuses on alleviating these issues. Implantable biosensors have more complex targets for sensing but are primarily investigated for neuromonitoring. The focus on monitoring and early warning of diseases like Parkinson’s disease and disorders like schizophrenia is the crucial benefit of these devices. Implantable biosensors are uniquely able to conduct real-time observations of biomolecules and chemicals in vivo.

Rationale

The topic of biocompatible electronics represents the intertwining of the significant fields of information technology hardware and biology. Complex technological hardware advancements are being made every year at an accelerated pace, and integrating the complexities of the human body is one of the ways that hardware technology seeks to better our lives. Biocompatible electronics are especially important in healthcare technologies, opening the pathway to the next generation of intelligent diagnosis, integrated diagnosis, treatment equipment, and medical service/management improvements [1]. Computational technology has already had a significant impact on the development of society, be it closely integrated information systems, digital commerce, the Internet, and social impact. The human aspect in the biochemical context is one field that is becoming increasingly relevant today.

According to Tian Lu et al. [2023], sensors are on pace in terms of development alongside two neighboring topics that are also on pace in today's age: the Internet of Things (IoT) and artificial intelligence (AI). Gathering data from sensors plays a vital role in the overall understanding of our human selves, the limitations wherein, and the decision-making throughout. In healthcare, this can be in the form of personalized diagnoses, precision medicine, intelligent medical sensing systems, health status prediction through Ambient Intelligence, exercise rehabilitation, drug therapy, and telemedicine. Sensors are also not an isolated field either. AI can bridge the gap for comprehensive assessment, and IoT devices can facilitate more efficient systems in the health sector. In the middle of these applications lies the importance of biocompatible electronics, as they are the devices that will bridge the physical biochemistry of humans and the technological capabilities of computer hardware.

Biocompatible electronics, however, are more than just isolated to research development in healthcare. The development in commercial use cases has already been seen in the realm of wearable biosensors. He et al.'s [2023] review of the aforementioned topic describes the current decade as the high-speed development stage of sensors in wearable devices. Examples are evident with the introduction of more intelligent and miniaturized wearables, such as Google's smart glasses in 2013 and the first Apple Watch released in 2015 [2]. The rather popular Apple Watch, in particular, demonstrates improved sensing capabilities with each iteration. They also echo the sentiment that Tian Lu et al. discussed, which is the impact artificial intelligence will have in developing these devices.

Each of the three forms of biocompatible electronics previously reported (wearable, ingestible, and implantable) can warrant its own extensive discussion on current developments, but perhaps the one whose applications and potentials are yet to be fully realized is implantable biocompatible electronics. Besides neurological applications in healthcare, implantable biosensors are also relevant in brain-computer interfaces (BCIs) [3]. These could be the future of the traditional interfaces with computers that we have known for the past few decades. One of the fascinating developments currently is the emergence of Neuralink. In the following two sections, we will discuss the current developments of implantable biocompatible electronics. We then further discuss the implications of the topic as a whole.

PEDOT: PSS

Implementing implantable biocompatible electronics can be done with several different materials. Zhou et al. [2024] review the current state of using metal-based materials, MEMS (micro-electromechanical system)-based silicon for MEAs (microelectrode arrays), CPs (conductive polymers), conductive hydrogels, and carbon-based materials [3]. One of the most promising materials in modern development is the CP poly(3,4-ethylene dioxythiophene) doped with poly(styrene sulfonic acid), short-handedly written as PEDOT: PSS. In their review of the recent advancements and property tailoring of such material, Seiti et al. [2023] describe PEDOT: PSS's role in the field of bioelectronics and the considerations and challenges future development entails [4].

PEDOT: PSS was first reported and developed in 1997. Bayer AG laboratories in Germany created PEDOT, which showed excellent conductivity, oxidized stability, and transparency when made into a thin film. PEDOT by itself, however, is insoluble and unstable in water, so there was a need for a doping process that attaches a counterion to the backbone of the polymer. The options for counterion can vary, but the most used one for water-based dispersions became the water-soluble poly(styrene sulfonic acid). Together, PEDOT: PSS is a valuable conductive polymer in the growing field of bioelectronics. Conductive polymers are one of the promising ways of achieving biocompatibility, being large synthetic organic macromolecules with electrical properties. PEDOT: PSS is cost-effective to fabricate, is commercially available, and exhibits many desirable traits for bioelectronic contexts, such as water solubility, chemical stability, physical stability, tunable conductivity, thermal stability, transparency, and biocompatibility.

The applications of PEDOT: PSS in biocompatible electronics are numerous, and each one branches into its own unique area of ongoing academic research. A few that Seiti et al. [2023] mention include flexible electronics (e.g., strain sensors and organic thin-film transistors), supercapacitors (that have a significant power density and short charging time), organic electrochemical transistors (used for biosensing in aqueous media) and optoelectronic devices (e.g., hybrid silicon solar cell technologies). To highlight one particular example, Figure 1 shows a graphic of the development milestones of flexible electronics of the past decade in a review of the subject done by Fan et al. [2019] [5].

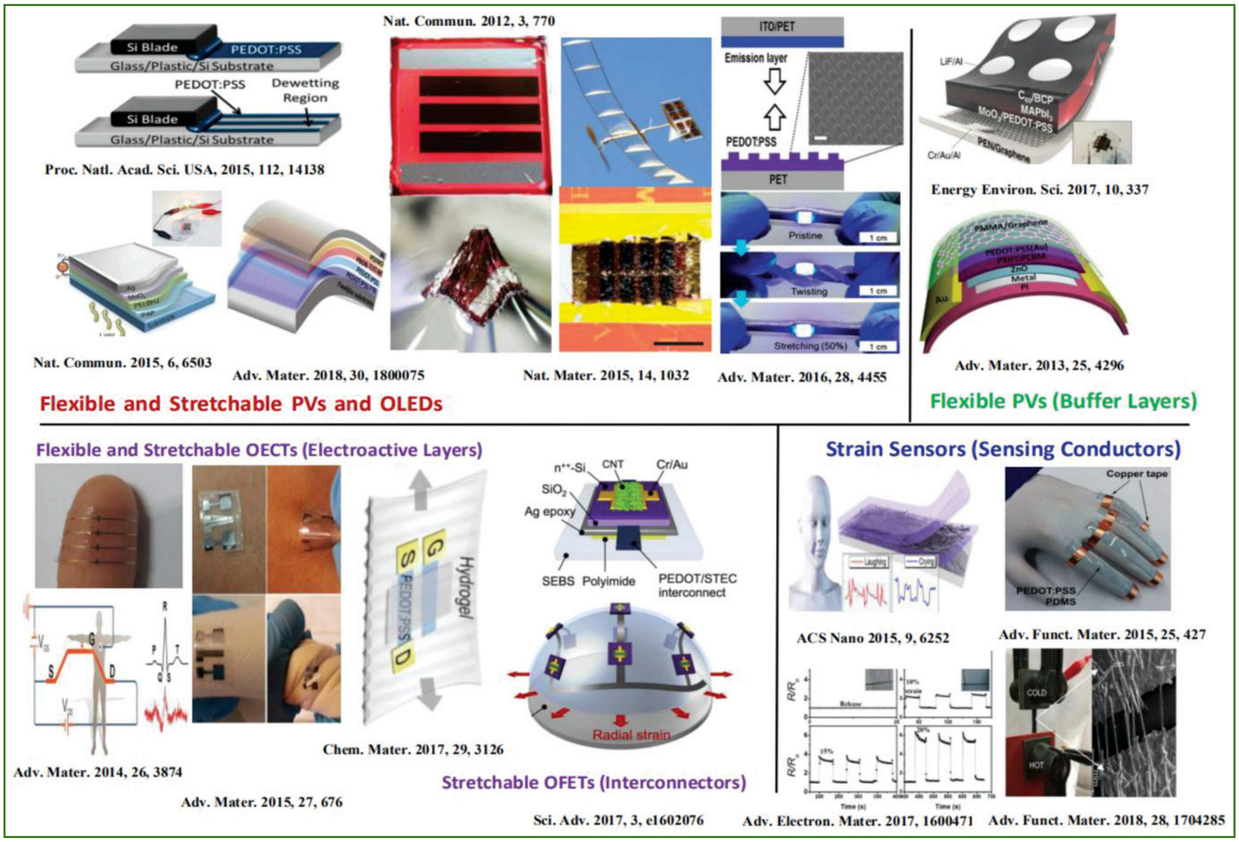

Figure 1 - Developmental milestones of flexible electronics from 2012 to 2018. Terms: PV (photovoltaic), OLED (organic light-emitting diode), OECT (organic electrochemical device), OFET (organic field-effect transistor). Image credit to Fan et al. [5]

While the applications and academic sub-categories have a wide range, the common factor in enabling their biocompatibility is PEDOT: PSS. Its incredible properties and flexibility make it a versatile material for biocompatible electronics.

Despite the immense significance of PEDOT: PSS in biocompatible electronics, Seiti et al. [2023] mention in the conclusion of their review that there is much work remaining in the academic research of the material. PEDOT: PSS and other composites of PEDOT require rigorous clinical validation and minimization optimization of property trade-offs. Studies are also required for long-term in vivo (implemented in a living organism) implantation. Their review delves deep into the categories for tailoring and improving PEDOT: PSS's properties for bioelectronics and the current research methods that are being applied to enhance those properties. Those categories of PEDOT: PSS properties are biocompatibility, conductivity, stability in saline solution, adhesion to the substrate, and potential (bio)-degradability. Figure 2 aggregates the structure, properties, and treatments of PEDOT: PSS in the review, while Table 1 summarizes the tailoring techniques mentioned for each category in the review.

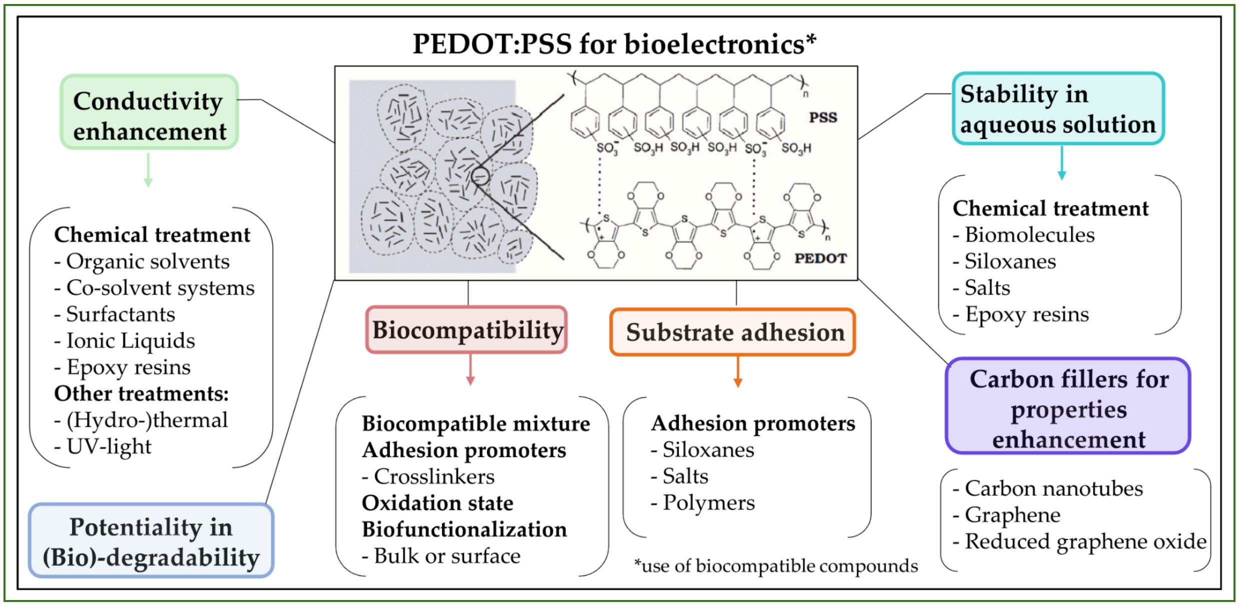

Figure 2 - PEDOT: PSS and its chemical-physical properties for bioelectronic applications. Image credit to Seiti et al. [4]

PEDOT: PSS Property	Tailoring Technique(s)
Electrical conductivity	• Hydrothermal treatment • Chemical/Thermal/Light-based secondary doping treatments • Use of Organic solvents (e.g., Dimethyl sulfoxide, ethylene glycol) • Biocompatible surfactant treatments • Use of epoxy resins
Stability and adhesion in wet conditions/saline solution	• Crosslinking techniques (e.g., crosslinker glycidoxy propyltrimethozysilane) • Addition of biomacromolecules (e.g., proteins, enzymes, electrocatalysts)
Biocompatibility	• In-vitro and in-vivo studies • Detoxification processes • Electrophysiological analyses • Biofunctionalization in bulk or surface with biomolecules or side groups of a mineralized extracellular matrix
Biodegradability	• PEDOT: PSS (PEDO-Tinks)/Graphene/PVA • Silk Fibroin/PEDOT: PSS (Clevios PH™ 1000)

Table 1 - Summary of PEDOT: PSS properties and tailoring techniques used to enhance them.

Interest in studying PEDOT: PSS has only recently grown at an exceptional rate for the past two decades. As more understanding of how to improve its capabilities and derive new material develops, so will its bioelectronic and biocompatible applications. Figure 3 shows the stark increase in the number of publications on the topics of PEDOT: PSS and bioelectronic or biocompatible PEDOT: PSS just in the past decade. There are now approximately 1000 publications annually, and that trend will likely continue as biocompatible technology develops and evolves.

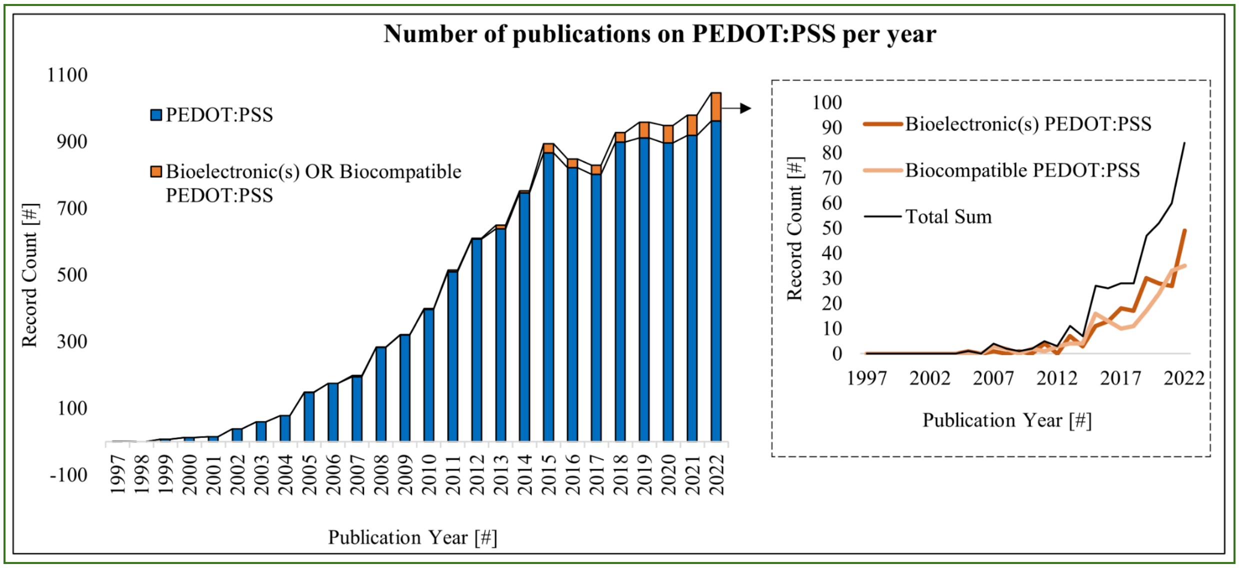

Figure 3 - Yearly PEDOT: PSS publications in the scientific community from 1997 to 2022. Image credit to Seiti et al. [4]

Of the many research articles that are currently being done about PEDOT: PSS, its properties, and finding ways to enhance those properties, we will now discuss one of the more recent research articles on a PEDOT composite known as PEDOT: CTPR. This study was conducted by CIC biomaGUNE [6] and showed increased biocompatibility. In conclusion, for this section, PEDOT: PSS is shown to be an integral part of the discussion of implantable biocompatible electronics, and its development in research paves the way to the next generation of biocompatible hardware technologies.

PEDOT: CTPR

While PEDOT: PSS excels in its versatility in conductivity, transparency, and flexibility, its biocompatibility and biodegradability have room for improvement. Dominguez-Alfaro et al. [2023] have shown promising results in using engineered proteins as a dopant instead of PSS [7]. Many strategies have been used to pair with PEDOT in search of technological improvements imperative to creating the next generation of implantable electronics. These include biopolymers and conducting additives. However, while results showed improved aspects in biocompatibility and conductivity, the performance compared to PEDOT: PSS falters significantly. Here, the strategy of using proteins has great potential in the search for an alternative dopant. As the building blocks of nature-based systems, the researchers postulate the effectiveness of using proteins as the flexible and adaptable platform in engineering diverse materials in morphologies and functions.

The protein that Dominguez-Alfaro et al. [2023] chose in their research article was consensus tetratricopeptide repeat (CTPR). CTPR protein units exhibit high stability, robustness, a high degree of tunability, and design flexibility while maintaining proper protein-structural folding. CTPR's demonstrable biocompatibility makes it a viable candidate for its application in biocompatible electronics in medicine and diagnostics. It has been previously used by itself or in combination with other materials for bioimaging, electrochemical sensors, self-assembled conducting materials, and photoconductive systems. The researchers successfully synthesized CTPR's use as a dopant for PEDOT. The synthesis methodologies involve a multitude of steps. They are summarized as follows: protein expression and purification (gathering of materials), crosslinking (forming the polymer of proteins), protein concentration tests, and microscopies/spectroscopies for protein verification. The end process of the synthesis was three CTPR proteins varying in length that were used for results testing: CTPR20, CTPR10, and CTPR3. Figure 4 below shows the protein representations and the overall chemical reaction scheme performed to form the polymer, a process known as oxidative polymerization. Collectively, PEDOT doped with CTPR is referred to as PEDOT: CTPR.

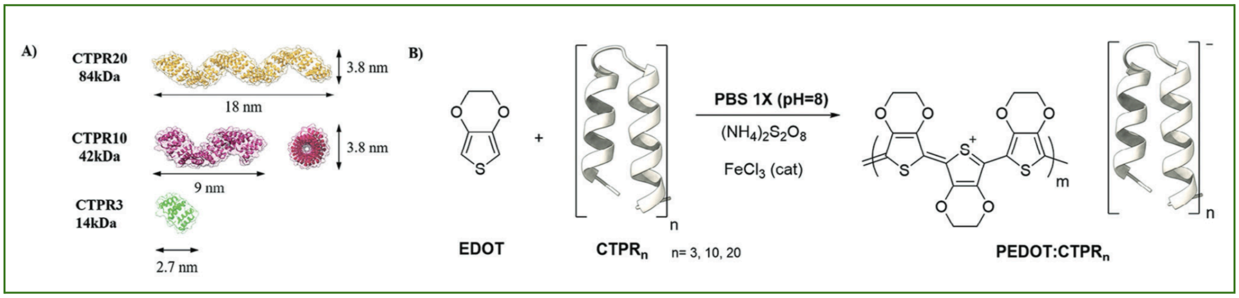

Figure 4 - A) The CTPR proteins of various lengths whose performance was studied as a dopant for PEDOT. B) The general reaction schema for the oxidative polymerization of PEDOT with CTPR proteins, forming PEDOT: CTPR. Image credit to Dominguez-Alfaro et al. [7]

After the composites of PEDOT: CTPR were synthesized, testing was conducted, results were gathered for different length composites, and their performance was compared to PEDOT: PSS. PEDOT: CTPR3 was the most promising composite compared to PEDOT: CTPR10 and PEDOT: CTPR20. The electrical conductivity of PEDOT: CTPR3 at 1.59×10^{-2} S cm^{-1} was much more significant than the other length composites, although still slightly lower than the PEDOT: PSS standard (2.0×10^{-1} S cm^{-1}). Additionally, PEDOT: CTPR3's ionic conductivity was much higher than the other composites (at 2×10^{-5} S cm^{-1}) and was on par with PEDOT: PSS's 1×10^{-5} S cm^{-1} value. Figure 5 shows these results.

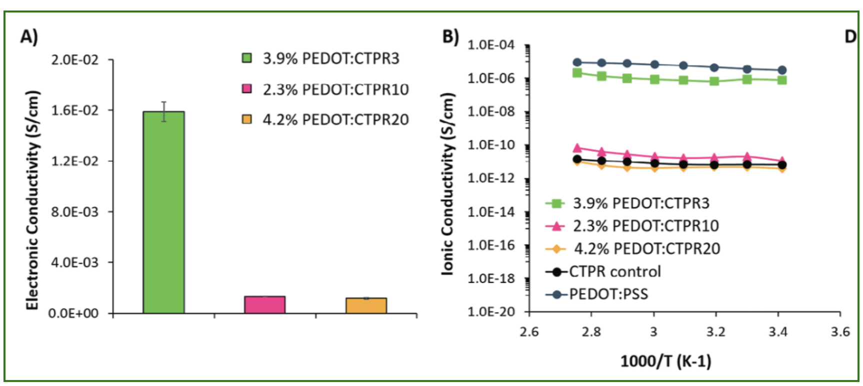

Figure 5 - A) Electronic conductivity comparison between PEDOT: CTPR composites. B) Ionic conductivity between composites and controls. Image credit to Dominguez-Alfaro et al. [7]

While PEDOT: CTPR3's results show great promise, it is not without its disadvantages compared to the more extended composites, particularly in its stability. Deterioration starts after the first 12 hours and up to 40% after 24 hours. Comparatively, PEDOT: CTPR10 and PEDOT: CTPR20 remain stable even after a month. While it may seem that PEDOT: CTPR (and specifically PEDOT: CTPR3) appears to only be sub-par compared to PEDOT: PSS, where it shines in clear advantage is in its better biocompatibility. A resazurin assay of cultivated embryonic mouse fibroblast cells (NIH3T3) on PEDOT: CTPR3 and PEDOT: PSS films was conducted for 24 and 72 hours. After 24 hours, PEDOT: CTPR3 showed a comparable but slightly lower viability (36.9 ± 2.9% compared to PEDOT: PSS's 42.9 ± 7.6%). However, after 72 hours, PEDOT: CTPR3 positively impacted the growth at 119.9 ± 2.4% (compared to PEDOT: PSS's 6.8 ± 1.1%) while not being cytotoxic. The researchers note this significant difference as PEDOT: PSS has been reported to have a potential cytotoxic effect on some cells. The visual results of the resazurin assay can be seen in Figure 6 below.

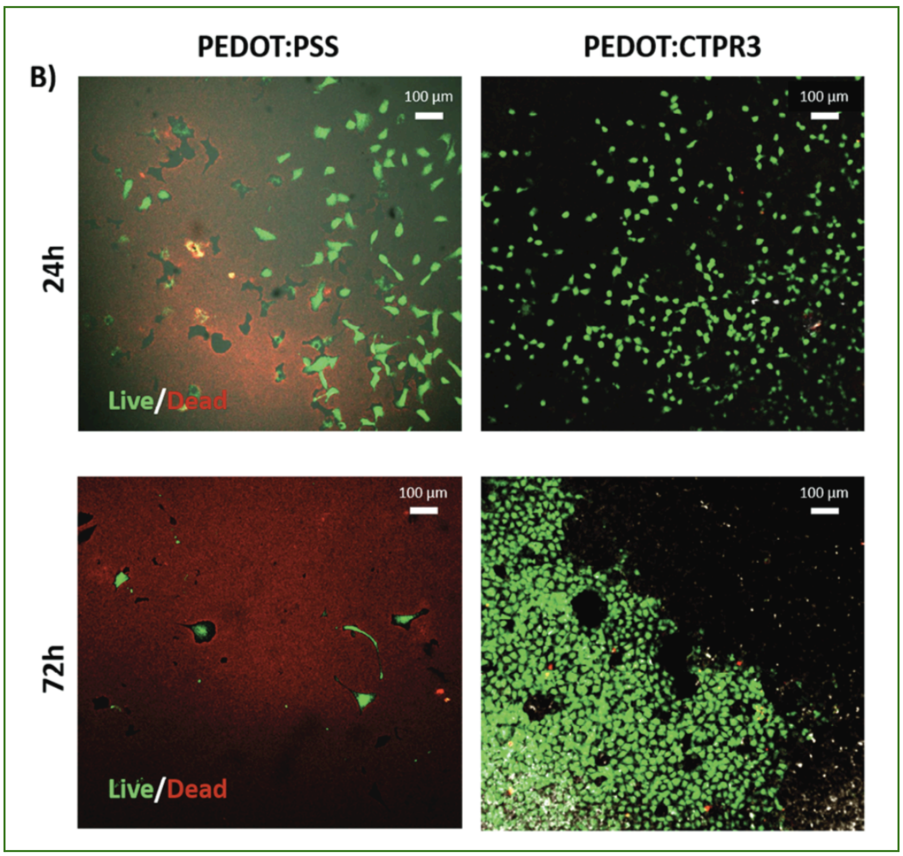

Figure 6 - Fluorescent confocal images of resazurin assay results for PEDOT: PSS and PEDOT: CTPR3. Live cells are green, while red cells are dead. Image credit to Dominguez-Alfaro et al. [7]

PEDOT: CTPR represents one of the current steps in advancing biocompatible electronics. While there are disadvantages compared to the gold standard of PEDOT: PSS, its conductivity tests as a protein composite of PEDOT is the first of its kind and an essential step in advancing this hardware technology.

Conclusion

While biocompatible electronics in the form of wearable, ingestible, and implantable biosensors are currently in the rapid development stage, especially for the latter two, this kind of hardware technology will inevitably become increasingly relevant and prevalent. We have already discussed the particular potential application of healthcare treatment and technology, and the results of continuous research are becoming tangible. In March of 2024, Neuralink, a firm focused on developing brain-computer interfaces, released a video of the successful implantation and use of their technology in the first human patient [8]. The patient, Noland Arbaugh, who suffers from quadriplegia (a dysfunction characterized by loss of motor/sensory function in the spinal cord and consequently to the limbs) due to an accident, was able to control and move a computer cursor solely with his thoughts. He could also perform other tasks such as reading, language learning, and playing computer games.

The development of the brain-computer interface of Neuralink has been reported on by Musk in 2019 [9]. In their efforts to create a flexible and scalable interface, three systems consisting of a neurosurgical robot, custom high-density electronics, and ultra-fine polymer probes were used. The robot inserts the thin threads of the polymer probes in an automated mode with manual micro-adjustments available. The electronics involve a custom application-specific integrated circuit (ASIC) that constitutes the modular recording platform for bi-directional data transfer. Enabling conductivity is the polymer probes, in which biocompatible PEDOT: PSS and iridium oxide (IrOx) were the tested candidates. Alongside the previous discussion in this report of PEDOT: PSS and PEDOT: CTPR as promising conductive polymers for biocompatibility and the growing number of published research articles in the past decade reported on by Seiti et al. [4], we can see the evidence that substantiates the increasing impact biocompatible electronics will have in both invasive and non-invasive ways.

The future of biocompatible electronics will likely have other substantial impacts outside of healthcare. Musk has already expressed the commercialization of implantable Neuralink technology [8], and wearable and ingestible devices already have options growing by the year. On the one hand, the increased integration of electronics in our bodies can lead to drastic improvements in cognitive and physical capabilities, paving the way to new heights of productivity and efficiency. In the way that generative AI, in the forms of chatbots, image generation, and writing companions, has recently surged in mainstream significance and applicability in the workplace and school, so can biocompatible electronics someday, perhaps with even greater impact. However, similar to how AI can have concerns overshadowed by its myriad capabilities (e.g., content theft, plagiarism, privacy, correctness, etc.), biocompatible electronics, especially implantable biosensors, are poised to face similar issues. Shaima et al. [2024] mention the role that brain interfaces such as Neuralink can have on criminal detection in examining brain patterns for memory recovery, emotional response, and analysis [10]. The room for bias is incredible, and while this hardware technology is still in the midst of ongoing development, ethical and privacy questions must be asked and answered.

Luckily, research on the ethics of biocompatible electronics is being conducted alongside technological research. One such example is Maynard and Scragg's [2019] framework of "risk innovation" for responsible and ethical development of innovative technologies [11]. In this framework, risk is not perceived solely through the lens of shareholder value to companies and economic beneficiaries but also through the lens of stakeholder value to customers, communities, and the public. By examining the risks in organizations and systems (e.g., geopolitics, regulation, trust), unintended consequences (e.g., co-opted tech, loss of agency, environment), and social and ethical factors (e.g., privacy, social justice, social trends), analyzing the patterns and clusters within, and iterating on the risks continuously, innovation can thrive responsibly without being hindered extensively. The innovation of biocompatible electronics is pertinent to this necessarily subjective analysis. Ultimately, it is up to the innovators and investors to recognize and act upon the implications of the technology they develop.

Acknowledgments

The primary author of this report would like to thank Brandon and Kyash for the acquisition of sources 3 and 4, respectively. The contents of those research articles were imperative for understanding the topic comprehensively, and their particular contributions are greatly appreciated.

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