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Smart Medical Devices: Integrating AI, Sensor Technology, and Bioengineering for Next-Generation Healthcare Solutions

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Annotation: Technological breakthroughs in sensor technology, artificial intelligence (AI), wireless communication, bioengineering, and data analysis contribute to the advancement of portable smart devices with affordable prices. The frequent use of smart devices improves the quality of life in healthcare, urban diagnosis, environmental monitoring, and many other fields. Smart health monitoring systems collect biological signals from the human body using smart medical devices. One of the most remarkable attributes of wearable and implantable medical devices is the capability to track the health condition regardless of the location of the patients and caregivers through wireless communication . Analysis of the data from medical devices has elevated the diagnostic capability from the expert knowledge of human physicians to an objective analysis of number crunchers. Hence, understanding data analytics and AI techniques applied to medical devices is a move towards the future of smart devices in the healthcare industry.

An increase in the aging population accelerates the demand for affordable remote health monitoring. Sensor technology is an essential part of wearables to

monitor vital signs. Wireless and connected monitoring devices are made portable and battery operated that lay a foundation for telemonitoring. The shift of patient care from main healthcare premises to home or community expands the early-stage recognition of diseases. The advance of human movement recognition methods reduces the complication of evaluating the physical quality of the elderly. The development of imagers, biomicrofluidics, sensors, actuators, and procedures in bioengineering enables smart wearables. Smartphone-based health devices connected over the internet of things improve the diagnosis and treatment efficiency of coronary heart disease patients and diabetes patients. Wearable medical devices integrated with sensors, actuators, thermal switches, records, and communication modules toward the measurement of 10 biological signals at home and evaluation of arrhythmias and diabetes events in hospitals are developed to reduce healthcare expenditure through automatic patient care.

1. Introduction to Smart Medical Devices

The COVID-19 pandemic has devastated public healthcare systems worldwide. The COVID-19 epidemic has prompted ongoing efforts to develop new preventive and therapeutic approaches, needing the introduction of novel medical treatments. The availability of consumables interfaces in the hospital/clinic and patients' living environments is one of their major advantages. In particular, chronic illness monitoring is getting more attention due to the rapid growth of cloud-based IoMT and the continued advancement of embedded systems. Wi-Fi, Bluetooth, NFC, and cellular technologies will be key enablers in designing point-of-care (POC) devices for home healthcare. Similarly, network routing schemes are being developed to integrate low-power sensor devices with the existing internet infrastructure. The lower cost and better performance of recent semiconductors/biosensors will democratize the internet of medical things (IoMT) solutions.

Smart medical devices (SMDs) are at the forefront of the digital revolution in the medical industry. Medical devices have traditionally been regarded as only diagnostic or therapeutic mechanical devices. Due to the integration of AI, bioengineering, and sensor technology, medical devices are becoming more intelligent, sensitive, and user-friendly. SMDs are achieving an advanced level of health data analysis by analyzing the huge amount of patient data that will be produced from wearables or implantable devices. SMDs provide unmatched long-term monitoring, and these intelligent systems can continuously analyze the data and identify the critical or nuanced changes in health data which will allow for precision-oriented early diagnosis or preventive prescribing of drugs.

A smart medical device typically consists of the non-invasive side (sensor front-end) and the invasive side (interfacing with the human body). SMDs are possible now because of the combination of bioengineering and silicon-integration, where on-chip silicon devices are being re-engineered using microbeads/3D graphenes for biocompatibility of blood/glucose adhesion, surface enzyme immobilization, cultivar specificity of antibodies, etc. Most recent advancements in AI for signal processing, machine learning (ML), and deep learning (DL) are making SMD analysis more accurate, sensitive, and user-friendly [1].

2. The Role of Artificial Intelligence in Healthcare

Artificial Intelligence (AI) refers to the simulation of human intelligence processes by machines. AI is a hugely broad term. Self-driving cars, voice recognition are all forms of AI in action. AI is currently being combined with existing tools and apps to help doctors, nurses, and other healthcare professionals become more effective and efficient. Integrating AI into healthcare solutions is challenging due to vast amounts of unstructured data generated by emerging technologies and systems in healthcare. Recent findings highlighted opportunities for scientists to innovate health management solutions with the latest technology, such as machine learning, and AI, with specific focus areas in rehabilitation, behavior change, predictive analytics, and mental health. AI has yet to play a significant role in new health management solutions. However, as awareness grows about the power of AI, the number of AI-enabled health management solutions is expected to grow significantly [1].

The medical field itself is being affected by AI technology. New AI health tools are being created that can aid individuals in their diagnosis without access to a doctor, like a strep throat diagnosis through voice analysis or heart disease predictions from ECG readings. Some hospitals have begun deploying AI for the screening of diseases like breast cancer and lung cancer, and AI chatbots are spreading to improve patient experience. However, severe ethical, legal, and regulatory issues need to be addressed. It is still unclear whether patients or hospitals can be held liable for an erroneous prediction.

There is excitement around AI in healthcare, especially as innovators reimagine how patient care might look. Algorithms can assess photos to indicate a future heart condition risk and help match patients to pertinent clinical trials. Wearable biometric sensors analyze heart rhythms and flow, quality of sleep, glucose, and cholesterol levels. Action alerts inform patients of new test results and possible disease indications. Automated systems deliver interventions in line with changing patient states. AI processes consequently reduce preventable mistakes and disease-related complications while enhancing access to care for all. However, the promises get complicated. [2][3][4]

2.1. Machine Learning Applications

The emergence of innovative academic scenarios has rigorously highlighted the use of AI in healthcare solutions. In reality, there are vast opportunities in diverse applications in AI that have been already studied, developed, and implemented in healthcare. To name a few, monitoring of cardiac arrhythmia based on ECG signals assisted with ML techniques before taking any medication, smart glucose management and diabetes control applications with wearable sensors, computerized semi-automated systems for assisted surgeries, drug administration, and drug delivery, seamless monitoring of vital parameters in remote or developing regions including smart COVID-19 rapid RT-PCR systems, etc., are to name a few of the healthcare sectors. The advantages of such healthcare-related AI will lightly be discussed. Integrating AI/ML in healthcare ensures the safety and well-being of patients at any time and location through remote disease assessment and monitoring. Furthermore, predictive screening and patient follow-ups provide easier management of healthcare. As a result, there will be a boost in patient outcomes by reducing hospital admissions and healthcare costs. AI/ML also maximizes control measures and shifts from traditional clinical treatment strategies by understanding the basic disease mechanisms [5].

ML is extensively used in case studies involving the healthcare integration of sensor technology to process extensive and complex datasets collected from wired or wireless sensors. The sensors such as IoMT, drones, and robots work as massive data-generating devices and transmit the clinical-related numerical, textual, or video/audio signals through the Internet for further analysis. An extensive amount of data can obscure analytical relationships between the parameters that are critical for decision-making abilities in biomedical diagnosis. ML/AI techniques help extract the analytical data from low-resolution or noisy data sets since some internal structures in ML/AI can extract the hidden information obtained from the formal relationship between the sample parameters and the measured signals. In the case of smart IoMT-based building blocks, the SML approaches can be classified into unsupervised and supervised strategies depending on the application purposes where the AI processing can be applied. SML is generally applied for the training phase for the generation of the learning machine, supervised by the availability of labeled training data containing a priori clinical diagnosis from the model, before operating in real-time decision-making [1].

2.2. Natural Language Processing in Patient Interaction

Software solutions such as chatbots or smart speakers are becoming more common in the medical industry. These voice-activated agents must comprehend and address medical inquiries and comprehend medical instructions and terminology. They must have a high level of robustness, comprehending errors and paraphrases made by users. Additionally, they must efficiently manage events, identify errors, and provide an audit trail for the user. The system ought to have a straightforward architecture to prevent a prolonged initial response for the action execution. Premium clients are worth considering if the system is feasible. Even if the solution is simply put on the market and potential customers are informed of prototype functionality and possible expansion options, there should be no need for expensive marketing processes [6].

Natural Language Processing is the branch of artificial intelligence that focuses on the interaction of machines and humans using natural language. In preclinical and clinical scenarios, NLP technologies are able to extract knowledge and insights from the massive amount of available literature and clinical notes, including tabular structured data obtained during patients' hospital stays. This potential application for automated data collection in a workflow and for straightforward decision support is manifold, but has not yet been widely implemented. Recent advances in NLP, including large pre-trained transformer-based language models and easy-to-use frameworks, provide fresh inspiration for implementing NLP-driven solutions to augment clinical data-, knowledge- and decision processing workflows [7].

A step towards the fusion of radiotherapy clinical routine and NLP is presented. A roadmap to embrace NLP as a technology for knowledge- and insight extraction from clinical natural language notes in radiation oncology is constructed and proposed. A brief overview of existing and emerging NLP models and tools is provided, with an emphasis on applications related to radiation oncology (i.e., clinical documentation and report generation, spectroscopy note processing, anomaly detection). Considerations for orchestrating and implementing NLP models in clinical workflows are outlined, including deployment requirements and development trajectories towards user-friendly tools and services for clinical professionals.

3. Advancements in Sensor Technology

Smart medicine uses sensing, data capture, and intelligence extraction to create wearable devices for health monitoring. Wearable sensors play a critical role in improving the user experience of smart medical devices powered by IoT, AI, and ML technologies. Vital signs sensors capture physiological signals from the human body for diagnosis. They include ECG, heart rate, pulse oximetry, blood pressure, temperature, and imaging sensors. Environmental sensors, including temperature, humidity, ambient light, and VOC sensors, monitor the environment and create a smart home ecosystem. Smart medicine uses sensor data with AI technology to improve prediction accuracy [8].

Miniaturized, affordable, and power-efficient sensors reduce the size and power consumption of wearable devices. The combination of soft and stretchable substrate with skin-adaptive sensing units promotes long-term skin interaction with minimal user discomfort. An essential future direction is to develop sensors with low mechanical modulus that can be comfortably attached to the skin [9]. The form factor of the sensors determines where they can be used. It is crucial to consider the form factor of the sensors during the design stage. Advances in MEMS sensors releasable from silicon wafers have been made by integrating the sensors with an ultrapure PDMS elastomer. Thus, comparable devices, such as MEMS cameras, MEMS imagers, and inertial MEMS sensors, can be manufactured in a handheld form factor. Several other approaches allow for the manufacture of flexible and thin sensors that can be utilized on a wide range of surfaces, from tiny components to 8-inch semiconductor pads, in batch production to lower the cost of individual devices.

3.1. Wearable Sensors

Rapid developments in sensor and wireless communication technologies have enabled the emergence of various wearable devices, which have attracted great interest in health monitoring. Wearable devices involve the integration of sensors, actuators, and processing units into compact packages that can be comfortably worn on a person's body. Such devices provide continuous, real-time, and noninvasive monitoring capabilities for human health conditions, lifestyle, and emotional index. Various diseases like cardiovascular diseases, diabetes, respiratory diseases, cancer, skin diseases, depression, and sleep disorders are the major causes of death, and the need for continuous monitoring devices has significantly increased. Health care resources are insufficient to monitor chronic diseases continuously. Personalized health monitoring is of paramount importance. Wearable devices are portable systems that are easy to use and afford. Wearable sensors can be employed in personalized health monitoring, disease prevention, and lifestyle modification [10].

Wearable sensors can monitor most biomarkers in biofluids like blood, sweat, saliva, and interstitial liquid, as well as physiological signals like motion, temperature, and pressure. The variety of analyzed biomarkers, novelty of sensing regimes, and simplicity of measurement give wearable sensors the potential for significant contributions. Wearable devices can monitor blood glucose, dehydration, cardiovascular system, physical motion, and sleep; to analyze sweat for electrolytes, glucose lactic acid, temperature, lactate, pH, and metabolic rate; to assess in situ analyses of blood/lung cancer molecules and early-stage energy metabolism; and to analyze saliva for stress, eating testimony, dehydration, and blood pressure [11].

3.2. Implantable Sensors

Continuous monitoring of physiological parameters through implantable sensors constitutes a revolutionary approach in healthcare. This approach alters the interaction between these sensors and the human body and the external environment. While currently each sensor is independent, there may be an array of sensors that communicate and form one holistic system that provides constant information on the patient's physiology [9]. By integrating artificial intelligence algorithms, these systems could detect patterns and trigger appropriate responses. The potential benefits of these self-providing systems are immense in terms of real-time and personalized healthcare. Implantable sensors can relay vital information regarding the physiological status of patients, allowing healthcare providers to remotely access and analyze real-time data. Universally implantable passive and active sensors can be used to monitor virtually any physical or physiological biomedical signal. Data valid filtering, extracting, feature selection, classification, and tracking can be applied to the received data to get a precise view of the tested physiology. This enables physicians to monitor patients' health remotely and even take proactive actions to intervene and adjust treatment plans if necessary. Even more revolutionarily, the implementation of this concept will include autonomously self-providing healthcare systems monitoring, reporting, and reacting to data coming from implantable sensors.

In the early-stage developments of such systems, a wireless communication platform was introduced for a clustered array of sensors communicating with the same receiver. These preliminaries can be adapted, enhanced, and build upon in future research. The acquisition of novel stimuli and processes within the human body, and the development of new devices and packaging platforms will enable wider utilization of long-lasting implantable sensors for the benefit of the healthcare community and society as a whole. Significant advancements in implantable sensors with varied engineering and biochemical approaches have been made toward sensitive, flexible, and conformal devices with effective power management and wireless communication methods. Continued efforts to enhance functionality, performance, and commercial viability by progressing toward larger arrays of smaller devices are anticipated. Data-rich implantable devices will further augment the impact of these methods, broadening their utilization in the pursuit of improved health. [12][13][14]

4. Bioengineering Innovations

Applications for measuring, processing, and interpreting the human physiology are expanding. Implantable sensors are now able to capture bioelectric signals to monitor the central and peripheral nervous systems. Their integration within the human body would enable a change in the brain-computer interface paradigm, allowing for more natural communication with smart devices while safer and more effective population and disease-specific machine learning algorithms for interpretation. Embedded sensors external to the body measuring vital signs and chemical levels via transdermal interaction are being introduced in the market. These technologies are estimated to shift billions if not trillions of dollars in the healthcare industry, revealing new targets for treatment, and bringing new clinical paradigms of health care from reactive to preventive. Continuous monitoring of physiological parameters is a revolutionary approach in healthcare. Once sensors are in place, healthcare providers can remotely access and analyze real-time data acquired by the sensors. This will enable physicians to monitor patients' health remotely, allowing for pro-active interventions, adjustments in treatment plans, and compliance with prescribed therapies [9]. Self-providing systems could autonomously monitor, report, and react to data received from implantable sensors. By integrating with AI algorithms, these systems could detect patterns, classify the input data, identify anomalies, and trigger appropriate responses. The potential benefits of such self-providing systems, that provide real-time personalized healthcare are immeasurable. Today, each sensor is still independent, yet it is possible that in the future an array of sensors will be implanted within the body, that communicate and form one holistic system that constantly provides information on the patients' physiology and health [15]. Creating such a multiple sensor system is challenging and requires constant communication, integration, and synchronization of information. Therefore, in the coming years researchers will have to address multiple challenges related to the development of implantable sensors. The first challenge is the long-term performance of the devices in vivo. Upon implantation, the devices will be exposed to chronic physiological parameters, enzymes, and chemical and physical signals that can affect their operation. It is unknown how the devices will react in terms of changes in the sensing element. In many cases, it is expected that long-term monitoring will cause complete loss of activity of the sensing element, and reduction of the lifetime of the whole implantable device. This point creates a need for examining the stability of devices over time in vivo.

4.1. Biocompatible Materials

The development of biomedical sensors capable of monitoring various targeted biomolecules has attracted significant interests in recent years. Both invasive and non-invasive types of monitoring devices have been proposed. Among them, devices with an implantable approach can offer continuous real-time monitoring of dynamic biologics, thus providing authentic and timely information on physiological states. Various biochemical materials including poly(3,4-ethylenedioxythiophene) (PEDOT), polyaniline, and other conducting polymers have been demonstrated for these devices. Additionally, biocompatible alternatives with semiconductor properties based on MoS2, graphene oxide, and metal oxides have gained attention for implantable bio-sensing. All of these materials have great advantages in terms of conductivity and tissue adhesiveness over gold or platinum-based devices which can potentially be used for long-term applications in biological environment. Along with the device design, the fabrication techniques of implantable biodegradable sensors must address intricacies of working with materials that are sensitive to conventional processing methods [16].

During the preliminary stage of the experiment, design of the device is dictated mainly by the choice of materials. One pinch of the material varies and the device must be redesigned. Affinity of the material to the photolayer for the lift-off process demands tedious optimization process. Packaging or protection of the device must be pre-planned. Compromises must be made among device designs. It is not easy to integrate smart devices into the human body as implantation necessitates careful consideration of device size, sensitivity, and biocompatibility. Devices that are too big may not be acceptable by patients and devices that are too small may be prone to loss with the death of cells. Devices must not cytotoxic allowing them to operate within tissues for decades. Additionally, motion of biomolecules among different regions must be studied so that designs can be modified suitably. The design and development of implantable biodegradable biosensors necessitate a holistic approach, where considerations of power supply, data communication, and implantation strategy are intricately linked with choice of materials and fabrication methods. [17][18][19]

4.2. Tissue Engineering

All tissues are composed of different cell types organized in a defined structure that can carry out various functions. An increasing number of people suffer from clearly defined tissue deficiencies and diseases, solely because tissue regeneration is not occurring or is slow. Tissue Engineering is a multidisciplinary field seeking to provide an alternative solution for tissue repair and regeneration. It is primarily concerned with the in vitro regeneration of diseased tissues, promoting healing through the supplementation of embryonic development as opposed to the existing therapeutic strategies. If successful, tissue engineering may dramatically change medical practice and provide the possibility of regenerating tissues or even organs [20]. Major expected results include improved healing processes and increased quality of life.

Such possibilities would impact a large portion of the general population since a variety of diseases arise from tissue deficiencies, such as acute trauma or chronic diseases in the liver, heart, kidneys, or pancreatic beta-cells. This would contribute to a better understanding of basic biological processes involved in morphogenesis or diseased tissue progression and the development of regenerative therapies. Decades of multidisciplinary research in the fields of biochemistry, cell biology, mechanical and chemical engineering, material science, and robotics have led to the establishment of techniques to provide constructs within which cells are able to proliferate, differentiate, and build a mutually supporting extracellular matrix allowing for tissue-specific functions [21].

Additional advances in bioengineering are expected to overcome many yet challenged obstacles or existing limitations. High-throughput approaches are about to discover materials or methods yet impossible to conceive manually. As such, the possible applications of tissue engineering are numerous but at the same time profoundly complex. As an overview of different technologies for regenerative medicine, it will be divided into two broad categories: constructs for cell-based therapies and conventional biomaterials for tissue organogenesis. Only selected approaches will be highlighted and discussed in greater detail. Considerable additional potential and innovative refinement could be expected in these and other important areas as well.

5. Data Management and Security

Successful clinical care and medical research rely on two major functions: acquiring healthcare data from heterogeneous data sources and converting it into integrated patient-centric representations. The necessity to collect, gather, and observe different medical parameters distinguishes telehealth and telemonitoring frameworks deployed around the world. Many important companies have invested in commercial systems to utilize telemonitoring for chronic diseases in hospitals, with health insurance organizations increasingly supporting commercial systems. Unfortunately, however, consumers are left with many disjointed platforms and devices presenting only a subset of their health status, while hospitals are dissuaded by the ever-increasing range of devices and the industry's proprietary tend to close solutions. Thus, it is superior to execute the next step, to aggregate the output of different devices on a leveled technological side [22]. This is why collecting, interpreting, and delivering data from different medical devices and applications is even more important now than it was five years ago.

Healthcare providers are on a journey to exploit the availability of data collected from medical devices entering health care organizations in order to improve patient care and medical research. Truthfully, they struggle with siloed and heterogeneous systems and rely on dedicated development efforts to extract the data. Many of the health-IT projects in use routines operational needs and technical barriers, tend to be neglected, and show limited payback. These challenges fall especially on patient care and rights protection. Medical facilities such as hospitals do not share health records with attentive stakeholders due to potential data breaches and leaking sensitive information. Concerning medical research, the challenge lies in data interoperability, analyses, and sharing without compromising participants' anonymity, privacy, and safety. [23][24][25]

5.1. Patient Data Privacy

The emergence of artificial intelligence (AI) has raised urgent and significant privacy concerns. The growing commercial market for AI-based healthcare technologies poses unprecedented privacy risks that have implications for health and health equity. This situation is underscored by the proliferation of consumer-facing AI chatbots targeting health, mental health, and wellness as a high-risk sector and the earlier-but-ongoing efforts to integrate AI into healthcare services offered by governments and large health systems. These advances in AI promise large improvements in health and huge returns on investments. The same data that underpin these opportunities, however, also has the potential to cause tremendous harm. Privacy breaches of patient information cause significant psychological stress and fear of returning to care, have unknown downstream health impacts, and are associated with longer-term declines in mental health. Due to a shift toward more in-patient consumption and use of health information, patient loss of control over personal data threatens individual agency to shape health pathways. Advancements in AI to derive insights or create new data could render patient data fully unaccounted for within commercial systems, rendering meaningful consent practically impossible.

Existing regulation of privacy protections has largely failed to keep pace with AI in healthcare, resulting in an opportunity for companies whose AI goes unregulated [26]. There is a need to safeguard the promise of healthcare AI for health improvements, while forcibly constraining the potential harms of health inequities. A conceptual framework for future regulation of AI in healthcare is proposed reflecting existing principles of information privacy relevant to AI-specific concerns. The framework emphasizes the role of patient agency across the regulation landscape, with the goal of informing policy development that is fundamentally guided by human needs. Wherever legal analyses establish statutory inadequacies, accommodation of unmet information privacy needs is vital because it speaks to an ethical legacy of inalienable rights. Novel inclusion of AI-specific protections within respective high-level regulatory frameworks worldwide is vital to ensuring that humanity rather than the algorithm has control over individual health pathways. In the implementation of overarching, high-level principles, technological shortcoming in compliance that precludes safety must be noted and avoided. Reasonable regulation requires human feasibility to follow compliance requirements. Where systemic innovation is required, regulators need to initially establish expected safety standards and development timelines within which all parties in a market must comply.

5.2. Cybersecurity Challenges

Emerging generations of networked devices such as IoT and wireless devices are transforming healthcare by providing smart and personalized patient care solutions. These smart medical devices are tightly integrated with AI technique, bioengineering, and sensor technology. However, manufacturing and deploying these connected devices massively raises the footprint for potential threats and attack surfaces against security and privacy. Medical IoT devices and service management systems often perceive multi-folded security and privacy vulnerabilities, including data breach, man-in-the-middle, and denial-of-service attack, which may hinder smart healthcare adoption and lead to disastrous consequences [27]. Unfortunately, yo-safety and cyber security has yet been put forward for efficient mitigation.

A vast number of smart medical devices such as Internet of Medical Things (IoMT) devices are currently connected to healthcare systems and are widely being adopted in domains like tele-conferencing, remote monitoring, clinical lab, and medical imaging. Medical IoT systems equipped with smart medical devices massively amplify healthcare service coverage, attendance, and scalability [28]. With the huge success of smart medical devices in providing timely and precise patient care, attackers may target data of their interest, like taking a shot through temporary denial of medical service or data manipulation, potentially endangering patient safety. Cybersecurity in healthcare is a critical concern due to the serious security vulnerabilities of medical devices.

Cyberattacks on medical devices not only damage how the devices perform their medical function, they can also heal patients by implanting malware that causes harmful side effects. Further trending of long-range and wireless connected medical devices are anticipated to drive their broader deployment and integration with healthcare manager systems, but with the cost of reduced operand control and increased attack surfaces. Cybersecurity technology adoption still lags behind, seemingly under the spell of traditional industry regulation tradition, lack of timely threat intelligence sources, and enforcement obstacles. On offline medical devices, risk remains as hacking, data tampering, and malware-laden supply-chains. Medical device hacking books have seen boom sales. [29][30][31]

6. Integration of AI and Sensors in Medical Devices

Smart medical devices writ large are becoming prominent in healthcare, fueled by advancements in electronics, sensor technologies, and artificial intelligence (AI). These devices can be divided into three categories based on the anatomy they interact with: external, intra-body, and attached smart medical devices with flexible, stretchable, and biocompatible mechanical features. Market-wise, smart wellness devices lead the sector with a 30% share, followed by intra-body smart devices that constitute a 20% share. AI techniques reside at the core of smart medical devices, as they allow the interpretation of the acquired data. Moreover, sensor technologies either detect biological signals related to diseases or apply therapies to patients. A comprehensive review of the integration of AI, sensor technologies, and bioengineering on smart medical devices is presented.

Smart medical devices can be divided into three categories based on their methods of interacting with the human body. External smart devices come in contact with the body surface. Intra-body smart devices are inserted/implanted inside the body, utilizing a communications relay on the outside. Smart devices with flexible, stretchable, and biocompatible mechanical features are attached to the tissue or organs, transferring and receiving signals to/from the body and environment [1].

Smart wearables can identify and categorize events associated to deviations from the healthy physiological values. Wellness wearables mainly include activity trackers, smart watches, smart glasses, ECG monitors, oxygen monitors, heart watches, biosensors, etc. The device design places a significant role in the market share. The field of wearable sensors has blossomed in recent years and off-the-shelf biosensors provide new perspectives unveiling the skin microbiome, sweat profile, glucose regulation to name a few. Future personalized medicine will draw even deeper from integrating wearables with customized smart devices. With the rapid acceptance of 5G communications, the competition within the smart wearable market is heating up.

6.1. Real-Time Monitoring Systems

Life is busy with an active lifestyle, and there are a huge number of tasks to take care of. The passage provided an overview of how the current and future paradigm of social and health management can be transformed through the convergence of AI, sensor technology, and bioengineering [32]. Over the past 10 years, researchers and technology companies have been exploring the use of wearable sensors to monitor physiological parameters and activities. These devices can record real-time information on usable gadgets such as wristbands or glasses or through a wearable piece of clothing. When incorporated with sensors, this wearable technology can measure health-related physiological signals, such as heart rate, body temperature, arterial oxygen saturation, breathing rate, and body movement [33].

To empower self-monitored interventions, it has to be mentioned that real-time feedback is useful both for patients and for the healthcare professional. A smart healthcare-monitoring system provides an easy-to-use interface and adequate tools for patients to better understand their disease and to see immediate and objective results of their actions on them. In an active lifestyle, the objective will be to improve behaviors, and this learning will give patients the empowerment to make decisions about their disease. Meanwhile, the health professional will have access to numerous individual data that enables the provision of personalized advice, prediction of events, prevention of disease incidence with public health policies, early diagnosis, and chronic control conditions. Since these outcomes rely on data that is secure and reliable, there is the expectation that there will be a relevant increase of sensors and wearables in clinical trials. This integration will dramatically accelerate the knowledge of diseases and developments of new treatments.

6.2. Predictive Analytics in Patient Care

Redundant procedures and care inconsistencies have historically weakened patient trust in care teams and led to poor health outcomes. Predictive analytics tools can proactively notify health care teams of patients who might require follow-up or immediate action owing to warning signs [32]. Algorithms can analyze signals from numerous devices, understanding which conditions pose the greatest risks of patient morbidity or mortality. Historical guidelines and predictive information have traditionally aided this effort, typically categorized as either clinical prediction models or machine learning predictive models. This classification can help identify high-risk patients for specific attention or interventions to avoid poor health outcomes and patient readmission rates. However, traditional approaches for personalizing a patient’s care path have required substantial human interpretation due to their complexity, sluggishness, or requirement for anatomical or physiological knowledge [34]. The advancement of artificial intelligence has enabled the creation of interpretable or easy-to-graph alternatives, such as decision trees, which could offer targeted recommendations regarding the specific follow-up tests for a patient. Automatic recommendations can be made for this lower-hanging fruit in terms of aiding care teams in correcting or accelerating at-risk patient paths. Furthermore, decision support could be enhanced even further by providing recommended annotations for audio, visual, and other data types or automatically generating reminders about past exposures, changes, or assumptions. For these efforts, a more robust AI will emerge through the continued compilation of data across an ecosystem of devices, patient portals, and care teams. This classification could likely be sufficient to significantly enhance non-patient-facing health care processes by 2025. However, there is uncertainty as to whether the underlying technological, ethical, or regulatory requirements would be sufficiently robust for patient-facing care teams. These predictions can afford health care systems transparency in how decisions are made.

7. Regulatory and Ethical Considerations

Medical devices are increasingly adopting AI support to analyze streaming data and identify patterns associated with different types of physiological signals. Some evidence and reliability of monitoring/detection are required for these medical devices and services in terms of the onset and progression in disease severity, which must be proven by medical professionals to satisfy regulatory approval. The accuracy of detection must be investigated using ancillary data to recognize the limitations of the prior monitoring modeling. These medical devices typically have a regulatory control mechanism initiated by safety, efficacy, and risk estimation because of potential hazards, which determine how rigorously and how extensively assessments are performed: from very stringent to little or no regulatory control [35]. Three main groups of medical devices with technology types are distinguished: Group I consists of medical devices with hardware technology only and high-established safety; Group II consists of medical devices using AI-based analysis as an add-on function with low-established safety but high acceptability; Group III contains innovative combinations of hardware and AI technology. Group III includes devices that have either newly developed and lower-established safety hardware devices, which require at least a pilot study or a clinical trial for prior investigation, or devices with very novel AI modeling themselves, which require comparability data to pre-existing methods in analyses. Regulatory demands in terms of the scope and extent of assessments vary substantially according to these three groups of smart medical devices. Regulatory pathways for the assessment of smart medical devices should be tailored to the development lifecycle of particular medical devices [36].

7.1. FDA Regulations on Medical Devices

Today's society brings rapid technological advances and hopes for the benefits it can bring. One of the most exciting developments is machine learning and other AI techniques. These artificial intelligence methods have emerged and gained significant interest. Promising to explain and tackle the most intricate problems in medical science and healthcare. The expectations are reset, and as it usually is in the healthcare area, the incredible benefits coupled with the potential issues need to be cautiously addressed to avoid disasters [37].

The medical firsts associated with AI are all headline-grabbing surfacing about surgery with robotic tools or change in diagnosis via an algorithm trained on millions of health records. Medical imaging is where advertising efforts and exciting possibilities are the most immediate. Most of the eyeballs, cameras, and expertise needed to collect data reside in the outermost part of healthcare, the hospitals and their specialists. It seems here that there is a possibility for AI with its different ways of catching medical patterns to help in getting the most out of the captured data and collect ahead of diagnoses.

The road to real-life adoption of those devices is not without its intricacies, problems, and hazards. A healthcare AI device is a very vague term for a box that captures incredibly sensitive data on a patient. Processing those images with the algorithms trained on even more sensitive data and vulnerabilities of sending all that information to retrieve an interpretation over the internet. What if the AI device is hacked, and the personal data of millions of patients is defective? What if the AI device diagnosed all Blacks with diabetes regardless of anything due to the unreasonably biased training data?

Sudden deaths of ethnic minorities due to misdiagnoses with medical cameras trained on such racial biases are even less fictional than unbelievable. Additionally, what is the certainty that the performance and the algorithm used on that device were as good as what was presented? Many studies proving the efficacy of the device accompanying the CE mark and the algorithm, which is typically a black box, may be poorly designed in statistical terms and even present magic numbers. Many devices may be scrutinized for years and years and yet still not reproduce well under the real-life screening.

Maybe due to the damage and dire consequences of an incorrect algorithm or simply due to the widely-known hope, it seems here that the need for legislative input, oversight of the governing bodies, and readiness for any litigation that the novel frontier would create need to be addressed upfront. However, on the European side, the approach, while acknowledging the need for regulations and knowledge of the devices, is vastly different. On the European side, one can get a medical AI device for a few hundreds of euros, while on the U.S. side of the ocean, the FDA has not given a grant to a medical AI device for almost 4 years. Regulation means the committee of experts basically analyzing diseases, patients, and how the algorithm was again carelessly analyzed for years and probabilistically verified on rigorous statistical design screening devices.

Medical devices are regulated at the federal level in the United States by the FDA. A device is defined as anything used for "diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals". There are several important features of this definition: all devices are regulated at the federal level; devices are defined by their intended use, which could either be for human or animal use; and most importantly, the fact that devices determine or alter the makeup (physiological, pathological, anatomical, etc.) of a living being included many products that could potentially be considered "medical".

After a product is determined "medical", the FDA must assess the device's application through the appropriate pathway. These pathways vary in their regulatory libraries and clinical testing requirements. Four recent AI devices are currently pre-market approved based on "A Message to AI Developers for FDA Approval of AI Devices". It focuses on robust testing of safety and efficacy, provision of transparency in liability and generalizability, intensive post-market monitoring for performance drift, and user education.

7.2. Ethical Implications of AI in Healthcare

The integration of AI into healthcare provides promise but offers new exciting challenges and deserves similar if not greater consideration when applying these technologies. AI provides healthcare technology with the opportunity to transcend the limits of human cognition. The implications of the immense power of AI must be thought through to ensure that society does not lose control over these powerful new capabilities. AI technologies adopt a novel approach to problems, including opacity in their operation, lack of inspectionability, and complexities in understanding the internal representations learned through the training process. This leads to the development of new ethical challenges, including transparency, bias, privacy, safety, responsibility, justice, and autonomy, aside from classic medical ethics [35].

These challenges arise directly as a consequence of the unique properties of AI. For example, while bias in diagnostic tests is a well-studied ethical challenge, it may arise in new ways under AI-based technologies. Also, while lack of privacy and abuse of privileged information has always been a danger in healthcare technologies, AI poses a new angle by which very personal health data can become less secure. In the past, healthcare-related access to private data was always held by a trusted institution, namely the hospital where the health history generated; with AI, it becomes easier to share data outside the institution or to compound datasets across many institutions or even social media, leaking sensitive information and hindering personal privacy.

Basic differences between traditional ethics in the medical domain versus emerging ethical challenges with AI-driven healthcare systems are presented. AI ethics is only beginning to receive attention. It is explored how AI is changing the landscape in smart healthcare, as well as novel ethical challenges related to AI technologies. Promising domains for further research on AI ethics are also proposed. AI is widely viewed as one of the most promising means to achieve improved healthcare access, augmenting the limited doctor supply, reducing medical error rates, targeting underserved populations, and finally delivering improved population health. AI, along with network-connected devices, ubiquitous sensors, and near-universal cloud computing, can provide personalized healthcare anytime and anywhere.

8. Case Studies of Smart Medical Devices

The development of intelligent healthcare systems has been made possible by advancements in sensor technology and cloud computing, among other forms of information collection technology. Through the Internet of Things (IoT), patient health data in the form of vital signs from wearable devices is shared in real-time with doctors, who can remotely inquire about the patient's health condition. A Smart Sensing Technologies-Based Intelligent Healthcare System for Diabetes Patients was designed using Artificial Intelligence and IoT-based monitoring [32]. The system continuously monitors different health parameters and delivers timely recommendations to the physician while alerting patients to take necessary actions. The system is equipped with a non-invasive blood sugar sensor based on NIR technology and uses an AI-enabled decision support system and fuzzy logic classification for the prediction of health conditions.

The device is used for prediction and control over different parameters like BP, sugar level, temperature, and a smartwatch for pulse rate. With the completion of the device, the patient health conditions will be recorded, and in case of higher parameter levels, alerts will be generated with the required precautionary measures, including physical exercise, food recommendations, and doctor alarms. The alerts can be sent via text, voice, and the App interface, and the emergency response team will be informed about the emergency situations.

The proposed device will monitor body temperature, heart beat, blood pressure, perspiration, and blood sugar level continuously without the need for finger prick tissue. The NIR-based light transmitter/receiver pair will transmit the infrared light through the skin to a photodiode and record the transmitted intensity. Normal glucose ranges and [Hb] levels for different age groups are stored in the memory unit. The glove will have NTC thermistor for body temperature measurement, force transducer for perspiration level detection, and a piezoelectric crystal for the measurement of heart beats by using a peizo-duo paired with a module for audio conversion.

8.1. AI-Enabled Diagnostic Tools

Traditionally, diagnostic finds in medicine have come from subjective human-led examinations of data, whether from a physical exam, subjective history, a laboratory test or an imaging study. Such diagnostics are intrinsically limited, because human cognition is not capable of considering at once the vast amounts of information that exist in even simple cases in clinical practice. These data existence explosions are compounded by the reliance on significant technological advancements for health care, and the ability to gather this information is outpacing the ability interpret this data. This provides an opportunity to remedy this inadequacy through computational techniques, commonly referred to as artificial intelligence (AI) [38].

Machine learning (ML) can reduce the volume of data to be considered at once, or alternatively analyze these data, where analytical approaches go beyond simple reductionism and construct logical and actionable inferences about the clinical setting. Such methods are broadly applicable to many platforms and devices for interrogation of biochemistry, physiology, and anatomy. The most broadly recognized machine-learning finds come from medical imaging, where vast amounts of anatomical information are processed for diagnostic and therapeutic activity. As image acquisition technology advances, the health systems and practitioners who must cope with the ever-increasing volume and complexity of imaging data are turning to AI techniques.

Certain large companies are venturing into the medical device market to meld AI with imaging systems, which provide an opportunity for testing and translation of AI workforce tools that improve diagnostic quality, efficiency, and patient care. The AI+ imaging system class is clearly justified and needed because images are increasing in size and complexity. However, this paradigm can be applied with equal force to many medical devices and devices outside of imaging. In fact, expanding AI to non-imaging devices could be an even larger opportunity, as there is less competition, the machines are newer, and hence open-ended and could benefit the largest obsident markets, including SM diagnostics, smart phones for bioengineering, and home devices for monitoring and data acquisition.

8.2. Remote Patient Monitoring Systems

Smart medical devices deliver high-quality healthcare remotely. They are gaining increasing acceptance in the medical domain, helping healthcare providers access patients' vital information and reduce the cost of care. The invention of novel, low-cost sensors combined with machine learning approaches is extending the power of telemedicine to complicated biosensors and lab instruments. Jointly, they exponentially amplify the prospects of smart medical devices. Development of non-invasive and wearable smart medical devices for in-hospital and out-of-hospital remote monitoring is discussed in this section [39]. Integration of advanced technologies for in-hospital and out-of-hospital medical diagnosis is crucial for maintaining uninterrupted healthcare during pandemics. Physiological signals are essential to monitor a patient's condition and detect any changes. Conventional health-monitoring techniques require the physical presence of a doctor, leading to transmission delays and delaying timely medical intervention. Therefore, a solution that allows doctors to remotely monitor their patients' health and notify them about their condition is particularly desirable [40]. Smart medical devices continuously monitor patients' clinical parameters and help doctors assess the clinical status of patients electronically. These devices typically include a wearable medical sensor, networking capabilities, a cloud server for data storage and analysis, and smartphone applications for end-users. Wireless medical sensors have been developed at an informative low cost, allowing patients to check their health status by themselves.

9. Future Trends in Smart Medical Devices

Today, smart medical devices are at the forefront of healthcare technological advancement. Healthcare stakeholders, including manufacturers, patients, clinicians, health systems, HTA authorities, and regulators, depend on a broad array of medical devices to deliver preventive, diagnostic, therapeutic, and monitoring services for health maintenance and disease management. Across the globe, there is a keen appreciation of the potential of medical devices in revolutionizing healthcare delivery. In the USA, for instance, the role of devices in ameliorating healthcare delivery is a key focus of the Federal Drug Administration's (FDA) 2020 Digital Health Innovation Action Plan.

Given the pace of technological advancement, smart medical devices are expected to become ubiquitous in healthcare systems across the globe. However, it remains uncertain whether healthcare stakeholders (especially patients, physicians, health systems, and regulators) are adequately prepared to accommodate this technological shift. Stakeholders need to be equipped with the knowledge, skills, and tools necessary to embrace the benefits that the interaction of AI with sensors and devices can provide. The objective of this article is to lay a comprehensive foundation on smart medical devices for healthcare stakeholders, highlighting the technologies involved and the current and envisioned future role of the devices in transforming healthcare.

Importantly, AI is an umbrella term that describes a system that can process data in a way that mimics human cognition. Machine learning refers to the subset of AI that encompasses techniques that allow a system to learn without explicit human intervention. Translational machine learning refers to the application of machine learning in a given field such as medicine. The use of the term "AI" in this article will be limited to the most common interpretation of it in healthcare, namely, ML techniques applied to healthcare data [38].

9.1. Telemedicine Integration

Telemedicine has grown from a niche service into a mainstream practice over the last two and a half years. Hospitals are now offering price-saving online care options as insurance companies begin to respond to an exponential rise in telemedicine utilization during the COVID-19 pandemic. In this rapidly expanding market, it is critical for developers to differentiate their product offerings for no other reason than to earn a seat at the table. In this section of the research, smart telemedicine technology is presented as form of technology that can generate competitive advantage in a crowded marketplace. This section researches controllable parameters that can impact telemedicine design and service. Using non-parametric analysis of variance to look at a new integration of call recording technology with Smart Telemedicine technology, it is shown how analyzing customer interaction data improves understanding of user motivation and allows for better technology design.

Telemedicine refers to the use of technology to exchange and deliver health information and services from one site to another. Telemedicine is often used synonymously with telehealth. However, telehealth describes a broader range of technology-mediated health services outside of clinical care. Telehealth may also include non-medical information and services delivered via telecommunications technologies. Telemedicine can be used to improve access, increase efficiency, and support the ongoing delivery of healthcare. However, there still remains limited knowledge of efforts to integrate telemedicine into organizations. This literature review examines the application of telemedicine across a number of healthcare organizations, addressing the key aspects of the organizational environment necessary for the successful adoption of telemedicine [41].

Smart Medical Devices are emerging technologies that leverage the confluence of advances in sensor technology, bioengineering, and artificial intelligence. With the reduction of size, cost, and power consumption of electronic components, these cutting-edge devices are becoming more ubiquitous and affordable in recent times. They hold the promise of transforming next-generation healthcare solutions and guidelines in a time and cost-saving manner. Bioengineering is playing an important role in developing biocompatible and implantable smart devices to perform physiological studies in a chronic and unobtrusive way. The significant cognitive and communicative dissonance between medical professionals and patients can lead to misdiagnoses. Artificial Intelligent (AI) tools have been developed to assist in disease interpretation, symptom detection, and medical recommendation.

9.2. Personalized Medicine Approaches

Recent advances in biomedical engineering, electronics, computer science, artificial intelligence (AI), and data analytics have enabled the development of innovative smart medical devices (SMDs) that are extending the benefits of biomedical improvements directly at home. Growing application areas include chronic disease management and sedentary lifestyle control, monitoring parameters like heart rate, blood pressure, and blood glucose, for instance. Smart Wearable Medical Devices (SWMDs) such as smartwatches, smartbands, and hand-held devices that measure one or multiple blood parameters together with analyzes based on proprietary machine learning algorithms are also becoming available thanks to the growth of the Internet of Medical Things (IoMT). SWMDs are developed with a biocompatible sensor material that affects blood parameters. Boasting AI and Integrated Compliant Electronics (ICE) processing in both edge and cloud, SMDs should be secure, robust, and privacy protecting devices that output real-time parameter values, trends, and anomalies together accompanied with contextualization information allowing users to predict need and severity of possible adverse events. SMDs are internet-connected biomedical devices operated at the edge or portable/mobile CDPUs and/or Cloud Data Processing Units (CDPU) linked to mobile and desk computers via Bluetooth, ZigBee, Wi-Fi, or 3G+. Data sources include SWMDs outputting biomedical signals and parameters in addition to data from smartphones and mHealth applications, and/or fixed installations of devices in healthcare facilities exporting biomedical images and signals [42]. Such devices need sensor material R&D, data collection from different sources, network/system architecture design, signal and parameter preprocessing (denoising, derailing), processing and analytics (AI based pattern and anomaly detection, classification, and contextualization), as well as output displaying platform.

There is an increasing interest in preventive, predictive, personalized, and participatory healthcare due to the rising costs of treatment and drugs. The term "4P medicine" has emerged in the last 20 years, indicating a full paradigmic shift from drug-centered healthcare to patient-center health prevention [43]. Such a 4P healthcare paradigm requires the timely collection and advanced analysis of a wide range of patient and population-related information. These data pipelines need to be automated and lost-free handling gigabytes of signals generated at the edge. Integration and analysis of health data would allow monitoring individuals' health and disease indicators and develop a digital human twin that would 'mirror' the evolution of health indicators, prediction their future trends, and warn individuals over probable future events. It can also perform in silico trials of personalized treatment strategies, or even new medication.

10. Challenges in Implementation

While smart medicine holds enormous potential for new products and better healthcare, overcoming technical hurdles will not be sufficient for successful adoption of new technologies. Some of the challenges include the ethical issues of patient privacy and data ownership and the societal risks from algorithmic bias in machine learning [35]. Healthcare is a privacy-sensitive domain by nature, and smart products that make use of personal data to enhance their effectiveness and value can threaten the personal and medical confidentiality of patients and their providers. Accordingly, regulation of data usage in smart medicine is becoming indispensable in addressing such issues. Existing standards related to data privacy in healthcare should also be reinforced in the context of further convergence of information technologies and operational technologies. Multistakeholder approaches involving providers, patients, regulators, and politicians are likely to be required and also be useful in arriving at solutions without overly stifling innovation.

Algorithmic bias is a well-known societal risk of machine learning, which is prevalent in a myriad of automated systems, including those in hiring, lending, justice, and policing. It has also been shown to occur in various healthcare systems, such as in patients' classification for heart failure. If unaddressed, this bias could hamper the accuracy and quality of healthcare. Biases in input features can be a cause for algorithmic bias, and can originate from several known sociotechnical factors. However, some of the features could be essential for building the model. Drawing from core principles and methodologies from AI alignment— a subfield of machine learning aimed at getting AI system goals to align with people's intentions—recommendations on what can be done to mitigate these issues must also protect and monitor model performance over time as both the data distribution and utility of features are subject to change. In recent years, society has begun to take the risks and ethical worries of machine learning seriously, and there is a growing scholarly literature that investigates the various social and ethical concerns around machine learning.

11. Conclusion

With the Internet of Things (IoT), bioengineering, artificial intelligence (AI), advanced microcontroller units (MCUs), and sensors' advancement, some great advancements take place in health care to address continuously changing health needs. Advanced health care devices are developed to provide smart monitoring and assist applications for different society types, such as individual health monitoring, community health monitoring, and hospital health monitoring. Diverse IoT-based bioengineering and health care devices and application scenarios such as smart home health monitoring, smart health-care technologies, smart contact lenses for health monitoring, an intelligent wearable for patient activity monitoring, smart shoes for elderly fall detection, smart wrist bands for non-invasive glucose monitoring for diabetes patients, and a smart non-contact health monitoring system for early detection of sleep apnea and vital sign measurement based on microwave radar and Li-Fi have received great attention. Smart medication adherence systems connected to healthcare management services via IoT have also appeared recently. Next-generation health care devices integrated with smart bioengineering-enabled wearable or non-wearable sensors, AI, and IoT are emerging.

Considering societal health care application needs, patient health monitoring, assist, or predict with AI and bioengineering-enabled health-care devices, system architectures, and a variety of case studies are summarized in this paper. Some AI-enabled smart non-invasive patient health monitoring and assistant devices for predicting patients' health conditions are discussed. They include diabetes patients and other disease patients. A recent smart wearable continuous non-invasive glucose monitoring wrist-band for diabetes patients is described, where its proposed health monitoring architecture with wearable integrated sensors, smart AI-enabled smart phone applications, network communication, cloud server, and distributed doctor portal architecture is proposed and discussed.

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