Examining the Design, Manufacturing, and Analytics of Smart Wearables

Abstract

Recent advancements in sensors, device manufacturing, and big data technologies have enabled the design and manufacturing of smart wearables for a wide array of applications in healthcare. These devices can be used to remotely monitor and diagnose various diseases and aid in the rehabilitation of patients. Smart wearables are an unobtrusive and affordable alternative to costly and time-consuming health care efforts such as hospitalization and late diagnosis. Developments in micro- and nanotechnologies have led to the miniaturization of sensors, hybrid 3D printing of flexible plastics, embedded electronics, and intelligent fabrics, as well as wireless communication mediums that permit the processing, storage, and communication of data between patients and healthcare facilities. Due to these complex component architectures that comprise smart wearables, manufacturers have faced a number of problems, including minimum sensor configuration, data security, battery life, appropriate user interfaces, user acceptance, proper diagnosis, and many more. There has been a significant increase in interest from both the academic and industrial communities in research and innovation related to smart wearables. However, since smart wearables integrate several different aspects such as design, manufacturing, and analytics, the existing literature is quite widespread, making it less accessible for researchers and practitioners. The purpose of this study is to narrow this gap by providing a state-of-the-art review of the extant design, manufacturing, and analytics literature on smart wearables-all in one place- thereby facilitating future work in this rapidly growing field of research and application. Lastly, it also provides an in-depth discussion on two very important challenges facing the smart wearable devices, which include barriers to user adoption and the manufacturing technologies of the wearable devices.

Keywords: advanced manufacturing, healthcare analytics, health monitoring, point-of-care device, wearable sensor, smart wearable, 3D printing.

1. Introduction

In 2015 alone, more than two million people died in the United States, most from chronic diseases (Murphy, Xu, Kochanek, Curtin, & Arias, 2017). Today, approximately 80% of Americans over the age of 65 and 60% of adults in general are known to have at least one chronic illness (Irving, 2017; Life Changes LLC, 2017). Along with the health impact, this severely affects patients' quality of life. Due to this increased mortality rate, widespread chronic disease, and comorbidity, the current generation has become more conscious of their health. This has led to a growing trend in modern healthcare management (Mück, Ünal, Butt, & Yetisen, 2019), wherein people now want to constantly monitor and diagnose their health status via smart wearables, and take appropriate action to prevent future health-related concerns.

Healthcare wearables have developed slowly, over time. The first device emerged in 1955, when Edward Thorpe and Claude Shannon invented the first wearable computer (Thorp, 1998). This was followed in the 1960s by the creation of one of the first wearable health devices; produced for patients with arrhythmia, it was known as the cardiac pacemaker (Cima, 2014). Technological advancements in the past decade have facilitated the evolution of all stages of healthcare wearables, from concept to creation. They now are capable not only of collecting high-quality real-time data, but also of analyzing the data collected and providing functionalities ranging from point-of-care (POC) diagnosis and prognosis to personalized treatment and rehabilitation. Thus, they have transformed from "wearable" to "smart wearable" technology. The increasing efficacy of smart wearable devices has also led to an increase in their popularity, as they now serve as a convenient and effective tool for regulating user health. Currently, one in six (15%) consumers in the United States uses a "smart wearable," including smartwatches or fitness trackers, and their sale was estimated to increase to ~110 million by the end of 2018 (Juniper Research, 2013). As a result, the current technological revolution in healthcare is actively changing the roles doctors and patients play within the healthcare system, expanding the potential of wearable healthcare devices (Appelboom et al., 2014).

Specifically, smart wearables are minimum-sensor configuration devices worn on the body that feature embedded intelligence. Popular smart wearables are often used as accessories; these include (but are not limited to) smart glasses, wristbands, and shirts (White et al., 2002). They have been popularized in the healthcare sector for their ability to track physiological signs such as blood pressure, heart rate, body temperature, and blood oxygen saturation (Raja et al., 2019; Windmiller & Wang, 2017). These configurations primarily depend on the methods of sensing being used, such as optical, electrophysiological, and electrochemical (Kamišalić, Fister, Turkanović, & Karakatič, 2018; Seshadri et al., 2019). For example, smart wearables measuring bioimpedance can be worn as smart shirts or wristwear, but not as a smart glasses; this is due to their inability to measure the target physiological signal when in the glass configuration (Cho, 2019). A number of commercially available smart wearables, as well as their configurations and the physiological signals measured, are listed in Table 1.

(Insert Table 1 about here)

Beyond simple physiological measurement, some smart wearables are also capable of diagnosing diseases and disorders such as sleep apnea (Rodriguez-Villegas, Chen, Radcliffe, & Duncan, 2014), Parkinson's disease (Rovini, Maremmani, & Cavallo, 2017), and atrial fibrillation (Chung & Guise, 2015; Raja et al., 2019). These wearables have an integrated framework that allows for data collection, connectivity to a cloud-based server for data transfer and storage, and embedded machine learning and data analytics algorithms that analyze data for diagnosis.

Recently, wearables have been developed with the ability to provide disease prognoses. These are often accompanied by a user interface for accessing health-related feedback and warnings of impending episodes such as epilepsy attacks (Johansson, Malmgren, & Alt Murphy, 2018), sleep apnea (Le, Cheng, Sangasoongsong, Wongdhamma, & Bukkapatnam, 2013; Patel et al., 2009; Rodriguez-Villegas et al., 2014), and other issues. Moreover, smart wearables are not limited to the above-mentioned applications. They can extend to treatment and rehabilitation applications as well (Patel, Park, Bonato, Chan, & Rodgers, 2012; Shishehgar, Kerr, & Blake, 2018). These applications include the monitoring of vital parameters while a patient in rehabilitation is at home and not at a healthcare facility. Overall, smart wearables offer

independence to patients in rehabilitation and an easy way of monitoring one's health. Fig. 1(a) summarizes a number of different healthcare applications of smart wearables.

(Insert Figure 1 about here)

In terms of manufacturing, smart wearables must be small and convenient enough for a user to wear. They should be lightweight, flexible, reasonably priced, and energy efficient (Koydemir & Ozcan, 2018). From a usability perspective, even if someone is not experienced with this technology, he or she should be able to understand and operate their device. Beyond their main functionality, these devices must hold other sensors inside them to create pathways for the data to be transferred to other media. This means that their wireless connection should be swift and free of interruption, allowing them to store and collect data on the patient's physiological signs without difficulty. Many functionalities are not achievable through traditional manufacturing processes. Fortunately, the rate of technological advancement (e.g., 3D printing technology) makes overcoming these potential issues likely in the near future.

Nonetheless, there are several challenges that still must be overcome by manufacturers, including data loss, security breaches, lack of personalization, ethical dilemmas, and more (Lymberis, 2003), all while working to improve the overall health of the user. These factors are important to the future development and acceptance of smart wearable devices (Park, Chung, & Jayaraman, 2014). Thus, their manufacturing is not a trivial task. It requires the proper balance of quality, efficiency, technology, and experience, without imposing burdens.

The main objective of this study is to conduct a thorough review and analysis of the literature on smart wearables, with a focus on three key aspects: (i) design and configuration, (ii) manufacturing, and (iii) data analytics. Most of the extant research on smart wearables focuses separately on one of these areas (Mosenia, Sur-Kolay, Raghunathan, & Jha, 2017; Rodgers, Pai, & Conroy, 2015). However, smart wearables require the integration of all of these aspects, and hence a comprehensive review of each topic in a single study will be useful for future researchers. Furthermore, this work brings special attention to the manufacturing aspect of smart wearables, a topic that is often ignored in wearable device review literature. To that end, we discuss advancements and challenges in the manufacturing technology, such as embedded 3D printing and kirigami.

The unique contributions of this study are as follows. First, along with providing a state-of-the-art review of smart wearables as diagnostic and monitoring devices, this research also considers their application as prognostic and therapeutic technology. This will allow researchers and practitioners to easily locate what is currently scattered information on smart wearables, especially in terms of their configuration, manufacturing, and data analytics, thereby enabling them in their future work. Moreover, based on the literature review, this work highlights several important opportunities for future research. Finally, to our knowledge this is the first review focusing on the overall manufacturing of smart wearables.

This study is organized as follows. Section 2 provides the research design used to conduct the literature review. Section 3 is comprised of a comprehensive review of the literature on smart wearable devices, addressing their configuration, manufacturing, and data analytics. Section 4 presents a detailed discussion of the current challenges faced by smart wearable designers and opportunities for future research. Lastly, Section 5 offers concluding remarks and plans for future work.

2. Research Methodology

The key objective of this review was to study and synthesize the available smart wearable research by collecting and reviewing prior studies in the field. Therefore, the research methodology consisted of a systematic literature review that included proper identification of the relevant literature, a thorough review, a synthesis of the findings, and some direction for future research. In the following sections, we discuss in detail the methodology that was employed.

Multiple electronic databases were explored to search relevant peer-reviewed articles on smart wearables. These databases included IEEE Xplore, PubMed, Elsevier, Wiley, BioMed Central, Emerald, and Multidisciplinary Digital Publishing Institute (MDPI). To find relevant articles, keywords such as "smart wearable," "POC device," "health monitoring," "healthcare analytics," "advanced manufacturing," and "wearable sensor" were used. We also searched patent literature databases including Google Patents and the United States Patent and Trademark Office (USPTO). Relevant articles were obtained from these databases, along with specific information on the topic that was considered useful for our search.

During the web search, over 130 articles were downloaded from various databases. To identify relevant articles that best fit the overall research goal, an initial screening was done of each title and abstract. Upon completion of the initial review, 90 articles were determined to be relevant and thus were reviewed in detail. Fig. 2 shows the overall process of article selection for the detailed review.

(Insert Figure 2 about here)

In order to analyze the breadth of the source and topical coverage, the 90 articles selected were grouped based on publication type, such as conference paper, journal article, or patent, as well as on the issues related to smart wearables that each contained. Figs. 3(a) and (b) depict the articles selected, organized according to year of publication and geographical region. Section 3 presents an overview of the related literature, grouped into three main categories as described below.

(Insert Figure 3 about here)

3. Literature Review

To provide a systematic and comprehensive review, this research was organized according to three aspects of smart wearables: (i) configuration, (ii) manufacturing, and (iii) data analytics. The following subsections briefly describe the state of prior work in each of these categories.

3.1 Configuration of Smart Wearable Devices

Current advancements in sensing technology have allowed for the development of a substantial variety of smart wearable configurations that cover a wide array of applications (Berglund, Duvall, & Dunne, 2016). Fig. 4 provides some of the key aspects of smart wearable devices, and Fig. 1(b) offers examples of such devices with different configurations. Examples of these configurations include smart shirts, smartwatches, sensor-based wrist gear, smart glasses, shape memory-based wearables, smart gloves, ear wearables, smart noses (Hussain, Kang, & Lee, 2014; Mukhopadhyay, 2015), and others, as described in the following subsections.

(Insert Figure 4 about here)

3.1.1 Smartwatches and smart glasses

Most popular smart wearables are smartphone-based; today, smartphones have become ubiquitous, and hence wearables that integrate smartphones are growing in popularity. One common example of such a wearable is the smartphone-based electrocardiogram monitor (Albert, Satchwell, & Barnett, 2012). Even though there are separate smartwatches and wrist gear that also provide quick access to a user's health-related information, these functions are also available on smartphones. It is important to note that because of these functions (and more), smart phones are oftentimes expensive and require substantial battery life; not all are capable of meeting this requirement (Matt, 2014). As a result, smartwatches and wrist gear are becoming more popular as an affordable alternative for monitoring certain health activities and the related statistics. In addition to wrist gear, a new technology known as smart glasses, developed by Google, is also now available in the marketplace. These glasses provide a hands-free experience for the user and constant connectivity to the Internet. Downsides include the wearer possibly experiencing eye strain and headaches, and the glasses may serve as a distraction from the user's natural peripheral vision (Barajas, 2014).

3.1.2 Shape memory-based wearables: exoskeletons

Devices providing ergonomic solutions include shape memory-based wearables that function as physical human-robot hybrids, while at the same time providing comfort during the wearable and user's interaction (Copaci, 2017). An example of a shape memory-based wearable is an exoskeleton for the elbows used for flexion-extension movement. This wearable can improve a user's medical rehabilitation, as well as evaluate the health status of stroke victims and patients with spinal cord injuries (Copaci, 2017).

3.1.3 Earables

Researchers at the University of California at Berkley have developed a wearable that is worn on the ear. It takes core temperature readings from the user's eardrum. Their product, called an "earable," uses infrared sensors to take the user's temperature. The data are then transmitted to a portable device via a Bluetooth connection. This device not only takes eardrum temperature, but also functions as a hearing aid via a microphone embedded in the device. It can be useful for infants, the elderly, and people with certain medical conditions. Currently, researchers are focusing on developing and producing customizable "earables" through 3D printing (Scott, 2017). Smart ears can be worn as headphones, and are ideal for long-duration usage. They can monitor vital signs while the user exercises and also be worn by infants, the elderly, and at-risk patients. Not only does this type of device gather physiological data, it can also act as a hearing aid, making it convenient for those with both health and hearing problems (Ota et al., 2017).

3.1.4 Smart gloves

 New technologies such as hybrid 3D printing have allowed for the development of wearables like smart gloves. This type of device is a form-fitting glove embedded with a programmable heater, temperature sensor, and associated electronic controls for thermo-therapeutic treatment. The hybrid 3D printing process allows for the assembly of components into complex additive manufacturing architectures and accurate data collection. As a result, they provide effective user personalization (Ota et al., 2016).

3.1.5 Electric noses

Researchers have recently manufactured a wearable electric nose in the form of a band that is worn on the upper arm, close to the armpit. It monitors and classifies different armpit odors to

measure skin hygiene and health status (Lorwongtragool, Sowade, Watthanawisuth, Baumann, & Kerdcharoen, 2014).

3.1.6 Smart shirts and sensor-embedded textiles

Smart shirts are convenient wearable devices that facilitate exercise by tracking heart rate, as well as providing other functions like preventing bed sores (Ajami, 2015). Sensor-embedded textiles are designed to provide a user with comfort and flexibility (Asogwa, Libeson, & Lai, 2018). Sensors in the textile are located close to the user's body, improving their mobility and flexibility (Heo, Eom, Kim, & Park, 2018; Tang, 2007). Below is a brief summary of recent technological advancements in textile wearables.

 MagIC is a smart textile system that monitors a user's daily health. It is mostly used by the elderly and cardiac patients for home monitoring. It is a washable vest that includes sensors woven into the textile that monitor a user's ECG and respiration rate. The technology includes a portable electronic board capable of monitoring the wearer's motion level and skin temperature. Data are transmitted via Bluetooth to a PC or PDA (Pantelopoulos, 2010).

Lifeshirts are form-fitting shirts that are light in weight and machine washable. They quantify cardiac performance and measure posture and physical activity. Sensors are embedded in the fabric that measure respiration. This prototype has reached a mature technological status and its creators are currently pursuing further performance and commercialization (Lmberis. & Dittmar, 2007). However, there are several challenges that need to be addressed in the development of embedded sensor textiles. These include (but are not limited to) the durability of the textile, ability to wash them without damaging the embedded electronics, and maintaining proper sensor placement even if the main fabric stretches.

3.1.7 Smart devices for physiological condition monitoring

These are non-invasive and comfortable devices that allow the user to continue with their daily life without disturbance. They are often worn as accessories that look like everyday items, but collect the user's physiological signs. Some forms of this technology that are currently being researched and developed are as follows.

Cuffless blood pressure meters: These devices eliminate the discomfort of an actual blood pressure cuff by taking blood pressure signals from the user's finger. Signal transmission is made possible by a Bluetooth link, enhancing portability. Researchers expect this device to eventually be developed into a ring or wristwatch (Hung, Zhang, & Tai, 2004).

Finger ring sensors: Researchers have developed two versions of this heart rate signaling sensor. The first is a wireless sensor that sends signals to a separate unit that displays and calculates heart rate. The second is an integrated version that includes the same functions mentioned above, but within the ring itself. However, researchers are still working toward miniaturizing this technology, as well as providing additions such as blood pressure monitoring (Hung et al., 2004).

SILMEE: This is an intelligent wearable vital-signs monitoring device consisting of a lightweight battery, sensors, and wireless communication obtained through Bluetooth, making it both convenient and light in weight. It can be controlled by smartphone, tablet, or PC, or run as stand-alone technology. It is capable of transmitting information in real time, and can store large amounts of information (Suzuki, Tanaka, Minami, Yamada, & Miyata, 2013).

Additional examples of smart wearables for physiological condition monitoring are shown in Table 2.

(Insert Table 2 about here)

3.2 Manufacturing of Wearable Devices

The personalization and durability of smart wearables are critical components in their manufacturing, if they are to enhance user experience. This is because users need personalized devices that adjust to their specific requirements. In order to personalize smart wearables, devices are often designed specifically for the patient; this personalization includes design, hardware, and specific data processing software the functions of which depend on the individual wearing the device. Improving the quality of patient care by applying personalized knowledge and providing recommendations based on the user and their activities are primary goals of personalization (Andreu-Perez, R. Leff, lp, & Yang, 2015; Hussain et al., 2014).

3.2.1   3D printing
3D printers can effectively control the manufacturing process because the features of the wearable device can be made into any shape and size. For example, in 3D printed shape-memory wearables, manufacturers can print a device based on the user's body, allowing them to personalize the item and create an original shape just for the user (see Fig. 5). Given the many advancements in this technology, 3D printing can now be used to develop electronic embedded systems within 3D printed objects that are capable of facilitating personalized sensing and care for users' health (Ota et al., 2016). Since 3D printing can help with the personalization of wearable devices, patients are now able to comfortably wear their devices knowing that they have the correct parameters adjusted just for them. Due to recent technological advancements, flexible wearables are also now being produced using 3D printing (Rieck, 2016). Thanks to their pliability, flexible wearables have become users' preferred choice. They are both elastic and comfortable for the user while also collecting health data and other vital signs. Although stretchable wearable devices have the potential to revolutionize the way wearables are manufactured, there are still challenges with the electrical components that they require because they tend to be unyielding and are unable to mimic skin properties (Van Hooijdonk, 2017). Fig. 6 shows a few examples of 3D printed flexible electronics.

(Insert Figure 6 about here)

3.2.2   Hybrid printing
Advancements in 3D printing technology have helped to develop hybrid 3D printing. This is a new additive manufacturing technique used to create soft electronics by combining matrix materials and electrically conductive inks with firm electronic components into a single stretchable wearable device (Brownell, 2017). The hybrid 3D printing method allows for the integration of many electronic applications into a single device, creating items with precise custom geometries (Rivera, Moukperian, Ashbrook, Mankoff, & Hudson, 2017).

Textiles also take advantage of hybrid 3D printing methods (Abtahi et al., 2018). The role of textiles in additive manufacturing is to act as a printing medium to create flexible electronically embedded objects. Properties such as interlocking fibers, sound and moisture absorption, stretchability, and launderability are all useful (Molla, Compton, & Dunne, 2018; Pettys-Baker

et al., 2018). Current research on 3D printed embedded electronics in textiles includes a new type of technique that prints layered fabric and uses textiles as the printing medium. This technology is capable of allowing for a combination of two textiles that can be used to embed conductive material within prints. Research has also investigated printing plastic onto fabric, with stiffens different selected areas of the fabric, controlling where and the direction in which the fabric bends. By constraining bends in the fabric, both simple mechanisms and complex interactive devices can be created (Rivera et al., 2017).

The hybrid 3D printed ear wearable known as the "earable" is manufactured using flexible materials so that each device can be personalized to ensure long-term comfort (Patel et al., 2012). The device includes a thermopile IR sensor, microphone, bone conducting actuator, integrated circuits for processing incoming signals, and wireless transmission based on Bluetooth. Bluetooth enables real-time transmission of core temperature readings and data that are sent to a smartphone application. In order to provide circuit functionality to the device while at the same time being able to manufacture the product through 3D printing, researchers use liquid metal microchannel interconnections of Galinstan metal rather than traditional metal wiring. This also allows for the production of personalized ear wearables through a monolithic printing process with 3D embedding of the Galinstan metal. As a part of the performance and reliability assessment, the sensors and ear wearables are operated on multiple devices in a variety of environments, including multiple users (Ota et al., 2017).

3.2.3   Electronics-embedded printing

Currently, there are several printing techniques for organic and inorganic electronics. These include screen printing, inkjet printing, nanoimprinting, and more (Yao, Swetha, & Zhu, 2018). Screen printing is mostly used because of its low cost and adaptability. It is employed in the manufacture of printed circuit boards. It creates traces of electrical conductors, as well as insulators. Screen printing has also been successfully employed in printing transistor-level organic electronics. Inkjet printing is a popular printing technique for high quality printed electronics. This method can be used without stencils to create patterns for electronic materials. It also allows for better resolution by using low viscosity inks, eliminating the need for binders during ink synthesis. Since inkjet printing is based on a drop-by-drop additive technique, it often creates pixelation that can cause non-uniformity in the end product pattern. An example of inkjet printing is the "e-nose," where sensible units are based on a flexible substrate (Lorwongtragool et al., 2014). As one of the most studied printing techniques, nanoimprinting has become one of the most successful for organic electronics. This process uses hard and soft molds to form patterns for a variety of electronic materials. The process usually begins with the creation of a negative mold with nanoscale features; the mold is then pressed against a solution-coated substrate at a precise temperature and level of mechanical pressure. Molds are usually manufactured from silica, polymers, and quartz. Advantages of this printing technique include 3D high-resolution patterning and low processing cost and time (Sevilla & Hussain, 2017).

(Insert Figure 7 about here)

Other examples (see Fig. 7) of embedded electronics include 3D printed methodologies that embed multilayer electronic circuit boards with additive manufacturing. These processes can print wearable platforms that are specifically personalized to the user's body type and overall health needs (Jomanov & Milenkovic, 2011). In this case, to create personalized thermo-therapeutic 3D printed wearables, researchers printed conductive channels in different configurations within the object to create resistors, capacitors, and antennas. The printed

components can be manufactured in stretchable and rigid substrates that also provide standalone functionalities. The printed conductive channels can also facilitate interconnection between silicon IC chips and embedded systems inside the printed device. Microchips are then inserted into a liquid metal to form liquid-based circuit components, devices, and interconnections. Then, IC chips and other electrical components are embedded within the substrate slots to form electrical connections with the liquid metal interconnections. The process continues by printing the layers, repeating the steps above to manufacture the desired stretchable and rigid objects (Ota et al., 2016).

3.3 Data Analytics Applications in Wearable Devices

The integration of advanced data analytics in a wearable device is what separates a wearable device from a "smart wearable" device. Where wearable devices are used simply for the collection of biorhythms and other signals, the incorporation of advanced data analytics in smart wearables allows users to perform a number of useful remote/POC applications involving diagnosis, prognosis, and rehabilitation.

3.3.1 Disease monitoring and diagnosis

Remote or POC diagnosis of chronic diseases is in substantial demand due to factors such as inaccessible healthcare services, shortages of caregivers, and the need for better management of disease (Pentland, 2004). It is often necessary when patients are homebound or elderly. In the last decade, the availability of electronic health data has facilitated the development of several data analytics algorithms that provide automated disease diagnosis (Bardy, 2002; Soper et al., 2006). The overall structure of smart wearables as diagnosis devices consists of a wearable sensor or data collection module that records, transmits, and stores physiological data; a data processing module where the data are filtered and advanced data analytics applied to extract biorhythms and achieve pathophysiology; and oftentimes a user-friendly mobile phone app to display the signals and/or diagnosis results. The information gathered can be saved for further reference by a qualified clinician (Bonato, 2010; Wei et al., 2018). Consequently, several advanced analytics functionalities of smart wearables have been made possible through improvements in data acquisition, signal quality, and storage. For example, a recent development in fast and energy-efficient data storage could improve the performance of wearable applications by 8.85 times, while at the same time saving the battery life of the phone (Huang, Badam, Chandra, & Nightingale, 2015). This can make long-term use and data collection from the wearable more convenient for the user, and in turn improve the related analytics. Several methods have also been proposed for improving the quality of the acquired data, enhancing the accuracy of the analysis (Du, Gerdtman, & Lindén, 2018).

The algorithm employed for diagnosis mostly includes supervised learning where the training of the data analytics model is done on a labelled dataset (i.e., data with input as well as output responses) and the validation is performed on a new patient's data with only the input vector. Some of the most used supervised algorithms for clinical diagnosis include random forests (Breiman, 2001), deep learning (LeCun, Bengio, & Hinton, 2015), support vector machines (Cortes & Vapnik, 1995), and others. The performance of the algorithm is based on the sensitivity (i.e., identification of the disease or disorder when it is present in a patient) and specificity (i.e., no disease identification when the patient is disease-free) of the model, where high sensitivity and specificity are desirable (Russell & Norvig, 2016).

3.3.2 Prognosis

The accessibility of smart wearables, their embedded analytics, and the collection of data and symptoms over time allows for a prognosis or forecast of undesirable health outcomes. This is particularly advantageous when the outcome is debilitating, as with epilepsy, sleep apnea, abnormal heart rhythms, dementia, and Parkinson's. Prior awareness can prevent event-related injuries such as driving-related accidents during epileptic episodes (Banerjee, Peterson, Oliver, Froehle, & Lawhorne, 2018; Le et al., 2013). The prognosis algorithm in a smart wearable is used to predict impending events such as seizures and episodes of apnea, and issue a warning to the patient via a mobile app or other user interface. As with disease diagnosis, high sensitivity and specificity are desirable for issuing timely and accurate warnings of impending episodes and to prevent unnecessary panic and wait times due to false predictions (Chaovalitwongse et al., 2005). Such warnings can even be automatically sent to caregivers and emergency medical care providers, and thus prove to be lifesaving.

3.3.3 Rehabilitation

Since smart wearables can collect user data over the long term and on a continuous basis, healthcare professionals can use these data not just for diagnosis, but also for other purposes such as evaluating the effectiveness of medications, setting up interventions, and determining the survival rate after critical surgeries (Afrin, Illangovan, Srivatsa, & Bukkapatnam, 2018; Davenport et al., 2007).

One such important application is clinical use in rehabilitation-stage analysis (Patel et al., 2012). Since an assessment of the responsiveness of a rehabilitation intervention in a clinical setting can take considerable time from both the patient and clinical staff, the use of smart wearables in rehabilitation (i.e., telerehabilitation) is particularly desirable. Advanced data analytics techniques can provide the necessary tools for quantifying the data collected from wearables into clinical prediction rules to identify a patient's response to an intervention (Lubetzky-Vilnai, Ciol, & McCoy, 2014).

There are several different types of rehabilitation wearables that perform multiple functions for patients such as helping with central nervous system disorders, improving walking, and supporting upper limb rehabilitation (Crucius, 2015). An example of this is motor recovery for post-stroke individuals (Sapienza et al., 2017). One study used a random forest algorithm to estimate the quality of movement of stroke survivors in terms of a functional ability scale. The automated estimates highly correlated with the scores generated by the clinical experts. Another example is the use of smart wearable sensors for real-time fall detection and prevention in senior citizens and adults with physical disabilities (Shibuya et al., 2015). That study used a support vector machine algorithm for fall classification, achieving a 99.5% specificity and 97% sensitivity. Additionally, as an extension of rehabilitation, smart wearables can also be worn as preventative measures against illnesses and other health risks, and for hygiene monitoring (Chen, 2017).

4. Discussion and Opportunities for Future Research

Since smart wearables monitor illness and disease, they are typically worn over a long period of time. Patients who use these devices not only expect to have constant monitoring of their physiological signs, they also want to know if their health is improving over time. Consumers who use their devices for tracking health and personal reflection often find themselves becoming more health conscious, thereby improving their overall health (Chen, 2017). However, wearables used in healthcare are fairly new and still in the development stage (e.g.,

e-noses, earables). As a result, there are no studies that show how patients' use of smart wearables to monitor chronic illness improves their quality of life over time. That being said, further research and experimentation are required in the area of smart wearables to fully investigate the long-term effects and reliability of these products (Lorwongtragool et al., 2014). In the following sections, we discuss current challenges and future research opportunities related to the adoption of wearable devices, and issues associated with their design and manufacturing technology.

4.1 Challenges to the Adoption of Smart Wearables

In order to achieve the goal of full acceptance of smart wearables, manufacturers must solve several challenges, both new and familiar. For example, there are several key aspects that have slowed the adoption of these devices, including data access, privacy, cost, battery life, comfort, physical appearance, functionality, the possibility of misdiagnosis, and product liability, to name a few (Bietz et al., 2016; Karahanoğlu & Erbuğ, 2011). These challenges can arise not only in devices such as trackers, but also in technology used for healthcare and the workplace. In this section, we briefly describe some key challenges that exist today, and therefore require further research to expand this type of product's adoption rate.

4.1.1   User acceptance

User acceptance and perception play an important part in the adoption of wearable devices (Wiegard, Guhr, Krylow, & Breitner, 2019; Yang, Yu, Zo, & Choi, 2016). Oftentimes individuals, especially the elderly, dearly value their autonomy and independence; therefore, they choose not to become dependent on wearable devices. Therefore, wearables are usually compact and light in weight, and designed to be unobtrusive and comfortable. They can be worn on different parts of the body such as the arm, leg, head, wrist, or elsewhere. These devices collect data through sensors, and have shown the importance of ongoing development to the creation of a health-based user experience. However, consumers oftentimes find these devices to be unreliable and untrustworthy when it comes to their health. This demonstrates the need for the integration of social and behavioral science research with marketing and education on smart wearable products.

4.1.2   Cost

Cost is also an important determinant that influences individuals adopting smart wearables (Barnes, Kauffman, & Connolly, 2014). Since wearable technology is still in its developmental stage, the cost tends to be very high, and often unaffordable to regular consumers (Sagar, 2017). In order to increase the adoption of these devices, they must be made more affordable. Similarly, in terms of the manufacturing of embedded electronics, although these devices offer economically viable materials and tools, they are still far more expensive than conventional and mature micro- and nanofabrication techniques. Another challenge is that the field of printed electronics is still struggling to achieve submicron-scale features that other techniques have already adopted (Sevilla & Hussain, 2017). Other printing techniques such as nanoimprinting are expensive because of the molds and short lifetimes, therefore affecting process expenditures as well as overall product cost. With advancing technology, it is projected that the manufacturing and assembly costs related to wearables will decrease by the employment of techniques such as "roll-to-roll" printing of textile-based wearables and the convergence of microelectronics, optics, and bio-technologies (Park et al., 2014). Another opportunity for cost reduction lies in the involvement of insurance companies as a stakeholder. Smart wearables can enable remote health monitoring, diagnosis, and prognosis with data wirelessly transmitted to clinicians. This could reduce or even eliminate the need for office visits, and consequently

decrease the cost of care for healthcare providers. Furthermore, this could also incentivize insurance companies and employers to provide wearables for free or at a premium discount (Barnes et al., 2014; Park et al., 2014).

4.1.3   Privacy

Even though wearable devices are capable of solving health-related problems, manufacturers have yet to resolve issues associated with privacy. Wearables are capable of managing and monitoring health data; therefore, it is important to protect those data and access to them (Milutinovic & De Decker, 2013). However, these devices do not yet have proper encryption because they lack the necessary computational power (Sagar, 2017). Physiological data and sensitive user information are usually transmitted wirelessly, making data prone to invasion and alteration and posing major challenges to secure transfer and storage for both consumers and manufacturers (Liu & Sun, 2016). Fitness trackers can even be manipulated such that the data collected are not the actual data obtained from the device's owner (Rieck, 2016). Privacy in smart wearables is also important in the workplace. Many employees wear these devices while at work. Some smart wearables might be repurposed as tools for stealing the company's sensitive information (Sagar, 2017). To solve these problems, manufacturers must engineer devices with data security in mind. This can be accomplished by developing devices that include custom security settings, Bluetooth encryption, and remote erase features, and by encrypting data elements such as passwords, user IDs, user information, and PINs.

4.1.4   Misdiagnosis

Misdiagnoses provided by smart wearables also raise concerns, limiting their wider adoption. Such misdiagnoses can be categorized as "self-driven" or "device-driven." Self-driven misdiagnoses arise when consumers who lack medical training misdiagnose themselves after receiving the physiological data generated by their device. Although the associated risk of self-diagnosis has yet to be carefully researched, it is believed that patients can become over-reliant on smart wearables and experience negative consequences from excessive self-monitoring (Piwek, Ellis, Andrews, & Joinson, 2016). Devices may also provide inaccurate data, and this misinformation may disturb the patient and create more problems when self-diagnosis is based on corrupt data (Foster & Torous, 2019). For example, although convenient, smart shirts still face major reliability issues when it comes to monitoring heart rates and other vital signs (Sawh, 2017).

As discussed above, smart wearables have embedded analytics and can provide diagnoses and prognoses for a number of diseases. However, due to inaccuracies and the non-generalizability of the underlying algorithms, they can also produce misdiagnoses either in the form of false positives (i.e., diagnosing a symptom or disease when it is not present) or false negatives (i.e., the inability to diagnose a symptom or disease when it is present). One recent study that used a smartphone-based app for melanoma detection had a sensitivity ranging from 6.8% to 98.1% and specificity ranging from 30.4% to 93.7% (Wolf et al., 2013). This variability emphasizes the dangers of using smart wearables in lieu of medical professionals. Another reason for device-driven misdiagnosis is insufficient quality of the signal collected from the non-invasive sensors used in the wearables (as compared to more invasive sensors). For example, the electroencephalogram or EEG signals collected from surface electrodes have low signal-to-noise ratios as compared to intracranial invasive EEG sensors, and also suffer from motion-related artefacts that often make seizure diagnosis and prognosis less accurate (Karuppiah Ramachandran, Alblas, Le, & Meratnia, 2018; Mormann, Andrzejak, Elger, & Lehnertz, 2006). Improving the diagnosis and prognosis algorithms and extensive and large-scale clinical

validation of smart wearables will eventually open new avenues for more reliable clinical application (Freestone, Karoly, & Cook, 2017; Peake, Kerr, & Sullivan, 2018).

4.1.5   *Product liability*

Wearables are oftentimes worn very close to the skin. As a result, some health risks may arise. These risks include inflammation and skin irritation (Hawkins & Feldman, 2017), burns, and other effects such as electrical shocks and unsafe acoustic sound pressure (Bridgman, Kwong, & Bergmann, 2019; Nilsson, Ingvast, Wikander, & von Holst, 2012; Rolphe, 2016). Burns are often due to the elevated temperature of the device itself and may lead to painful blisters and skin damage (Chatterjee et al., 2015; Nichols, 2016). Overheating is usually caused when the temperature of the component increases due to the lengthy amount of time the device remains in use. Wearable devices can also cause electrical shocks from current leakage (J. H. Kim et al., 2010). Excessive current leakage is caused by defective circuitry or components that are accidentally exposed. The possibility of electrical shock increases when the device is worn while being charged. For devices worn in places such as the eardrum, unsafe sound pressure levels may occur if the device is improperly manufactured. Hearing aid components may have improper calibration or design or may not be operating correctly, leading to temporary or permanent hearing loss (Nilsson et al., 2012).

 In addition to the health risks mentioned above, smart wearables also have other modes of failure such as permanent stretching and poor adaptability to the human body. In additive manufacturing, the limitations of printed textiles include permanent stretching over time, which affects both the quality and durability of the products, making them less adaptable to human skin. Also, when printing large objects, there is usually a significant gap between the sections (Rivera et al., 2017). Currently, there are no proper software packages that address this issue. For embedded electronic systems, overall product quality can become a problem because their individual components are usually printed separately, thereby causing higher variability in the overall quality characteristics of such systems (Sevilla & Hussain, 2017). For wearable and attachable skin applications, several key challenges remain unaddressed, including the lack of skin adaptability, absence of reliable data transfer between the device and human user, and noise and signal leaks (Pang, 2013).

More importantly, there are numerous challenges to the development of smart wearables that are related to product liability concerns (Terry & Wiley, 2016). To address these concerns, manufacturers should consider a number of strategies while the wearable device is still in development, including conducting extensive research and experimental and clinical testing on the device, cybersecurity, and health hazard analysis; providing clear safety and user instructions; and obtaining appropriate regulatory approval (Mills, Watson, Pitt, & Kietzmann, 2016). Getting timely approval from the Food and Drug Administration (FDA) for smart wearables can be a daunting task for manufacturers, due to the many regulatory requirements. However, these are of the utmost importance for consumer safety (Sumra, 2018). These challenges must be addressed for smart wearables to be technically viable and easily accepted by users.

4.2 *Challenges with Manufacturing Technology*

Although smart wearable devices are becoming more popular, they still have major issues that need to be addressed to provide better user experiences. These include their ability to be personalized based on the user's requirements, quality, secure and effective transmission of data, and battery size. Overall, to successfully manufacture wearable devices that are capable

of sensing vital signs, devices must be crafted in such a way that they are not only comfortable and personalized, but also durable and provide a functional user interface. To that end, the transition between firm surfaces and flexible and wearable shapes must be a successful one (Windmiller & Wang, 2017). Different types of manufacturing address this issue, including hybrid 3D printing, where the main goal is to effectively integrate a soft electronic interior with a 3D printed exterior. Additionally, when creating durable devices, manufacturers must test and use the proper components and materials. These two key components are important not only for hybrid 3D printing, but also for any smart wearable manufacturing method (Valentine et al., 2017)**.** The following sections describe key challenges to the manufacture of wearable devices.

4.2.1   *Additive manufacturing*
Next-generation sensors are expected to be flexible, stretchable, and capable of attaching to any surface. These sensors will also be small and portable. Additive manufacturing enables the development of these small and convenient sensors via the printing of circuitry in flexible plastics. This technology has the advantage of easily changing from one material to another, and can integrate many materials. Researchers believe that 3D printing is an important first step towards making wearable devices affordable and comfortable, and thus enhancing user experience (Van Hooijdonk, 2017). However, while additive manufacturing offers advantages such as personalization and the use of multiple materials at the same time, challenges that must be addressed include longevity, the effective manufacture of stretchable materials, and consistency in quality.

Manufacturers have recently begun addressing a major hurdle to the adoption of smart wearables, the miniaturization of sensors and electronic circuits. Oftentimes, the size of the sensor, electronics, or battery that are incorporated into these devices is quite large, making them obtrusive and uncomfortable for long-term monitoring applications (Patel et al., 2009). Today, with the adoption of new technology, researchers have developed miniature circuits that entail sensing capabilities, radio transmissions, microcontroller functions, and front-end amplification (Patel et al., 2012). Sensors are now integrated to create sensor platforms that can reduce the number of components, making the sensors smaller, lighter, and much cheaper (Jomanov & Milenkovic, 2011). For example, an accelerometer (used in wearables for activity monitoring) developed by Bosch integrated MEMS, a signal conditioning circuit, and processing core, all in one ultra-small 2 x 2 mm^2 unit (Bosch Sensortec, 2019).

Part of the miniaturization hurdle, the battery (which is a key component) is also becoming a serious problem. Batteries in smart wearables are necessary but oftentimes heavy and sizeable. Although minimizing the battery is a possibility, size restricts limited battery capacity (Williamson et al., 2015). The development of a compact battery that is capable of providing an appropriate life capacity to a wearable device has become a challenge for both researchers and manufacturers. Although wireless wearables are more attractive to users, the wireless transmission of data is an energy-intensive operation. Hence, the development of newer generations of Bluetooth devices provides an alternative by offering long periods of operability without the need for recharging. For example, new low-power Bluetooth functionality such as BLE (Bluetooth Alliance, 2010) and Zigbee (Zigbee Alliance, 2010) can provide twice as much extension of battery life (Dementyev, Hodges, Taylor, & Smith, 2013).

4.2.2   *Kirigami*
Scholars are working on designing a form of origami that can create stretchable and flexible conductors. Researchers at the University of Michigan are using kirigami to minimize

unknown points of strain in flexible materials that occur during manufacturing (Gershgorn, 2015). The process involves making small incisions in the conductive material to spread the stress over a larger area, allowing for the prediction of strain points. With this method, the material can expand and be more flexible due to distributed stress. This approach is in the prototype stage, and researchers hope that it will be a breakthrough in flexible materials (Gershgorn, 2015). MIT researchers have also used kirigami to make bandages and wearable devices for knees and elbows. Normally, these bandages bend frequently, making them difficult to attach to the skin. The researchers' solution was to take the material and make patterns in it in the form of cuts, so that it could absorb the strain of bending and make the bandage more effective. These bandages and printed electronics were tested for use. It was reported that all of the kirigami-cut bandages and printed electronics remained in position (i.e., attached to the skin), even after bending the material 100 times (Kotok, 2018). However, like other manufacturing techniques discussed above, kirigami also faces challenges in terms of production quality since each product is made separately, raising the possibility of inconsistency in both the material and cuts.

Challenges to the design and manufacture of smart wearables also include their sensing methods. Despite advancements in this technology, their efficacy is limited by their ability to comprehensively measure the electrophysiological and physical parameters. Oftentimes, using a single sensing method is insufficient for diagnostic and prognostic applications. Consequently, the future of sensing methods for smart wearables includes multi-modality sensing capabilities in a single wearable. One example might be a hybrid chemical-electrophysiological sensing method that combines these two sensing methodologies for a more comprehensive and accurate analysis of a user's health status (Heikenfeld et al., 2018; Imani et al., 2016).

5. Conclusion and Future Work

The continuous rise in chronic illness and disease has directly impacted the demand for smart wearables. This demand is also influenced by current developments in technology such as the Internet of Things, the ongoing demand for effective, fast, and personalized healthcare services, and soaring healthcare costs. Today, most wearables are worn on the body, but thanks to conductive and sensor-embedded fabrics, soon wearables will be linked very closely to textiles, making sensors almost indistinguishable. Due to companies like AiQClothing and Hexoskin, new research in biometric garments is rapidly being developed. As expected, this study revealed that future manufacturing technologies are more inclined towards 3D printing. This may be due to the fact that 3D printing is becoming both affordable and personalized while at the same time allowing for miniaturized sensor configuration, making these devices smaller and more comfortable and effective. Since manufacturing techniques have begun to shift towards new development (such as in 3D printing), the manufacturing techniques included in this research focused heavily on those of additive manufacturing and flexible electronics.

Although the last few years have seen an increased interest in smart wearables both in academia and industry, the publications in this area are very scattered. This makes it extremely difficult for researchers and practitioners to synthesize the existing knowledge base in the field and further develop these highly advanced technological products. This work has attempted to narrow that gap by providing a systematic literature review of the existing work on the design, manufacture and data analytics of smart wearables. In addition, this study has highlighted opportunities for future research, mainly with respect to two aspects: a) user adoption (primarily design and configuration issues), and b) manufacturing technology. Further work

is also needed that investigates advanced data analytics and artificial intelligence methods built into smart wearables to minimize the misdiagnosis of disease.

Conflicts of Interest

The authors have no conflicts of interest to disclose.

Acknowledgements

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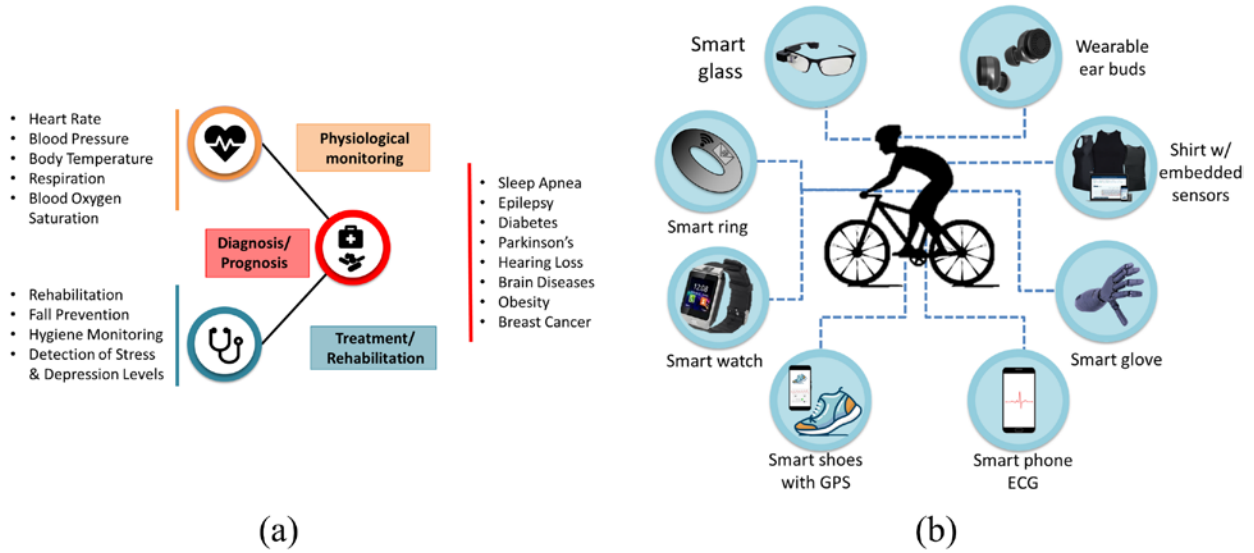
Figures:

Figure 1: (a) Common applications of smart wearables, and (b) common smart wearable configurations (adapted from Google Images).
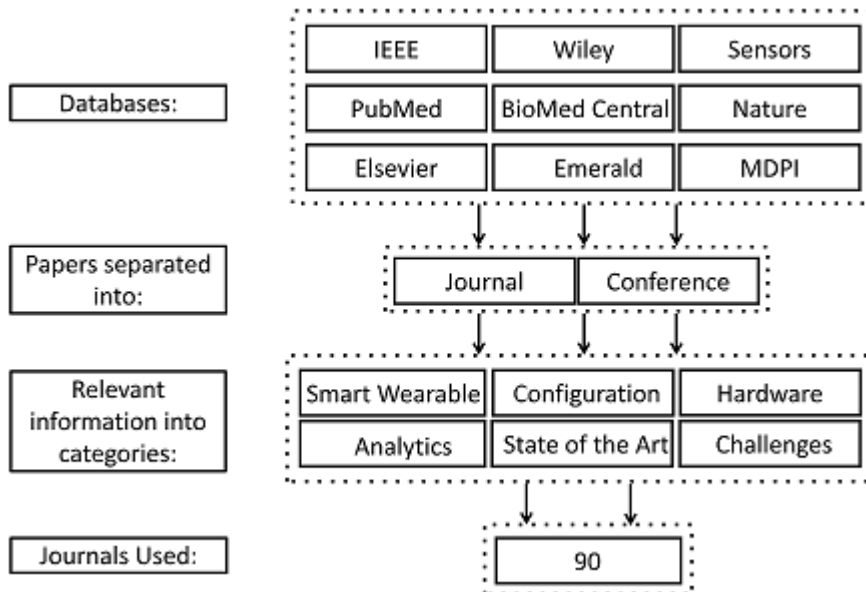

Figure 2: Article selection process for detailed review.
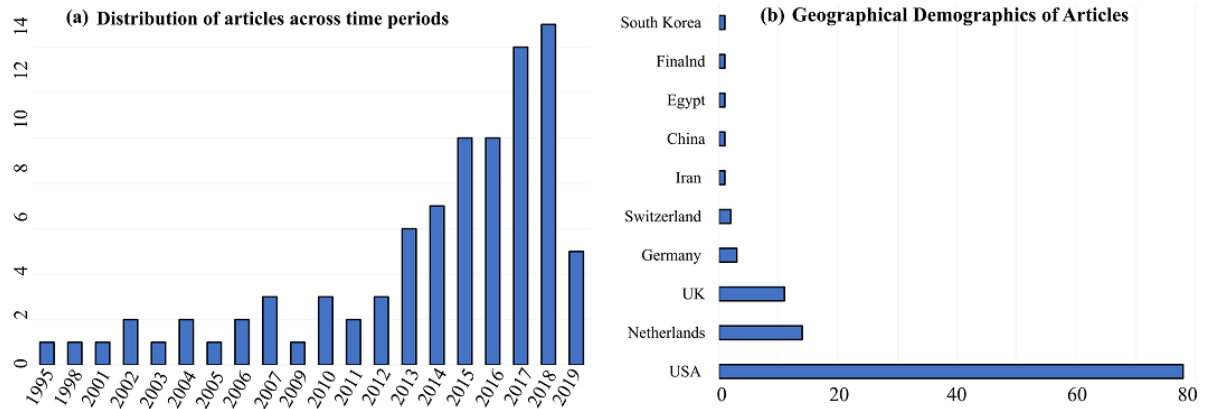
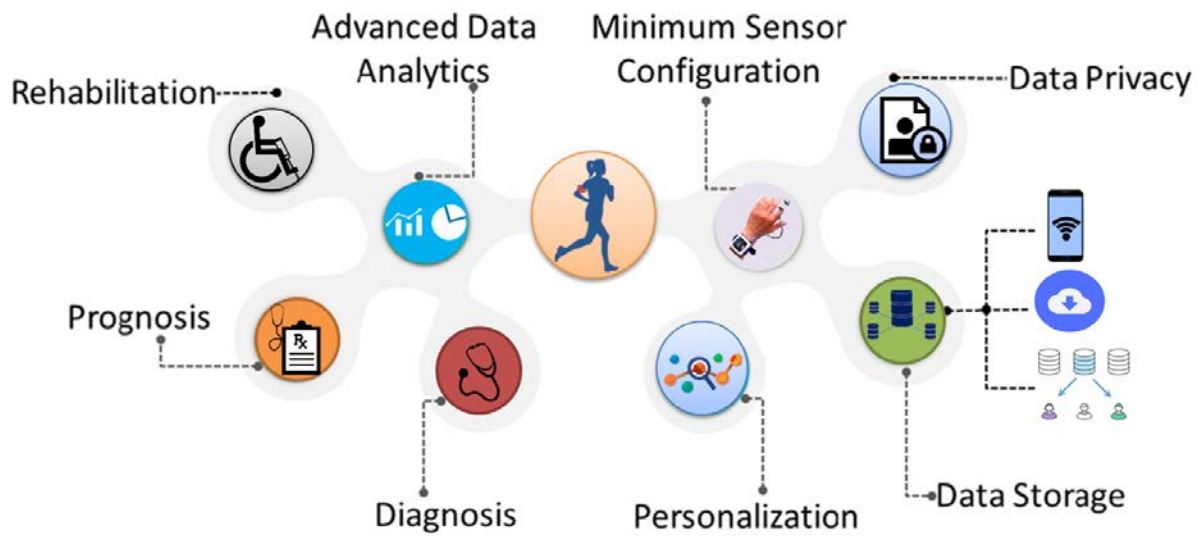Figure 3: Distribution of articles (a) over time and (b) across geographic regions.

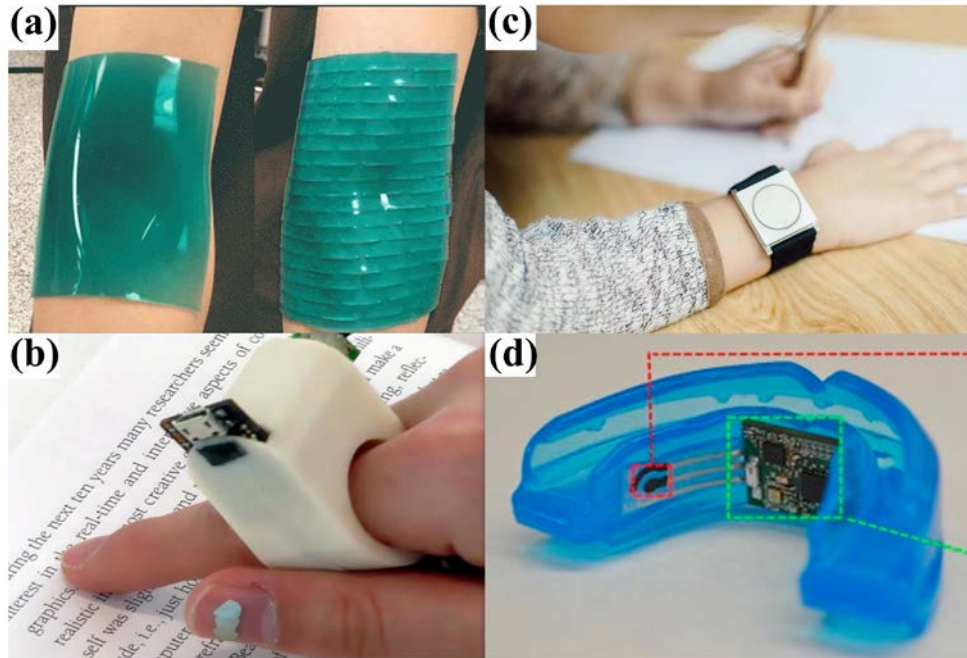

Figure 4: Key aspects of smart wearables.

Figure 6. Examples of 3D printed materials and smart wearbales: (a) A flexible bio-adhesive film that maintains adhesion to the skin during movement and bending made using a laser kirigami technique. Reproduced with permission from (Zhao, Lin, Yuk, & Zhao, 2018). (b) World's first FDA cleared smart watch that senses epileptic seizures and sends alerts to caregivers (Empatica, 2019). (c) A finger-worn device that assists visually impaired individuals with reading paper-printed text. Reproduced with permission from (Shilkrot, Huber, Liu, Maes, & Nanayakkara, 2014). (d) Mouth wearable for real-time and non-invasive monitoring of salivary uric acid level. Reproduced with permission from (J. Kim et al., 2015).
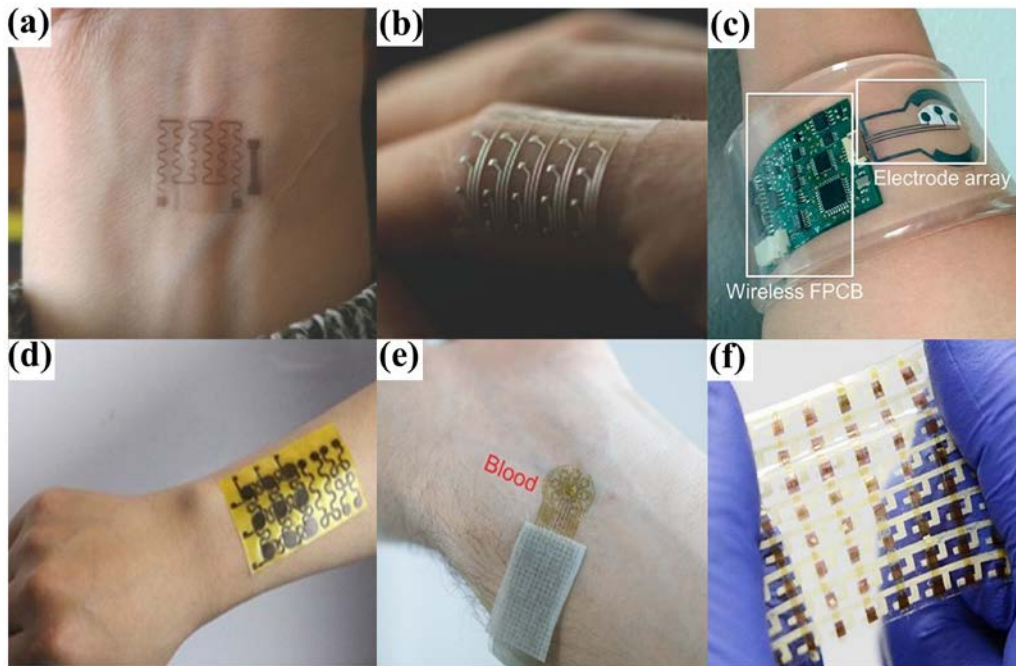
Figure 7. Examples of advanced manufactured electronics: (a) Ultrathin skin mounted wearable. Reproduced with permission from (Joh, Lee, Seong, Lee, & Oh, 2017). (b) A hybrid 3D-printed wearable that conforms to the shape of the body. Reproduced with permission from (Valentine et al., 2017). (c) Wearable sensor that extracts and analyses sweat for diagnosing and monitoring diseases. Reproduced with permission from (Emaminejad et al., 2017). (d) A rehealable, fully recyclable, and malleable electronic skin that mimics some properties of natural skin with potential applications in prosthetics and health care (Zou et al., 2018). (e) An ultrathin, soft, and skin-conforming sensor for continuous monitoring of blood flow variations. Reproduced with permission from (Webb et al., 2015). (f) Electronic devices that can be reversibly stretched for use as medical patches or electronic skin. Reproduced with permission from (Sim et al., 2019).

Table 1 Comparison of Commonly Available Smart Wearables

Wearable device	Sensor(s)	Measured physiological signal	Cost	Reference
SEM Glove	Pressure sensitive sensors	Grasping capability in neurological rehabilitation	Unavailable	(Nilsson et al., 2012)
Fitbit	Accelerometer, barometer, gyroscope	Heart rate, sleep, calories, activity, weight	$60-$300	(Venkatraman & Yuen, 2015)
Embrace	Accelerometers, gyroscope, electro dermal activity and temperature sensors.	Monitors physiological stress, arousal, sleep and physical activity and helps with epilepsy.	$250	(Empatica, 2019)
Relief Band	Neuromodulation sensor	Treatment of nausea and vomiting.	$175	(White et al., 2002)
Ear Wearable	Thermopile IR Sensor	Core body temperature and hearing.	Unavailable	(Ota et al., 2017)
LiftWare	Common motion sensors	Measures and compensates hand tremors	$196	(Miocinovic et al., 2016)
AliveCor	ECG (electrocardiogram) electrode sensors, accelerometer,	Atrial fibrillation	$100-$200	(Albert et al., 2012)

Table 2 Example of Smart Wearables for Physiological Condition Monitoring, Diagnosis, and Prognosis

Wearable device	Functionality	Description	Reference
ViSi Mobile®	Physiological monitoring	FDA-approved cuffless blood pressure measurement sensor	(Sotera Wireless, 2019)
OneRing	Physiological monitoring	Monitoring and identification of Parkinson's motor symptoms	(Koslow, 2016)
Kardia™ band	Diagnosis/Prognosis	A band for Apple watch that records medical-grade electrocardiogram signals and detects atrial fibrillation	(AliveCor, 2019)
BioStamp nPoint®	Physiological monitoring	FDA 510(f) cleared wearable sensor for monitoring motor symptoms, vital signs, and sleep metrics	(MC10 Inc., 2019)
Breast cancer screening bra	Diagnosis/Prognosis	Wearable bra for diagnosis/ early detection of breast cancer	(Salber, 2014)
Muse™ headband	Treatment/Rehabilitation	Wearable sensor that uses brain activity for guided meditation and stress management	(Muse, 2019)
Sign Language Recognition system	Treatment/Rehabilitation	Prototype of wearable sensor that can translate sign language into the English language	(Wu, Tian, Sun, Estevez, & Jafari, 2015)
MusicGlove	Treatment/Rehabilitation	Hand rehabilitation in patients with reduced hand movement	(MedGadget, 2014)