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STATE-OF-THE ART REPORT

context

Smart textiles for healthcare and
medicine applications (WG1)

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ABSTRACT

The aim of this document is to provide information on the state-of-the-art related to the topics covered by each working group within the CONTEXT project. It provides information on materials and technologies used to develop smart textiles with targeted performance, general applications of smart textiles in the field, case-studies on the use of smart textiles, opportunities for smart textiles considering the needs of each field, trends on the development of smart textiles in terms of market and technical expectations.

This paper gives an overview of the potential of smart textiles for healthcare & medicine, ongoing developments, state-of-the-art products and future developments.



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1. INTRODUCTION

There are remarkable improvements and new potentials in the textile field over the last few years thanks to the integration of smart materials and electronics. These new textiles are called “smart textiles” and smart textiles can be defined as textiles that are able to sense and respond to changes in their environment.¹ Significant progress has been done in smart textiles in parallel to the improvements in the microelectronics, artificial intelligence and new lifestyle of the population. Lately, there is an increasing trend of integrating intelligence in our daily environment. These novelties brought innovative high-tech applications and new market segments to the conventional textile. Also, that gathered specialists from different field and created an interdisciplinary technology. The smart textile market is a niche of the future that is in full development with unique applications for different use cases. Smart textiles find many applications in different fields. In particular, the projects in healthcare, military and defense, sports and fitness, automotive, entertainment, and personal protective equipment field, respond a real need. Today, these applications allow us to avoid many accidents, diagnose earlier, treat certain conditions in a more effective way and, potentially, extend life expectancy for the end-users.

Smart textiles have the potential to face numerous health and well-being challenges, such as diabetes, obesity, mental health, neurodegenerative diseases, cardiovascular diseases, stroke, cancer, motor rehabilitation and for regeneration of organs.

2. SMART TEXTILES FOR HEALTHCARE AND MEDICINE APPLICATIONS

2. 1 Smart textiles for monitoring and sensing

Currently, the world's population is expected to rapidly increase and reach 9.9 billion by 2050 (according to the Population Reference Bureau). The shift in global demographics shows that the population is aging due to a decline in mortality rates. As a result of the growing geriatric population, as well as the increasing incidence of chronic lifestyle diseases, Western countries are addressing high costs for medical and long-term care needs. Those market drivers are pushing the interest in smart textiles for remote monitoring and sensing.

There are already wearable products on the market which were used to monitor activity and the wearer's health parameters such as pulse rate or oxygen rate; however, smart textiles may transform the monitoring and the collection of these data, guaranteeing more accurate and realistic results while preserving the comfort, thus re-defining their potential impact on healthcare.

2. 1. 1 Smart textiles for monitoring and sensing obtained by integrating electronics

Several studies investigated the utilization of e-textiles for health scenarios. These innovations may revolutionize the way in which medical practitioners operate. These textiles require digital components and embedded batteries to work. Generally, for this type of applications, the utilization of conductive fibers or inks is very common with the traditional textile processes such as knitting, weaving, printing etc. Reliability, performance consistency over time, and comfort are the most important points to guarantee their adoption. Some examples of smart textiles products or projects are described below.

Rhode Island University Biomedical Engineering Department has done researches on quantitative measurement of akinesia in Parkinson's disease. This disease is a motor disorder which affects upper and lower limbs, limiting movements ability with frequent tremors.²

Researchers developed a smart glove (fabricated with a neoprene textile with circuits made from conductive thread, including a flex sensor to detect the range of motion, an inertial sensor to detect tremors, and Bluetooth module for data transmission) to monitor Parkinsonians.^{3,4} These smart gloves give the possibility to determine the degree of mobility and potentially optimize the efficiency of prescription medication.

Two smart wearable projects were realized by Bioserenity for the monitoring of sleep disorders and neurology: Somnonaute and Neuronaute. The mission of the company is to provide continuous care to patients and health professionals with the acquisition and interpretation of electrophysiological examinations, such as EEG (electroencephalogram), ECG (electrocardiogram) and PSG (polysomnography).⁵ For this aim, the company has collaborated with IFTH (French Institute of Textile and Clothing) to develop a wearable system with the integration of conductive flexible textile circuits and sensors.⁶

These sensors are positioned to obtain the required biosignals continuously to diagnose, analyze and give the posology adapted to the patient. Again, one of the benefits of this development is conserving the comfort of traditional textiles cloths, which improves the quality of the collected data.



Figure 1 - Bioserenity - Ambulatory mobile solutions for the diagnosis and monitoring of patients

A similar technology called “Hitoe” is developed by Toray for daily use.⁷ Hitoe is not a medical device but it gives the possibility to collect bioelectric information continuously thanks to a highly conductive knitted polyester nanofiber fabric impregnated with a conductive polymer (PEDOT: PSS).⁸ The heart pulse is sensed by the potential difference on each pulse of human heart. Hitoe functional material is washable thanks to Toray’s advanced processing technology for high impregnation and the utilization of nanofibers which make the fabric resistant to washing cycles and obtain a high contact with the skin.⁹

In another project supported by the Swiss Innovation Agency, the goal was to develop a textile low impedance ECG electrode with optimized electronics for heat stress monitoring for fire fighters. For this, an Ag/Ti-coated PET yarn was developed to embroider textile electrodes. The electrodes showed a low electrical resistance of $<10\ \Omega$ and good skin contact with low skin irritations, particularly as an integrated electrode humidification system was applied. The electrodes were integrated into a semi-elastic polyester belt for the application on the wearer's chest.¹⁰

Besides applications for occupational safety, the clinical applicability for overnight monitoring was assessed in order to screen patients for breathing related disorders during sleep. When compared to reference gel electrodes, ECG belt data showed acceptable quality (with regard to Signal-to-Noise ratio, SNR) and accuracy (standard error of estimate of 0.4%, Pearson r of 0.91). Therefore, it was concluded that the ECG belt is an applicable tool for continuous ECG patient monitoring.¹¹

Likewise, Nuubo¹² is a wearable medical technology company which offers e-textile technology BlendFix sensor electrodes, for remote ECG monitoring with a cost-effective, simple, transparent and non-intrusive method.



Figure 2 - Hitoe™ bio-electrode conductive nanofiber fabric



Figure 3 - NUUBO wearable ECG unit

HealthWatch¹³ is another company pioneer in harnessing e-textile technology to produce fashionable, seamless knitting, smart-digital garments with interwoven sensors unobtrusively measuring vital signs of hospital-grade quality. The company's first product is a sensor-rich heart sensing textile garment incorporating 12-lead ECG with heart rate detection, skin temperature, respiratory, and body posture, allowing ECG and wider vital signs monitoring, compatible with gold standard ECG monitoring.

Moreover, there are also some examples of connected maternity clothes. A bally band is knitted with conductive fibers to monitor uterine activity and assess fetal well-being.¹⁴ The technology permits to collect biosignal from the infants and send them thanks to the RFID tag and a knitted antenna designed also by Drexel University.¹⁵

Smart socks are also a highlight product in smart textiles. Taxisense in collaboration with IFTH has developed smart socks to reduce fall events for patients at risk. These knitted socks with conductive and piezoresistive fibers are designed for daily use and provide the same comfort of regular socks. Furthermore, these smart socks¹⁶ may help prevent diabetic foot ulcers by alerting the wearer when there is so much pressure due to bad posture or bad-fitting shoes, as diabetic patients have reduced nerve functioning. Siren e-socks are also in the market for preventing foot ulceration by monitoring continuously the foot temperature. The monitoring system sends the collected information to the health professional, to help tracking the possible inflammations.



Figure 4 - Taxisense e-socks (on the left) and siren e-socks (on the right)

Likewise, Sensoria partnered with the Michael J. Fox Foundation and Neuroscience Research Australia to launch a clinical trial for investigating how Sensoria smart textiles socks can improve care for Parkinson's disease by collecting data and by testing a haptic feedback that can prevent "freezing of gait" events in patients.^{17, 18}



Figure 5 - Sensoria-socks

Optical fibers have also many advantages for the utilization in wearable systems. They are light-weight, insensitive to electromagnetic fields, not releasing heat and they resist to water and corrosion.¹⁹ Examples of luminous textile applications have been realized within the TecinTex and ParaTex projects.²⁰

In these projects, soft, ductile, skin-friendly POFs were developed by melt-spinning technology. Due to their ductility and small, yarn-like diameter, the melt-spun POFs were successfully integrated into textiles for sensing and therapy applications. For that purpose, the project team used both embroidery, as well as weaving and stitching. POFs incorporated into textiles have then been used to sense a range of metabolic parameters such as heart rate, arterial blood oxygenation, breathing rate, and pressure.^{21, 22} The friction of these textile sensors against artificial skin models was lower than that of conventional medical bed-sheet, demonstrating a high level of comfort to the end-user; another important factor was breathability, which was proven to be similar to conventional, cotton-based textiles. In initial (nonclinical) trials with healthy subjects, such photonic textile sensors were shown to be equivalent to their medical counterparts such as pulse oximeters²³ and breathing rate detectors.²⁴

→ ULIMPIA³⁴

In the ULIMPIA project, sensor yarns are integrated into a textile carrier material. When processed into a plaster, they can record the temperature, pH and moisture of a wound and transmit them wirelessly. The continuous sensor-based wound monitoring can give an early indication of potential complications, particularly with chronic wounds.



Figure 6 – Ulimpia bandage

→ THERAFOLG-KOMP³⁵

The objective of the THERAFOLG-KOMP project is to develop a system that uses textile sensors to enable the success of compression therapy to be measured and to make the results visible and useful for patients, doctors and manufacturers of medical devices. Acceptance of treatment should be improved by digital feedback of the success of the therapy.

→ Bio- Radar^{36, 37}

The Bio-Radar is a non-contact system to measure vital signs accurately, such as respiratory and cardiac signal. For now, the prototype is focused on the respiratory signal exclusively. This system is based on the Doppler effect principle, that relates the received signal properties with the distance change between the radar antennas and the person's chest-wall. The received signal will be a phased modulated version of the transmitted signal, which occurs due to the chest-wall motion while the patient is breathing. This motion changes the travelled distance of the electromagnetic waves causing the phase modulation. The prototype is composed by a Continuous-Wave radar, performed by a Software Defined Radio operating with a 5.8 GHz carrier, two textile antennas for transmission and reception respectively, and a LabVIEW interface, where the digital processing algorithm is applied to extract the respiratory signal. This system has a wide range of applications, such as the continuous monitoring of critical patients, the control of patients with sleeping disorders, or even on safe drive in a car for example. Thus, it can be included in different environments, by customizing and designing textile antennas.

2. 1. 2 Smart textiles for monitoring and sensing without electronics

Chromic materials have an application area in smart textiles without electronics. These materials can change their color according to external conditions and may utilized for functional purposes.³⁸ Different kinds of chromism are named after the stimuli that cause color changes.³⁹

The external stimuli "X" can be varied in the presence of an intelligent factor that it is the pressure, the temperature, light, humidity, etc. They can return to their original state when this factor is removed. Commercial photochromic and thermochromic colorants that change rapidly and reversibly from colorless to colored state when activated by stimuli like ultraviolet irradiation, temperature or pH are well established class of colorants for manufacturing of niche products. We can use photochromic and thermochromic systems in applications like medical thermography, plastic strip thermometers, photochromic lenses, etc.⁴⁰

On of the example is for the use of x-chromic textile is a smart dressing, which changes color to detect injuries of handisports. This textile was developed by British researchers,⁴¹ who found this fall intensity detector.

3. SMART TEXTILES FOR MEDICAL TREATMENT

Smart textiles for therapeutic purposes are the most specialized systems for medical applications. The goal is to achieve healing. Patients can receive more consistent treatment dosages than with standard mechanisms by wearing these devices, which could be useful in applications such as drug delivery, pain management, asthma management, and insulin delivery for various chronic disorders (e.g. chronic pain, bedsores and ulcers, asthma, COPD, diabetes, etc.).

3.1 Smart textiles for medical treatment obtained by integrating electronics

In this part, some examples on the smart electronic textiles used for medical treatment are pointed out. The PHOS-ISTOS⁵³ project has been funded by Europe in the 7th Framework Program in 2013. The aim of the project to develop an alternative method to photodynamic therapy for the treatment of pre-cancerous skin condition Actinic Keratosis. The collaboration between INSERM, MDB Texinov and ENSAIT resulted in development of a light emitting textile which can be developed to replace the rigid LED panels.⁵⁴ Plastic optical fibers are woven or knitted to create a flexible, homogenous light emitting fabric and connected to a specific light source. The novel device "Fluxmedicare" is flexible and ambulatory.

The flexibility of the device gives the possibility to adapt patient morphology which makes the light emission more homogeneous, where the light emission power was less necessary so the pain of the treatment.⁵⁵ The portability of the device gives the possibility to decrease the costs of the treatment and treat more patients in the same time. Furthermore, this development is applicable in many different treatments like for jaundice of new born, fluorescence diagnosis etc.



Figure 7 - NeoMedLight - medical devices for phototherapy for treating neonatal jaundice

Another example is from NeoMedLight, which is a company that develops medical devices for phototherapy. They have developed “Bilicocoon” to treat neonatal jaundice in collaboration with Brochier Technologies.⁵⁶ The device has 2 parts: light emitting textile woven with optical fibers and a light source. Furthermore, this device may be used in mucositis, dermatitis, wound healing/tissue regeneration and pain management issues.

One of the benefits of this technology is that it permits the newborn to be kept next to the mother in the first hours while the mother can continue to holding the baby or breastfeeding. A similar approach has been developed at Empa using melt-spun POFs.⁵⁷ In this concept, however, no treatment of the fiber was required, as light-outcoupling was obtained by optimizing the weaving patterns of the POFs. The project resulted in a proof-of-concept prototype.⁵⁸ Engineers at the Wyss Institute for Biologically Inspired Engineering at Harvard University have developed smart textile-based soft robotic exosuits that can be worn by soldiers, rescue workers and fire fighters, and also help elderlies and people suffering from neurodegenerative disorders to enhance their mobility.⁵⁹

3. 2 Smart textiles for medical treatment without electronics Smart wound-care materials

3. 2. 1 Smart wound-care materials

Wound healing is a multi-phases and multi-factorial physiological process. To achieve an ideal wound care product, which may be classified as ‘smart’, it is necessary to understand the processes that occur on the injured surface like inflammation, epidermal regeneration etc. The following characteristics are required for the ideal modern and smart wound-care material: bio adhesiveness to the wound surface, ease of applications, easily sterilized, inhibition of microbial invasion, ease of wound exudate removal, biodegradability, biocompatibility, oxygen permeability, non-toxicity, low cost etc.

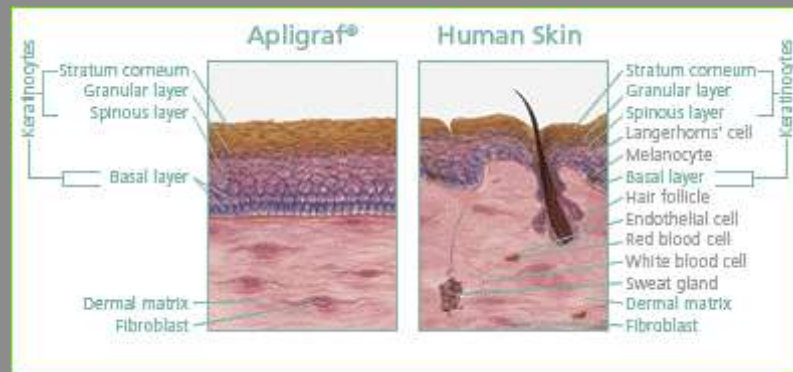


Figure 8 Apligraf – living, bi-layered cell based product to heal both Diabetic Foot Ulcers and Venous Leg Ulcers

The reconstruction of skin in tissue engineering has been mainly focused on the development of stratified constructs mimicking the bilayered structure of the epidermis and dermis.

Conventional fabrication techniques such as manual dispensing, molding, freeze drying, and porogen leaching have been used extensively in skin tissue engineering for the fabrication of cellular scaffolds.^{67, 68} Novel approaches have used free-form deposition⁶⁹ to miniaturize in vitro models. Although easy to implement, they lack the engineering control required to fabricate architecturally complex tissues.⁷⁰ Bioprinting which refers to the 3D printing of biological materials and cells for the generation of living tissue enables precise layer-by-layer deposition and fabrication of complex designs. Owing to the highly stratified and complex structure of the skin, bioprinting offers unique advantages for developing clinically relevant skin constructs that capture native heterogeneity and architecture.

Medical treatments that deal with healing processes are of great importance for dental interventions. The one of the most important procedures in periodontology is the preservation of the supporting apparatus of the tooth. Aggressive forms of periodontal disease are reflected in the great loss of bone tissue so that one of the main methods of treatment is the so-called guided bone regeneration and involves the use of bio membranes that can be made from smart textile. The desirable characteristics of the membrane utilized for guided bone regeneration (GBR) therapy include biocompatibility, cell-occlusion⁷¹ properties, integration by the host tissues, clinical manageability, space-making ability, and adequate mechanical and physical properties.

→ Bioconjugation

In addition to encapsulation, the bioconjugation process can be used to couple the bioactive agents to the textile surface via chemical or physical methods to prepare drug-releasing textiles. To achieve conjugation the textile must be made amenable to the bioactive agent/drug by functionalization of its surface. Many suitable techniques are available, which include plasma treatment, chemical activation, and grafting.

3. 2. 3 Textile-based drug release systems

Fibrous scaffolds have been extensively used in regenerative medicine applications. Specifically, biomedical textiles with fibrous structure have a long history in treatment, repair, and replacement of tissues. Due to the similarity of the medical textiles based fibrous scaffolds to the extracellular matrix (ECM) structure, these constructs are attracting noticeable attention for the tissue engineering (TE) applications. Researchers in the field of polymer science, textile, and fiber technologies have attempted to develop different fabrication methods and to synthesize materials for soft tissues TE.

Currently some of the commercial biomedical textile products, available in the market, are TIGR Matrix⁷⁷ (to reconstruct the breast tissue after cancer or as an abdominal wall closure) developed by Novus Scientific, Uppsala, Sweden; ULTRAPRO ADVANCED⁷⁸ (inguinal and ventral hernia repair), produced by Ethicon US, LLC, USA; and INTERGARD SILVER⁷⁹ (as woven/knitted vascular grafts) created by Maquet GETINGE Group in Rastatt, Germany.

Different designs (e.g., woven, knitted, and bioprinted) provide specific structural and mechanical properties for the scaffolds, which are appropriate for tissue regeneration or replacement.



Figure 9 - TIGR Matrix- resorbable matrix which reconstruct the breast tissue after cancer

Electrospinning has been used to fabricate cardiac scaffolds from completely decellularized porcine cardiac ECM.⁹⁴ The as-obtained scaffold was able to preserve the ECM composition, self-assemble into the same microstructure of native cardiac ECM and retain key mechanical properties.

In contrast to the case of large-diameter arteries, where there are already practical non-tissue engineered grafts, there is an urgent need to develop biomimetic scaffolds for clinically regenerating blood vessels of small sizes⁹⁵ (typically, <6 mm). Researchers have investigated the in vitro and in vivo performance of bilayer scaffolds, with one layer featuring low porosity and another layer exhibiting high porosity either on the luminal or adventitial side.⁹⁶

Compared with the vascular scaffolds made of a single layer of nanofibers with high porosity, the bilayer scaffolds significantly reduced blood leakage, indicating that a low porosity layer is needed when constructing a multilayered vascular scaffold to achieve both good cell infiltration and low blood leakage. Within the Zurich Heart Project,⁹⁷ novel approaches are developed for enhanced pulsatile ventricular assist devices (VAD's), where the risk of thromboembolic events on the artificial surfaces in contact with blood remains a major challenge. In particular, these events limit the usage of VAD's to be applied in patients during short or mid-term therapy.⁹⁸ As found in nature, an intact autologous layer of endothelial cells possesses the best-known anticoagulant properties, and therefore mimetic materials are developed for stable and confluent attachment of functional endothelial cells, mainly based on tailored morphology, surface topography and chemistry.^{99, 100}

3. 2. 4 Antibacterial smart textiles

It is well-known that 2 million people are dying annually out of bacterial infections in the Hospital. A major part by which these bacteria are transferred is by the textiles. It is therefore believed that making the textiles antibacterial will considerably reduce the infection. It is also clear that the smart antibacterial textile should sustain its properties in the same processes that the regular textile undergoes in the Hospital, namely, many washings at temperatures such as 75 and 92°C.

During the Projects Lidwine¹⁰¹ (FP6) and Sono (FP7)¹⁰² a new coating technique was developed that coated various textiles with nanoparticles of metal oxides such as ZnO, and CuO. The coating technique uses ultrasonic waves. The coated fabric withstood 65 washing cycles at 75°C and small losses of the coated materials were measured. The killing of *S. Aureus* was almost log 5.¹⁰³

A successful experiment was carried out in a hospital where bed sheets, pillow covers, pajamas, and bed covers were all knitted from cotton coated with nanoparticles of ZnO, and 21 patients were dressed and slept on these fabrics. The control was composed of 16 patients that dressed and slept on regular cotton fabrics. A distinct difference in bacterial contamination was detected in the comparison between the two populations.

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4. OPPORTUNITIES AND TRENDS

This paper gave an overview of the potential of smart textiles for healthcare & medicine. The global market for smart textile is projected to show a strong growth in the next 5 years, fueled by technological, demographic, economic, and business trends indicating that these growth rates may continue or even accelerate in the years beyond.

For example, according to Allied Market Research,¹⁰⁵ the global smart textile market size is expected to reach \$5.4B by 2022 from \$943 million in 2015 at a CAGR of 28.4% from 2016 to 2022, while IDTEchEx expects a lower \$2B by 2029.¹⁰⁶ More in details, Market Research Future (MRFR), set a CAGR of 9.5% over the 2018–2027 period for the global medical smart textile market.¹⁰⁷

Continuous heart rate monitoring is a growing area in healthcare, as well as systems for diabetic patients, such as glucose-sensing devices and insulin-delivery carriers for optimized dosage of insulin according to detected glycemic levels, which are anticipated to dramatically change diabetes management and patient monitoring. Most of the applications can thus be found in hygiene, surgery, therapy, drug-release systems, wellness, and biomonitoring.

In the future, the release of different drugs could be controlled in response to signals collected by biosensors based on different reactions by the human body. Certain technical challenges still need to be tackled for smart textile to be adopted and deployed widely in the future.¹⁰⁸

For example, systems should be capable of operating under different conditions, such as in humid or wet environments and in warm temperatures, without losing performance during activities like swimming, showering or sunbathing. Smart textiles and stretchable electronics demand washability and dryability and the electrodes must not break when the device is folded or bent. Moreover, the need to meet the strict regulations for medical devices, which are heavily regulated due to their safety implications and functional requirements, is something that should be taken into account in the future when bringing the smart textile systems from laboratory testing environments to the market.

5. CONCLUSIONS

Smart textiles find variety of applications in healthcare and medicine from sensors and actuators through wound-care materials, drug-release systems to tissue engineering scaffolds. By using smart textiles, advanced solutions for sensing, monitoring and actuating are made available. Sensors can be placed throughout the fabric of the clothing in order to get a detailed report of the status of the individual including heart rate, breathing rate, sweat rate, posture, and movement related information. They support the healing processes, improving safety and comfort of living of the patients ensuring their mobility in a friendly way while collecting the data. At present from the whole variety of textile sensors and actuators for healthcare, textile electrodes are those that are mostly commercially introduced due to the availability of the materials and well-developed technological approach. But also, there are a great number of offered solutions and scenarios for manufacturing textile biosensors that are still at the prototyping stage. Some products are already accepted by the industry and introduced to the market, but the process of development technology transfer to manufacturing is burden due to the high costs of fabrication, and commercial introduction and use.

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