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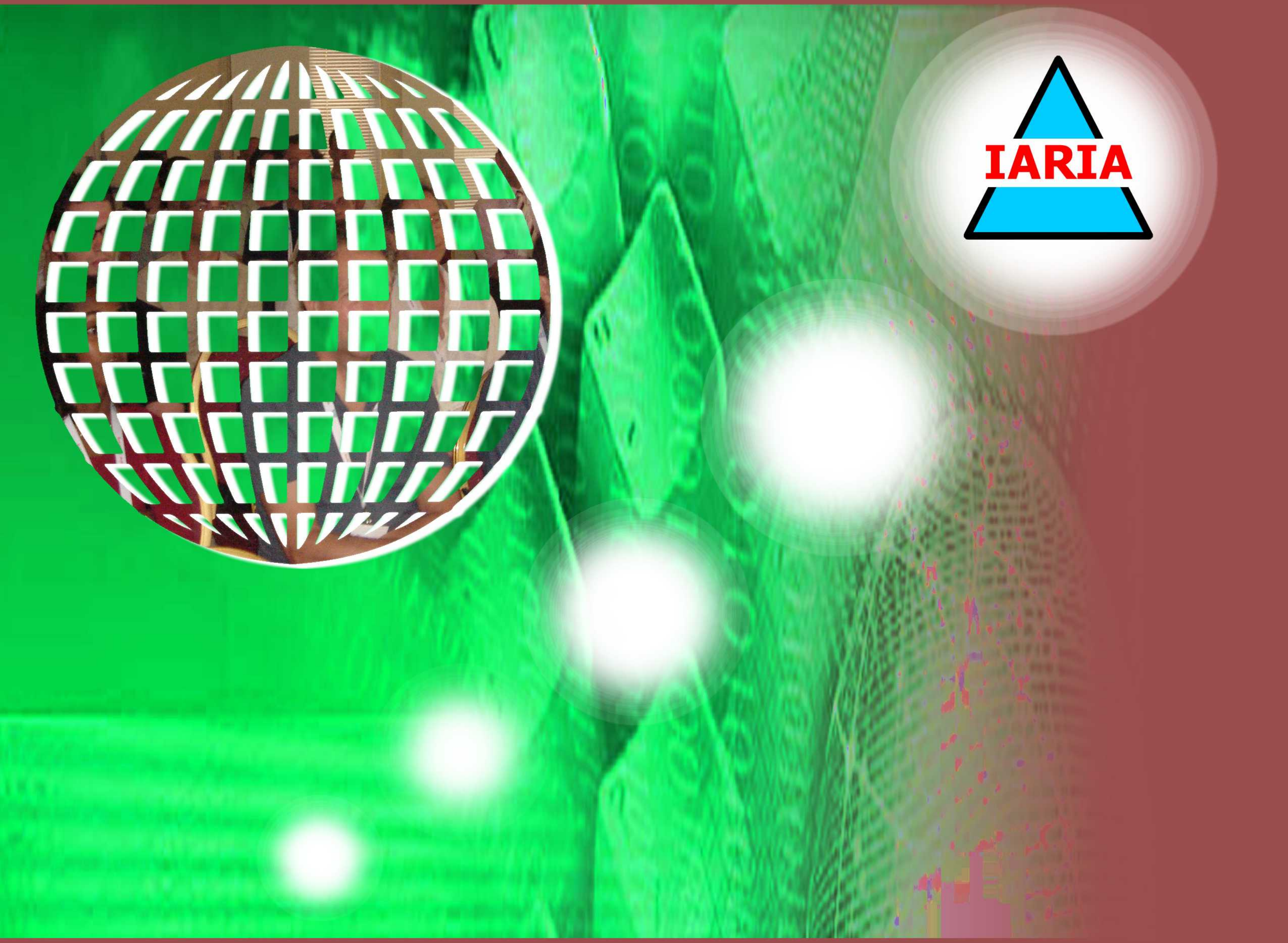

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CONTENTS

Integrating Blockchain Technologies with the Italian EHR Services

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***Abstract*—The increase of population life expectancy and of patient mobility makes necessary the development of new reliable and trust models for health provision within a patient-centric approach. For this reason, many proposals have been carried out to make the current healthcare systems able to collect and analyze the great amount of patient clinical data produced by the health organizations in an interoperable way and according to shared processes. However, despite the ability of collecting such clinical data, approaches aimed at assuring that these data are produced strictly following quality processes still lack. This work presents a permissioned blockchain architecture designed to assure integrity of data and processes related to Electronic Health Records coherent with the Italian Interoperability Infrastructure. The proposed architecture is compliant with both the Italian Regulation on Electronic Health Record and the European Regulation on privacy. A proof-of-concept prototype implemented on the top of Hyperledger Fabric framework validates the feasibility of the proposed architecture against two relevant use cases, showing that the application of blockchain technology to the healthcare sector could provide important benefits in terms of process and data integrity and quality.**

Keywords*—electronic health record; blockchain; patient-centric architecture

I. INTRODUCTION

An important issue for the well-being of citizens is to have health systems suitable to the modern society and able to exploit the most recent technology, so that they can be efficient, reliable, scalable, and capable of providing adequate care to a large number of people, both in the medium and long term.

Evolving these systems – aimed firstly at preventing health diseases through the lifestyle monitoring of people and the use of innovative and non-invasive therapies based on precision medicine – is an essential condition for containing public spending and the sustainability of the same national health systems.

In the attempt to achieve this goal, huge efforts are underway in EU countries to digitize health processes for increasing usability and reliability for patients and healthcare personnel, allowing for a reduction in time and costs.

The areas in which improvements can and must be achieved are still many, and the margins of enhancement allowed by emerging technologies like permissioned blockchains for the secure and transparent processing of distributed workflows can be really substantial, such as to revolutionize prevention and treatment approaches [1]. Indeed, current IT systems are rooted on data producers (e.g., hospitals and healthcare companies) with the aim of collecting health information, while infrastructures and protocols designed to guarantee traceability and a "patient-centric" approach are lacking, if not completely absent. This complicates and makes healthcare costlier for citizens, as well as favoring the incidence of accidental errors and frauds, often with serious consequences in terms of public health.

The integrity and traceability of health documents and processes provided through blockchain technologies can also increase confidence of patients and physicians in emerging fields like Telemedicine.

One of the major IT solution to advance healthcare in the last decade is the Electronic Health Record (EHR), which is a "longitudinal collection of health data and documents about an individual's lifetime with the purpose of supporting continuity of care, education and research, and ensuring confidentiality at all times" [2]. EHRs allow improving the management of health processes by increasing efficiency and decreasing costs.

In [1], we proposed a blockchain network to support the decentralized management of EHRs, specifically designed according to the Italian EHR interoperability architectural model. In the context of that work, we developed a proof-of-concept prototype and performed a set of simulations for showing the effectiveness of our design, and the advantages of deploying a blockchain network for implementing access control and auditability at fine grain.

The present work extends the previous contribution by specifying the integration approach between the blockchain network and the EHR infrastructure, both in terms of architecture and implementation. We point out the main interactions among the different layers composing the system, discuss how these interactions can be implemented through the blockchain technologies, and show their workflow for some use cases. We also present and discuss, with a series of experimental sessions, new and more effective implementations of access control at the blockchain layer, which are in line with the new strategies and tools offered by the blockchain development platform used.

The rest of the paper is organized as follows. Section II describes relevant background and related works. Section III presents our contribution, giving the system requirements and its core architecture. Section IV details the prototype developed, whereas Section V concludes the paper.

II. Background and Related Work

In this section, firstly, a general overview on the Italian EHR interoperability framework is presented, paying attention on its main limitations and how they can be overcome. Secondly, the most significant scientific related work is described.

A. *The Italian EHR interoperability framework*

The Italian National Health Service (SSN) is a system of organizations, facilities and services that have the purpose of guaranteeing all citizens, under conditions of equality, universal access to the equitable provision of health services. The Italian Constitution provides for legislative protection of the State and the Regions for the protection of health. The State determines the *essential levels of assistance* that must be guaranteed throughout the national territory, while the Regions plan and manage health care in their area in full autonomy [3].

In the last decade, several public health service organizations have undertaken many initiatives in order to improve the quality of health services by applying information and communication technologies. The most significant efforts performed regard the design and implementation of Health Information Systems (HISs) [4], and in particular EHR systems. These ones permit to collect the digital health information related to a patient produced by the healthcare facilities and services on the national territory [5].

In order to overcome the problem of interoperability among the different regional EHR systems, since 2012 specific Italian norms have been issued, leading national Institutions (Agency for Digital Italy, Ministry of Health, Ministry of Economy and Finance, with the technical support of the National Research Council of Italy) to define the national EHR interoperability architectural model. This model is based on a set of regional IT platforms that interact each other by means of a national framework, namely National Interoperability Infrastructure (INI), as shown in Figure 1.

Each regional IT system has the aim of indexing into a registry the digital clinical documents related to its patients, whereas such documents are stored into the data repositories typically located at the health facilities [6].

INI is conform to the registry/repository paradigm based on the IHE XDS Integration profile specifications, with the scope of facilitating the sharing of patient EHRs across health enterprises within an *affinity domain*, which is a set of technical policies and codes shared by a group of healthcare facilities that intend to work together [7].

With regards to the data structure, two different approaches are used for managing digital documents and metadata.

Clinical documents are structured conforming to the HL7 CDA Rel. 2.0 standard [8], which consists of two main sections: *header*, containing contextual data (like patient name, author, etc.); *body*, devoted to the representation of the clinical content. Each type of clinical document is structured according

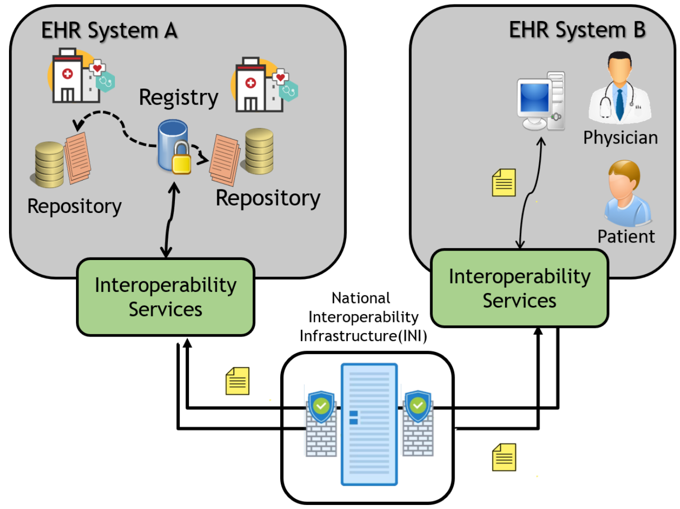

Fig. 1. Italian EHR interoperability framework.

to the Italian Implementation Guides, which are national localizations of the HL7 CDA Rel. 2 standard.

Metadata are a set of data that describe the clinical documents produced by the clinical facilities, with the aim of facilitating their indexing and retrieval. Such metadata contain information like patient identifier, author, document reference and so on. They can easily be mapped to the contextual data memorized in the header of the HL7 CDA Rel. 2.0 documents. The structure and the types of the metadata comply with the IHE XDS profile.

Moreover, the processes that formally describe all the activities that each involved actor has to perform have been modeled. Such processes describe the steps to index, search for, and retrieving patient health metadata and documents, wherever they are memorized on the national territory. All the regional IT systems have a regional node, which is the interface among the internal services and resources and the other regional nodes. Each interaction among such regional nodes, based on consolidated international health informatics standards, are mediated by INI. Along with the architectural model and the business processes, the functional and privacy requirements, as well as the technical specification for assuring interoperability are defined and applied [9].

These shared technical specifications permit the regional EHR systems to collect patient health documents, make authorized health professionals able to consult such documents if the patient has provided her/his consent, and interact with other regional EHR systems to exchange clinical information.

B. *Issues and new directions*

Despite the efforts made so far to develop a national federated architecture for the interoperability of EHR systems in Italy, significant actions are still to be taken in order to ensure an effective and correct implementation of the health interoperability processes.

Specifically, every interoperability process is in part executed through one only regional EHR system (inside a Region) and the other part is executed by other IT systems that interact with the regional system through INI. INI permits to control and partially track the requests coming from regional EHR systems, whereas the interactions occurred within a regional system are logged by this last one. For these reasons, it is complex, for the Regional EHR system, to verify that all the activities of a specific process are appropriately executed, unless to analyze all the event logs generated by the distributed systems involved. Moreover, even considering a regional context, the operations performed are often tracked by different autonomous subsystems, not allowing this way the possibility to certify that the tasks executed are compliant to the desired workflows.

A complementary architecture, opportunely designed to store in a reliable and effective way the operations executed and interoperable with the national architectural framework, would allow ensuring patients, health professionals, and government organizations that the health data are produced according to the specified and shared procedures.

C. Related work

In the last years, many academic and industry works concerning blockchain technologies and their applications have been performed in various sectors besides fintech.

Healthcare, alongside with the supply-chain industry, has probably one of the highest prospects on opportunities from these technologies. A search for the term “blockchain” on PubMed returned 21 results in 2017, 74 results in 2018, 132 in 2019, and 134 results in the first half of 2020. According to a recent study [10] by Frost & Sullivan, blockchain in healthcare is slowly starting to migrate from pilot proof of concept to commercial deployments, mainly across select enterprise-level B2B-focused use cases (e.g., credentialing, claim adjudication, supply chain, and so on). The expected revenue will be 500.7 million US$ in 2022, and pharma companies will probably be the early adopters of blockchain systems compared to other healthcare stakeholders. Various companies have already implemented or are working on putting a blockchain system to the test for a healthcare use case, (e.g., [11] [12] [13] [14] [15]), and as for July 2020 there are at least ten major healthcare blockchain consortia [10] [16]. Below, for the sake of brevity, we will limit our discussion to three major projects, which have resulted in working implementations. Indeed, they exploit different and significant approaches to the management of EHRs that have influenced our work.

MedRec [17] is a project initiated in 2016 by MIT Media Lab and Beth Israel Deaconess Medical Center, with the aim to overcome four important issues in the healthcare context: fragmented data, slow access to medical data, systems interoperability, and patient agency. It provides a decentralized approach in which the permissions, data storage location, and audit logs are maintained in the blockchain, while all healthcare information remains in the already pre-existing EHR systems. The project has developed two blockchain platforms both built on Ethereum’s framework, but with major differences. Version 1.0 [18] was a small-scale, private network with specific APIs, whilst the current version 2.0 is developed using Go-ethereum (Geth) and Solidity, but with changes to the amount of information stored on the blockchain for improving the scaling and privacy properties of transactions. Other major differences concern the consensus and governance protocols. MedRec 1.0 uses the Ethereum’s proof-of-work protocol with appropriate parameters, where the mining process would be performed by medical researchers, who in turn would gain access to aggregated and anonymized data useful to further medical research. However, this approach poses concerns about the security and governance of patient data. In the current version, therefore, the EHR providers maintain the blockchain, resulting in a small and closed set of nodes that can reach consensus without the cost of mining. Providers use a proof-of-authority to append new blocks, and also to determine who is in their group.

Patientory [19] is both the name of a digital health company established in 2015 and a no-profit association for developing and governing the PTOYNet blockchain. PTOYNet is a fork of Quorum, which in turn is an enterprise-focused version of Ethereum, mainly implemented by developers of JPMorgan Chase. Quorum executes smart contracts within the Ethereum Virtual Machine, but uses alternatives to the mining-based consensus protocol of Ethereum; moreover, it has built-in the feature of transaction confidentiality thanks to end-to-end encryption. PTOYNet has been adapted from Quorum in order to store healthcare records and manage their transactions through the PTOY token, providing an ecosystem for healthcare organizations to collaborate and innovate in a completely decentralized fashion. In exchange for PTOY, patients and healthcare organizations are able to use the network to rent health information storage space and execute health-specific smart contract payments and transactions. Patientory Inc. gains its revenue from the Software as a Service (SaaS) annual contract, as well as from population health management services from the aggregation of data on the platform: machine learning services for supporting physicians to perform medical diagnoses, patient-provider UIcare coordination, and patient engagement. In 2018, the company launched on the market a mobile distributed application (DApp), which leverages the services offered by the PTOYNet platform. At the time of writing, the approximate return on investment (ROI) in PTOY if purchased at the time of launch is -98.75% [20].

Medicalchain [13] is an infrastructure to securely store and share EHRs: any interactions with EHRs are recorded as transactions on the network, but the EHRs are encrypted and stored in data stores within appropriate regulatory jurisdictions. Its first implementation was released in February 2018 and is built on a double blockchain. The first blockchain is a permission-based Hyperledger Fabric architecture, which allows varying access levels to the EHRs: users can control who can view their records, how much they see and for what length of time. The second blockchain is Ethereum, which is used to run all the applications and services for the Medicalchain platform through the ERC20-compliant cryptocurrency token MedToken (MTN). MTNs have been offered through an initial coin offering (ICO) crowd selling process started on February 1st, 2018. At the time of writing, Medicalchain has a current supply of 500,000,000 MTN with 308,865,295.76 MTN in circulation, with an approximate ROI of -98.88% [21].

The previous examples should point out the difficulties of realizing a blockchain EHR management system, both in terms of technical deployment and governance. These difficulties are exacerbated by the EU regulations in different ways. For example, the storage of EHRs in the ledger is not only inappropriate since blockchain systems do not have the requisites of massive databases, but they make very difficult to enforce the right to data modification or erasure under particular circumstances, as stated by the Articles 16 and 17 of the General Data Protection Regulation (GDPR) [22]. More generally, blockchains underline the challenges of adhering to the requirements of data minimization and purpose limitation in the current form of the data economy.

III. The Proposed Architecture

In this work, we discuss an innovative blockchain architecture that, as its core functionality, enforces the integrity of the clinical data and processes managed through the Italian EHR infrastructure by implementing the auditing of the actions performed on such data and their resulting status in a decentralized, interoperable, tamper-proof and timeline ledger. The blockchain system acts as middleware and network infrastructure, which is interposed between the application (regional EHR services) and network layers. Depending on the coupling level with the application layer, and the additional requirements with respect to the INI technical specifications [9], the blockchain system could optionally provide for the specification of access control policies, also complementary to policies defined through INI, and the enforcement of their relative authorization rules by means of ACLs (Access Control Lists). This can allow specific healthcare ecosystems belonging to INI (hospital chains, health districts, etc.) to enrich and customize the data management and access to care functions for their patients.

The proposed architecture is compliant with both the recently introduced GDPR and the national EHR interoperability architectural model described in Section II.A. Indeed, the design of the architecture was driven by the functional and non-functional requirements listed in Tables I and II. These requirements stem from the framework of fundamental rights of the GDPR and the organizational constraints for the national EHR interoperability architectural model. They can be subdivided in mandatory (M) and recommended (R) requirements, and further grouped into basic (B) requirements and those deriving from needs related to patients (P) and those arising from the needs of health organizations (O).

Patients' needs are related to their privacy and the rights to data access (Article 15 GDPR) and data portability (Article 20 GDPR), which provide patients with control over what others do with their personal data and what they can do with that personal data themselves.

TABLE I
MANDATORY REQUIREMENTS (MBR: MANDATORY BASIC REQUIREMENT; MPR: MANDATORY PATIENT REQUIREMENT; MOR: MANDATORY ORGANIZATION REQUIREMENT)

MBR1	Identification and authorization for all the actors
MBR2	Document indexing functions: the reference IT system for a patient has the responsibility of memorizing index metadata related to all his/her documents, even if they are produced and archived by health facilities managed by other IT systems
MBR3	Search and retrieval functions for documents related to a specific patient
MBR4	Backup and restore functions
MBR5	Audit operations are required: it is necessary to track all the operations carried out by all the actors
MBR6	Data and process integrity has to be assured
MPR1	Patients must be able to hide their data from healthcare practitioners
MPR2	Patients need to have the ability to know how and when their data are accessed and for what purpose. This will be possible through the *disclosure* property, as indicated in the EU directives
MPR3	Patients must be able to search for and retrieve their health data in the system
MOR1	The holder of the data treatment is the healthcare organization that produced data
MOR2	Healthcare organizations must provide protection to the data they hold

The basic requirements (MBR1-MBR4 and RBR1) are assured by the implementation of the Italian national interoperability technical specifications for EHR systems [23] [24] for both primary and secondary uses. Instead, MBR5 and MBR6 requirements stem from the blockchain adoption. Indeed, the blockchain functionalities allow to have corroborate and auditable evidence that all workflows at the application layer are correctly executed, provided that these workflows were coded as appropriate (sets of) transactions.

The requirements MPR1, MPR2, and MPR3 are satisfied thanks to the introduction of the blockchain infrastructure and the use of access policies applied to the patient's health documents. The MOR1 requirement is satisfied by the principle defined for the EHR: in fact, the organization of the author of the document is also the owner of it. The use of ACLs allows the patient to have total access control to his/her health documents. Functional requirements MOR2 and ROR1 are assured because data access control is managed through ACL in the blockchain. The RPR1 requirement is guaranteed because all information requesting/accessing health documents is stored in the blockchain. Moreover, in the blockchain, the ACL provides a quick and easy way to modify the access policies on health documents by the Healthcare Organizations, therefore, the requirements ROR2, ROR3 and ROR4 are satisfied.

A. Architecture overview

Each regional EHR system provides both a set of IT services for i) the management of regional health documents and ii) the interoperability with other regional EHR systems. These last services can be used by the actors of other regional systems, through the INI interoperability infrastructure. They are:

TABLE II
RECOMMENDED REQUIREMENTS (RBR: RECOMMENDED BASIC REQUIREMENT; RPR: RECOMMENDED PATIENT REQUIREMENT; ROR: RECOMMENDED ORGANIZATION REQUIREMENT))

RBR1	Anonymization / pseudo-anonymization data functions
RPR1	Patients should be able to provide access to healthcare practitioners that are not entitled to access their data
RPR2	Functions for allowing a patient to send data produced by certified devices to organizations for storage and management
RPR3	Patients must be able to hide their data from specific healthcare practitioners
ROR1	Every healthcare organization can manage security policies in line with regulations, but with a certain level of autonomy
ROR2	Every healthcare organization should be able to design its own security policy and to enforce it. The definition of the access policies must be implemented in total freedom and through a highly flexible mechanism
ROR3	Healthcare organizations should be able to change quickly and easily the access policies of a given document
ROR4	The access control procedure should not add a significant administrative overhead

- *Search for document:* a healthcare professional searches for health documents (by satisfying search criteria) for a patient coming from another Region.
- *Create or update Document:* a healthcare professional creates or updates a healthcare document related to a patient coming from another Region.
- *Delete Document:* a healthcare professional deletes a specific document previously created for a patient coming from another Region.
- *Transfer Patient:* the management of the metadata index related to a patient is transferred to another regional system.
- *Retrieve Document:* a healthcare professional retrieves a specific document.

The access to services has to be allowed only to authorized actors with respect to national, regional and local access policies (e.g., policies derived from the patient's will).

The actors get access to the system thanks to one of the two authentication methods prescribed in Italy, which are SPID or CNS. SPID [25] is the unique system of access with digital identity to the online services of the Italian Public Administration, in accordance to the Electronic Identification and Trust Services Regulation (eIDAS). CNS [26] is a device (i.e., a Smart Card or USB stick) that contains a "digital certificate" of personal authentication.

Both individuals and companies are identified by an Italian identifier, named *fiscal code* (CF).

The main actors of the national interoperability system are:

- *Patient:* any citizen accredited on the EHR system, who needs health care.
- *Region:* territorial entity with its statute, powers, and functions according to the principles established by the Italian Constitution.
- *Health Organization:* any public/private health company authorized by the Ministry of Health.
- *Admin Officer:* an administrative official in charge of patient registration and accounting for a health company.
- *Organization Physician:* a physician working in a health organization registered in the network, who is in charge of carrying out diagnostic examinations or medical reports for patients, thus creating their health data.

The national access policies are based on the following attributes:

- *role:* the requestor role;
- *locality:* the location of the requestor when she/he performs the request;
- *purpose of use:* the reason for the request;
- *resource type:* the kind of document requested;
- *organization identifier:* the identifier of the health professional's organization;
- *subject identifier:* the identifier of the requestor (health professional's fiscal code);
- *resource identifier:* the patient's fiscal code;
- *consent:* the consent provided from the patient to the health organization to the care treatment;
- *action identifier:* the type of request operation.

The standard used for the exchange of authentication and authorization data is OASIS SAML 2.0. The assertions are transported in the header of SOAP messages, which are exchanged between the regional platforms and INI, in the context of interoperability services. The attributes present in the assertion are compared with the ACL to allow access or not to EHR data and services.

Figure 2 shows the modules relating to the regional EHR services, those related to the Interoperability Services, and the *mapping module* allowing the interaction of the regional EHR services with a permissioned blockchain, where the function of the nodes composing the blockchain network are defined and implemented in relation to the computing facilities of the organizations providing the services. This module is in charge of assuring the correct mapping of participants, data and interactions. In particular, for each regional EHR service request, this module: i) specifies the participants, assets and transactions that are involved in the blockchain system to fulfill the request, ii) encodes a transaction proposal, and iii) submits such proposal to a blockchain peer. It is worthwhile to stress in this respect that the participants in the blockchain network are identified by the mapping module in relation to the entities managed at the higher layers of the overall architecture. Actual participants are indeed enrolled, identified and authenticated at the application layer, which is also responsible for defining user access permissions to data and resources according to attribute-based access control policies. At the blockchain layer, further access control lists are instantiated and enforced for such participants.

B. Blockchain network overview

Our system is a kind of permissioned blockchain where, according to recent design principles [27], network nodes have different functions and can be subdivided in *validating*, *endorsing* and *ordering peers*. This approach decouples agreements about interoperability processes from the consensus

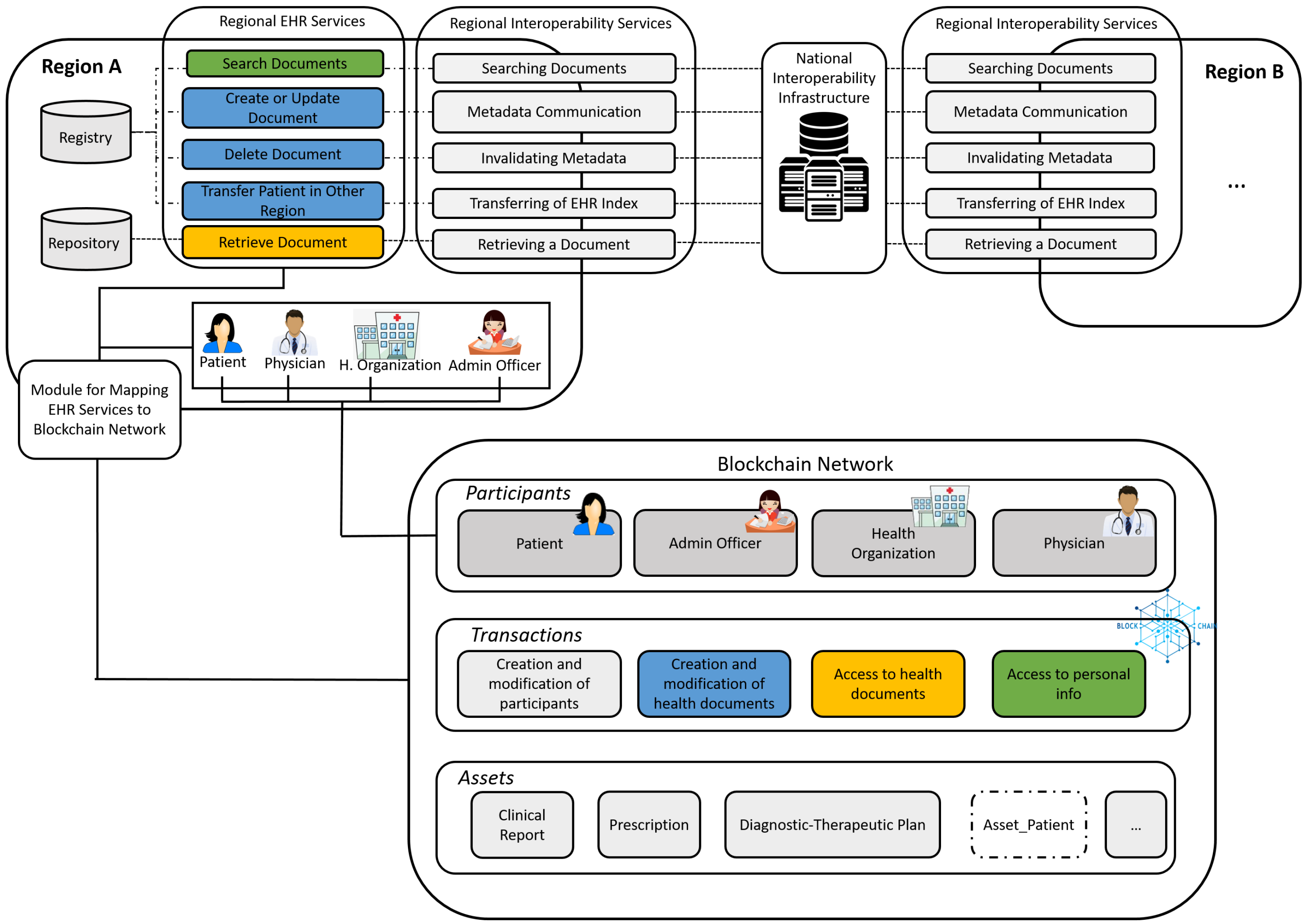

Fig. 2. The proposed blockchain architecture integrated with the EHR services.

concerning the transactions and their ordering, which have to be recorded in the blockchain.

Validating nodes have their own copy of the ledger: they are healthcare-related companies, institutions and control agencies that check for transaction I/O versus the current status of the ledger.

Endorsing peers are validating nodes that, on the basis of a consensus policy provided at the application layer, have got the additional task of checking transaction correctness both syntactically and by running them. Endorsers can be defined on a per-transaction basis, and this role is typically assumed by the entities involved in a given transaction, or the organizations they belong to. For example, in case of a pharmaceutical prescription, the endorsers could be the healthcare company to which the physician who made the prescription belongs or a regional institution representing the SSN. In the Italian scenario, the endorser role could be acted by SistemaTS (the Italian IT framework where all the digital prescriptions are memorized and retrieved by the pharmacies for the dispensations of the medications).

Ordering peers are nodes that – through a suitable consensus protocol, implemented in a dedicated module – have to assemble transactions in blocks and select the next block of the chain for the relevant blockchain. Ordering nodes do not need to store any blockchain, nor they are aware of transaction contents: they just assemble the endorsed transactions received in blocks and communicate the next block to the validating nodes for the relevant blockchain via a gossiping protocol. Ordering nodes can be supplied by the same organizations that provide validating peers, or by different organizations, depending on the governance and trust models defined for the consortium of organizations involved in the blockchain network.

Finally, the users of the blockchain network in our context are patients, physicians and other personnel of the healthcare sector. They require services at the application layer that are encoded as suitable transactions to be submitted to the blockchain by the mapping module (Figure 2).

Transactions define the logic for the management of participants and health documents through the blockchain. According to the national EHR interoperability architectural model described in Section II.A, the actual participants profiles and patients' health documents are stored and accessed through the regional EHR systems. The blockchain network introduced with the proposed architecture keeps track how such profiles and health data are produced or consumed. Specifically, patient profiles have got corresponding blockchain assets just in case the blockchain is used to complement or substitute the EHR systems for the specification and enforcement of access control policies. In these cases, the patient-related asset encodes the patient identifier, plus a list of identities or roles having some privileges on patient's documents. These ACLs are defined according to the patient-centric requirements for access data management, as optionally provided at the application layer, and in function of the roles and data types supported in the technical specification for EHR interoperability [28]. It is worth noting that if the access control policies are the high level ones defined in [29], they can be implemented in the blockchain through smart contracts, as they are defined system-wide rather than at the level of individuals.

Unlike participants, *each* health document is represented as a blockchain asset. This asset contains a set of metadata derived by [23] and the link to the actual document. In the application scenarios envisioned in this work, the aforementioned link is only used for tracking purposes, since the indexing functions are offered at the application layer; however, this element could be used as a real hyperlink to the document if the indexing functions were provided via blockchain. Some of the fields specified in assets encoding health documents are (see Figure 3):

- *authorPerson:* defines the CF identifier of the author, in our case the physician that created the asset;
- *authorRole:* defines the role of the author (like general practitioner);
- *authorInstitution:* defines the CF identifier of the company in which the physician who created the asset works;
- *patientID:* the CF identifier of the participant for whom the document is created;
- *classCode:* defines the class of the document (prescription – PRS, medical report – REF, and so on);
- *confidentialityCode:* defines the level of confidentiality of the asset (unrestricted, low, moderate, normal, restricted, very restricted);
- *mimeType;* identifies the MIME type of the indexed document.

Transactions are articulated in the following four sets, depending on their scope:

- *Creation and modification of participants:* various transactions permit to create and modify the blockchain assets related to individual participants. Participants are univocally identified in the system by their CF, which can be set and modified only by the creator of the participant, following the rules given in Section III.A. The whole process is managed by the mapping module in accordance with the access control rules for the participants defined at the application layer. Typically, as detailed previously, assets are created only in case participants represent patients, and only when the blockchain is used to manage fine-grained, patient-centric access control policies.


```
{
"creationDate": "2020-06-30T07:08:20.815Z",
"authorPerson": "RSSDVD65D15F839N",
"authorRole": "MMG",
"authorInstitution": "ULSS N -
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"obscured":"yes",
"healthcareFacilityTypeCode": "Ospedale",
"mimeType": "text_x_cda_r2_xml",
"mimeTypePracticeSettingCode": "AD_PSC001",
"title": "laboratory report",
"typeCode": "Referto di laboratorio",
"patientCF": "DRSLSN87A13F839Z",
"docType": "APR",
"companyId": "050037",
"hash": "dfd8d7c3c9aa503191c333e917e94cd359ad5a77",
"size": "7239"
}
```


Fig. 3. Example of a blockchain asset encoding a health document.

- *Creation and modification of health documents:* consistently with the fact that only agents previously authorized by the high-level policies in [23] and/or by a patient can create or update their health documents, these rules apply also for the related assets managed in the blockchain. Only the creator of a health document (and its corresponding asset) can subsequently modify it, but in any case this will be tracked in the blockchain through a suitable transaction. If provided as functionality by the access control policy, the patient can give read access for the document to other participants in the network, and this will be tracked in the blockchain through a specific transaction affecting the asset encoding the patient's profile (see next item).
- *Access to health documents:* this kind of transactions allows the access to the health documents of a patient. By default, other than by their creators, health documents can be read by the patients to which they refer to and by the practitioners indicated in [23], in function of the purpose of use of the document. If the blockchain is used to implement patient-centric access control policies, these last are implemented as a specific set of read ACLs provided in the patient's profile. By tracking access requests, this kind of transactions implements the MBR4 requirement of disclosure (see Section III.A)
- *Access to personal info:* patients must give their explicit consent to other participants (e.g., healthcare companies) for reading the information encoded in their asset. This kind of transactions implements the requirement MPR1 and is regulated by another set of specific read ACLs in

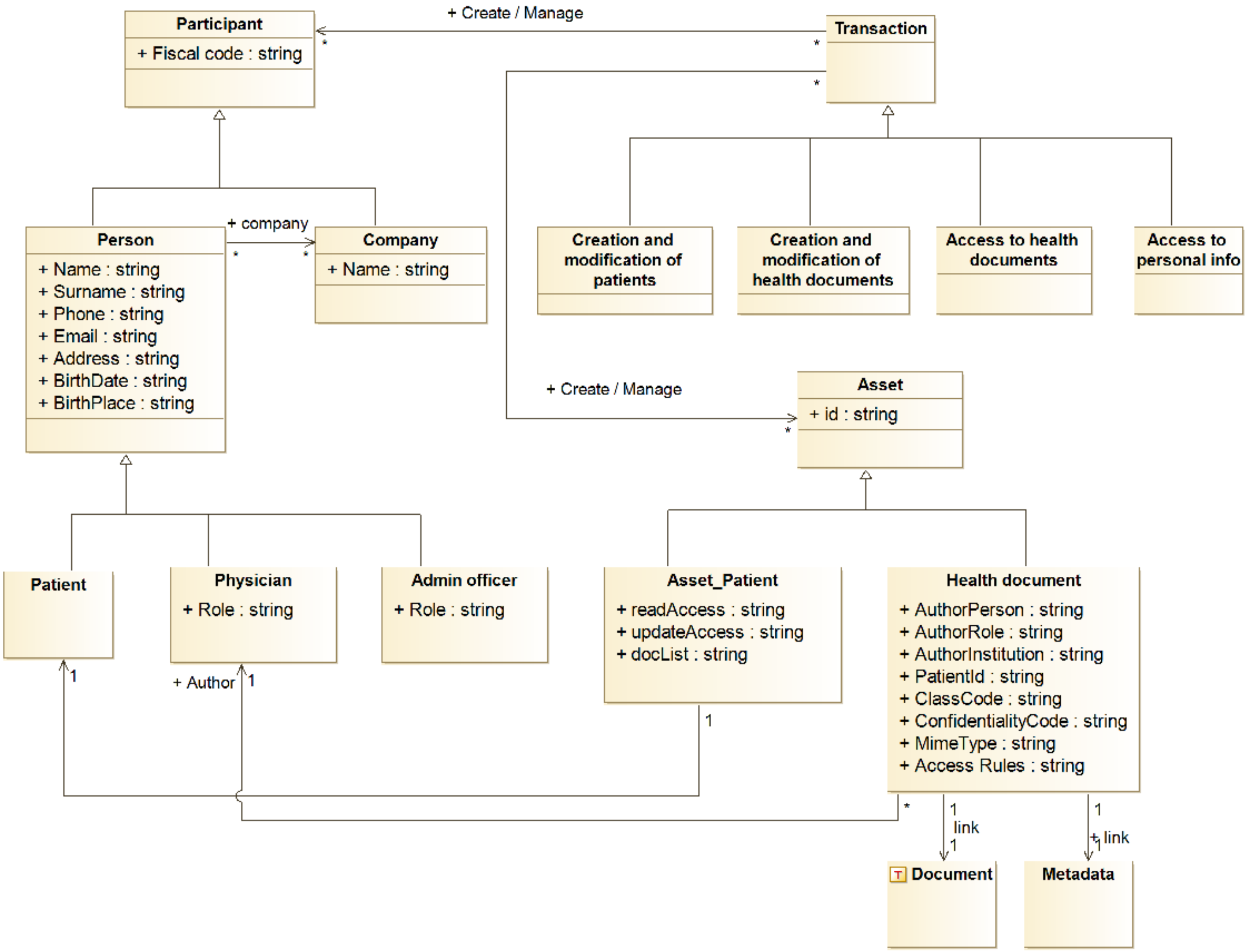

Fig. 4. Class Diagram of participants, data and transactions managed in the blockchain network.

the patient's profile.

A class diagram representing the various participants, data and transactions that are managed in the blockchain network is given in Figure 4.

C. Use cases

This section aims to give a more comprehensive overview of the overall architecture resulting from our proposal of integration of a blockchain network with the Italian EHR Interoperability Framework. It describes the interactions among its different layers in the two use cases of document search and document retrieval.

Document search

Figure 5 shows the sequence diagram related to the search for one or more health documents by a physician. The physician, authenticated on the EHR regional system, uses the Search Documents service depicted in Figure 2, which forwards the request to INI through the Searching Documents interoperability service. These interactions are concisely indicated as an "Access" phase performed by the physician in Figure 5, who at this point will have the search request submitted to INI. INI carries out the validation of the request by verifying if the user has the access right to the service and, if these checks are passed, then forwards the request to the Regional Services. In turn, a node implementing a regional service: i) forwards the request to a blockchain peer, which reads the ACLs provided by the asset of the patient to whom the documents belong; ii) compares those ACLs with the metadata encoded in the assets of the required documents; and iii) returns a list of metadata that the physician is authorized to access (the list may be empty).

Document retrieval

Once the physician has received a list of references to the documents satisfying the search query, she/he can carry out the document retrieval request, according to the same logic described above. In this case, as shown in Figure 5, the

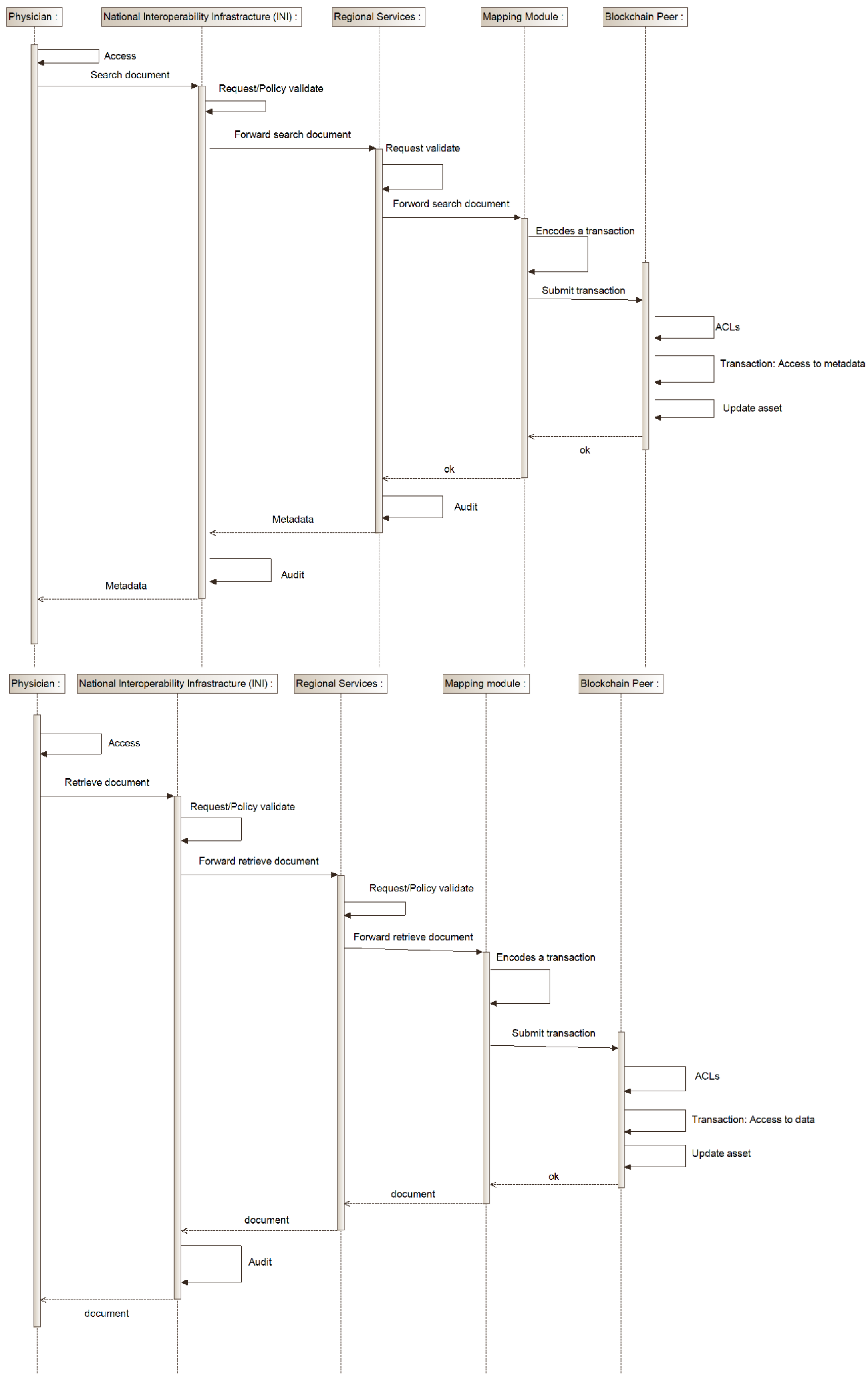

Fig. 5. Sequence Diagrams that illustrates the interactions among the actors of the architecture for document search (top) and retrieval (bottom).

blockchain peer, after the comparison of the ACLs coded in the patient's asset with the metadata contained in the document's asset, returns to the physician the required health document, or an "access denied" error.

IV. Implementation and Results

In [1], we implemented a prototype of a permissioned blockchain network, in order to assess the proposed architecture. At the time, we deployed a blockchain network and enrolled some templates of participants using Hyperledger Composer [28]. Then, we used the Hyperledger Fabric v1.2 runtime [29] to perform a set of simulations, in order to show the effectiveness of the enforcement of patient-centric access control policies through the blockchain for some relevant use cases. The ultimate scope of those simulations was to show that through blockchain technologies it is possible to easily and effectively implement all the functional requirements illustrated in Section III.

In this extended contribution, we pursue the same goal but with the following major differences:

- *participants are not actually enrolled in the blockchain network.* This complies with the overall architectural framework described in Section III.A and with the role and functions of the blockchain network as detailed in Section III.B;
- *ACLs are no more defined through Hyperledger Composer.* This stems primarily from the fact that Hyperledger Composer was considered an obsolete project by September 2019. However, implementing the ACLs by working directly at the chaincode and/or asset levels allows for the specification of more flexible and powerful ACLs, as we will show shortly.

The complete set of functional requirements listed in Tables I and II gives rise to a patient-centric data management framework, where individuals have the capability to set permissions for their documents in a punctual way (e.g., set for a specific physician the read access to a specific document). However, according to the technical specifications [23], patients can manage their documents in a much less punctual way. Permissions to read and edit documents are indeed enforced on the basis of system-wide rules stemmed from roles such as *general practitioner*, *hospital physician* or *pharmacist*, which the patient cannot change. What patients can do are some actions like obscuring a given document to all other actors, obscuring all their information and documents, or delegate some other people to manage their health documents (as in the case of patients with severe health conditions). In such respect, the recommended requirements listed in Table II can be seen as complementary to the mandatory requirements already provided by standard implementations of the regional EHR services, and that can be effectively and reliably implemented through the blockchain technologies.

In the rest of this section, we will show how it is possible to use Hyperledger Fabric chaincode and assets to implement ACLs with different levels of granularity, so to enforce at the blokchain layer access control policies that integrate more or less extensively those provided by the regional EHR services.

Figures 6 and 7 show two possible implementations of a patient asset, in relation to more or less stringent ACLs.

The patient asset in Figure 6 has a complex structure in order to indicate: i) who can read or update the asset (through the *readAccess* and *updateAccess* strings); ii) who can create a patient's document (through the *docCreateAccess* string); and, iii) who can read or update specific patient's documents (through the *docReadAccess* and *docUpdateAccess* strings). The patient asset in Figure 7 has a less complex structure, corresponding to the fact that patients can still decide who can read or update their assets, but they can not set access permissions related to specific health documents. In both cases,


```
{
"patientCF":"DRSLSN87A13F839Z",
"readAccess":"MRFGCM80A07F839J",
"updateAccess":"MRFGCM80A07F839J",
"docList":
 [
  {
   "id":"DOC_1",
   "docReadAccess":"PGRATN70C12F839S_RSTHGR75F12F839A",
   "docUpdateAccess":"PGRATN70C12F839S",
   "typeCode":"Prescrizione",
   "creationDate":"27-07-2020"
  },
  {
   "id":"DOC_2",
   "docReadAccess":"PGRATN70C12F839S_MRNALB68D15A213D",
   "docUpdateAccess":"PGRATN70C12F839S",
   "typeCode":"Referto di laboratorio",
   "creationDate":"10-07-2020"
  }
 ]
}
```


Fig. 6. Asset with document-oriented ACL management.


```
{
"patientCF":"DRSLSN87A13F839Z",
"readAccess":"MRFGCM80A07F839J",
"updateAccess":" ",
"docList":
 [
  {
   "id":"DOC_1",
   "typeCode":"Prescrizione",
   "creationDate":"27-07-2020"
  },
  {
   "id":"DOC_2",
   "typeCode":"Referto di laboratorio",
   "creationDate":"10-07-2020"
  }
 ]
}
```


Fig. 7. Asset without document-oriented ACL management.

every patient's health document is listed in the *docList*, which represents the timeline of all patient's documents and is used to set the ACLs related to specific documents.

A. Fine-grained ACLs

Let us first consider an access control scenario like that in our previous work [1], where patients can manage punctual permission to authorize specific participants to read or update their documents.

Figure 8, Figure 9, Figure 10 and Figure 11 show a comparison of the ACLs implemented with Hyperledger Composer and the new implementation via chaincode. Specifically, these figures show the possible implementation of two ACLs, for the management of the read permission to the patient asset and a health document, respectively.

While Hyperledger Composer allows to set permissions at a higher level, working with chaincode requires the knowledge of a chaincode-oriented programming language (in this case Java), but allows the specification of more complex, fine-grained ACLs.

For instance, Hyperledger Composer requires a participant and a resource to set up an ACL. Thus, the participant must be explicitly enrolled in the blockchain network through a suitable *membership service provider*.

In the context of our architecture (see Section III), this is a strong limitation that would preclude from having more assets

```
rule ReadPatientsInfo {
  description: "Only allowed participant can read patients info"
  participant(p): "org.electronic.health.record.**"
  operation: READ
  resource(r): "org.electronic.health.record.Patient"
  condition: (r.companyList.includes(p.companyId))
  action: ALLOW
}
```

Fig. 8. Hyperledger Composer ACL for reading patient info.

```
@Transaction()
public Patient readPatient(Context ctx, String patientCF, String submitterId) {

    boolean exists = patientExists(ctx,patientCF);
    if (!exists) {
        throw new RuntimeException("The asset "+patientCF+" does not exist");
    }

    Patient patient = genson.deserialize(new
    String(ctx.getStub().getState(patientCF),UTF_8), Patient.class);


    if (submitterId.equals(patientCF) || patient.getReadAccess().contains(submitterId)){
        return patient;
    }
    else{throw new RuntimeException("You are not allowed to see patient's information");}
}
```

Fig. 9. Chaincode ACL for reading a patient asset.

```
rule ReadDocIfPermitted {
  description: "Participant can read doc if in the list"
  participant(p): "org.hyperledger.composer.system.Participant"
  operation: READ
  resource(r): "org.electronic.health.record.Doc"
  condition: (r.readAccess.includes(p.CF))
  action: ALLOW
}
```

Fig. 10. Hyperledger Composer ACL for reading a document.

```
@Transaction()
public HealthDocument readHealthDocument(Context ctx, String healthDocId,
                                         String submitterId, String patientCF){

    boolean exists = healthDocumentExists(ctx,healthDocId);
    if (!exists) {
        throw new RuntimeException("The asset "+healthDocId+" does not exist");
    }

    HealthDocument newAsset = genson.deserialize(new
    String(ctx.getStub().getState(healthDocId),UTF_8), HealthDocument.class);

    Patient patient = genson.deserialize(new
    String(ctx.getStub().getState(patientCF),UTF_8), Patient.class);

    String access = "";
    List<DocList> patientList = patient.getList();
    for ( DocList docList : patientList){
        if (docList.getId().equals(healthDocId)){
                access = docList.getDocReadAccess();
        }
    }
    if (newAsset.getPatientCF().equals(submitterId) || access.contains(submitterId)){

        return newAsset;
    }
    else{throw new RuntimeException("You are not allowed to read the document");}
}
```

Fig. 11. Chaincode ACL for reading a document.

communicating with each other, and from managing ACLs through assets other than through identities.

Simulations have been carried out in the Hyperledger Fabric 2.0 runtime in order to verify that the implementations of the ACLs via chaincode, along the same lines as previously illustrated, permit to enforce the authorization rules performed by INI. These simulations consist in the realization of a scenario in which a patient is able to provide explicit authorization to a specific health organization to access his/her own prescription document produced by a general practitioner. The implementation of this scenario was carried out by exploiting the feature provided by the chaincode concerning the possibility of making the assets relating to the patient and that relating to the health document able to communicate each other.

The results reached give corroborate evidence that all the requirements listed in Tables I and II could be easily and effectively implemented trough blockchain technologies.

B. Obscuration of patient's documents

This section provides a proof-of-concept for the implementation of the "document obscuration" functionality using the proposed architecture based on the blockchain technology. This capability could be necessary for some type of documents containing sensitive data about major health problems or addictions. In some cases, the practitioner at document creation time has to specify that it has to be obscured because of national regulations; however, patients have to be able to obscure or make their documents visible at their choice [23].

We will illustrate a very simple workflow, where a document is first created as visible by a practitioner and then is obscured by the patient (to whom it refers to).

The document creation is realized by the transaction showed in Figure 12.

This transaction requires an Id for the health document and a JSON String with all the fields of the asset as showed in Figure 3. During this phase, the physician can set the field "obscured" either on "Yes" or on "No" (see Figure 3); in this

```java
@Transaction()
public void createHealthDocument(Context ctx, String healthDocId, String jsonString) {

    boolean exists = healthDocumentExists(ctx,healthDocId);
    if (exists) {
        throw new RuntimeException("The document with id "+healthDocId+" already exists");
    }
    HealthDocument doc = genson.deserialize(jsonString, HealthDocument.class);
    Patient patient = genson.deserialize(new String(ctx.getStub().getState
    (doc.getPatientCF()),UTF_8), Patient.class);
    ctx.getStub().putState(healthDocId, jsonString.getBytes(UTF_8));
    DocList list = new DocList();
    list.setId(healthDocId);
    list.setTypeCode(doc.getTypeCode());
    list.setCreationDate(doc.getCreationDate());
    patient.getList().add(list);
    ctx.getStub().putState(doc.getPatientCF(), genson.serialize(patient)
    .getBytes(UTF_8));
}
```

Fig. 12. Transaction to create a health document.

```java
@Transaction()
public HealthDocument readHealthDocument(Context ctx, String healthDocId, String submitterId){

    boolean exists = healthDocumentExists(ctx,healthDocId);
    if (!exists) {
        throw new RuntimeException("The asset "+healthDocId+" does not exist");
    }
    HealthDocument doc = genson.deserialize
    (new String(ctx.getStub().getState(healthDocId),UTF_8), HealthDocument.class);

    if (doc.getObscured().equals("Yes") && !submitterId.equals(doc.getPatientCF())){
        throw new RuntimeException("You are not allowed to read the document");
    }
    if (doc.getObscured().equals("Yes") && submitterId.equals(doc.getPatientCF())){
        return doc;
    }
    else{return doc;}
}
```

Fig. 13. Transaction to read a health document.

example, the choice is "No", whilst the document ID was set to "TEST_DOC".

At this point, both the patient to whom the document refers to and the other authorized participants in the network can read the document launching the transaction in Figure 13, which results in an outcome like that showed in Figure 14.

Actually, any other participant in the blockchain, can read the document. This is because the field "obscured" is set on "No" for this document,as shown by Figure 15, and the access control policies concerning participants in this case are enforced at the application layer.

Now, if the patient sets to "Yes" the "obscured" field through the transaction shown in Figure 16 and then launches the read transaction, he/she can read the document and verify that the obscured field has actually been modified (Figure 17).

The last step of this simulation consists in showing that with any other ID different from that of the patient, the obscured document cannot actually be read. Figure 18 shows the result of a read attempt by a random ID, which turns out in the error "No document satisfying your request", as provided by the readHealthDocument transaction.

```
[INFO] submitting transaction readHealthDocument
with args TEST_DOC,DRSLSN87A13F839Z on channel mychannel
[SUCCESS] Returned value from readHealthDocument: {"classCode":"REF",
"authorInstitution":">ULSS N - TEST^^^^^2.16.840.1.113883.2.9.4.1.3&ISO^^^^080109",
"formatCode":"Referto","comments":"","authorRole":"MMG","docType":"APR",
"mimeType":"text_x_cda_r2_xml","confidentialityCode":"N","title":"laboratory report",
"creationDate":"2020-06-30T07:08:20.815Z","patientCF":"DRSLSN87A13F839Z",
"typeCode":"Referto di laboratorio","companyId":"050037","obscured":"No",
"healthcareFacilityTypeCode":"Ospedale","mimeTypePracticeSettingCode":"AD_PSC001",
"authorPerson":"RSSDVD65D15F839N","eventCodeList":"P99",
"hash":"dfd8d7c3c9aa503191c333e917e94cd359ad5a77"}
```

Fig. 14. Result of read transaction submitted by the patient.

```
[INFO] submitting transaction readHealthDocument
with args TEST_DOC,RANDOM_ID on channel mychannel
[SUCCESS] Returned value from readHealthDocument: {"classCode":"REF",
"authorInstitution":">ULSS N - TEST^^^^^2.16.840.1.113883.2.9.4.1.3&ISO^^^^080109",
"formatCode":"Referto","comments":"","authorRole":"MMG","docType":"APR",
"mimeType":"text_x_cda_r2_xml","confidentialityCode":"N","title":"laboratory report",
"creationDate":"2020-06-30T07:08:20.815Z","patientCF":"DRSLSN87A13F839Z",
"typeCode":"Referto di laboratorio","companyId":"050037","obscured":"No",
"healthcareFacilityTypeCode":"Ospedale","mimeTypePracticeSettingCode":"AD_PSC001",
"authorPerson":"RSSDVD65D15F839N","eventCodeList":"P99",
"hash":"dfd8d7c3c9aa503191c333e917e94cd359ad5a77"}
```

Fig. 15. Result of read transaction performed by a random Id.

```java
@Transaction()
public void obscureDoc(Context ctx, String healthDocId, String obscureValue, String submitterId){

    boolean exists = HealthDocumentContract.healthDocumentExists(ctx,healthDocId);
    if (!exists) {
        throw new RuntimeException("The asset "+healthDocId+" does not exist");
    }
    HealthDocument doc = genson.deserialize
    (new String(ctx.getStub().getState(healthDocId),UTF_8), HealthDocument.class);

    if (submitterId.equals(doc.getPatientCF())){
        doc.setObscured(obscureValue);
        ctx.getStub().putState(healthDocId, genson.serialize(doc).getBytes(UTF_8));
    }
    else{throw new RuntimeException("You are not allowed to do this!");}
}
```

Fig. 16. Transaction to obscure a document.

```
[INFO] submitting transaction readHealthDocument
with args TEST_DOC,DRSLSN87A13F839Z on channel mychannel
[SUCCESS] Returned value from readHealthDocument: {"classCode":"REF",
"authorInstitution":">ULSS N - TEST^^^^^2.16.840.1.113883.2.9.4.1.3&ISO^^^^080109",
"formatCode":"Referto","comments":"","authorRole":"MMG","docType":"APR",
"mimeType":"text_x_cda_r2_xml","confidentialityCode":"N","title":"laboratory report",
"creationDate":"2020-06-30T07:08:20.815Z","patientCF":"DRSLSN87A13F839Z",
"typeCode":"Referto di laboratorio","companyId":"050037","obscured":"Yes",
"healthcareFacilityTypeCode":"Ospedale","mimeTypePracticeSettingCode":"AD_PSC001",
"authorPerson":"RSSDVD65D15F839N","eventCodeList":"P99",
"hash":"dfd8d7c3c9aa503191c333e917e94cd359ad5a77"}
```

Fig. 17. Read transaction launched by the patient after obscuration.

```
[INFO] Submitting transaction readHealthDocument
with args TEST_DOC,RANDOM_ID on channel mychannel
org.hyperledger.fabric.contract.ContractRuntimeException:
        Error during contract method exectution
Caused by: java.lang.RuntimeException: No document satisfying your request
at org.example.HealthDocumentContract.readHealthDocument(HealthDocumentContract.java:92)
```

Fig. 18. Error in read transaction.

All the above tests were performed using the Hyperledger Fabric extension for VSCode that supports versions of the Fabric framework from 1.4 onwards [30].

V. Conclusion and Future Work

This paper has presented a blockchain architecture for the decentralized management of clinical documents collected in EHRs, compliant with the GDPR. The proposed architecture is designed for facing the integrity and traceability issues concerning the current national EHR framework for the inter-operability of the regional systems in Italy. The architecture lies on a network that represents the new core components that, integrated with the federated EHR IT system, permits to easily and effectively implement the health processes in a verifiable and correct manner. The proposed network is coupled with a suitable access control and security framework to protect patient's health data. This framework respects a set of functional and non-functional requirements identified on the basis of the Italian norms and the GDPR principles, without prejudicing neither the usability of the system nor its scalability and management. A proof-of-concept prototype of the architecture has been developed to prove its feasibility in two real scenarios. For this reason, a set of transactions opportunely identified are mapped with the application services. Even if the proposed work is customized for the Italian context, the methodology adopted permits to simply decline it to other contexts.

Future work is planned for implementing a testbed in order to evaluate the effectiveness of the EHR management system resulting by integrating it with the blockchain network illustrated in this work.

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Development of a Wearable Vision Substitution Prototype and Determination of a Suitable Sensory Feedback Method

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Abstract—**This paper introduces a Sensory Substitution Device (SSD) prototype, which aims to support conversation situations. The purpose of the SSD is to convert facial expressions into emotions based on the seven basic emotions according to Paul Ekman and the Facial Action Coding System. The paper describes a study by which vibration and temperature stimuli have been compared and a suitable feedback method for the SSD prototype was selected. As a result of the study, vibration stimuli were selected for the feedback of the SSD, as these were recognized more reliably, more quickly and were perceived as less distracting on average by most of the subjects. The SSD prototype was further developed on the basis of the results. The work in progress of the SSD prototype design is described in detail.**

Keywords-Non-verbal communication; Basic Emotions; Vibrotactile Interface; Visually impaired; Vision Substitution; Sensory Substitution Device; FACS.

I. INTRODUCTION

The following paper is based on the work in progress paper about the development of a wearable vision substitution prototype, presented at ACHI 2020 [1]. Everyday face-to-face communication situations use a variety of communication channels. In addition to the verbalized information, several non-verbal cues are communicated, which have to be interpreted by the communication partners. These include, e.g., facial expressions, intonations, and gestures. Sighted people can use all these communication channels, which allows them, e.g., to interpret facial expressions. According to studies, in this way, they are able to read emotions to understand their interlocutor better. Since our emotions are involuntarily reflected in our facial expressions, they reveal valuable information [2].

Blind and visually impaired people are limited in the interpretation of a communication situation as they are not able to process the visual non-verbal information. For this reason, the communication situation can only be analyzed incompletely. Although an emotional valence can be determined through the interlocutor's intonation, this is only possible when the other person is speaking. While a visual impaired person speaks, he or she is not able to determine the emotional valence, since the interlocutor is listening and, therefore, only non-verbal cues are transmitted.

A survey carried out with focus groups of blind people and disability experts proves that there are several key needs of non-verbal information that blind people may need to access during social encounters [3]. These include, but are not limited to, the facial expressions of a person standing in front of the user. Based on this demand, the purpose of this work is to design an interface prototype that assists people with visual disabilities in everyday conversations. The proposed system is based on vision substitution, and thus, it can be classified under Sensory Substitution Devices. The goal of the SSD is to communicate the facial expressions of the conversation partner to the blind user in a conversation situation by converting the visual information into tactile stimuli.

The paper is structured as follows. In Section II, the theoretical basics for sensory substitution and related work are presented. Section III describes the relationship between emotions and the Facial Action Coding System (FACS), which is used for the SSD prototype emotion recognition. Section IV presents the procedure of choosing a suitable feedback method for the SSD. In Section V, the prototype of the SSD and important design decisions are described. Finally, Section VI summarizes the paper and describes the next steps.

II. SENSORY SUBSTITUTION AND RELATED WORK

The term sensory substitution was introduced at the end of the sixties and describes the transformation of sensory stimuli from one sensory modality into another, in order to substitute a sense that is missing or impaired by illness or disability [4]. At that time, Paul Bach-y-Rita and his colleagues developed the first SSD, which was dedicated to the scientific investigation of the plasticity of the brain in congenitally blind people. This SSD converts image information into pressure stimuli on the skin and enables blind people to find their way around the room. For this purpose, the image from the video camera is displayed on the skin using a vibrotactile belt that is worn on the stomach.

Nowadays, sensory substitution devices for vision are largely divided into tactile and auditory substitution systems.

These consist of the sensor, in this case, a video camera, and a human-machine interface (HMI), which consists of a coupling system and a stimulator [5]. The coupling system receives the stimuli recorded by the sensor, interprets them, and forwards them to the stimulator. In this way, the recorded information is analyzed, converted, and sent to the user through either the tactile sense or the hearing.

In the following, examples of vision substitution are presented, and the research needs are derived.

Lykawka et al., for instance, presented a tactile interface that allows users to navigate in environments including obstacles and to detect the movements of people and objects. The system converts the visual information into tactile feedback and conveys it with the help of a vibrotactile belt [6].

Bernieri et al. dealt with visually impaired people's mobility. The authors describe a prototype of a smart glove that complements the classic cane. The proposed glove provides vibrotactile feedback on the position of the next obstacle in the range [7].

In [8], a text reading system called FingerEye is proposed, which translates text into audio information or braille.

Bhat et al. also presented a system that aids reading texts. Additionally, it assists in recognizing objects. Both stimuli are translated into audio output [9].

The interaction assistant ICare, described in [10], deals with choosing an appropriate face recognition algorithm to build an assistant for social interactions. It also describes the prototype, of which the feedback method is also aural.

While a lot of research has been done to meet a wide range of needs of people with visual disabilities, less attention has been given to the development of assistive devices that satisfy the need for access to non-verbal communication in social interactions. However, there are a few systems that deal with social interaction, among other functions, and are available for purchase.

Orcam MyEye 2.0 [11] is a wearable device, which is worn on the temple stem of eyeglasses and it combines several features. With the help of a camera on the front and a loudspeaker on the back, the device can read texts, recognize the time, identify goods by their barcodes and recognize people, by storing and voicing their name out loud. All recognitions are translated into audio information and conveyed through a loudspeaker.

Microsoft SeeingAI [12] is an application for the Smartphone, which shares a lot of features with the Orcam MyEye. Moreover, it offers a feature, which recognizes and describes scenes, people, and people's emotions. All types of recognition are translated and represented by audio feedback. To enable the recognition and translation, a photo of the object to be analyzed has to be taken.

An important shortcoming of SeeingAI and Orcam MyEye is that the solutions provide only aural outputs. People with visual impairment rely on their hearing to perceive their environment. Therefore, aural signals that are played by an assistance system during social interactions, such as face-to-face communication, could be perceived as disturbing as they may interfere with the hearing of the speech of the communication partner or the own speech. Moreover, SeeingAI is able to recognize people and emotions, but not to communicate these in real-time. Instead of this, the user has to take a photo first. Orcam and SeeingAI thus are not sufficient solutions to support face-to-face communication.

What is needed is a system that communicates non-verbal cues in real-time and whose output is based on a different sense than the hearing, on which verbal communication is perceived.

A common alternative to audio-vision substitution is to use vibrotactile feedback, which was already used for a haptic belt in the described work about navigation [6]. McDaniel et al. also presented a haptic belt to assist in communication situations [3]. The focus of the work is on communicating non-verbal cues, like the number of people in the visual field, the relative direction and distance of the individuals with respect to the user. The output of the belt is created and delivered to the user continuously and in real-time through the haptic belt with vibrotactile feedback. Experiments have shown that non-verbal communication can be successfully conveyed through vibrotactile cues.

In addition to the vibrotactile feedback, it is also conceivable to use other tactile feedback methods for the SSD to be designed. Temperature feedback would be one such possibility. However, this has not been used in SSDs yet, but for direct heating or cooling of the human body [13], [14].

Since temperature feedback has not yet been used in SSDs, it should be examined which of the tactile feedback methods described is best suited to convey emotions during a conversation. Building on this, the SSD prototype presented in [1] can then be adapted and expanded.

III. EMOTIONS AND THE FACIAL ACTION CODING SYSTEM

Every emotion sends signals, which are most visible through our voice and facial traits. According to Paul Ekman, there are so-called basic emotions that are understood by all cultures in the world, since they can be recognized through universal facial expressions. The seven basic emotions include the emotion groups anger, happiness, sadness, disgust, contempt, fear, and surprise. Emotion groups mean that there can be different forms and intensity levels of emotions in a group [2], [15].

Although the basic emotions can be separated well in terms of their nature and their characteristic facial expression, mixed emotions occur more often than pure emotions [16]. Some examples of mixed emotions are listed below:

- Rejection of a loved one can evoke both sadness and anger.
- When we feel threatened, we are afraid, but often we are also angry. For example, we could be angry with ourselves for feeling fear if we found out afterwards that it was completely unfounded.
- Anger can come with contempt. If we find that we have reacted angrily, we can despise ourselves for it.

- It often happens that the emotion of contempt alternates with the emotion disgust. For example, if a person does something disgusting, we may find it disgusting and, therefore, despise the person.

Moreover, emotions should not be confused with moods, because unlike emotions, they can last up to two days [2]. However, emotions come and go within minutes or seconds. For example, the emotion surprise lasts at most a few seconds. After that, it ends in fear, happiness, anger, or other emotions, depending on the quality and nature of what surprises us [2]. For the development of the prototype, this means that it is important, among other things, that the emotions can be recognized quickly by the user as these can change quickly.

The basis for the analysis of facial expressions and the emotion recognition in this project is the FACS, an anatomically based coding system for all visually perceptible facial muscle movements and also a common standard for the recognition of basic emotions and their intensity. The system assigns Action Units (AUs) to almost every visible movement of facial muscles. AUs can be divided into two categories. One part of them refers to the upper face and one part to the lower face. An Action Unit can combine single or multiple muscle movements. A combination of certain AUs can be assigned to emotions. Besides, the intensity of the muscle movements is differentiated based on a five-tier ranking. In order to determine the emotions of a facial expression using FACS, it has to be deconstructed in AUs [17], [18]. For example, if a face has the combination of the AUs "Inner brow raiser", "Outer brow raiser", "Upper Lid Raiser" and "Jaw drop", this facial expression would indicate the emotion of surprise [2], [18].

IV. Choosing a feedback Method

As previously reported in [19] this section describes the process of deciding on a suitable feedback method for the stimulator of the proposed SSD. The goal of this project is to create an SSD that conveys the emotions of the interlocutor in real-time, meaning that the stimulator feedback should be conveyed during a conversation. The study described below focuses on tactile feedback methods since these are received through a different sense than the hearing and, therefore, would not interfere with verbal communication.

A. Approach

In order to investigate which tactile stimuli are best suited to convey emotions during a communication situation, a quantitative study was carried out in which the tactile stimuli heat, cold, and vibration were compared. Data were collected through a laboratory experiment in which test subjects received various tactile stimuli. During the experiment, detection rates of the stimuli and the reaction times to them were measured. The experiment's within-subject design ensured that each test subject could test all three stimuli types. After the experiment demographic data, information on the perceived distraction by the stimuli as well as other dependent factors was collected using a questionnaire.

B. Experimental Setup

The test subject's task in the experiment was to read a text aloud and to respond to heat, cold, and vibration stimuli while reading. Depending on the stimulus type sent, the reading volume should be adjusted in the following way: The vibration stimulus calls to read on in a normal volume, the heat stimulus is the signal to continue reading aloud and the cold stimulus signals to read on in a whisper.

The stimuli were always sent at the same text passages and appeared both at the beginning of a paragraph and in the running text and lasted about 2 seconds. After the signal stopped, the volume had to be maintained until the next stimulus would be sent. In order to not influence the reaction times, the test subjects sat with their backs to the experimenter and, therefore, could not see when the stimuli were sent.

To generate the tactile signals a Groove vibration motor and two Peltier elements of the size 8 x 8 x 2,6 mm were used. The temperatures chosen are 40 °C for the heat stimulus and 10 °C for the cold stimulus. When choosing the temperatures, the orientation was based on the selected temperatures in related works [13], [14], a pretest carried out, and the 45 °C limit, which is the temperature that could lead to first degree burns [20].

C. Evaluation

In the study, a total of 55 test subjects were tested of which 36.21% were female, and 64.79% were male. The average age of the subjects was 24.34, while the youngest person being 17 and the oldest 40 years old.

Each test person received 12 stimuli during the reading process and thus 4 of each stimulus type. However, not all signals were always recognized correctly. Sometimes certain stimuli were not noticed and, therefore, there was no reaction to measure.

Before statements could be made about reaction rates and reaction times, the data first had to be cleared of outliers with the help of the SPSS software. Except for one outlier, all data were used for the calculation. This was the reaction time of a test person to the heat signal. The person recognized only one of four transmitted heat signals and reacted to it only after more than 9 seconds. Since this is a far above average reaction time, it was assumed for the subsequent calculations that the person did not recognize any of the four heat signals.

After cleansing the data, the reaction rates and response times could be calculated. Table I shows the frequencies of tactile stimuli recognition. When analyzing the frequency of reactions to the stimuli, it was found that it was often the case that people did not recognize a particular stimulus type in all four interventions. However, this does not apply to the recognition of the vibration signal, as it was recognized by all 55 test subjects at least once.

TABLE I. STIMULI RECOGNITION AS PREVIOUSLY REPORTED IN [19].

Stimuli	Recognition rate	Number of recognized stimuli / Number of interventions	Number of test subjects, who recognized stimuli
Vibration	98.63%	217 / 220	55
Cold	91.36%	201 / 220	52
Heat	80.45%	177 / 220	49

Furthermore, the vibration signal was most frequently recognized. Of 220 stimuli sent in total, 217 were correctly recognized, resulting in a recognition rate of 98.63%.

The cold stimulus did a little worse with a recognition rate of 91.36%. Moreover, only three subjects out of 55 did not react to any of the cold signals sent.

The heat stimulus has been recognized least frequently, resulting in a recognition rate of 80.45%. Out of 55 people, 49 people responded to the heat stimulus at least once. The remaining six people did not adapt their volume when reading.

A reason for the differences in the recognition rates of the vibration and the temperature feedback could be the different perceived intensity of the sent stimuli (see Fig. 1). In the questionnaire, 58.63% of the test persons classified the intensity of the vibration stimulus as strong or too strong and 0% classified it as weak or too weak. In contrast, the other two stimuli were more often classified as weak or too weak. The heat stimulus was classified by 58,62% and the cold stimulus by 39% as weak or too weak. The weaker perceived intensity of the temperature stimuli could also be related to the temperature of the test subject's hands, on which the actuators were worn. The temperature of the hands was not measured, however.

The reaction times to the stimuli were compared using the dependent t-Test. Since normally distributed samples are a prerequisite for the application of a t-test, the Kolmogorov-Smirnov test was carried out to test the whether the samples for reaction times were normally distributed [21]. The SPSS software was used for data analysis of the reaction times to the different stimuli. The test showed in the SPSS examination that the samples of reaction times for the vibration, heat and cold stimuli are normally distributed. For this reason, the t-test to dependent samples was applied.

For the calculation, the signal types were compared in pairs (see Table II). Looking at the number of comparison pairs for the groups, it is noticeable that they vary from group to group. The reason for this is that a comparison can only be made if a person has reacted to both signal types. This is not the case with all of them, since not all test persons have recognized every stimulus type. For example, the vibration signal was reliably detected at least once by each

TABLE II. RESULTS OF THE DEPENDENT T-TEST AS PREVIOUSLY REPORTED IN [19].

Groups for t-test	Cold / Vibration	Warm / Cold	Warm / Vibration
Number of pairs	52	46	49
Reaction time mean values	2.097 / 1.376	3.059 / 2.059	3.091 / 1.1372
t-statistic	9.386	9.356	17.173
p-value	.000	.000	.000
Effect size r	.80	.81	.93

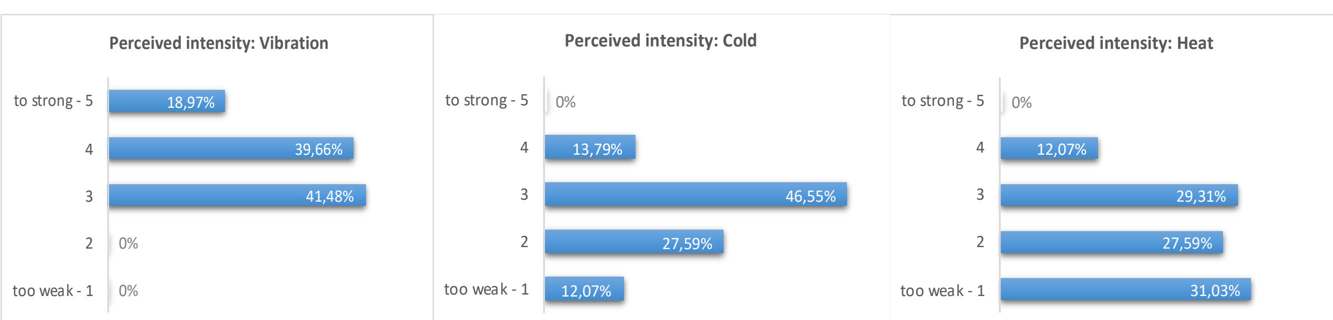

Figure 1. The perception of the stimuli types in terms of intensity.

test person, but only 49 of 55 test persons detected the heat signal. As a result, only 49 comparison pairs could be formed for the vibration/cold group. In the following, the results of the t-test are presented in pairs.

On average, the response time to the vibration stimulus was significantly shorter than to the cold (t=9.386, p=.000, n=52). The effect size r=.80 corresponds to a large effect.

A similar result is obtained when comparing heat and cold. The reaction time to the cold stimulus is significantly shorter than to the heat stimulus (t=9.356, p=.000, n=46). The effect size is r=.81 and also corresponds to a large effect.

The mean values of the reaction times to heat and vibration stimuli differ the most. The response time to the vibration stimulus is significantly shorter compared to the heat stimulus (t=17.173, p=.000, n=49). Therefore, there is also a larger effect size with r=.93.

A similar outcome to the t-test can be seen when the response times are correlated with the intervention type (see Table III). This results in strong, highly significant positive correlations between the intervention type warm and the reaction time for all 12 interventions. In contrast, there is a highly significant negative correlation between the intervention type vibration and the corresponding reaction time. There are no significant correlation values between the cold intervention type and the reaction time ($p<0.05$).

The reason why the temperature stimuli also performed worse in terms of reaction times could be that the Peltier elements also need some time to adapt to the set heat and cold temperatures. Besides, the differently perceived intensity of the stimuli may also play a role here (see Fig. 1). For example, a person who is not very sensitive to heat would probably only notice the heat stimulus at a maximum temperature of 40 °C. In contrast, a person who is more sensitive to heat would determine the increase in temperature more quickly. It should be noted that the heat temperature has already been chosen very close to the limit of a potential burn trauma [20].

In the questionnaire the test subjects were asked, among other things, to sort the signals according to the degree of distraction from speaking. In this way, the vibration stimulus was ranked 1.6 as the least distracting on average. The heat signal followed with the rank 2.1 and the cold stimulus with the rank 2.7 on average distracted most from reading.

This ranking is also reflected in the evaluation of the perceived comfort of the signals (see Fig. 2). The vibration signal was rated as rather pleasant or pleasant by 65.51% and as rather unpleasant or unpleasant by only 12%. In contrast, the two temperature signals were perceived as pleasant less often. The heat signal was even classified by 20.69% and the cold signal by 39.66% as rather unpleasant or unpleasant.

The perceived intensity also seems to influence the degree of distraction. Some test subjects reported that they were distracted by a signal that was too weak, as they were too focused on not missing it. This is also reflected in Fig. 1. The vibration was not rated too weak by any, whereas the heat of 58.62% and cold of 39.66% were rated as weak or too weak. A stimulus that is perceived too strongly does not seem to have an influence on the degree of distraction. Even if 58.63% perceived the vibration stimulus to be strong or too strong, it still distracted the least on average.

TABLE III. PEARSON CORRELATIONS OF THE VARIABLES REACTION TIME AND INTERVENTION TYPE AS PREVIOUSLY REPORTED IN [19].

Interventions	**Intervention type warm**	**Intervention type vibration**
1. Intervention (n=54)	r = .474**; p = .000	r = –.570**; p = .000
2. Intervention (n = 53)	r = .656**; p = .000	r = –.500**; p = .000
3. Intervention (n = 45)	r = .555**; p = .000	r = –.585**; p = .000
...	...	...
12. Intervention (n = 45)	r = .471**; p = .000	r = –.613**; p = .000

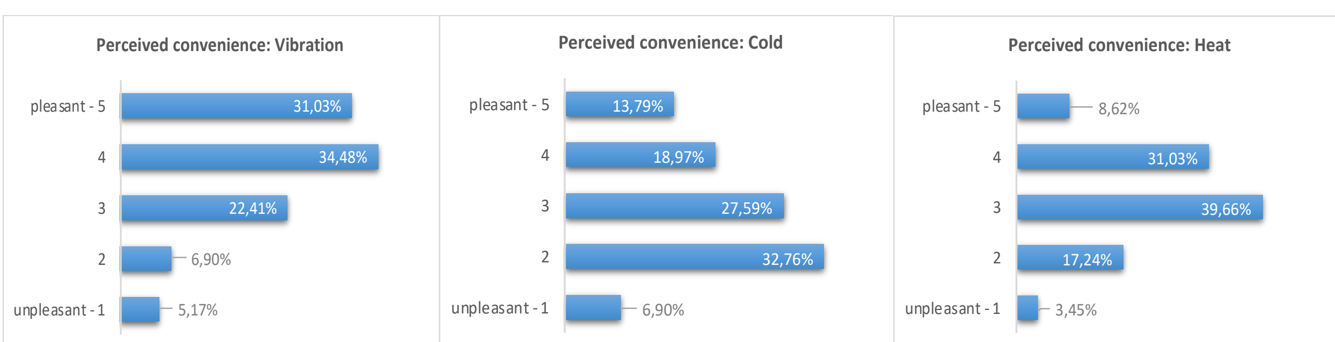

Figure 2. The perception of the stimuli in terms of convenience.

D. Feedback method selection

Based on the evaluation of all stimuli tested, the vibration stimulus is best suited to convey emotions and is, therefore, selected as a feedback method for the tactile interface. The vibration stimulus impresses with higher detection rates and shorter reaction times, which have the advantage that even emotions that only last a few seconds could be recognized quickly.

Moreover, since the aim of the project is to support communication rather than divert from it, the degree of distraction is also a key criterion. The vibration feedback, which was classified as the least distracting on average, is convincing at this point, too.

The temperature feedback did worse and is hence, not suitable for conveying emotions. Nevertheless, it can prove useful to aid communication.

One possible application would be to convey other non-verbal information, such as moods, as these have higher latency. The detection rates, however, are significantly lower than those of the vibration stimulus. The temperature stimuli were also more often perceived as unpleasant, which makes the use of Peltier elements unattractive for an interface.

For this reason, it should first be investigated how the perception is and whether the temperature stimuli are better recognized if larger Peltier platelets are used or if the stimuli are sent for longer than two seconds.

V. PROTOTYPE CONSTRUCTION AND DESIGN

This section discusses the architecture of the SSD prototype and design decisions made in this project. The prototype's architecture is formed by four main components:

- Camera unit
- Smartphone
- Notebook / FaceReader
- Haptic device

The camera unit records the interlocutors face during the communication and is, therefore, the sensor of the SSD. It is attached to glasses so that the face of the communication partner is always in focus. The camera uses a smartphone for the power supply, which sends the captured photos continuously and in real-time to the FaceReader software. The smartphone thus represents a supplement to the main sensor.

A notebook is used to run the FaceReader software [27], which analyzes and categorizes the photos by utilizing the FACS. Both together form the coupling system of the substitution system. After categorization, the results are sent to the haptic device.

The haptic device is the stimulator of the SSD. It consists of a controlling unit and a vibrotactile glove. The controlling unit receives the signals from the FaceReader Software via a Bluetooth module and controls the vibrotactile glove. Depending on the classified emotions, the associated vibration motors vibrate. In the following, the technical procedure and components of the system will be described in greater detail.

A. Camera-Unit and Smartphone

As previously reported in [1] the predecessor prototype was working with a Logitech Brio 4K webcam, whereby the device was not mobile. For this reason, the webcam is now replaced by the HD Mini camera from Spyschool [22], which is attached to the temple of eyeglasses, similar to the proposed face recognition device in [10]. For the power supply of the HD Mini Camera, an android smartphone is used, which can be carried in the pocket. The smartphone also runs the application CameraFI for the HD Mini Camera und sends the image of the camera to the notebook in real-time. Fig. 3 shows the Camera-Unit connected to a Smartphone. In order not to strain the battery of the smartphone, a special power bank can be used for the power supply of the camera.

In the previous paper, the use of the smartphone camera was described as an alternative. In this case, the smartphone would be carried in the breast pocket. Although this could be very convenient and cheap, this turned out to be impractical for this application, as the camera would not be pointed at the face of the conversation partner and would, therefore, lead to restrictions in emotion recognition. By attaching the HD mini camera to glasses, the conversation partner's face is always in view.

Figure 3. Camera-Unit connected to a smartphone.

B. Notebook / FaceReader

The notebook is used to run the FaceReader software [27]. In order to recognize the emotions of the interlocutor, it is not necessary to develop software that will recognize faces and analyze facial expressions. This task can be undertaken by the FaceReader, which is an automatic analysis tool for facial expressions. It utilizes the FACS and is, therefore, able to recognize the seven universal emotions and their intensity, which are described in Section III as well as neutral facial expressions. The functionality of the software in relation to emotion recognition is described below.

When the software has detected the presence of a face with the Viola-Jones algorithm [23], a 3D model of the face is created. The model is generated using an algorithm based on the Active Appearance Method of Cootes and Taylor [24]. With the help of the model, points are placed around and in the face, and around those parts of the face that are usually easy to recognize such as eyebrows, lips, nose, and eyes. Furthermore, the texture of the face is also determined.

In this way, not only the position and shape of the face but also the shape of the eyebrows, wrinkles, and the like are described.

The classification of facial expressions is based on the training of an artificial neural network [25]. Training material from over 10,000 images was used for this purpose. The FaceReader also uses the Deep Face classification method [26], which allows the face classification from image pixels and the recognition of patterns with a neural network. Hence, the face does not necessarily have to be completely visible. It is sufficient if the position of the eye area can be determined. The Deep Face classification method is used when modeling with the Active Appearance method is not possible. More detailed information about the functionality of the system can be found in the FaceReader white paper [27].

After the classification in FACS, the recognized emotions are forwarded to the haptic device. If the FaceReader cannot recognize a face because the communication partner has moved or the image quality is poor, no analysis is possible. This information is also forwarded to the haptic device. Due to the privacy aspects of having a camera recording during a conversation, we constructed the prototype as a closed-loop-system. This means the recordings are interpreted by the FACS software instantaneously and no video recording remains on the server.

C. *Controlling unit*

The controlling unit's main component is an ESP32-WROOM-32U (ESP32). It controls the vibrotactile glove, which will be described in section D and is controlled by a built-in Bluetooth module. In this way, the filtered real-time data from the analysis of the FaceReader are sent to the ESP32 controller via Bluetooth. The data sent include on the one hand the emotions of the conversation partner in real-time. On the other hand, the user is also notified if no analysis is possible because the conversation partner has moved, or the lighting conditions are insufficient. A notification is also sent as soon as the analysis can be continued. The vibrotactile glove is controlled on the basis of the received data. A detailed description of the hardware used for the controlling unit and the vibrotactile glove can be found in the wiring diagram in Fig. 4. The ESP32 is in this graphic the U2-component. The close-up view of the controlling unit and vibrotactile glove hardware is presented in Fig. 5.

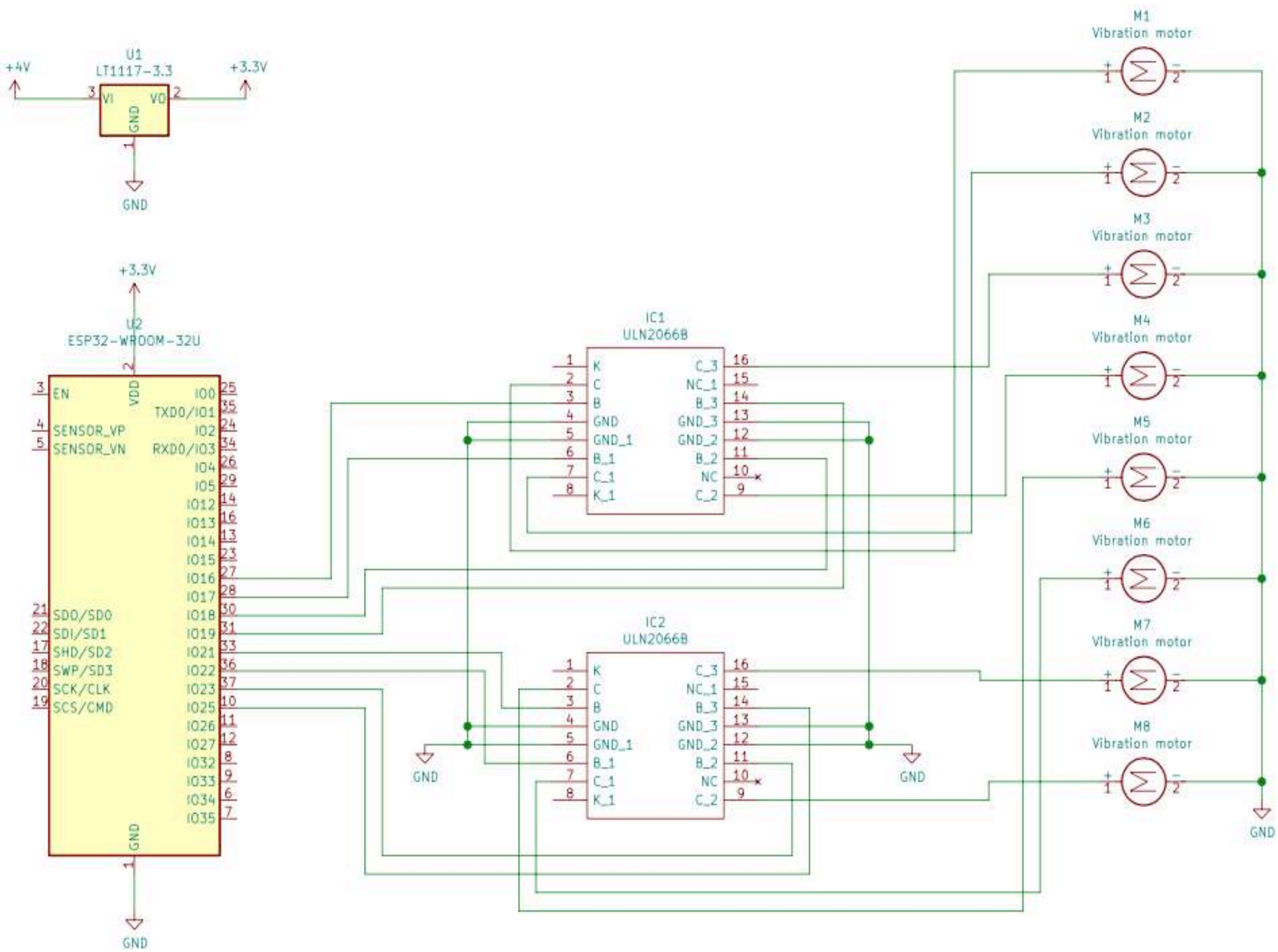

Figure 4. Wiring diagram of the haptic device.

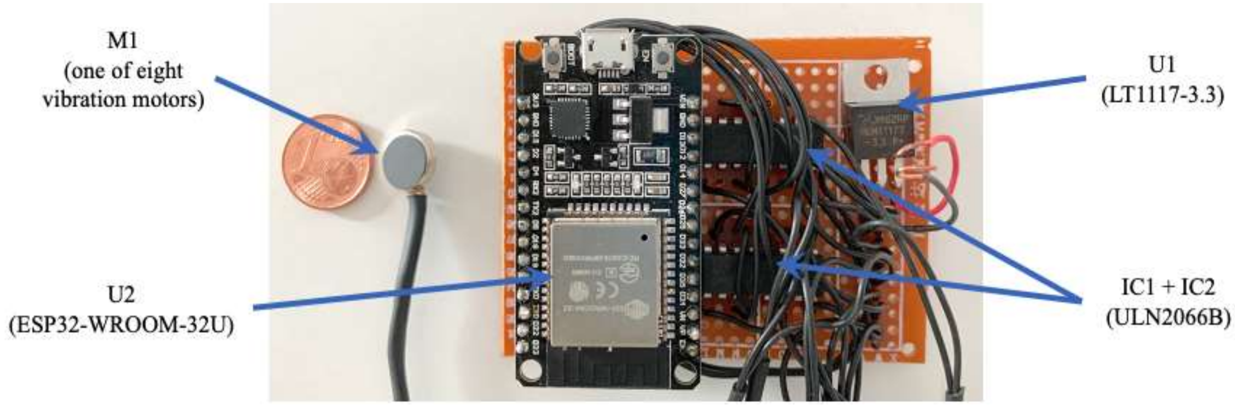

Figure 5. Close-up view of controlling-unit and vibrotactile glove hardware.

Important upgrades to the last prototype are the use of the ESP32 and the light and flat BL-5C Nokia battery instead of a power bank. In contrast to most Arduino controllers, the ESP32 has a Bluetooth module and also offers WiFi connection to the chip. For future developments, the categorization of the data recorded by the camera could possibly be shifted to the chip. It would therefore no longer be necessary to use a notebook, which runs the FaceReader software for the analysis.

Thanks to the built-in Bluetooth module and the use of the BL-5C battery for the power supply, it is also possible to make the controlling unit very light and compact. The controlling unit including the battery is therefore no longer worn on the neck, but on the wrist. The length of the cables that connect the controlling chip with the vibrotactile glove is thus reduced to a minimum and ensures more freedom of movement.

D. Vibrotactile glove

As previously reported in [1], it was planned to expand the predecessor prototype with Ekman's seven basic emotions. The task of the predecessor prototype was to convey the emotional valence of the interlocutor to the user. The haptic interface thus consisted of two vibrating rings, one of which represented the positive and the negative valence. In the following, the improvements of this haptic component of the prototype are described.

One of the most important decisions that were made concerning the haptic device was the selection of the feedback method. As described in Section II, vibrotactile cues for vision substitution have proven to be a good alternative to aural cues in terms of navigation and social interactions [1][2]. Moreover, in the study described in Section IV, in which various haptic signals were compared, vibration signals also proved to be particularly suitable for conveying emotions. For this reason, it was decided in this project to use vibration signals for the haptic interface.

Another design decision that was made was related to the placement of the vibration actuators. Some described vision substitution systems in Section II have successfully used and tested vibrotactile cues in haptic belts or gloves [1][3]. Since SSDs for navigation use both vibrotactile cues in haptic belts and gloves, it follows that this also applies to communication for which only haptic belts were previously presented.

In order to keep the haptic device small and easy to put on for future experiments, it was decided to develop a vibrotactile glove that can be worn on the non-dominant hand. The haptic glove is based on a set of vibration motors attached to an elastic bicycle glove.

Initially, it was planned to use fewer vibration motors to save costs, so that an emotion could be signaled by one or a combination of different vibration motors, but this idea was discarded. Although the basic emotions can be separated well in terms of their nature and the associated facial expression, it is necessary to take into account that mixed emotions occur in addition to pure emotions [2]. If an emotion were addressed via a combination of several vibration motors, it would not be possible to convey mixed emotions. For this reason, the prototype was developed so that a vibration motor always addresses exactly one emotion. Figures 6 and 7 show the haptic device when it is worn.

Each of the seven vibration motors, which are attached to the fingers the back of the hand, signal a basic emotion. The eighth vibration motor is attached to the palm and vibrates when the software cannot recognize a face. This happens on the one hand due to poor lighting conditions or if the communication partner has moved and, therefore, cannot be recognized by the camera.

As more vibration motors are necessary, it was decided to use smaller vibration motors so that they can be attached to all fingers without the motors touching each other and distorting the signal.

Figure 6. Front of the haptic device.

Figure 7. Back of the haptic device.

VI. Conclusion and Outlook

This paper has introduced the prototype of an SSD designed to assist people with visual impairment in daily face-to-face communication situations.

An important sub-goal was to select a suitable feedback method for the SSD stimulator. This was done by means of a within-subject design study in which test subjects tested and compared vibration and temperature stimuli. Unlike many substitution solutions that send aural feedback signals, the focus here was on tactile stimuli, since these are received on a different channel than verbal communication.

Since the SSD was developed to aid communication, great importance was also attached to creating a test environment in which the test subjects should react to the stimuli while they are speaking.

The vibration stimulus emerged as the clear winner in this study as it convinced with higher detection rates and shorter reaction times than the ones of the temperature feedback. Furthermore, the vibration stimulus was also classified as less distracting during speech and perceived more rarely as unpleasant. For this reason, the temperature stimuli were classified as unsuitable for conveying emotions in communication.

Nevertheless, it is necessary to investigate how the perception of the temperature stimuli changes when the signals are sent for longer periods or larger Peltier platelets are used. With unchanged reaction times and improved detection rates, the use of temperature stimuli to support everyday conversational situations would also be possible, e.g., to convey moods, as these have a higher latency.

However, since this project is focused on conveying emotions that can last only a few seconds, it was decided to choose the vibrational stimulus as a feedback method for the SSD.

In the next step the previously presented prototype of [1], which conveys the emotional valence of the conversation partner, was expanded. The further development of the prototype was aimed at making the prototype more mobile and providing the user with more detailed information about the emotional state by extending the prototype with the basic emotions according to Ekman [2]. This is made possible by recording the interlocutor during communication with a portable camera and determining the emotions in real-time, using the FaceReader software. Subsequently, the recognized emotions are translated into tactile information and transmitted to the user via a vibrotactile glove, which can be worn on the non-dominant hand.

Thus, the camera-based recording of facial expressions, the recognition of emotions, and finally, the conversion into mute vibration movements on a hand, an unobtrusive signal transmission can be ensured. Additionally, the device is discreet, and the user is free to gesticulate with the dominant hand.

The next milestone is the implementation of a qualitative study using a guided interview. The cognitive interest of the work is to discuss which non-verbal cues people perceive in face-to-face conversation situations, which of them are important for a smooth conversation, e.g., to avoid misinterpretations or to better understand their interlocutor. On the other hand, the SSD prototype will be experimentally validated as part of a master's thesis. It is planned to survey to what extent the developed substitution system helps to recognize emotions in a conversation situation and how this could be expanded or improved in order to optimize the support of a communication.

It is important to note that there is still room for improvement in terms of mobility. Here, for example, the

FACS analysis could be shifted to the haptic device or the smartphone. However, the degree of mobility of the SSD solution is sufficient for the planned experiments.

Future developments could include passing on individual AUs to the user. Since these can occur without indicating an emotion, their feedback could also provide valuable information for communication.

Furthermore, there might be even more communication situations, which might benefit from the SSD and are currently not in focus of our research. Besides substituting physical limitations of being able to visually perceive the interlocutor, there might be a useful application for people who simply are not capable of interpreting facial actions correctly. Therefore, training scenarios for various communication settings could benefit from a direct and discreet form of an independent non-verbal-cue interpretation device. In order to get a better insight into the advanced applications for the SSD, further studies together with the applied social sciences department are being prepared. Especially during the training of nursing professions and social workers, the nonverbal feedback of their counterparts might provide useful insights.

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New Types of Human Computer Interactions through Digital Healthcare in France

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***Abstract* - The Healthcare sector, like all other sectors of our society, is strongly impacted by digital transformations and must tackle huge problems (especially of costs), hoping digital devices help to solve them. We propose to consider it through new uses of Interactive Devices in the scope of Artificial Intelligence (AI) solutions for the improvement of Human Computer Interactions, principally through Telemedicine Platforms in France. First of all, we define our scientific position and the methodology used. Secondly, we present the use of data in telemedicine with data processing and some cases analysis of AI applications in telemedicine. We then analyze the effects of the combination of the two technologies. Furthermore, we consider the impacts of the Covid pandemic with new types of remote interactions, especially for the elderly. We discuss the main challenges of this digital transformation with the risk of a "solutionist" and "technocentric" approach, sometimes forgetting that health is above all based on a human dimension and human interactions. We also outline the question of territories and the integration of telemedicine in the healthcare system. Finally, we give a conclusion focusing on the main challenges undertaken as well as providing some perspectives, integrating lessons of the Covid pandemic. More globally we outline the importance of the digital transformation of the French Healthcare System with new types of human computer interactions both for the resilience of the healthcare organizations, improving care and cure with territorial dimensions, with the new challenges of the Covid pandemic.**

Keywords - Artificial Intelligence; Telemedicine Platforms; Territories; Healthcare; Digital Transformations; France; Covid pandemic.

I. INTRODUCTION

Healthcare is an essential sector in the digital transformations of our entire society, using interactive devices. In the developed countries, Healthcare systems must tackle huge problems (especially costs), hoping digital devices help to solve them and also help to improve the quality of care and their results. It is also the problem of traceabilily of medical acts. An approach may be through uses of interactive devices such as artificial intelligence solutions for the improvement of human-computer interactions through telemedicine platforms [1].

In France, the Isaac's report [2] clearly highlighted the main challenges of this transformation, with digital technology enabling the transition from curative to more predictive medicine. More recently, Villani's report [3] stressed the importance of Artificial Intelligence (AI), particularly in the healthcare sector. The Institute's Montaigne report considers e-Health as a priority project to transform the French Healthcare System [4].

The question of healthcare is linked to the territories, in particular with the subject of social and territorial inequalities in health [5], with the concern of "medical deserts", with issues of traceability of care acts and health pathways, with the possible contributions of telemedicine to improve it and experiment new innovative ways.

This French healthcare system, already in a severe crisis (the question of operating costs having led to hard staff reductions in recent years) has been strongly impacted since March 2020 by the Covid pandemic, imposing in particular the search for new solutions based on digital tools and new uses of data [6].

In this paper, we examine the background of the transformation of the healthcare system and the current context of the development of telemedicine platforms and AI. We clarify the scope and the objectives of the survey that deals with the production and use of healthcare data on telemedicine platforms. Then, we intend to address, through an example, the issue of the AI solutions to implement better Human Computer Interactions in telemedicine. To get a relevant picture of the recent situation, we choose the examples amongst new worldwide trends and French implementations. During teleconsultations, there are no physical examinations, so they seem somewhat like tele regulation and are required to reduce uncertainty in diagnosis. We intend to identify how combining AI and telemedicine may specifically support and improve the process of a remote medical consultation. Finally, we try to bring out the main findings concerning technical approaches as well as other considerations.

The transformation of the French healthcare system has become vital due to the combination of demographic evolution and the epidemiologic transition. With the decrease of infectious diseases that have led to the model of hospital, important changes have been brought with the rise of degenerative diseases and multi chronical pathologies. In this context, the patients are more and more involved in their healthcare pathway. They use search engines to get information on Internet, they share opinions and feelings on social networks, they interact on platforms to obtain medical appointments and they take charge of their healthcare records.

With the implementation of Healthcare Information Systems (HIS) in doctors' offices or hospitals, important volumes of medical data are produced. They gave rise to the implementation of data warehouses for archiving them in secure ways and managing their use. With multi-chronic pathologies, data for analysis are not only medical parameters but they come from different sources, on issues such as nutrition, habits and behavior, environment, etc. This wide scope of data is produced by the interactions of patients on digital platforms, characterized as social technical devices. Moreover, the chronic patients' healthcare requires the coordination of all the healthcare providers in the hospitals and in the ambulatory system. The different stakeholders have to exchange information for the organization of their patients' healthcare pathways and the monitoring. Medical data are produced and recorded in the different Electronic Healthcare Records (EHR) on proprietary software and in the "*Dossier médical partagé*" (DMP) in France, used till recently as repositories. But the priority is to enable data retrieval and sharing. Healthcare coordination should be based on interactive devices and updated data.

After an introduction (Section I), in Section II, we first define our scientific position and the methodology used. Then, in Section III, we present the use of data in telemedicine and Artificial Intelligence data processing. In Section IV, we consider observations on AI applications in telemedicine through cases analysis. In Section V, we then analyze the effects of the combination of the two technologies. In Section VI, we analyze the consequences of the Covid pandemic on the human computer interactions. After a discussion in Section VII, we give a conclusion focusing on main challenges tackled and perspectives for future works, integrating new uses of data and information and communication challenges.

II. Scientific Position and Methodology

In a research-action approach, this paper associates two researchers, one with a university position and the other with a more consulting position and implication in experimental activities on the deployment of interactive devices, such as AI and telemedicine projects in the territories. Their complementarity allows for a back and forth between theory and practice, by comparing practical results with theoretical issues, to produce knowledge for action.

This work therefore lays in the field of Human Computer Interactions (or Interfaces) - HCI, which corresponds to the analysis of the means or tools put in place so that humans can work with machines, mainly computer tools, by controlling them to develop or improve services in healthcare. We place ourselves in the perspective of analyzing the development of new services for users of our health system (organizations, professionals, patients, etc.) in a dual dimension of care and social perspectives.

There are questions of ergonomics, ease of use and adaptation to the conditions and contexts of use, and ethics, particularly concerning uses of data and societal issues (limiting inequalities) and therefore the ambivalence of these tools: undeniable possibilities for improving care and its quality and traceability, but also risks of technical abuses (technicism) or rationing of care.

We position our research within the interdisciplinary field of information and communication sciences, in the perspective outlined by F. Bernard [7], proposing to articulate the four dimensions of links and relationships (interactions in a systemic dimension), meaning, knowledge and action. We insist on the complementarity of information and communication, stressing both the importance of information to shape organizations and data for their management and development, and also of communication to foster change [8], by promoting cooperative dynamics, articulating the project and storytelling dimensions of all actors [9], both human and socio-technical devices. We propose an approach that we call Information and Communication Organizing Ecosystems (ICOE). The notion of "organizing" was proposed by Weick [10], focusing on processes, and interdependence of interactions, to study human activity by means of "sensemaking recipe" in a set of dynamics to try to grasp the complexity of organizations. For us, information and communication contribute to the shaping and ecosystems, which can be organizations, companies, groups or territories. We thus articulate the approaches of Economic Intelligence and Quality [11], in the wake of Wilensky [12], when he speaks of Organizational Intelligence, without forgetting the innovation dimension in process approaches [13].

In the wake of Goffman [14], we particularly mobilize the notion of situation (situations of activity, management, information, communication, decision, evaluation, etc.) with all the ambivalence of technology [15]. Tensions exist between those who are in favor of new uses of digital technology to improve patient services, such as G. Vallancien [16] and those who fear regression, rationalization may meaning rationing or "uberization" (standardization and precarization of the health professions), such as the National Board of Doctors or *Conseil National de l'Ordre des Médecins en France* [17]. Using the "situational and interactionist semiotics" proposed by A. Mucchielli [18], we analyze situations of activity, also integrating the dimension of emotions and leadership [19] and trust building in complex projects [20]. The aim is to promote new services for patients and healthcare professionals, with the importance of information (data uses) and communication to improve cooperation with a strong territorialization and proximity dimension, with the emergence of new professions such as data scientist or specialists about human data interfaces [21], with specificities in the health sector.

III. The Use of Data in Telemedicine and the AI Data Processing

We intend to examine the use of healthcare data on telemedicine platforms and then, the AI solutions that could improve the processes. The recent trend in new technologies is melding telemedicine with AI. Figure 1 gives an idea of the advance of those two technologies. For getting a comprehensive overview of the context, we can observe the expected expansion in telemedicine and AI in the twenty next years through the following chart extracted from a study of the English National Health System (NHS).

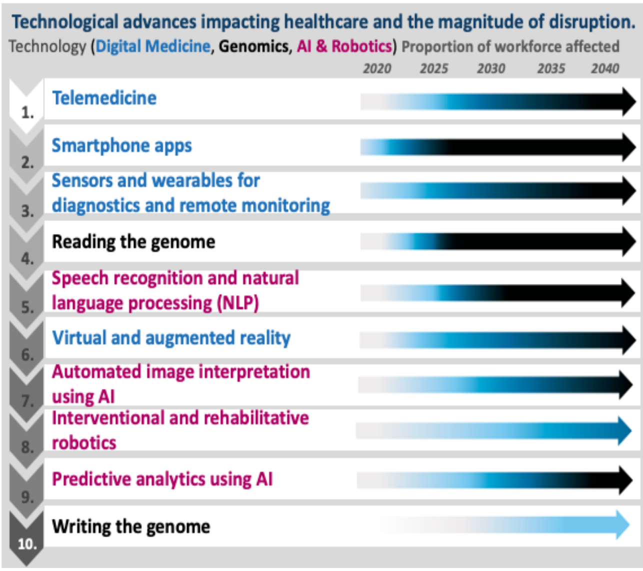

Figure 1. Top 10 digital healthcare technologies and their projected impact on the NHS workforce from 2020 to 2040 [22].

A. The Use of Data in Telemedicine

According to the French regulation definition (telemedicine decree: 2010), five situations or types of telemedicine can be distinguished: tele consultation, tele expertise, tele monitoring (for chronic diseases), tele assistance and medical answers for emergency regulation. The types of patients addressed by telemedicine are:

- Every patient in contact with their general practitioner within their healthcare pathway,
- The dependent elderly,
- Patients with chronic diseases: diabetes, heart failure, renal failure, Chronic Obstructive Pulmonary Disease (COPD), etc.
- Outpatients after surgery in hospital.

In terms of technological structure, a telemedicine platform is a connecting device, where the central data repository is related to interfaces. For teleconsultations, there are instantly interactions between the patients and the doctors, who receive measurements and answers, as well as view and analyze patients' health data through a web portal. The portal is customized for the exchanges between stakeholders: patients and professionals, according to the medical specialties. It can be accessed from a computer browser or also from a smartphone on a mobile app with an ergonomic workflow interface. The integration of algorithms for a preliminary analysis of medical data and imaging is now expanding. The platform has to support the entire process chain for providing services:

- The medical appointment, linked to calendaring,
- The collect of the patient's agreement,
- The stakeholders' authentication,
- The diagnosis and medical report,
- The prescription (for drugs, etc.),
- The data recording,
- The billing and payment processes.

Usually, booking a telemedicine appointment is possible through this interface where it can be scheduled. The waiting line may be displayed on a dashboard, and a virtual (space organized as a waiting room for the patients. (Sometimes documents can be exchanged beforehand (questionnaire, measurements, medical imaging, etc.). Recording the National Healthcare Insurance (*Caisse Nationale d'Assurance Maladie*) card is the usual way to check the identity of the patient. Some other forms can be found like the patients' agreement and the eligibility questionnaire. The payment system and the online prescriptions can be supplied through the portal. Additional services consist of the integration of the EHR (Electronic Health Record) for adding data and the report of the teleconsultation, with eventually the telemedicine video record.

The Healthcare Insurance Fund may provide a financial aid to physicians for purchasing the following connected devices: oxymeter, stethoscope, dermatoscope, otoscope, glucometer, electrocardiogram (ECG), doppler device, echograph, device for blood pressure measure, camera, tools for ocular and hearing tests and equipment for breathing functional exploration. As a socio technical device, a telemedicine platform contributes to the transformation of the healthcare system mainly with an extended use of data through Human-Computer Interactions. As there is no physical presence for the patient and consequently no auscultation, the doctors have to secure their medical acts by whatever means possible. Different types of data are needed for improving the general process that includes mainly assessment, diagnosis and medical prescription. Data have to be retrieved and completed for the anamnesis, the medical case history. The diagnosis that is sometimes based on medical imaging requires decision support systems, as prescription too.

B. AI Data Processing and Solutions

1) Machine learning, deep learning:

With the implementation of EHR in hospitals and the extension of Information Systems (IS) for the healthcare production, medical data began to be mass produced; then, the data management could develop with the creation of algorithms. As data mass production reduces the limitation in the use of statistical rules, AI devices are more and more reliable with deep learning. They were first learning algorithms, with data analysis (neural networks) and the capability for the machine to deduct rules to get a result. AI applications were especially numerous for the analysis of medical imaging, allowing the development of diagnosis support systems, for example in cardiology or ophthalmology, with satisfactory rates of reliability. Genetics is now providing huge amounts of data, which paves the way to the search for predictive models. Thus, AI solutions strengthen the evolution towards a personalized, preventive, predictive and participative medicine.

2) Mass production of healthcare data:

Human-Computer Interactions increased with the patients' empowerment, developed in France since the March 4th 2002 (Law about *Sickness People Rights and Quality of Health System* with the idea of "Health Democracy"), as they access, more frequently through social technical devices; they not only use various search engines to get relevant information, but mainly digital platforms on computers or smartphones to know the conditions and costs of healthcare, getting on line appointments or healthcare appreciations, discussing on forums, using connected objects or contributing to design innovative products. Data can also be retrieved from the informal exchanges on the social media that have become at the origin of useful information related to healthcare (behavior, habits, ways of living, feelings). In a more global approach towards the determinants of healthcare, information lead to new perspectives in retrieving more data and crossing them to build algorithms that could help to improve the patients' healthcare. The data integrates not only medical, but social, psycho-social information to obtain the signs of any evolution in the living conditions of a person and the risks of degradation.

3) Different uses of AI:

The following figure displays the main uses of AI in healthcare:

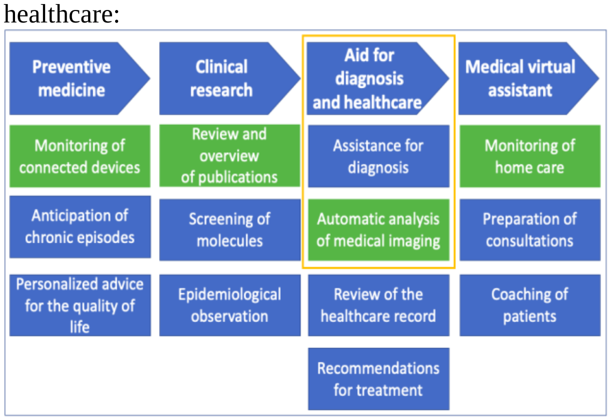

Figure 2. Typology of AI uses in healthcare (the mature uses are pointed out in green) [23].

Through the main characteristic of AI, which is to manage huge amounts of data and provide quick results, we try to clear the applications that would especially enhance the value of the telemedicine process, combining data retrieval, data analysis and the decision support system.

- *Retrieval of the Appropriate Information*: AI applications can retrieve the patients' information automatically, from EHR and other sources. Basically, machine learning can help to analyze clinical data in a patient's EHR to provide patient care recommendations.
- *Automatic Analysis of Medical Imaging:* AI solutions are especially relevant for analyzing huge masses of data from medical imaging. In 2018, DeepMind developed a software using a neural network learning system for detecting ophthalmic pathologies from scanner eye retina imaging [24]. The detection focuses on age-related macular degeneration (AMD), diabetic retinopathy, glaucoma or retinal detachment. DeepMind obtained a precision of around 94% for the AI application it developed. Such AI solutions in medical imaging can provide aid for diagnosis, which helps to secure them.
- *AI Advice for Prescriptions*: Machine learning algorithms may recommend treatment options and solutions for the patients.
  They help the doctors when recommending prescriptions by taking into account the existing ones, checking and validating prescriptions to make sure that the drugs prescribed are compatible with the patient's data.

IV. THE OBSERVATION OF AI APPLICATIONS IN TELEMEDICINE

A. The Analysis of New Trends for AI in Telemedicine

Some applications for telemedicine now use machine learning to help the medical professionals with diagnostic support based on symptoms and patient health data. New trends pivot on the capabilities and benefits of AI in combining high speed data retrieval from very different sources, analysis of huge amounts of data and its results with the decision support system. AI solutions may be used for the patients' orientation, helping to screen patients in telemedicine as they do for emergency calls.

B. Data Collection before a Consultation

Lemonaid Health, an AI application before virtual video consultations: Lemonaid provides video consultations with medical professionals [25]. It uses machine learning at the beginning of the process with the evaluation of the patient's state of healthcare. The patient has to complete a questionnaire online that includes medical history, current medicines, allergies and regular symptoms. An AI model of screening based on the complexity of the case analyzes the information obtained to categorize the patient and orientate him to the suitable healthcare provider. Doctors evaluate the situation, usually during a video consultation available with an assigned healthcare professional.

C. Personalized Diagnosis Support

The telemedicine application Ada Health (Germany): A diagnosis support for telemedicine [25] uses a machine learning AI application to provide personalized diagnosis support. The patient has first to complete his medical profile in an initial survey. A chatbot uses a series of questions to identify possible symptoms.

D. A Case Example of Telemedicine Using AI

1) MédecinDirect: MédecinDirect is a telemedicine platform [26] that provides medical advice and remote consultations through contracts with companies and mutual funds for their stockholders. Facing the increase of the activity in remote medical consultations, MédecinDirect uses AI solutions in order to keep the quality level and to reduce the length of time for providing an answer. They fulfill two major aims: improving the anamnesis and securing both the diagnosis and the prescribed treatment.

2) Analysis Based on the Reasons for the Consultation: The healthcare practitioners have to ask different questions for the clarification of symptoms and to retrieve the patients' medical history, without omitting to get important information. Built on the use of a great number of exchanges recorded on the platform, the analysis aims at standardizing the different healthcare professionals' answers. After the analysis of the major reason for the consultation from natural language, AI solution proposes to the doctor a complete set of relevant questions in order to better define the medical case history. A conversational agent may be integrated into the process of asking questions.

E. Decision Support System

AI is used for creating an inference engine that enables the provision of medical recommendations to doctors for the exclusion of serious risks, for making diagnosis and assisting medical prescription.

Following the publication of Villani's report, the creation of the French "Health Data Hub" (HDH) 2019 is part of the French strategy for IA: improving the accessibility to mass data, the project aims at supporting the development of IA uses. This national platform consolidates French healthcare data from different sources (mainly National Health Insurance, in French Assurance Maladie and hospitals) and in the long run, the project may answer to advanced needs of data for IA techniques and succeed in multiplying the possibilities for data treatments.
A call for projects for the HDH was organized for "The improvement of medical diagnosis by IA"; among the approved projects in 2020, the building of a database of ophthalmological images illustrates the extension of IA uses for designing decision support systems for the healthcare professionals: such services will encourage the development of new types of medical consultations.

The health data hosting by Microsoft is the subject of controversy in a context of discussions about the digital sovereignty.

V. The Effects of Combining Telemedicine and AI Technologies

A. The Impacts for the Doctors

The processes are noticeably different between remote medical consultations and consultations with the physical presence of the patients, and change the relation doctor / patient. Patients reactions are not the same when there exists a "mediator artifact" (computer, tablet, etc.) between medical professionals and patients. This fact explains why some doctors are still reluctant to the practice of telemedicine.

AI and telemedicine are complementary. AI really contributes to securing the whole process of a teleconsultation. First, getting accurate information about the patient's state of health helps the professionals in their assessment. Then, any information improving the decision-making and enabling to confirm the appropriate diagnosis is really valued. Finally, the prescription is much more reliable if the doctors get all the information about the patients' other drugs and prescribed medicine. AI algorithms have to be trustworthy, especially since they are used for healthcare. The use of AI solutions may be time saving for doctors. They can give them more time for doctor-patient interaction. So AI may be a real help for doctors in the teleconsultation process, but some challenges have still to be solved [27]; it introduces a risk due to an insufficient accuracy in the results of AI. Retrieving significant amount of data for the training procedure in order to create reliable algorithms is very important. The data retrieval and their standardization are very important factors facilitating faith in the algorithms created.

B. The New Scopes for the Patients

The development of teleconsultations seems to result not only of recent changes in regulation and of the context of "medical desertification", but also of the patients' current needs.

Some policy holders have access to telemedicine platforms with their healthcare insurance contracts; more patients want to avoid waiting for a medical consultation going to the doctor's office and use such platforms for getting information fast and accurately. With the empowerment for their healthcare, patients are more involved in digital processes, like booking online for medical appointments or filling in information forms before consultations. They also communicate about their patients' experience on social media and forums, so that they contribute to producing data that can be retrieved for AI in healthcare. This observation leads to the questioning concerning the evolution towards digital medicine, with direct access for patients to the information automatically produced by AI, and less human interactions with the healthcare professionals. This will strongly change the doctor-patient relationship, which has hitherto focused on the human dimension of interactions.

VI. The Consequences of the Covid Pandemic on the Human Computer Interactions in Healthcare

The ambivalence of technology and the tensions between technophiles and technophobes are been reduced with the new needs that Covid 19 has brought to the word. In France, according to G. Babinet, the Covid-19 is revealing the low level of digitization in the healthcare system [4].

A. The emergence of the digital medicine

In June 2020, the Montaigne's Institute think tank estimated the potential value creation of e-health in France at between €16.1 and €22.3 billion per year [4]. This economic value creation can be divided into 5 categories of innovations and impacts:

. 3.3 to 4.7 billion through patient empowerment and the prevention of complications, particularly for chronic diseases.

. 3.4 to 4.7 billion through dematerialization and data exchanges, with optimization of the medical time of healthcare professionals.

. 3.7 to 6.4 billion through telemedicine, notably with the use of teleconsultations to limit hospitalisations.

. 2.4 to 3.4 billion through the automation and optimisation of care pathways in both primary care and hospital and at their articulation between these two sectors.

. 3.3 to 4.2 billion through transparency and decision support, by limiting the redundancy of healthcare acts and overpayments.

The health crisis due to the present pandemic has brought out a transformation of both the patients and the doctors' uses.

With the important needs for medical consultations during the lockdown period, the number of teleconsultations exploded. The obstacles to the acceptance of this model of healthcare seem lower. Telemedicine may address the increasing medical needs.

"Video consultation has become part of the daily life of the French," Doctolib says. The health crisis is largely responsible for this, since teleconsultations have really exploded during the confinement: from a total of 100,000 video consultations carried out between the launch of the service in January 2019 and February 2020, the number has risen to 4.6 million, an increase of 4.5 million acts in barely six months. Another revealing figure: in the last six months (February – August), 32,500 healthcare professionals have used Doctolib, compared to only 3,500 before the epidemic, which is almost 10 times less. General practitioners represent 69% of the users of the video consultation, details Doctolib. Next come psychiatrists (7.5% of users), gynaecologists (4%) and paediatricians (3.3%). Although telemedicine is used in all regions, the majority of procedures are currently carried out in Ile-de-France (46.5% of appointments), ahead of the Auvergne-Rhônes-Alpes (10% of appointments) and PACA (8.5%) regions [28].

It may be part of an evolution towards the "smart medicine" with the "all connected", in a convergence between the networks for persons, objects, process and data towards the Internet of Everything (IoE) [29].

A digital revolution for medical practices may really have begun with new habits that are really different from the face-to-face medical singular conference and may change it deeply. The combination of advanced technologies may stimulate the appropriation and extension of the digital medicine, but without forgetting the indispensable human dimension of medicine.

For facing the pandemic situation, in a hasty way, many tools (apps or telemedicine platforms) were provided to the healthcare professionals, mainly free. After this period of exponential expansion in their diffusion then in their appropriation, the uses may now be extended, owing to the existing risk of second wave or other pandemic situations. This may lead to another generation of telemedicine platforms sharing data among multiple users and integrating data from video assessment, patient electronic profile, event logs from connected devices with the Internet of Things (IoT) for improving the remote healthcare management [30].

Such technological developments pave the way to digital and personalized medicine. The concept of 4P Medicine (Leroy Hood, Institute for Systems Biology, 2013) is composed of 4 dimensions: Personalization, especially with the patient's genetic profile, Prevention, with a global approach for healthcare rather than a focus on diseases, Prediction, with the most appropriate medical treatments for the patient, and Participation, involving the patient's responsibility in his healthcare. Another "P" has often been suggested as 5th with Pertinence or Proof of the effectiveness of the medical service rendered to the patients, or even "P" as Pathway, with the evolution towards the management of the patients' healthcare pathways. A new "P" may also be considered with the development of Platforms assembling diagnosis, treatment and clinical trial process and connecting the different healthcare professionals involved [31].

B. An innovative combination of technologies addressing healthcare concerns

AI may be used with the analysis of rare but significant events for detecting the first indicators in order to predict a pandemic. Multiple information sources, including data from the social networks, may be combined in analytical datasets for very complex analysis creating correlations and connections for defining the distinctive features of a viral pandemic model. AI technologies may also help to forecast the needs for medical and nursing staffs, anticipate the situations, and assess the risks for the patients. Furthermore, an AI model using computed tomography may enable to detect the virus through a rapid diagnosis of patients: a recent study showed that the algorithm produced have higher sensitivity compared to the evaluation of the images and clinical data by radiologists [32].

Telemedicine may also help to support emergency care from remote facilities [33]. As the recent pandemic pointed out, telemedicine may be requested to provide medical answers in emergency situations requiring urgent regulation; a mobile telemedicine platform like Nomadeec, developed by Exelus, enables tele-triage, teleconsultation and tele expertise for remote diagnoses and patient orientation decisions. It provides services as elements of a paramedical check-up, that can be sent to the professionals or video conferences. If the request is not a real emergency, the patient may be orientated to a healthcare permanency. Diagnosis recommendations and decision-making tools are based on AI. Several medical devices can be Bluetooth-connected to the platform for digital capture of vital signs: a thermometer, a blood pressure monitor, an oximeter, a stethoscope, a glucometer, an electrocardiogram device, etc. and the interface displays the relevant data, photos, videos on the same screen. Tele prescriptions are included. Real time transmissions can be sent to hospitals, syntheses, reports and mails automatically generated.

A Covid-19 orientation algorithm has been provided by the Ministry of Health for self-evaluation during the current pandemic. Based on cases study and scientific watch, it integrates severity and unfavorable prognosis factors as variables. The answers to the questionnaire determine the orientation of the patients; the results are presented on a decision map. This process of online questionnaire filling is now proposed by some hospital groups: they ask their patients to fill the form before coming for a consultation or hospitalization. This evolution is a step for more patients' empowerment in the management of their healthcare.

The scope for teleconsultations includes the chronic pathologies follow up. The monitoring of the patients suffering from chronic diseases may also be enhanced thanks to a combination of technologies. It often requires remote surveillance that may be based on the regular data collection from connected devices. With the pandemic, the preparation of a mobile app has been achieved within the scope of the prevention program called "Integrated care for older people" (Icope), implemented by the Gérontopôle in Toulouse. Icope monitor may help for frailty screening: it aims at evaluating and following the elderly person's main functions: mobility, memory, nutrition, state of mind, eyesight and hearing. This program is part of the program Inspire of the World Healthcare Organization (WHO) launched for identifying the aging people who are mostly in risk of chronic pathologies as Alzheimer's disease, atherosclerosis, osteoarthritis, cancer or Age-related Macular Degeneration (AMD); the main goal is to reduce care dependence through targeted and personalized prevention strategies. The elderly persons are encouraged to register their own data. Alerts are automatically generated in case of functional decline or loss; as they are received in the Icope monitoring center, a nurse calls the elderly person and then informs the general practitioner who may plan a teleconsultation or a tele expertise for getting the advice of a geriatrician or of another medical specialist.

AI may be value-adding in the analysis for the patient risk stratification in order to plan healthcare interventions.

HoloLens 2 is an example of extended uses of the virtual reality (VR) with the pandemic: in order to reduce the time spent with contaminated patients, the doctors in the hospitals of the Imperial College Health NHS Trust equipped themselves with Microsoft helmets: the device preserves the human appearance; medical notes or images such as radiographs and scanners can be projected on the visor above the patients; the wearer may interact with the virtual elements through movements or voice; a camera can film and transmit in live the images via a video stream on a platform to a computer located in another room for other doctors, which enables to limit the number of professionals in contact with the patients.

The pandemic circumstances may lead to hasty the appropriation of pioneering techniques that have to be evaluated in terms of security and ethics in order to consider their possible extension over time and their integration in the healthcare management process.

C. Profound changes for the healthcare professionals

Considering the doctor patient relationship, the pandemic leads to a paradigm shift as many consultations may now become digital, particularly if they are related to a prescription renewal or to a chronical disease monitoring.

The health crisis also points out that the medical resources have to be spared; in order to answer to the needs for homecare, it would be important to rely on all the healthcare providers involved.

Recently, the Ministry of Health has recommended to the Regional Healthcare Agencies (in French, "Agences Régionales de Santé", ARS) to organize for the patients suffering from the Covid-19 the extension of the use of tele expertise in different specialties: pneumology, infectious diseases, geriatrics, palliative care, physical medicine and rehabilitation; this evolution may prefigure changes in the medical organization.

The technologies may help to secure the different process for appropriate delegation of tasks. Thereby, the data registration of the patient's medical history and the description of the symptoms before a teleconsultation may be supported by decision aid based on AI tools for being carried out by a nurse or an orthoptist in ophthalmology.

In France, the lockdown period has brought several changes in the healthcare regulation: the nurses are now authorized to practice the remote monitoring called telecare; the midwifes may perform teleconsultations for remote pregnancy monitoring; speech therapists, occupational therapists are now authorized to practice teleconsultations, and psychomotor therapists, remote tele-rehabilitation. Physical therapists may manage telecare for their patients and the remote pharmaceutical monitoring may be planned for fragile persons.

Physiotherapy is considered as important for patients during or after their stays in an intense care unit for the improvement of the functional mobility. The remote respiratory tele rehabilitation gets equal results compared to pulmonary rehabilitation in a follow-up care and rehabilitation unit [34]. The tele rehabilitation process is also a support to develop the autonomy of the patients in order to keep them at home. It might be extended to cases of ambulatory orthopedic surgery, or after a stroke:

teleconsultations could be regularly scheduled with the surgeons or neurologists, and telecare with the physical therapists.

Finally, it was observed that the Covid pandemic and the lockdown period induced anxiety and worsened the suicide risk. Phone, teleconsultations and telecare are considered as means of improving the psychiatric follow up in distress and decompensation situations. Those specific modes of intervention have to be secured and supported by technological tools and data processing, for collecting accurate information at the different steps of the process: before, during and after the interaction with the patients; AI tools are adequate for retrieving the data from different sources and analyzing them.

D. The perspective of breakthrough innovation in the organization of the homecare monitoring

The development of chronic diseases and the increase of the elderly population make urgent some changes in the homecare monitoring. This necessary evolution for healthcare at home should accelerate in order to cope with other pandemic situations.

AI may be an innovative way for adding value in the management of the elderly patients' pathways, for instance with the use of predictive information thanks to the behavioral data recording. Teleconsultations for geriatrics and other specialties (psychiatry, cardiology, dermatology, pneumology, endocrinology, neurology) may be planned with the hospitals and the telecare process may enable to follow up situations remotely in relation with a nurse or another caregiver at the patients' bedside.

Furthermore, technologies may improve a real populational approach, in order to identify the urgencies and priorities with the detection of frailty situations. Developing the teleconsultations and connected devices monitoring may help to avoid hospitalizations. The extension of the telecare may complete the digital medicine with interventions of different healthcare providers.

Sharing the healthcare professional resources on a territory may enable to deal with their rarefaction. Some establishments for the elderly (in French, "*Etablissement d'Hébergement pour Personnes Agées Dépendantes*", EHPAD) experiment their intervention on their territory as an "EHPAD out of the walls" or "EHPAD at home"; such changes offer many opportunities for homecare: portable devices can eventually track vital signs such as blood pressure, heart rate and temperature; healthcare measurements devices might be connected to the EHPAD platform for providing direct information for remote patients monitoring; teleconsultations may be organized with the EHPAD for geriatric evaluation, psycho geriatrics in case of crisis, and monitoring for wounds and pressure sores, palliative care, drug iatrogenic. The EHPAD coordinating doctor may analyze the iatrogenic risks in relation with the general practitioners. The EHPAD occupational therapist may provide specific support to the patients and the psychologist help to reduce the elderly' anxiety or behavior disorders.

The whole remotely digital organization at home may also be improved for many services: an example is the direct delivery of the medicine after their prescription during a teleconsultation.

According to S. Bertezène, "the Covid crisis first exacerbated all the dysfunctions, then there was immense organizational resilience" and solidarity with innovative ways. The territorial cooperation dimension was essential, notably through the CPTS (Health Territorial Professional Communities / *Communautés Professionnelles Territoriales de Santé*) or the GHT (Territories Hospitals Groups / *Groupements Hospitaliers de Territoires)*, including the EHPAD.

S. Bertezène insists on the imperative for less administration and constraints and on the importance of trust in all the actors. She develops the notion of "hidden costs" of bureaucracy, which, if controlled, would allow for salary increases and investments. The resilience of the healthcare system implies restoring meaning and give the means to act as the government has committed itself to do [6].

VII. Discussion

The interactive devices studied (AI, telemedicine) are certainly very promising and should constitute major levers of the digital transformation to make the health system evolve from a purely curative and fee-for-service medicine to a more preventive medicine, as envisaged by the Isaac's report [2]. The Covid pandemic has made these transformations even more imperative.

We have already highlighted in the wake of J. Ellul [15], the ambivalence of technology and the tensions between technophiles and technophobes. In France, the Descartes' country, engineers have always occupied a privileged place, with the risk of technological "solutionism" drifting away from technocentric approaches, with tools too often developed without real consultation with users, whether they are health professionals or patients and their families. The integration of new project management methods (known as "agile", integrating users into the various stages of project development) such as the method for developing trust in complex projects, for instance the Fears - Attractions - Temptations (FAcT)-Mirror method proposed by G. Le Cardinal [20], are interesting approaches. Developing trust is essential to promote resilience of the whole French healthcare system.

New tools also renew territorial approaches to health and in particular those of health inequalities, which can have an individual, social (isolation and poverty) and collective dimension, concerning not only individuals, but the collective dimension of territories, the question of "medical deserts", territories without health professionals, these "medical deserts" being also "digital deserts" [5] with specific work on AI and rurality, data and weakened territories or smart cities and smart territories.

Another essential aspect is the evaluation of the impact of these new devices and their added value in improving services for both health professionals, patients and their families. This is another area of research we are working to propose, still in an approach based on information and communication issues, a more contributory evaluation by integrating the expectations and emotions of all stakeholders, tool designers, users: health professionals, patients and their families. These patients are gradually affirming their role with the notion of "health democracy" enshrined in the law on "Patients' rights and the quality of the health system" of March 4th 2002.

All these developments imply a new “territorialization” of health management, with an affirmation over the past thirty years of “healthcare interface organizations” (healthcare networks, multi-professional healthcare centers, home hospitalization, etc.) to overcome the barriers between urban medicine and the hospitalization sector, or new territorial groups of urban medicine, with whom there are still challenges of coordination and traceability of acts.

All these digital transformations are also reflected in the affirmation of new coordination professions [35] and also to give meaning to data, not only data scientist but also human data mediation [21]. But if we have outlined the challenges of the digital transformation of the health system through the implementation of new devices, mainly AI and telemedicine, we must not forget the whole human dimension of healthcare, well emphasized by M.J. Thiel, with the suffering and anxiety of illness and the end of life [36].

VIII. Conclusion

With the rise of more uses in telemedicine, we are witnessing a new step in the transformation of the healthcare system, with major challenges to overcome. The Covid pandemic has fostered the evolutions [6].

The digital process in telemedicine is a Human-Computer Interaction, both requiring and producing data. It contributes to the increase of the volume of healthcare data and therefore to the possible development of AI. Telemedicine is based on data exchanges between the stakeholders and data processing. Data collection in this case is even more important than when there is physical presence in a medical consultation. The doctors have to act without any information from the patient’s auscultation. The relevant information must be available, thus the necessity to gather as much data as possible, i.e., recent information, then, to select the required information and to get support when making a decision.

The use of AI strengthens the requirements of the information systems interoperability, as data are collected from different sources where their meaning may be different. Data entered into an AI system should be complete and accurate. A healthcare data normalization engine, curated and versioned data sets for the terminologies could be used. But in order to improve the quality of the available data, especially with large-scale data sources, we would need some of the standardization tools for curating the data that do not yet exist [37],[38]. A standard terminology, such as the Systematized Nomenclature for Human and Veterinary Medicine (SNOMED) Clinical Terms achieves semantic interoperability. Archetypes provide the shared meaning of data with the specifications of its format.

Furthermore, the implementation of AI solutions highlights the complex ethical questions about the use of medical and behavioral personal data, with the upcoming extension to genetics. From an ethical point of view, beyond the patients’ free consent, the use of their healthcare data mandates a differentiated exploitation according to their sensitivity.

The future trends may be the temptations to use AI for services to patients without any human interaction, in answer to their various questions about the seriousness of the symptoms, how to understand, what to do, when seeing a doctor is essential. We have outlined the risk of any only “solutionist’ approach, as medicine is managing human beings and not only materials or connected objects. The challenges are very important and shape the whole future of our society. Health is an essential sector to observe the issues and challenges of the digital transformation of our entire society and new uses of data, with their ambivalence [15]. As productions of new technical devices, they can allow essential and imperative transformations (cooperation based on trust among all the actors) but also with risks of abuses (more controls and bureaucracy). The path to resilience can include some hard stones ...

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Recognition Method for a Temporary Change in Walking based-on Anomaly Detection and Classification

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***Abstract*—In recent years, the global population of the elderly has increased, and one of the challenges faced by this population is the increased vulnerability to falls. Two approaches to alleviate this problem are determining actions that cause these falls and preventing falls using the detection results. A temporary change in walking (i.e., stumbling and staggering) is a typical cause of a fall. However, existing studies do not focus on a temporary change in walking; they only distinguish between walking or other activities and recognize walking speed. In this paper, we propose a method to detect the change in walking using change point detection (i.e., anomaly detection for time series data) and a classification method for the multiple types of change. Moreover, we assume four cases classified using available data, and we propose the parameter setting of the proposed method for each case to be applied in diverse scenarios. During the evaluation, four anomalous walking videos (where, anomaly represents a temporary change) are used. Thus, the accuracy of the anomaly detection of the proposed method is up to 93.5%, and the four types of detected anomalous walking are classified into three clusters in 89.1% of cases based on each characteristic.**

Keywords–Walking recognition; Classification; Anomaly detection; Human activity recognition.

I. INTRODUCTION

This paper is an extended version of the paper presented at eTELEMED 2020 [1]; a summary of the major extension is presented below.

- We propose a method for parameter setting, which assumes four cases. The method is described in Section IV.
- We define a baseline method to compare the accuracy between the proposed and existing methods. The baseline method is described in Section V-C.
- The evaluations of the baseline method and new cases of the proposed method are added.

The global population of the elderly has grown in recent years, and one of the challenges faced by this population is an increased vulnerability to falls [2] [3]. Older people are more likely to be seriously injured by falls; further, falls lead to expensive hospitalization. In the USA, the cost for fall-related injuries was approximately $50 billion in 2015 [2]. Human activity recognition is a research field that focuses on addressing these problems [4]. The approaches for solving these problems using human activity recognition are divided into two types. The first approach is fall detection, which can detect falls soon after they occur. Several studies on this topic have already been conducted [5]. These studies indicate that this approach prevents fall-related injuries from becoming severe [6] [7]. The second approach is detection of actions causing falls, which can help reduce the incidence of such scenarios. These actions include stumbling and staggering, and they are caused by a temporary change in walking gait. Thus, it is necessary to recognize a change in walking. In addition, the change needs to be classified because it includes actions that are not related to falls, such as standing still. However, existing studies on walking recognition can distinguish between only walking and other activities [8], and they can recognize walking speed [9]; however, they do not focus on a temporary change in walking. Most of these studies recognize activity from common features among multiple persons if there is a clear difference between target activities (e.g., walking and sitting). Various methods can be used to identify these activities. However, detecting a change in walking is difficult because the difference in each person is larger than that in each action. In other research areas, a stumble detection system for powered artificial legs has been proposed [10]; however, its application is not possible in cases without artificial legs.

In this study, we propose a method to detect a change in walking using change point detection and anomaly detection for time series data. Change point detection is performed for each time series walking data. Although anomaly detection and parameter setting of the anomaly and change point detection methods require accumulated data, the effects of individual differences are mitigated. Moreover, the accuracy of the method depends on the parameters. Therefore, we propose a parameter setting method for multiple cases depending on the type of data accumulated data. In addition, the classification of multiple types of change using a method that clusters the results of the change point and anomaly detection is also proposed.

The rest of the paper is organized as follows. Section II presents related works. Section III presents our proposed detection and classification methods. Section IV presents the parameter setting method. Section VI evaluates our proposed method, and Section VII concludes the paper.

II. RELATED WORK

This section represents existing works of related research fields, viz., walking recognition and fall detection, and prerequisite technology of the proposed method, which is an image-based human posture estimation.

A. Walking Recognition

Walking recognition is one of the research fields of human activity recognition, which is human activity recognition is defined as the ability to recognize human activities using sensor data [4] [11] [12]. Each recognition method, including walking recognition, comprises two steps: data collection using sensors and human activity estimation based on the collected data. Some examples of sensors are cameras, wearable sensors,

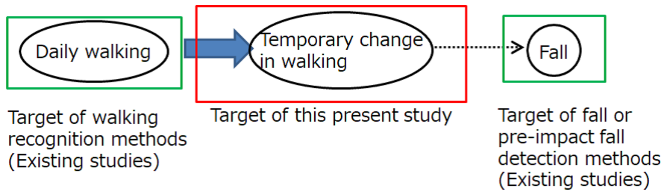

Figure 1. Relationship between this work and existing works.

and object-tagged sensors [13] [14] [15]. Walking recognition methods also employ these two steps.

Currently, several studies on walking recognition have been conducted; these studies focus on differences in sensors, target actions, and estimation methods. Khan et al. have detected walking and five other activities (i.e., sitting, standing, washing hands, driving, and running) using accelerometer data obtained via change point detection [8]. Further, they employ a genetic algorithm for the optimizing the parameters of change point detection to improve its accuracy. Thus, the accuracy of the detection is 99.4%–99.8% [8]. Trung et al. classified five types of walking (i.e., walking on a flat ground, upstairs/down stairs, and up/down a slope) with a 90.4% accuracy based on the accelerometer data using a support vector machine [16]. Davis and Taylor recognized walking speeds (i.e., normal speed, half the normal speed, and double the normal speed) and classified walking and 11 other activities (e.g., running, skipping) from the data of video-based four joint coordinates [17]. This classification is based on a threshold calculated statistically from the motion of the joint coordinates. Haescher et al. classified walking speed into four speeds (i.e., 1, 2.5, 4, and 5 km/h) based on the capacitive sensor data [9]. This walking recognition has numerous applications such as automated surveillance, monitoring systems to identify people that may be injured or require assistance, and estimation of the amount of activity [9] [17].

Unlike this study, the above mentioned studies do not focus on a temporary change in walking. However, this study can be used in combination with the previously mentioned studies to detect walking in several activities using the existing methods and to recognize a change in walking using our method.

B. Fall Detection

Fall detection is another research field in human activity recognition. Two approaches can be adopted to reduce the damage of a fall.

The first is fall detection, which detects a fall after or just before it occurs. It is classified into two types; the first one is fall detection, which refers to detection after a fall, and pre-impact fall detection, which refers to detection just before a fall [5]. There are several studies on fall and pre-impact fall detection, which focus on differences in sensors such as an accelerometer [18] (fall) [19] (pre-impact), a gyroscope [20] (fall), a video [21] (fall), and a depth sensor [22] (pre-impact).

The second one is detection of a temporary change in walking, which may cause falls. This approach helps to reduce the incidence of falls through detection and the provision of countermeasures to the temporary changes in walking. In this paper, we propose a detection method of a temporary change. Figure 1 presents the relationship between this study and the existing ones, as well as the flow from daily walking to fall. A temporary change is observed in daily walking if an incident occurs; some changes lead to falls. Existing studies on walking recognition target daily walking, and fall detection target falls or pre-impact falls. This study aims to detect the temporary change in walking. Therefore, existing studies and this present study do not exhibit a competitive relationship.

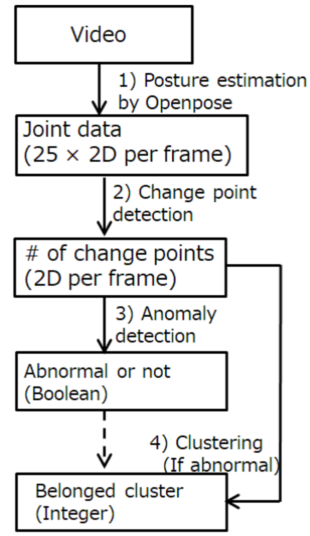

Figure 2. Overview of the proposed method using dataflow.

C. Image-Based Human Posture Estimation

In our proposed method, human joint coordinates are used as input for change point detection. These coordinates can be extracted using the existing methods. In this paper, OpenPose [23] is used to extract the coordinates. It outputs two-dimensional (2D) 25-joint data per image via deep learning-based posture estimation. Our proposed method is not constrained by OpenPose. If coordinates can be obtained, the output of other image-based posture estimation methods such as ArtTrack [24] and DeepCut [25] can be used. Our method can be applied in non image-based methods such as motion capture or depth sensor.

III. Recognition Method for a Temporary Walking Change

The input of the proposed method is the coordinate data of human joints during walking. This method comprises three steps: change point detection, anomaly detection, and clustering. It determines anomalous walking, which exhibits behavior that temporarily differs from daily walking. Anomalous walking detection can be employed to analyze the causes of falls. The input is obtained from videos using OpenPose. In this paper, we use a video ($1,920 \times 1,020$ resolution and 30-fps frame rate) of a person walking. The video of the person is captured from the front while the person is walking towards the camera.

Figure 2 presents the overview of the proposed method using the dataflow from the video data to determine anomalous walking. The preprocessing of the proposed method is the posture estimation performed by OpenPose. OpenPose has the ability to detect a human and estimate posture from the video.

Moreover, it outputs joint coordinates, which are 2D 25-point data obtained from one frame of the video.

The joint coordinate data are inputs of proposed method. The three steps of the method are presented below.

1) Change point detection determines whether each joint point or relationship between two joints is a change point. The output is the number of change points in each frame as detection is processed for each joint point and the relationship of each frame.
2) Anomaly detection detects anomalous walking using the number of change points. The result is output per overall walking data (data from one video).
3) Clustering classifies the anomalous walking detected by the second step. It is processed only if input walking data are detected as anomalies.

The processing of each step is performed via unsupervised machine learning. It means that manual data labeling is not required. However, the first and second steps need some preprocessing to determine the parameter of each machine learning algorithm. Preprocessing involves the preparation of the parameter determination standard. Thus, parameters are provided as a value relative to the standard. For example, when the parameter is three and if the result is greater than three times the standard, it is considered abnormal. About 1 or 2 min of walking data are required for each subject. In the evaluation, we use 20 videos of the daily walking data for each subject, with an average length of videos of approximately 3s. Thus, the total time of the walking data is approximately 1 min.

To distinguish daily walking, the terms "daily walking" and "normal walking" are utilized. "Daily walking" means input data given by a human as non-anomalous walking, and "normal walking" means output data detected by the proposed method as non-anomalous walking. In the next sections, the details of each step and each parameter are explained.

A. Change Point Detection for Human Joint Data

Change point detection is processed in each frame data using the target frame and previous frames consecutive to the target. The data format of the output data of OpenPose is 2D 25-point data per frame. Each data presents the 2D coordinate of the joint coordinate. Two methods can be employed to deal with the data; the data are treated as one 50-dimensional (50D) data or the data are treated as 2D 25-point data. The advantage of the method that uses it as 50D data, the relationship between each joint can be considered. As an example of the relationship, if the head position is lower than the shoulder position, the relationship is considered abnormal because the position of the head is higher than that of the shoulder in daily walking. However, when some joints significantly change, it affects the entire result. The effects may cause accuracy loss because the coordinates of a part of the joints are possibly changed significantly by the misestimation of OpenPose. Conversely, if the data are processed as 25-point data, the problem does not occur. Instead, the relationship cannot be considered. To solve this problem, we propose the use of difference data of all pairs of joints in addition to the 25-point data. This enables us to deal with the relationship using the sets of 2D data. In this method, the misestimation only affects a part of the difference and joint data, and not the entire result. Hereafter, the difference data of the pairs of joints are simply called "difference data."

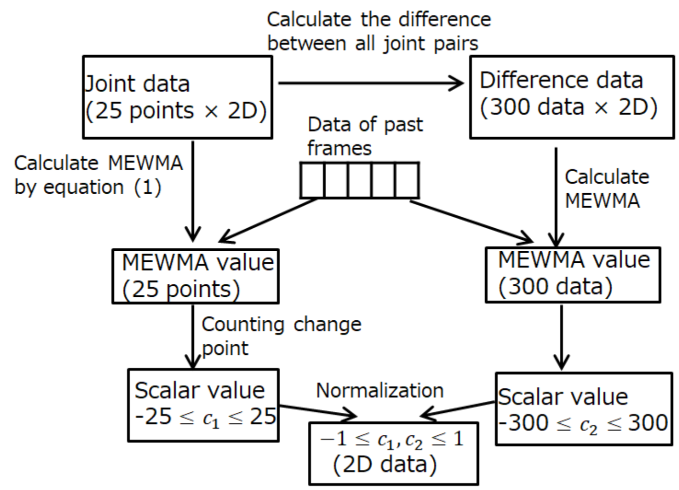

Figure 3. Dataflow of change point detection.

The total number of data is 325, which is obtained from difference data, which is 300 and joint data, which is 25. The result of change point detection from these data is output as the number of change points. In this method, we divide the result of the joint and difference data to distinguish a change in the movement of joints and the relationship between joints. Thus, the output is one 2D data per frame.

Figure 3 presents the change point detection flow as a dataflow. The input data are the joint data of 25 points, and the difference data consist of all pairs. We employ the multivariate exponentially weighted moving average (MEWMA) algorithm as the change point detection algorithm because it only uses target walking data and is not affected by individual differences [26]. The MEWMA algorithm uses data from the target frame and from previous frames consecutive to the target. If the number of frames is n (i.e., nth frame is the target frame), the MEWMA vector is defined as

$$Z_i = \lambda X_i + (1-\lambda)Z_{i-1} | i = 1, 2, 3, \dots n, Z_0 = 0 \quad (1)$$

X_i denotes the input vector, which is the coordinate data of the joint or the difference data of each frame. The change point can be detected by utilizing the MEWMA vector as

$$T^1 < h_1, T^2 > h_2 | T^2 = Z_n^T \Sigma_n^{-1} Z_n \quad (2)$$

Z_n denotes the MEWMA vector and Z_n^T its transpose; Σ_n^{-1} denotes the variance-covariance matrix of Z_n; and h_1 and h_2 denote the thresholds ($0 < h_1 < h_2$): h_1 is the case, in which a change in the movement during walking becomes small, and h_2 is the case when a change in the movement during walking becomes large. The counter of the change point is decreased when $T^2 < h_1$, and the counter is increased when $T^2 > h_2$. This helps distinguish the cases, in which the movement becomes small or large.

Preprocessing is required to determine the thresholds (h_1, h_2). In preprocessing, the average value of T^2 is calculated using Equation (2) utilizing the data of several minutes of daily walking. h_1 and h_2 are calculated by *the average value of* T^2 × *constant value*. Thus, when the value is T_d^2, h_1 and h_2 can be represented as $\frac{T_d^2}{g_1}$ and $g_2 T_d^2$, respectively. g_1 and

g_2 are constant parameters and the determination method of g_1 and g_2 is described in Section IV.

Using the MEWMA algorithm for all joints and differences, the range of the counter value is $-25 < counter < 25$ (joints) and $-300 < counter < 300$ (differences). Finally, the counting results are normalized by dividing by 25 or 300. The outputs of change point detection are the 2D data, and the form is suitable for the anomaly detection mentioned in the next section.

B. Anomaly Detection for the Number of Change Points of Walking

The input data are 2D data per frame obtained from change point detection. Anomaly is defined as a temporary change in the movement in daily walking. Thus, the data of daily walking are required for each person. The data are prepared as a set of the result of change point detection for daily walking for a few minute; this set is called "normal data."

Anomaly detection is performed in each frame by comparing the normal data and target frame. Thus, anomaly detection is repeated in each frame by adding target frame data and removing it after the detection. We use a local outlier factor (LOF) for anomaly detection as it can be calculated in each data. Moreover, its feature is suitable for repetition [27]. LOF is calculated by comparing local densities. The local density is calculated using reachability distance (RD) expressed as

$$RD_k(p,q) = max(k - distance(q), d(p,q)) \quad (3)$$

where p and q denote the points of 2D data, d(p,q) is the Euclidean distance between p and q, and k-distance(q) denotes the Euclidean distance between q and the k-nearest neighbor of q. The local density, which is termed local reachability density (LRD), is expressed as

$$LRD(p) = (\frac{\Sigma_{q\in kNN(p)} RD_k(p,q)}{k})^{-1} \quad (4)$$

where kNN(p) denotes the set of the k-nearest neighbor of p. Using the LRD, LOF is expressed as

$$LOF(p) = \frac{\Sigma_{q\in kNN(p)} \dfrac{LRD(q)}{LRD(p)}}{k}. \quad (5)$$

The value of LOF is large when the target is an outlier. LOF indicates whether the target frame is an anomaly; however, the result of the frame is not used to detect anomalous walking directly, because an anomaly frame may appear in the misestimation of OpenPose. Therefore, in this method, the condition of anomalous walking is the walk that includes two or more continuous anomalous frames. To distinguish anomalous walking, the walk characteristics are defined as the average number of change points of the continuous two or more anomaly frames.

Figure 4 presents an example of anomaly detection. There are 10-frame data, and the LOF is calculated for each frame. Figure 4 presents the case of frames 1 and 2. In the field of the LOF calculation, each frame data is deleted after calculation. The frames identified as outliers are collected if there are two or more continuous frames, and the walking including the frame considered as outlier is identified as anomalous walking. The characteristics of anomalous walking are the average values of the frames considered to be outlier, excluding the first frame of the continuous frame.

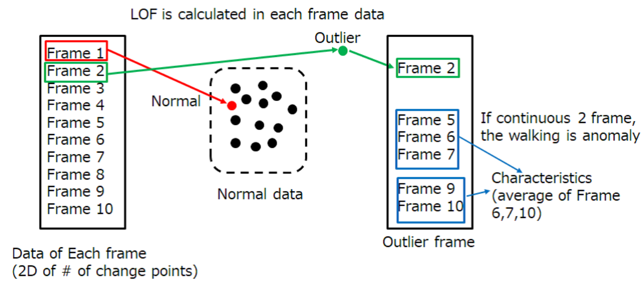

Figure 4. Example of the anomaly detection method.

C. Anomalous Walking Classification

The 2D characteristic data of anomalous walking are obtained from one video. When there are multiple anomalous walking videos, clustering algorithms can be used to identify the characteristics and walking can be classified. In this paper, we use K-means clustering, which is a typical clustering algorithm. In K-means clustering, the parameter given by a human is only the number of clusters k. In K-means clustering, each point, which means the characteristics of walking, is randomly classified into k clusters. Next, the following two steps are repeated until convergence.

1) The center of gravity of each cluster is calculated.
2) Each point is reclassified into the cluster, which has the nearest center of gravity from the point.

By clustering, the detection of anomalous walking and classification of the walks is completed from the walking videos. In this method, the longer the video, the higher is the probability of the video to include multiple instances of anomalous walking, because anomaly detection handles the video as one data unit. In classification, it is assumed that there is only one instance of anomalous walking per video. Thus, a long video should be divided per several seconds. However, videos that are too short are not suitable for the method. The minimum length of the video is two steps because walking has a periodicity of two steps.

IV. Parameter Setting Method in Various Cases

The accuracy of the proposed method largely depends on the parameter value. The optimal parameters depend on the individual and the type of temporary changes in walking. Therefore, parameters should not be set in advance, but instead be determined for the given data using an appropriate method. In this paper, we propose a method for the parameter setting for multiple cases, under the assumption that sufficient data are not available.

A. Common Parts of the Parameter Setting Method

In this method, parameters that need to be determined are as follows.

- n: The number of frames to calculate the MEWMA vector (Equation (1)).
- λ: The weight of the input vector in Equation (1) ($0 \leq \lambda < 1$).
- g_1, g_2: The parameters for determining the threshold value of change point detection. The parameters of

TABLE I. Assumed cases in the proposed method.

	Daily walking	Anomalous walking	Individual data
Case 1	○	○	○
Case 2	○	○	×
Case 3	○	△	×
Case 4	○	×	×

joint data are defined as gc_1 and gc_2, and the parameters of difference data are defined as gd_1 and gd_2.

- l: The threshold of anomaly detection of LOF. If the value of $LOF > l$, the frame is identified as outlier.

There are seven parameters, and it is impossible to find the best combination of these parameters because of the risk of combination explosion. Therefore, we use a greedy algorithm to determine the parameters. The greedy algorithm is used for repeating the two steps, which select a parameter and determine the best condition when only the selected parameter is changed. The repetition is performed until all parameters are determined. The order of the parameters to be changed is determined by the order of the calculations. The order is n, λ, gc_1, gc_2, gd_1, gd_2, and l.

The results vary depending on which indicator is targeted for optimization. In the next sections, the assumed cases and the indicators corresponding to the cases are explained.

B. Assumed Cases and Parameter Setting for the Cases

The available data for the parameter setting are different from the cases. The data required in this method are those of daily walking and anomalous (temporary change) walking for each individual. One of the requirements is the presence of sufficient data for each individual. Therefore, there are three requirements for the data. We assume five cases, depending on which requirements the data satisfy.

Table I represents the assumed cases. The requirement of anomalous walking is divided into three cases caused by the multiple types of anomalous walking. Anomalous walking is classified into two categories, in which the movement becomes small or large. The circle indicates that both data are available, whereas the triangle indicates that only one data point is available. The cross indicates that no data of anomalous walking is available. The requirements of daily walking and individual data are simply divided by whether the data are available. If the data are not available, the method is not applicable. Therefore, Case 4 has the smallest number of data.

Figure 5 presents the flowchart of the parameter setting. The indicator changes because of the requirement of anomalous walking. If data of anomalous walking are fully available, the F-measure is used as an indicator and calculated using precision and recall as expressed in Equations (6), (7), and (8):

$$precision = \frac{TP}{TP + FP} \quad (6)$$

$$recall = \frac{TP}{TP + FN} \quad (7)$$

$$F - measure = \frac{2 \times precision \times recall}{precision + recall} \quad (8)$$

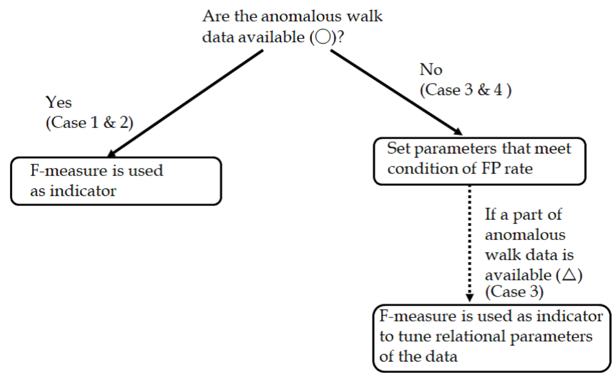

Figure 5. Flowchart of parameter setting.

where TP denotes true positive, FP denotes false positive, and FN denotes false negative. In other cases, the F-measure cannot be calculated because the calculation of TP requires data of anomalous walking. Therefore, in these cases, the FP rate is used. The FP rate is calculated using the ratio wherein daily walking is assessed as anomalous walking. The calculation of the FP rate is feasible because the data of daily walking are available in all cases. In general, the FP rate and TP rate are inversely correlated. A threshold is set for the FP rate, and parameters are selected such that the FP rate is below and closest to the threshold. Subsequently, if part of the data of anomalous walking are available, its relational parameters are (gc_1 and gd_1 or gc_2 and gd_2) changed so that the F-measure is maximized.

V. Evaluations

We evaluated the accuracy of the proposed method using four types of anomalous walking. Section V-A shows the detail of anomalous walking and subsequent sections show evaluation results.

A. Evaluation Method and Environment

In the proposed method, we evaluate the accuracy of the detection and classification of anomalous walking. Thus, it is important to prepare data of anomalous walking, for which the correct answer is known. We prepare the data of daily walking and change in walking from daily walking to anomalous walking. We included three adults as subjects. The detail of walking is presented in Figure 6. The walks start 6.6 m away from the camera and change to anomalous walking after reaching 2.4 m. The following are the four types of anomalous walking.

- Back: Go back one step and start walking again.
- Side: Walk 40 cm from side-to-side.
- Stop: Stop and start walking again.
- Wide: Take one large step (1 m).

The resolution of the videos is $1,920 \times 1,020$, and the frame rate is 30 fps. Each subject performs each type of walking (daily walking and four types of anomalous walking). Thus, the number of data of each type is 60. The average number of frames of each type of walk is presented in Table II.

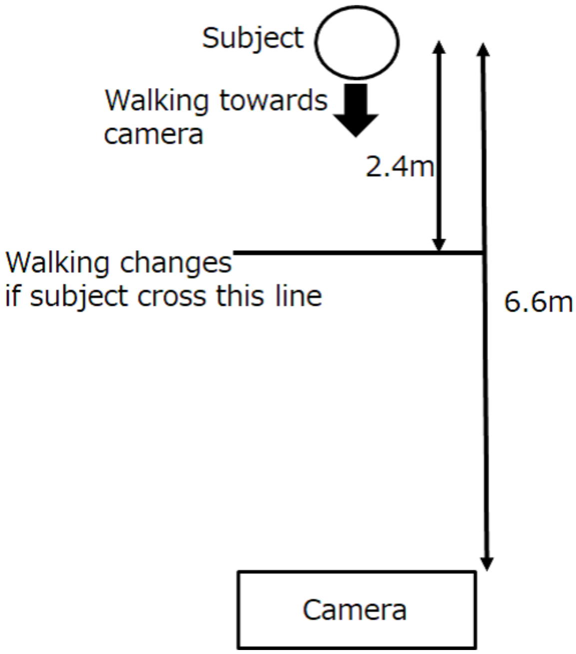

Figure 6. Walking during evaluation.

TABLE II. AVERAGE NUMBER OF FRAMES IN EACH WALKING TYPE.

Walking type	Daily walking	Anomalous walking
Daily	91	0
Back	49	83
Side	39	67
Stop	50	58
Wide	39	25

B. *Transition of the Number of Change Points in Change Point Detection*

In this section, the transition of the number of change points is presented. The transition of the number of change points was achieved using Case 2 to summarize the results of all subjects. It is an interim result of the proposed method; however, it presents an overall trend of each type of anomalous walking. The data of daily walking is used only when determining the parameters, and change point detection is performed for the four types of anomalous walking.

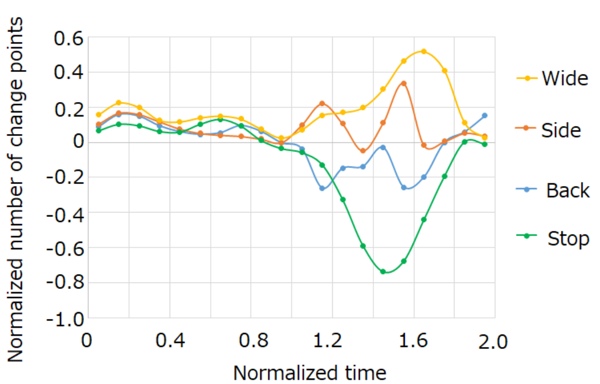

Figure 7. Transitions of the number of change points of joint data.

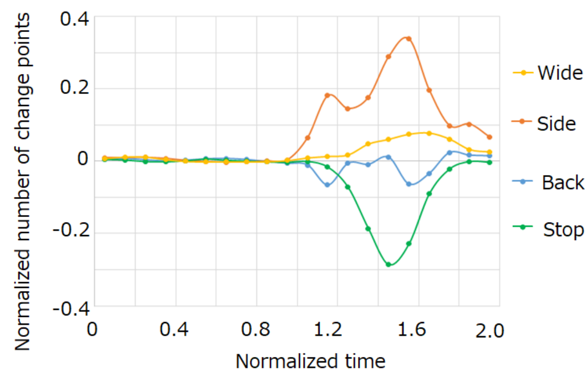

Figure 8. Transitions of the number of change points of difference data.

Transitions of the number of change points are presented in Figures 7 and 8. These figures show the average number of change points for 60 walks performed by three subjects. The x-axis indicates normalized time; 0-1 indicate daily walking, and 1-2 indicate anomalous walking. The boundary between daily walking and anomalous walking is determined by human confirmation in every frame. The y-axis shows the normalized number of change points. The data are plotted every 0.1 point on the x-axis as the average number of change points in the range. The positive values in the result indicate a change from walking movements to intense movements, whereas the negative values indicate a change in movements to small movements. Even for daily walking, the values of the joints are positive because of the periodic change in foot movement. However, the relationship between the joints does not change, and the values of difference are almost 0. Figures 7 and 8 demonstrates that the transition of the number of the change points changes between daily walking and anomalous walking; further, it is different in each type of anomalous walking. In Side and Wide, the values are both positive; however, a change in the difference in Wide is smaller than that in Side. The change in Wide is only a change in stride, and the change in the positional relationship between the joints of the body is smaller than that in Side. With regard to Stop and Back, the values of Stop are smaller than those of Back, and Stop is characterized by the temporal stopping of the movement of all joints. Thus, this method can detect the difference between each type of anomalous walking. Therefore, the proposed method can be used for analyzing the trend of each walking type. Moreover, the result of change point detection can be utilized for anomaly detection and classification. However, in the actual operation, the types are not provided. Thus, an analysis should be conducted after this classification if the method is used for the analysis.

C. *Accuracy Evaluation of Anomalous Walking Detection by Comparison with the Baseline Method*

We evaluate the accuracy of anomaly detection of the proposed method by performing a comparison between the proposed and existing methods. However, it is difficult to perform direct comparison as the existing methods for walking recognition do not target temporary changes in walking, as previously mentioned in Section II. Therefore, we define a statistics threshold-based method, which is one of the typical

TABLE III. RESULT OF ANOMALY DETECTION FOR EACH TYPE OF ANOMALOUS WALKING IN THE PROPOSED METHOD.

Walking type	Subject A		Subject B		Subject C		Total	
	TP	FP	TP	FP	TP	FP	TP	FP
Back	20	0	20	0	20	1	60	1
Side	14	1	16	1	19	1	49	3
Stop	20	0	20	1	20	2	60	3
Wide	16	2	20	1	16	2	52	5
Total	70	3	76	3	75	6	221	12

TABLE IV. RESULT OF ANOMALY DETECTION FOR EACH TYPE OF ANOMALOUS WALKING IN THE BASELINE METHOD.

Walking type	Subject A		Subject B		Subject C		Total	
	TP	FP	TP	FP	TP	FP	TP	FP
Back	19	11	20	9	19	5	58	25
Side	17	4	20	16	20	2	57	22
Stop	13	5	18	9	14	4	45	18
Wide	13	6	13	5	15	7	41	18
Total	62	26	71	39	68	18	201	83

techniques in human activity recognition, including walking recognition [17] [28], as a baseline method and compare its accuracy with that of the proposed method.

1) Baseline method: In walking recognition, the data of waist movement are often utilized because waists are close to the center of gravity of humans. Moreover, the movements of the center of gravity are related to anomalous walking targeted in this study [28] [29]. Therefore, the baseline method uses the coordinate data of the waist for anomaly detection. The absolute coordinate data of the waist cannot be utilized as they are retrieved from the video. Therefore, the relative coordinate data from the neck are used because the coordinate data of the neck are on the central line of the body, and the change in the relative position between the neck and the waist is small in daily walking. It is divided by the ratio of the distance of each frame between the neck and the waist and the distance at the start of walking, because the size of the body is changed based on the distance from the camera. If the x-coordinate after the correction is significantly changed, walking is judged as anomalous walking. The average (m) and standard deviation (σ) of the x-coordinate are calculated, and if the x-coordinate is beyond the range of $m \pm 2.2\sigma$, the walking is judged as anomalous walking. The constant value "2.2", which is the parameter of the baseline method, is determined so that the F-measure is maximized.

2) Comparison result: Tables III and IV present the result of the anomaly detection for each type of anomalous walking. In the proposed method, Case 1 is assumed, and the parameters are detected by the greedy algorithm described in Section IV. To avoid overfitting, cross-validation is performed by dividing the number of each type of data by 15 and 5, which are indicated as training and test data. Therefore, four sets of parameter exist. Table V presents all parameter sets; the parameters are of different combinations, even in the same subject. Therefore, multiple local solutions in the parameter setting algorithm exist.

In Tables III and IV, TP and FP denotes true positive and false positive respectively. The number of data of each walking type and each subject is 20. Thus, if TP is 20, the TP rate is 100%. FP indicates that daily walking is misjudged as anomalous walking. Each video includes daily walking because the walking is changed from daily walking to anomalous walking. Therefore, the number of data of daily walking is 20 in each walking type and each subject. Comparing each method, the precision is 94.8%, recall is 92.0%, and accuracy is 93.5% in the proposed method; the precision is 83.6%, recall is 70.8%, and accuracy is 74.6% in the baseline method. The accuracy is calculated using Equation (9)

$$accuracy = \frac{TP + TN}{TP + FP + TN + FN} \tag{9}$$

where TN is the true negative. TN and FN are not shown in the table since they can be calculated by (240 (the total number of data) $-TP or FP$). All indicators show the performance of proposed method is above the baseline method. Moreover, the accuracy of the proposed method is high ($> 90\%$) according to the standards in [4].

The difference of FP between the proposed and baseline methods is larger than that of TP. As shown in Section V-B, there are periodical foot movement even in daily walking. The baseline method may misjudge such movements as anomaly. In contrast, the proposed method can avoid the misjudgement using both joint and difference data.

D. Accuracy Evaluation of Anomalous Walking Detection by Comparison between Each Case

Table VI lists the result of the anomaly detection of each case of the proposed method. In Case 4, the condition of the FP rate is $\leq 10\%$. Please note that the FP rate can be away from 10% because the used data of parameter setting and accuracy evaluation is different. In this evaluation, the initial value of parameter setting is randomly detected. In actual cases, the parameter of Case 2 is useful for the initial value. Therefore, the parameter sets are summarized in Table VII for reference. Please note that there are four sets because the evaluation is performed in cross validation.

The performance indicators are summarized in Table VIII. In comparison, accuracy decreases as the amount of available data type decreases. However, even in Case 4, the accuracy is higher than that of the baseline method. In Case 4, the TP rate is lower than that of the baseline method. The condition of FP rate should be higher than 10% to avoid it because the TP rate is inversely proportional to the FP rate.

The cases of the proposed method can be switched as data are collected. Therefore, in actual operation, the parameter setting method should be selected depending on the data available at the start, and it should be switched as data are collected.

Based on the comparison between Cases 1 and 2, the difference in accuracy is small. However, the difference is caused because a part of the accuracy of Case 2 is significantly low. Table IX shows the details of the results of Case 2. The TP of Wide of Subject C is 9, and the TP rate is 45%. The reason for the low TP is the unsuitability of the parameters for the subject because Case 2 cannot consider individual differences. To avoid this problem, the proposed method should be performed as Case 1, thereby collecting as much data as possible.

By comparing Cases 3 and 4, it can be inferred that the accuracy is improved not only by increasing the TP of Side and Wide but also by decreasing the FP of Stop as FP is

TABLE V. PARAMETER SETS OF CASE 1 IN THE PROPOSED METHOD

Parameters	Subject A				Subject B				Subject C			
n	31	36	32	34	38	32	31	38	31	35	36	31
λ	0.6	0.8	0.58	0.5	0.51	0.62	0.34	0.51	0.05	0.43	0.8	0.51
gc_1	1000	1000	100	1200	1200	100	1000	1200	80	1560	1000	100
gc_2	3.4	3	4.2	4.6	3	4.2	3.6	3	4.2	1.6	3	5
gd_1	820	900	300	1580	1160	1120	1260	1240	700	1260	680	1200
gd_2	5.4	8	4.4	4	8	4.4	4	8	4.4	5.2	7.2	4.2
l	2.3	4.2	2.2	3.1	3.8	2.2	3.2	3.5	2.8	3.1	4.2	2.2

TABLE VI. RESULT OF ANOMALY DETECTION IN THE PROPOSED METHOD FOR EACH CASE.

	Back		Side		Stop		Wide		Total	
	TP	FP	TP	FP	TP	FP	TP	FP	TP	FP
Case 1	60	1	49	3	60	3	52	5	221	12
Case 2	59	6	52	0	60	3	48	8	219	17
Case 3	60	8	50	4	60	4	32	1	202	17
Case 4	60	7	30	4	60	8	31	1	181	20

TABLE VII. PARAMETER SETS OF CASE 2

Parameters	Set 1	Set 2	Set 3	Set 4
n	15	31	34	35
λ	0.5	0.56	0.44	0.60
gc_1	800	1100	1400	1400
gc_2	2	4	4.2	4.2
gd_1	800	1260	1240	1120
gd_2	2	3.6	3.6	3.6
l	4.5	2	2.3	2.3

TABLE VIII. SUMMARY OF PERFORMANCE INDICATORS OF TABLE VI (%).

	TP rate	FP rate	Precision	Recall	Accuracy
Case 1	92.1	5.0	94.8	92.1	93.5
Case 2	91.2	7.1	92.8	91.3	92.0
Case 3	84.2	7.1	92.2	84.2	88.5
Case 4	75.4	8.3	90.0	75.4	83.5

TABLE IX. RESULT OF ANOMALY DETECTION IN CASE 2.

Walking type	Subject A		Subject B		Subject C		Total	
	TP	FP	TP	FP	TP	FP	TP	FP
Back	20	4	20	1	19	1	59	6
Side	16	0	18	0	18	0	52	0
Stop	20	1	20	0	20	2	60	3
Wide	19	3	20	1	9	4	48	8
Total	75	8	78	2	66	7	219	17

caused by the daily walking being misjudged as a temporary change. Therefore, a part of the data of anomalous walking can improve the accuracy of anomaly detection.

Comparing the results of each walking type, the TP of Back and Stop is 100% except for Case 2. This indicates that changes in movement that become small are easy to detect using the proposed method. This is because daily walking includes periodic foot movement and the feature prevents the detection of Side and Wide. Therefore, if you attach importance to the TP of Side and Wide, the indicator using parameter setting should be included in the conditions of the TP of Side and Wide. For example, the condition of the maximization of the F-measure while satisfying the TP rate of each type of anomalous walking is more than 90%.

E. Anomalous Walking Classification

Clustering is performed in the TP of Case 2 in anomaly detection. For accuracy evaluation, Case 2 is evaluated via cross-validation. However, the TP cases detected via cross validation are not suitable for clustering evaluation as the features of anomalous walking are calculated based on different parameter sets. Therefore, Set 1 of Table VII is used for all data to detect anomalous walking. Case 2 is used so that the same parameters can be used for all data of subjects.

Table X presents the result of clustering into four clusters. The number of clusters is the same as that of walking types. Each cluster is indicated by a number because of unsupervised clustering. In this result, clustering is performed separately for each subject, and we group each cluster of each subject with the highest match rate. Clustering does not classify four types of walks into four clusters. Back and Stop are grouped, and the clusters appear divided, such as Back and Stop, Side, Wide, and others. To explain this result, the characteristics of each walking type are plotted in Figure 9. Back and Stop overlap and create the same cluster, indicating that the movement tendencies of Back and Stop are the same, and that the difference is only the magnitude of the value. The trend is probably caused by the stopping motion because Back includes the motion of Stop. This is because stopping is required to switch the front step to the back step. The differences indicate the stopping time length.

We perform clustering into three clusters based on the grouping, and the result is presented in Table XI. In this result, the anomalous walking is classified into three clusters (Back and Stop, Side, and Wide), and the accuracy rate is 89.1%. The rate is medium as per the standard of [4], and it classified walks better than the existing method of walking recognition.

In terms of anomaly detection, clustering may exhibit

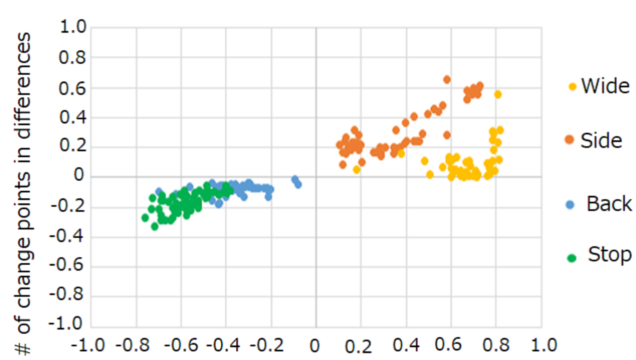

Figure 9. Characteristics of anomalous walks of each type of walking.

TABLE X. RESULT OF THE CLASSIFICATION INTO FOUR CLUSTERS FOR EACH TYPE OF ANOMALOUS WALKING.

Walking type	Cluster 1	2	3	4
Back	46	0	7	1
Side	0	52	4	2
Stop	50	0	10	0
Wide	0	2	13	33

TABLE XI. RESULT OF THE CLASSIFICATION INTO THREE CLUSTERS FOR EACH TYPE OF ANOMALOUS WALKING.

Walking type	Cluster 1	2	3
Back	46	0	8
Side	0	54	4
Stop	58	0	2
Wide	0	10	38

individual differences of walking. Figure 10 presents the plots of the same data in Figure 9, which are indicated by colors according to each subject. For Side and Wide, the figure indicates that the subjects have different tendencies of point distribution.

VI. Discussion

According to the evaluation results, in the proposed method, the accuracy of detection and classification of anomalous walking is sufficient compared to other human activity recognition methods [4]. However, the proposed method requires the data of subjects to set parameters. Thus, it can be used to detect abnormal walking in a particular person. Therefore, the main application could be the reduction of incidents in nursing homes and companies that are repeatedly used by specific people. In this paper, we did not evaluate the accuracy in the elderly, and for practical use, future research will need to conduct experiments in the elderly.

VII. Conclusions

Detecting the temporary change in walking that causes falls can help alleviate problems such as expensive hospitalization and injury. However, existing methods only recognize the walking speed or whether a person is walking. In this paper, we proposed an anomalous walking detection and classification method that employs three processes: change point detection, anomaly detection, and clustering. Thus, instances of anomalous walking were detected in 92.1% of cases using 240 videos that included the change from daily walking to anomalous walking. Furthermore, in 89.1% of cases, the detected instances of anomalous walking can be classified into three clusters. The average length of the video is 87 frames (30 fps) for the longest motion. The result indicates that the proposed method can detect and classify a temporary change in walking. Moreover, this method can be used to the analyze the action that causes falling. We evaluated the method using video data, whereas the required input of the method is the coordinate data of the joints. Thus, the method has a wide range of application. For example, the method can be applied to wearable technology such as motion sensors if it can obtain the coordinates of a sufficient number of joints. In practical use, the application of the method will be expected for older people because they are vulnerable to falls. Thus, in future work, we will additionally perform evaluations for the elderly to verify the effectiveness of the method for elderly.

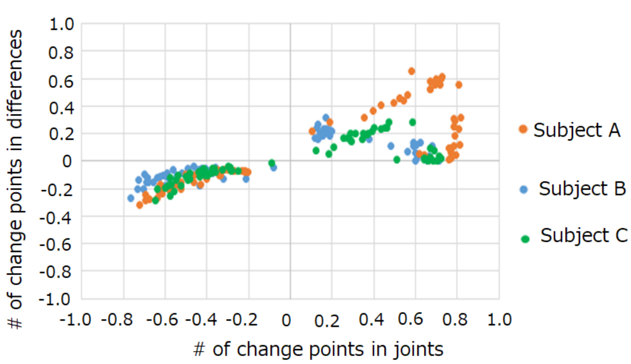

Figure 10. Characteristics of anomalous walks for each subject.

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Spring Assist Unit for Individuals with Walking Disabilities

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***Abstract*-Latter-stage elderly people, as well as people with diseases such as hemiplegia, often have a walking disability, which increases their risk of falling and suffering injuries. The magnitude of the angular velocity during both the heel rise phase of walking (kicking the floor) and swing phase (swinging the toe forward) is lower for disabled people compared to healthy individuals, owing to their lower muscle power. We have developed a spring assist unit that fits in the heel of a shoe and helps disabled people raise their heel when beginning to walk. Experimental results demonstrate that it substantially assists in walking and normalizing gait. We also report a correlation between body weight and optimal spring stiffness, and that the spring assist unit does not affect the individual's walking posture.**

Keywords-walking disability; walking assist unit; spring; walking posture; muscle power.

I. INTRODUCTION

This paper is an extension of the paper initially presented at the Twelfth International Conference on eHealth, Telemedicine, and Social Medicine [1]. In this paper, we discuss additional experiments that we conducted with elderly people to show the effectiveness of our proposed system.

As the percentage of elderly people worldwide increases [2], so too will the number of functionally impaired people, such as those with hemiplegia. People with such diseases, as well as latter-stage elderly people often have walking disabilities that increase their risk of falling and consequently suffering injuries [3]. Tao *et al.* reviewed gait analysis using various wearable sensors [4]. They indicated that gait analysis using wearable sensors is useful for estimating fall risk, although they did not describe the gait of people with walking disabilities.

Our study compared the walking gaits of hemiplegia patients and healthy students. We showed that the magnitude of the angular velocity during the phase in which the subject kicks the floor (heel rise phase) and swings the toe forward (swing phase) is lower for disabled people than for healthy counterparts. This is likely due to the lower muscle power of hemiplegia patients [5]. Thus, assisting the raising of the heel and swinging the toe forward while walking could help disabled people walk with a gait closer to that of younger and healthier individuals.

The Solid-Ankle Cushion Heel (SACH) foot (1D10, Ottobock, Germany) [6]) and the Energy Storage And Return (ESAR) foot (Vari-Flex, Össur, Iceland)[7]) are provided for foot amputees to improve their gait. These prosthetics help the wearer raise their heel and lift their toes. Unfortunately, such devices cannot assist individuals with only walking disabilities.

Mooney *et al.* reported result showing that the ankle exoskeletons does not exclusively reduce positive mechanical power at the ankle joint, but also mitigates positive power at the knee and hip as show in experiments with six participants without walking disabilities [8]. Leclair *et al.* developed an unpowered ankle exoskeleton using flexible air spring [9], although they did not conduct demonstration experiments for the people with disabilities. We also previously developed a prototype shoe in which a coil spring was built into the heel and a leaf spring was built into the back half of the sole. Experimental results demonstrated that our device reduced the magnitude of muscle power needed to raise the heel and swing the toes forward. We also demonstrated that there may be a correlation between body weight and optimal spring stiffness and that a spring assist unit would affect walking posture.

We have thus developed a new shoe incorporating a spring assist unit built into the heel. Using springs with 3 kg to 11 kg of stiffness, our results demonstrate that there is surely a correlation between body weight and optimal spring stiffness and that the spring unit did not actually affect walking posture, unlike the previous prototype shoe. The main scientific contribution of this paper is that our newly developed device reduced the magnitude of muscle power without negative effects. This contribution was shown through an experiment targeting elderly people.

After introducing two kinds of foot prostheses, the SACH and ESAR feet in Section II, we describe in Section III the differences in gait between a hemiplegia patient and a healthy person in order to clarify the necessary characteristics to be addressed. A prototype shoe that incorporates a coil spring and a leaf spring is then described and evaluated as a walking assistance device in Section IV. The structure of the spring assist unit and the preliminary experimental results gathered from healthy young students are described in Section V. We then validate the effectiveness of our system using an experiment with elderly people in Section VI. Section VII concludes with a summary of the key points.

II. WALKING ASSISTANCE MECHANISM WITH PASSIVE FOOT PROSTHESES

Since there are no walking assistance devices for individuals with walking disabilities, such as latter-stage elderly people and hemiplegia patients, we instead cover walking assistance devices for foot prostheses in this section. There are two types of walking assistance mechanisms employed for passive foot prosthesis devices.

The SACH foot [10], shown in Figure 1, was designed to provide shock absorption and ankle action characteristics close to those of a normal ankle without the use of an articulated ankle joint. The action of the SACH foot is achieved by the use of two functional elements: a properly shaped wedge of cushioning material built into the heel and an internal keel-shaped structural core at the ball of the foot to provide a rocker action. Its primitive form was developed toward the end of the 1800s.

The ESAR foot, shown in Figure 2, has weak push-off power and an adequate rollover shape for the foot, which increases the energy dissipated during the step-to-step transition in gait. Wezenberg *et al*. reported that the ESAR foot was more effective than the SACH foot in reducing metabolic energy while walking [11], and Houdijk *et al*. reported that it improved step length symmetry [12].

Figure 1. Examples of the SACH Foot (1D10, Ottobock, Germany).

(a) WD: SmartWatch 3, Sony (b) WD mounted on foot

Figure 3. Measuring device and WD mounting method.

Figure 2. Examples of the ESAR Foot (Vari-Flex, Össur, Iceland).

III. DIFFERENCES IN GAIT BETWEEN HEMIPLEGIA PATIENTS AND HEALTHY PEOPLE

We analyzed the walking gait cycles of healthy individuals and those with walking disabilities using a wearable device (WD) [3]. The individuals with walking disabilities had one-side paralysis and periodically received treatment at a rehabilitation facility. We measured the output data from an acceleration sensor and a gyroscope sensor in a WD mounted on the front of a shoe to estimate the kicking power and change of angle between the foot and the floor, as shown in Figure 3. For this measurement, we used a Sony SmartWatch 3 as a WD.

We measured the angular velocity around the X-axis and the acceleration of Y-axis as shown in the Figure 3(b). The measured data were stored every 40 ms as JSON format in the memory of a smartphone. Figures 4 and 5 show examples of changes in acceleration, angular velocity, and angle for a healthy participant and one with a walking disability, respectively, over the course of two steps. Each flat period (roughly the center period) in these figures represents when the entire sole of the shoe touched the floor. Moving average lines of 120 ms are plotted in Figures 4 and 5. The maximum angular velocity at point A indicates the kicking power when

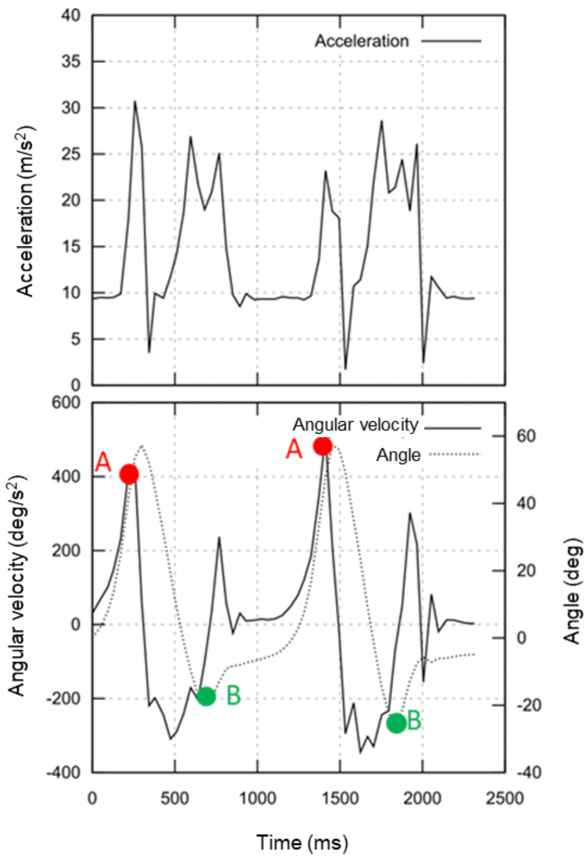


Figure 4. Angular velocity, angle, and acceleration for the unimpaired participant.

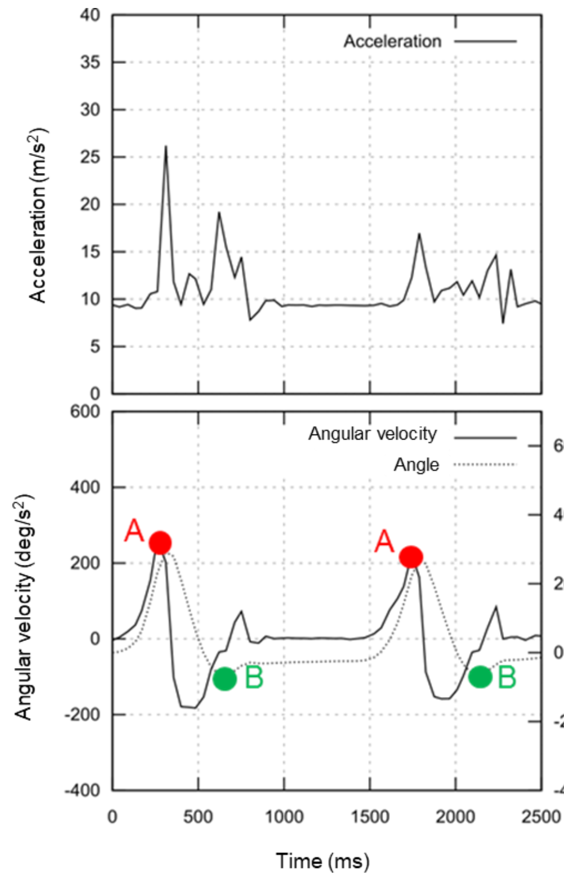


Figure 5. Angular velocity, angle, and acceleration for the participant with a walking disability.

raising the heel, and the minimum angle at point B indicates the angle to the floor at terminal swing.

The lowest angular velocity at point A of the unimpaired participant in Figure 4 was approximately 420° s^{-1}, whereas the highest angular velocity at point A of the participant with a walking disability was only 250° s^{-1}. Thus, the participant with a walking disability clearly had a weaker kicking power when raising their heel compared with that of the healthy individual, indicating a clear difference in gait.

The highest angle at point B of the unimpaired person in Figure 4 was approximately −18°, whereas the lowest angle at point B of the participant with a walking disability in Figure 5 was approximately −8°. Thus, the swinging speed of the individual with a walking disability was also slower than that of the healthy participant. Similarly, the participant with a walking disability had difficulty raising their toe during the terminal swing phase.

Tables I and II list the averages and standard deviations (SD) of the measured data for angular velocity at point A and angle at point B. The angular velocity at A is clearly different for unimpaired participants and those with walking disabilities. There is also a measurable difference between them in the angle at point B. However, the ranges of these values will sometimes overlap.

IV. PROTOTYPE SHOE TO ASSIST PEOPLE WITH WALKING DISABILITIES

As described in Section III, individuals with a walking disability, such as those who suffer from hemiplegia, clearly have a weaker kicking power when raising their heel and swing power when swinging their toe forward. We first developed a shoe, shown in Figure 6, that assists individuals with walking disabilities. This shoe has a coil spring and a leaf spring that enables the wearer to raise their heel more easily. The spring force of the coil spring is 15 kg and the shoe has a roller to avoid the toe accidentally tripping.

We compared the kicking powers (angular velocity) when the heel is raised between a normal shoe and our proposed assist shoe when worn by a stroke patient. The data are shown in Figure 7, wherein the vertical and horizontal axes show the kicking power and the number of steps taken by the individual, respectively. The kicking power with the assist shoe was lower and more stable than that with the normal shoe.

For a test trial, we then conducted an experiment with a group of eight students who were asked to walk as if they had a disability while wearing a normal shoe and the assist shoe. The measured data are shown in Figure 8 with the kicking power measured by the sensor for each of the participants (*i.e.*, eight healthy students and a disabled person). The blue and orange bars in Figure 8 show the average kicking power of participants wearing the normal and assist shoes, respectively. The highest point of the error bars represents the maximum kicking power for each individual. For every participant except one, the kicking power with the assist shoe was lower and more stable than that with the normal shoe. We also examined and observed that the shoe helped them to raise the foot slower using less power than the normal shoe and that this compensation power was stable. Measured data in Figures 7 and 8 confirm these observations.

We also took integrated electromyogram (iEMG) measurements for two individuals with walking disabilities to confirm the effect of the assist shoe. We used the wireless EMG logger from the Logical Product Corporation [13]. The wireless EMG sensors were attached along the gastrocnemius muscle at the back of the calf and thigh of the right leg, as shown in Figure 9. Measured data, taken with a sampling rate of 500 Hz, is shown in Figure 10 wherein the vertical and horizontal axes denote the peak of the EMG signal measured by the iEMG sensor for each step and the number of steps, respectively. The iEMG readings for the assist shoe were lower than those for the normal shoe for both individuals. Thus, the compensation effect of the proposed assist shoe was also confirmed using iEMG.

TABLE I. ANGULAR VELOCITY AT THE TERMINAL STANCE.

Participant	Average (deg./s)	SD (deg./s)
Unimpaired participant	509.36	18.91
Participant with walking disability	342.06	86.52

TABLE II. ANGLE AT THE TERMINAL SWING.

Participant	Average (deg.)	SD (deg.)
Unimpaired Participant	−17.76	8.02
Participant with disability	−7.45	8.02

Figure 6. Assist shoe prototype.

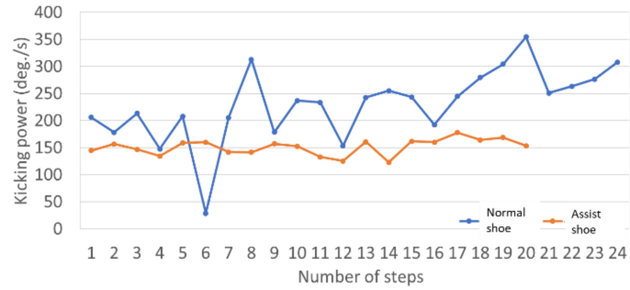


Figure 7. Kicking power when heel is raised with normal shoe (blue) and proposed assist shoes (orange) from a stroke patient.

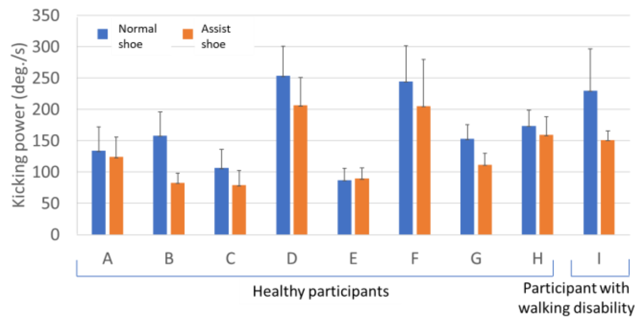
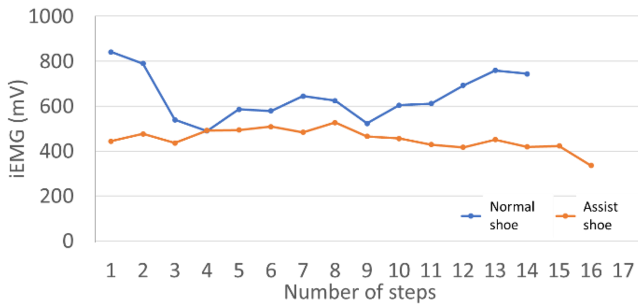


Figure 8. Kicking power when heel is raised with normal (blue) and proposed assist shoes (orange).

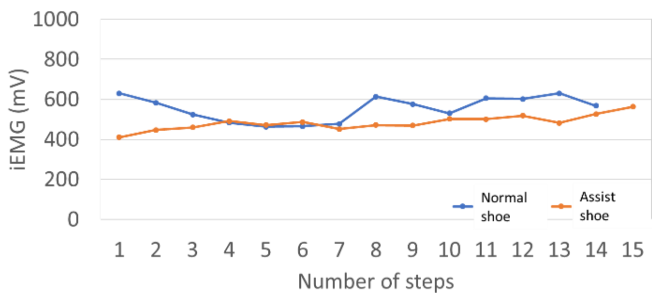
It is clear that the proposed shoe compensates for muscle weakness. However, most evaluators, including the authors, felt that the timing to generate a spring reaction force was too early for them to walk smoothly; the timing at which the knee comes out in front of the ankle is best, and participants had to change their gait motion to effectively use the spring power. In addition, we noticed that there would be a correlation between body weight and the most effective spring power, which would affect the walking posture.

The prototype shoe also features a toe roller. However, it is difficult to have individuals with walking disabilities intentionally trip over an obstacle, so we could not quantitatively evaluate this feature.

Figure 9. Placement of EMG sensors.



(1) Person with walking disability #1



(2) Person with walking disability #2

Figure 10. iEMG data when heel is raised from participants with walking disabilities.

V. Spring Assist Unit to Help Disabled People Walk

As described in Section IV, many participants felt that the timing for generating the spring reaction force was too early for them to walk smoothly. Thus, to address this, we proposed new shoes.

A. *Structure*

We focused on clarifying the correlation between body weight and optimal spring stiffness, the effect on walking posture, and developing the spring assist unit shown in Figure 11. The mechanism for this unit is very simple as it comprises only a conical coil spring and a V-shaped attachment cover made of thin stainless steel. We adopt the conical spring from the power of 3, 5, 9, or 11 Kg. The spring is selected so that it is buried in the sole of the shoe when they step.

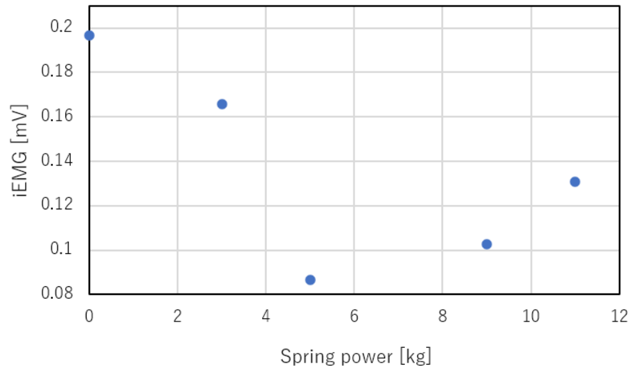
B. *Preliminary evaluation of assistance effects*

The prototype assist shoe shown in Figure 6 has a coil spring and a leaf spring and was made for the right foot. In contrast, the spring assist unit shown in Figure 11 was built into the heel part of the left and right shoes, as shown in Figure 12. To measure the degree of assistance given by these mechanisms and to evaluate the safety of these mechanisms, we ten students without walking disabilities to wear shoes with different spring stiffnesses and walk straight for 6 m while we measured the iEMG as a preliminary experiment before using participants with walking disabilities. For safety, we used people without walking disabilities as participants first. We also measured the motions of the head and mid-hip to analyze the effects on walking posture. Wireless EMG sensors were attached to the gastrocnemius of the right leg, as shown in Figure 9, to gather iEMG data. The participant's posture was measured using an MS-Kinect [14].

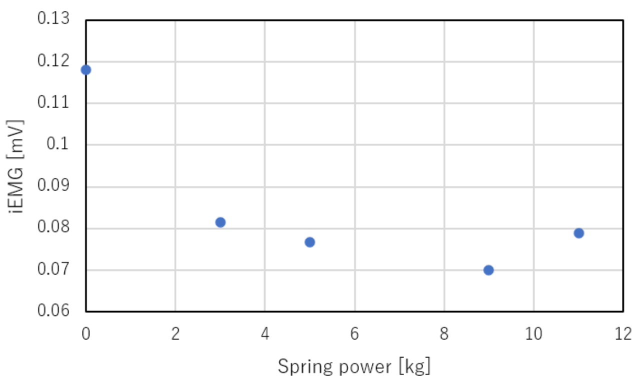
Figure 11. Two views of the spring assist unit (heel-up spring).

Figure 12. Pair of shoes with built-in spring assist units.

Examples of the measured iEMG vs. spring stiffness for two participants (A and B weighing 57 and 70 kg, respectively) are shown in Figure 13. The iEMG values were lower for each spring stiffness compared to the case without the spring assist unit. The value for Participant A was lowest at 5 kg and that for B was lowest at 9 kg. The spring stiffness resulting in the lowest iEMG signal was used to determine a relationship with the participant's body weight. The spring stiffness at the lowest iEMG vs. participant body weight is shown in Figure 14. For example, the lowest iEMG of participant A was at 3 kg of spring power; this is represented as a point at 57 kg of body weight and 3kg of spring power in Figure 14. Visualizing this data allowed us to reveal a linier correlation between participant body weight and the magnitude of spring stiffness at the lowest iEMG reading.



(a) Participant A (weight 57 kg).



(b) Participant B (weight 70 kg).
Figure 13. Examples of measured iEMG vs. spring stiffness.

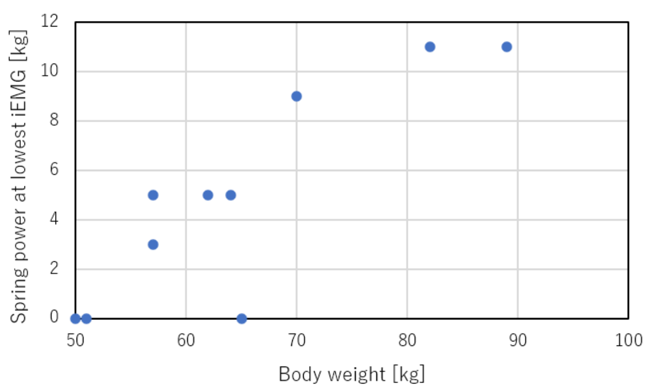
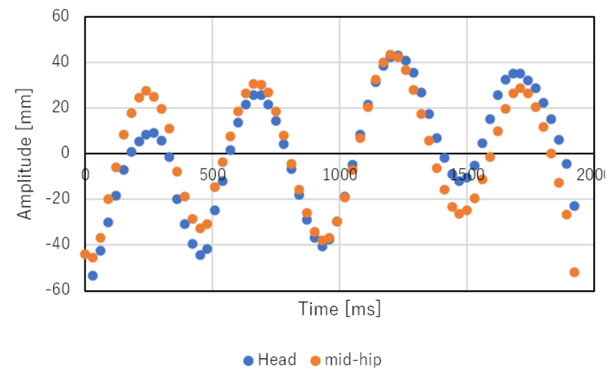
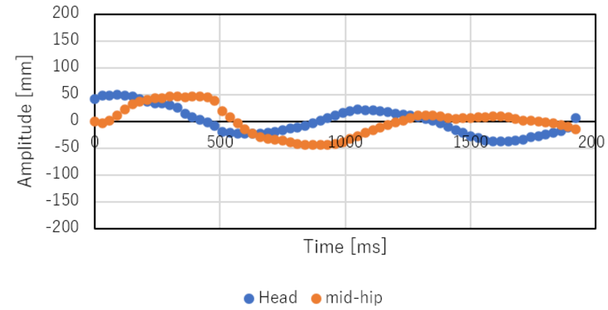


Figure 14. Spring power at lowest iEMG vs. participant body weight.

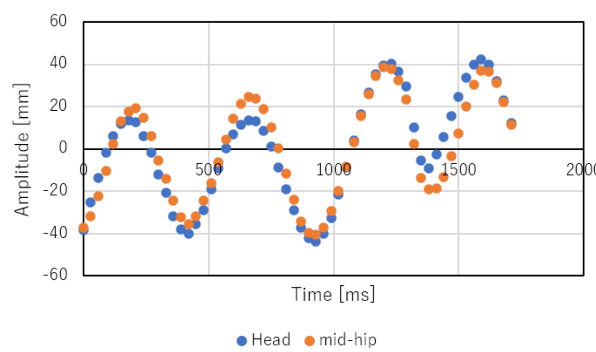
The measured positions of the head and mid-hip for Participant C are shown in Figure 15 for walking without a spring assist unit and in Figure 16 for walking with the most effective spring assist unit. For both Figures 15 and 16, the vertical and horizontal axes denote displacement and elapsed time, respectively. We expressed "amplitude" as the position



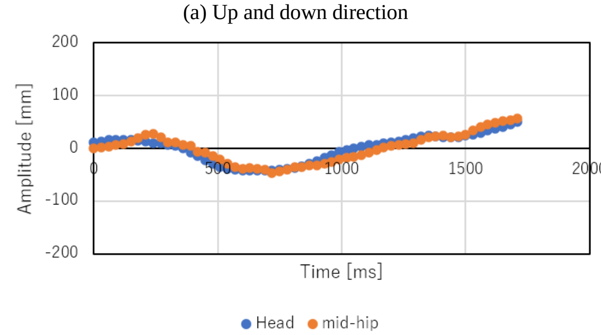
(a) Up and down direction



(b) Left and right direction
Figure 15. Motion of Participant C without spring assist unit.



(a) Up and down direction



(b) Left and right direction
Figure 16. Motion of Participant C with spring assist unit.

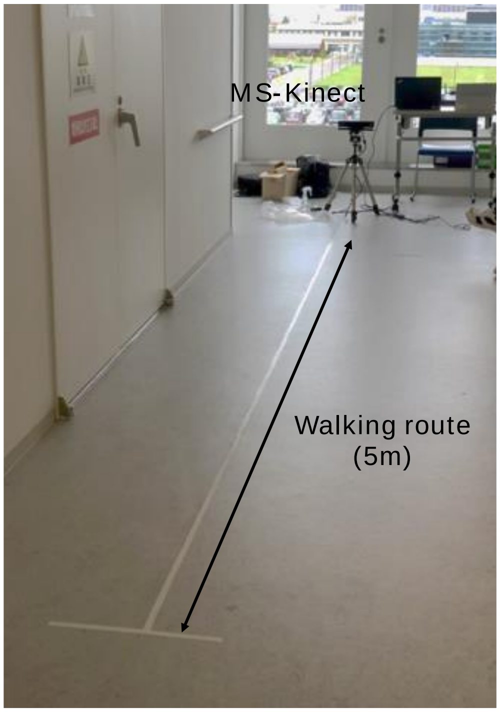


Figure 17. Experimental setting.

Figure 18. An elderly participant walking.

measured by the Kinect in these figures because the data were measured as swinging by the steps. Blue and orange points denote the amplitude of the head and mid-hip, respectively. Changes in the up and down motion (UD) are shown in Figures 15(a) and 16(a) whereas changes in the left and right (LR) motion are shown in Figures 15(b) and 16(b). Without a spring assist unit, the UD motion of the head and mid-hip clearly mimics a sine wave, as shown in Figure 15(a). The LR motion of the head and mid-hip also changes, but apparently not like a wave as in Figure 15(b); and the period for this cycle does not differ from that of the UD motion. Thus, there are no significant differences between participants walking with or without a spring assist unit.

TABLE III. AVERAGE PEAK-TO-PEAK RANGE FOR LR AND UD MOVEMENTS MEASURED OVER TWO STEPS FOR HEALTHY STUDENTS PARTICIPANTS [MM].

Spring power [kg]			0	3	5	9	11
Participant A	Head	LR	47.28	34.10	28.54	21.49	30.29
		UD	36.04	33.48	41.07	44.84	42.06
	Mid-hip	LR	32.20	17.11	22.65	17.94	17.44
		UD	29.66	25.80	28.71	22.32	33.61
Participant B	Head	LR	47.51	72.87	76.96	71.06	81.35
		UD	13.46	14.68	16.01	18.51	19.18
	Mid-hip	LR	18.83	24.34	22.50	26.19	29.52
		UD	25.87	26.81	28.95	22.72	25.00
Participant C	Head	LR	65.83	57.55	56.28	69.76	69.74
		UD	67.89	58.62	62.61	66.90	66.97
	Mid-hip	LR	33.35	33.74	29.23	35.00	32.37
		UD	60.87	67.42	68.07	65.31	54.42
Participant D	Head	LR	38.53	41.79	48.00	30.45	51.25
		UD	34.61	37.23	34.01	27.94	30.43
	Mid-hip	LR	31.46	35.64	44.38	23.28	40.88
		UD	38.68	48.60	45.03	45.38	26.01
Participant E	Head	LR	34.44	53.31	77.44	63.40	67.88
		UD	30.45	23.43	36.62	21.16	34.64
	Mid-hip	LR	39.86	68.98	71.58	79.92	83.73
		UD	38.71	38.20	34.67	32.90	37.70

From these figures, we also confirmed the safety of the mechanism in people without walking disabilities.

The average range of each step's peak during both LR and UD motions for participants A through E, who tried springs of 0 kg to 11 kg, is shown in Table III. Although there are differences between participants and spring stiffnesses, they seem to be random with no obvious patterns.

A participant who tested the assist shoe shown in Figure 6 and the pair of assist shoes shown in Figure 12 commented that "I had to step on the shoe to walk smoothly in the shoe shown in Figure 6, whereas I did not feel any effect of the spring units when walking with the shoes shown in Figure 12. I could walk smoothly without any additional actions." We thus concluded that the spring assist unit does not affect walking posture.

VI. EVALUATION OF THE SYSTEM BY ELDERLY PEOPLE

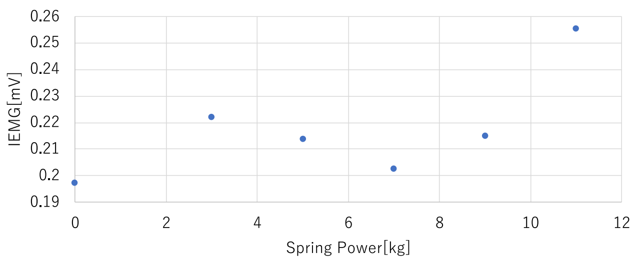
To examine the performance of the assistance device in a more practical environment, we enrolled elderly people for the evaluation because many lack sufficient power to raise their leg, a similar condition to disabled people.

A. *Experimental setting*

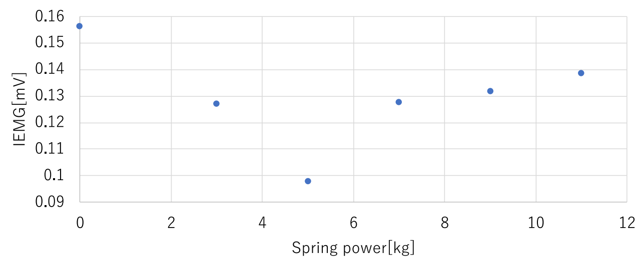
Seven participants named Participant 1 to Participant 7 (ages 79, 78, 84, 76, 76, 87 and 89 years old, respectively) were involved in the experiments. Three participants, Participant 5, 6, and 7, were female and the others were male. Figure 17 shows the experimental setting wherein participants walked straight for 5 m along the white line. Posture and EMG were measured using a Kinect and iEMG on the left leg, as shown in Figure 9. Figure 18 shows an elderly participant walking during an experiment. Participants attached the iEMG to their feet as shown in Figure 18. Each participant walked with our proposed device with and without springs of 3, 5, 7, 9, and 11 kg power, as shown in Figure 11.

B. *Experimental results*

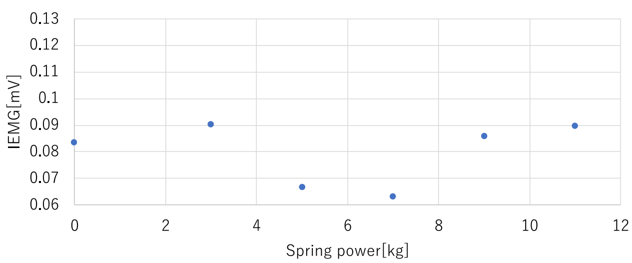
Figure 19 shows the iEMG values vs. the spring power for each participant. The vertical and horizontal axes show the voltage of the iEMG and the spring power used by each participant, respectively. Result shown in Figure 19 (e), (f) and (g) were obtained from the female participants. We observed similar trends as for the experiment involving healthy students (Figure 13). Many participants said that they could walk more easily using the springs. Participant 5 said that it was hard to walk because the shoe did not fit; however, the effectiveness of the spring was still evident. Lower iEMG values were obtained with and without the spring assistance



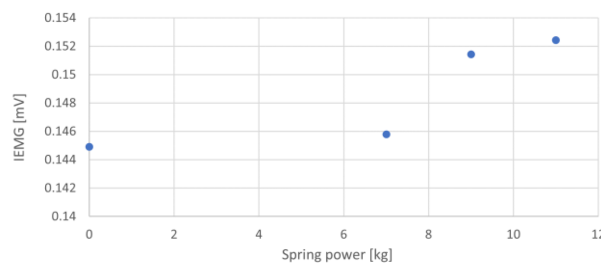
(a) Participant 1 (60 kg, 79 years old)



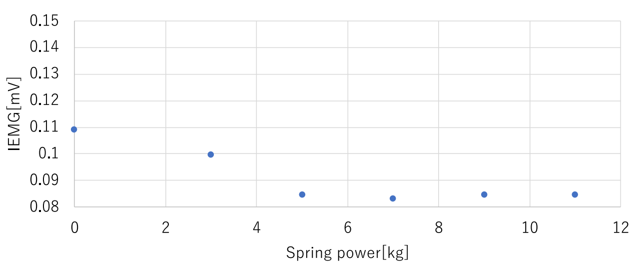
(d) Participant 4 (56 kg, 76 years old)



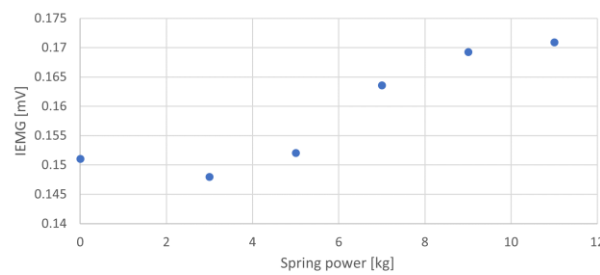
(b) Participant 2 (60 kg, 78 years old)



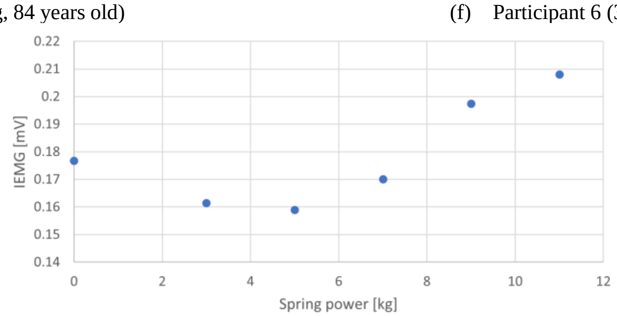
(e) Participant 5 (48 kg, 76 years old)



(c) Participant 3 (60 kg, 84 years old)



(f) Participant 6 (38 kg, 87 years old)



(g) Participant 7 (57.5 kg, 89 years old)

Figure 19. Spring power vs. IEMG for each participant.

devices for both the 80-year-old and 76-year-old participants (Figures 19(c) and (d), respectively).

Figure 20 shows the spring power at the lowest iEMG value vs. body weight for each participant. As for the younger participants (Figure 14), there was a linear correlation between the participant's body weight and the spring power at which the lowest iEMG signal was obtained.

Figures 21 to 25 present the measured positions of the head and mid-hip for Participants 1 to 5, respectively. Each figure shows the posture during walking (a) without a spring assist unit and (b) with the most effective spring assist unit (*i.e.*, 7 kg, 7 kg, 7 kg, 5 kg, 3 kg, 3 kg, and 5 kg for Figures 21 to 27, respectively). We confirmed that not only the UD motion, but also the LR motion of the head and mid-hip changes periodically and that two cycles of UD motion are likely to occur during each period of LR motion. We considered that UD motion occurred with each step whereas LR motion occurred with each right or left step. This trend is different in the younger participants shown in Figures 15 and 16 and is likely due to aging. An especially large LR motion was observed in Participant 3 and the period of Participant 5 was smaller because of the step length. However, there were no significant differences between participants walking without a spring assist unit and those with one, similar to Figures 15 and 16.

The average peak-to-peak range for each step during the LR and UD motions of each participant with varying spring stiffnesses of 0–11 kg is shown in Table IV. Although there are differences between participants and spring stiffnesses, these are again random with no obvious patterns, similar to Table III.

From, this experiment, we could not confirm the difference in the results between gender. Chumanov *et al.* showed that females walked with greater peak hip internal rotation and adduction than males, as well as gluteus maximus activity [15]. However we could not confirmed this trend from Table IV. Ko *et al.*, [16] show that women walked with higher cadence and shorter stride length than men and had less hip range of motion, greater ankle in the sagittal plane, and greater hip in the frontal plane. We could not confirm the gender-based difference from Table IV.

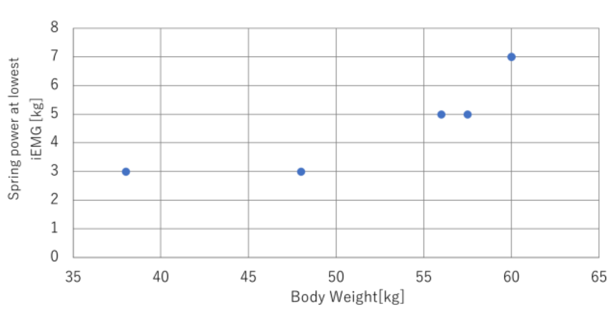
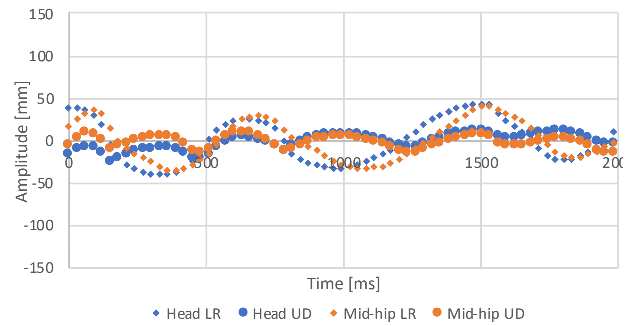
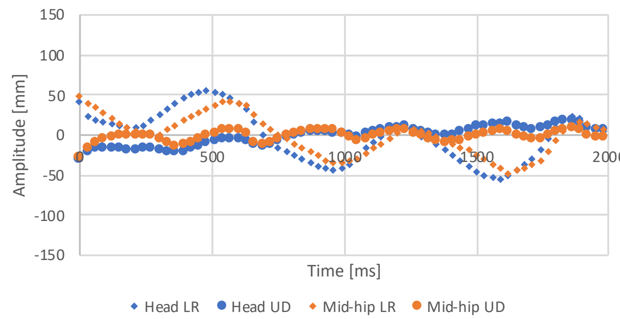


Figure 20. Spring power at lowest IEMG vs. body weight.

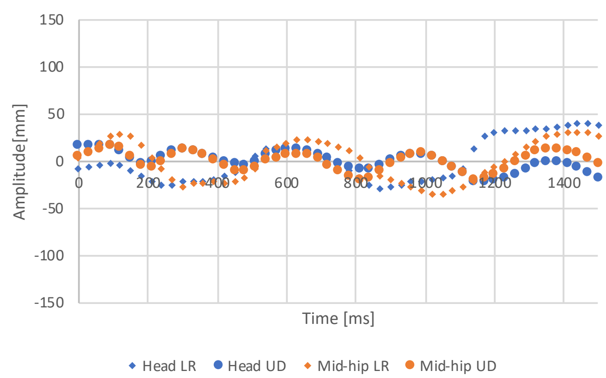


(a) Without spring

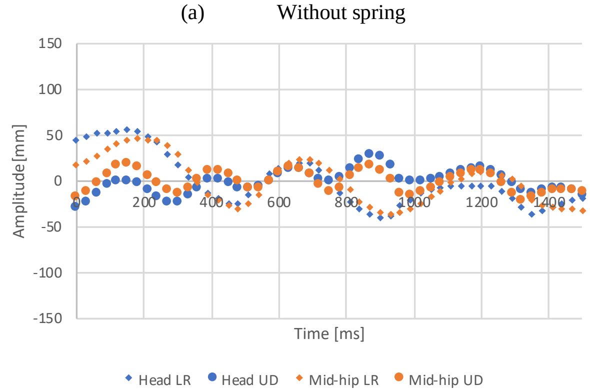


(b) With a spring assist unit (7 kg)

Figure 21. Motion of Participant 1 obtained by the Kinect.

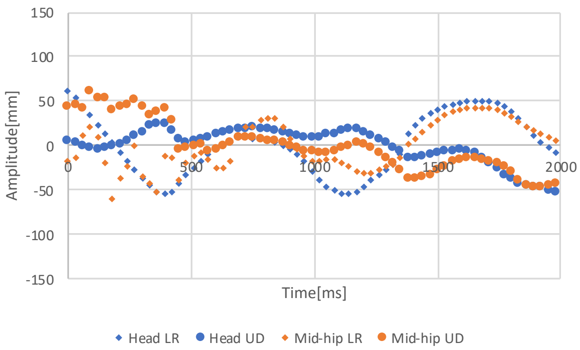


(a) Without spring

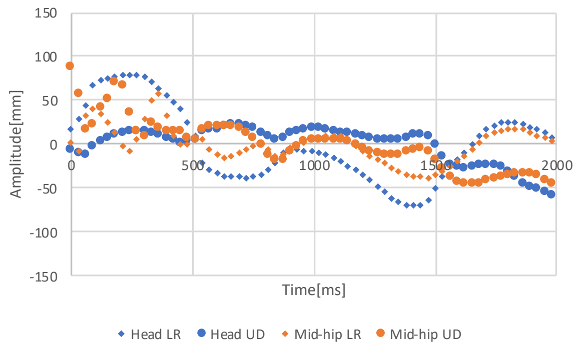


(b) With a spring assist unit (7 kg)

Figure 22. Motion of Participant 2 obtained by the Kinect.

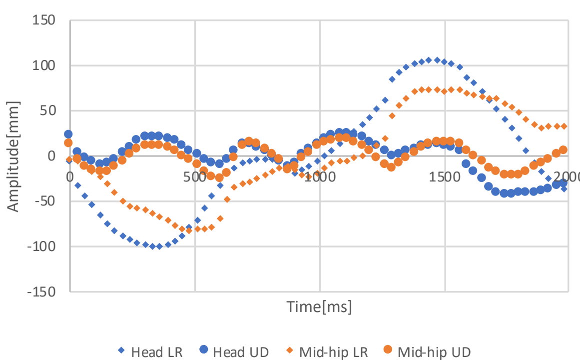


(a) Without spring

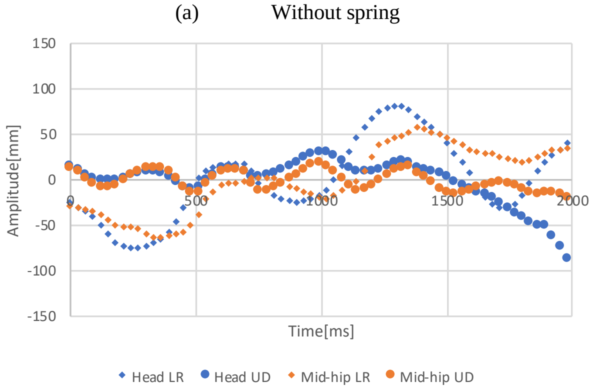


(b) With a spring assist unit (7 kg)

Figure 23. Motion of Participant 3 obtained by the Kinect.

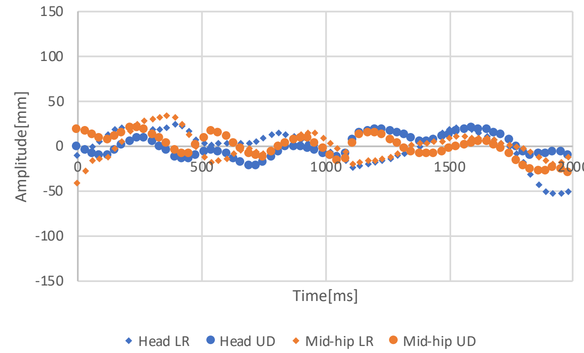


(a) Without spring

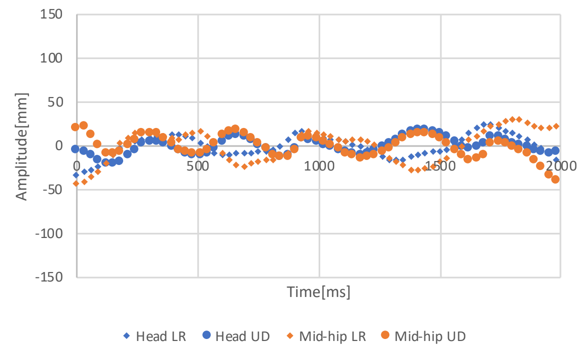


(b) With a spring assist unit (5 kg)

Figure 24. Motion of Participant 4 obtained by the Kinect.

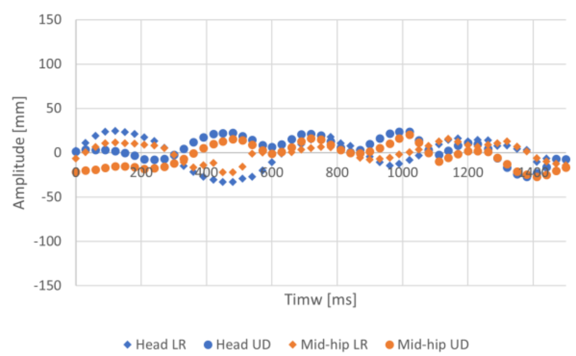


(a) Without spring

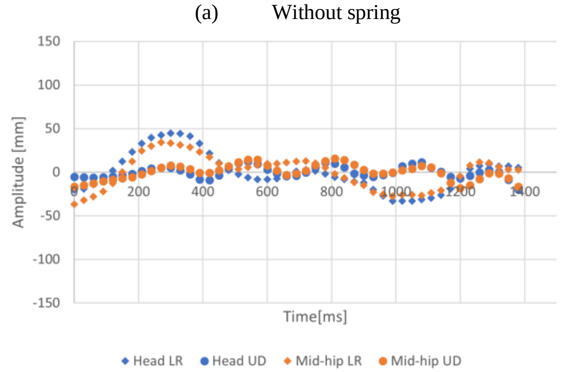


(b) With a spring assist unit (3 kg)

Figure 25. Motion of Participant 5 obtained by the Kinect.

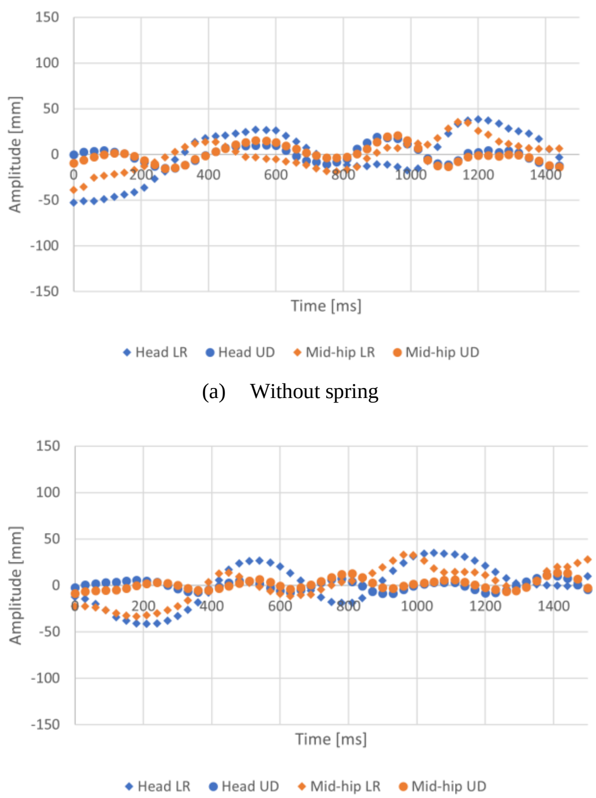


(a) Without spring



(b) With a spring assist unit (3 kg)

Figure 26. Motion of Participant 6 obtained by the Kinect.



(a) Without spring

(b) With a spring assist unit (5 kg)

Figure 27. Motion of Participant 7 obtained by the Kinect.

VII. CONCLUSIONS

It is difficult for individuals with walking disabilities to raise their heels because of their lower muscle power. Therefore, most shuffle their feet when walking and sometimes stumble or trip over something and fall down. The shoes that we developed with the spring assist unit enable people with walking disabilities to raise their heels more easily and walk more smoothly. The electromyogram (EMG) was measured to analyze the efficacy of our assistance device. The EMG values for devices incorporating various spring stiffnesses were all lower than for those walking without the spring assist unit. There was a linear relationship between the spring stiffness at which the lowest EMG signal was observed and the participant's body weight. These results demonstrate the assistive effect of the spring assist unit and that there is a linear correlation between body weight and the optimal spring stiffness of such devices. The spring in the shoes should be provided depending on user's weight.

We also measured the positions of the head and mid-hip with and without the spring assist unit for spring stiffnesses of 3 to 11 kg. Although there were differences between the participants and between the optimal spring powers, including devices with no spring, the differences were random without any obvious trends. The results also demonstrate that the spring assist unit did not affect walking posture. These trends were true for not only healthy young students, but also elderly people. Therefore, spring shoes afford wearers the chance to walk comfortably without affecting the posture in both people without walking disability and elderly people. Spring shoes are also expected to be applicable for people with disabilities when the strength of spring is adopted to the weight of users.

Our future work will include the launch of a commercial version of this spring assistance device.

TABLE IV. AVERAGE PEAK-TO-PEAK RANGE FOR LR AND UD MOVEMENT MEASURED OVER TWO STEPS FOR ELDERLY PEOPLE [MM]

Spring power [kg]			0	3	5	7	9	11
Participant 1 (79 years old)	Head	LR	66.88	60.40	57.97	68.29	75.61	65.40
		UD	20.68	10.13	22.21	7.59	13.89	11.83
	Mid-hip	LR	62.42	59.12	51.13	53.55	63.88	57.20
		UD	19.438	16.87	21.83	15.63	13.02	19.04
Participant 2 (78 years old)	Head	LR	41.25	59.01	42.44	56.36	54.62	50.98
		UD	15.82	25.08	19.39	15.36	14.53	18.56
	Mid-hip	LR	58.50	58.97	55.10	58.71	62.14	77.81
		UD	26.25	26.36	25.53	26.58	24.64	26.05
Participant 3 (84 years old)	Head	LR	71.67	91.23	78.08	71.68	82.36	73.21
		UD	13.32	8.30	16.74	26.26	10.41	21.85
	Mid-hip	LR	53.25	44.67	43.69	47.30	65.53	47.34
		UD	24.49	18.28	24.93	30.66	27.17	31.38
Participant 4 (76 years old)	Head	LR	60.62	69.26	91.38	79.01	75.42	76.53
		UD	19.44	23.61	13.56	22.83	20.01	13.70
	Mid-hip	LR	51.08	61.32	66.90	59.02	47.74	58.85
		UD	32.25	31.89	23.30	28.10	26.78	26.75
Participant 5 (76 years old)	Head	LR	30.45	30.99	52.27	45.35	41.29	40.08
		UD	15.28	20.30	17.85	20.30	11.63	10.23
	Mid-hip	LR	31.10	37.87	46.90	34.01	38.90	32.52
		UD	24.56	23.84	22.21	23.24	14.79	17.67
Participant 6 (87 years old)	Head	LR	41.99	36.825	36.95	37.61	38.90	22.61
		UD	22.64	20.76	25.87	19.07	16.52	16.06
	Mid-hip	LR	25.74	33.13	25.26	26.78	30.39	21.17
		UD	20.15	25.156	18.779	21.16	14.14	16.19
Participant 7 (89 years old)	Head	LR	46.55	48.94	41.169	45.0	34.58	39.54
		UD	28.181	14.1	15.61	18.09	14.29	14.01
	Mid-hip	LR	43.29	31.80	31.61	40.55	28.28	32.91
		UD	29.93	29.63	23.97	24.95	13.19	19.95

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