

## Adoption of blockchain as a step forward in orthopedic practice

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### Abstract

Blockchain technology has gained popularity since the invention of Bitcoin in 2008. It offers a decentralized and secure system for managing and protecting data. In the healthcare sector, where data protection and patient privacy are crucial, blockchain has the potential to revolutionize various aspects, including patient data management, orthopedic registries, medical imaging, research data, and the integration of Internet of Things (IoT) devices. This manuscript explores the applications of blockchain in orthopedics and highlights its benefits. Furthermore, the combination of blockchain with artificial intelligence (AI), machine learning, and deep learning can enable more accurate diagnoses and treatment recommendations. AI algorithms can learn from large datasets stored on the blockchain, leading to advancements in automated clinical decision-making. Overall, blockchain technology has the potential to enhance data security, interoperability, and collaboration in orthopedics. While there are challenges to overcome, such as adoption barriers and data sharing willingness, the benefits offered by blockchain make it a promising innovation for the field.

**Key Words:** blockchain orthopaedics, robot knee data, blockchain health, data management orthopaedics.

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The Blockchain originated as an accounting and management technology for electronic currencies. Although the first work on cryptographically secured blockchain was described in 1991, it wasn't until 2008 that this technology gained popularity when "Satoshi Nakamoto" invented the public Distributed Ledger Technology (DLT) of the Bitcoin cryptocurrency.<sup>1</sup> The Bitcoin network represents a public peer-to-peer electronic monetary system where participants can exchange electronic money without the need for a centralized "third party". The data in the blockchain is organized according to a network that manages a database in a distributed way with a chronological sequence and is connected to each other through cryptographic evidence. This data is not stored on a single computer but within a distributed network of nodes, making the system and data highly resistant to external attacks and technical errors. In fact, as the

blockchain represents a decentralized system, all computers participating in the network around the world store identical copies of blockchains. For this reason, attempts to modify the information contained in a blockchain network are ineffective when information is scattered across multiple individuals at once. As the data in the blockchain is stored in a chain of blocks, when new information is added, a new block is created with a chronological sequence. This information is then sent out to every computer that stores the information, which independently checks its chain to ensure the data and the unique digital fingerprint ("the hash").<sup>2</sup> After Bitcoin, several attempts have been made to apply this technology to other sectors. Specifically, blockchain technology could be used in a number of applications outside finance for archiving and data protection. In the healthcare sector, data protection and cybersecurity law have a significant impact on protecting

confidential patient information. The blockchain could have significant strengths in managing individual patient data. All data saved on the blockchain is encrypted, added in chronological order, and saved using cryptographic keys that help protect the identity and privacy of patients. Since the data on the blockchain is replicated in multiple "nodes", the availability and integrity of the data stored on the chain are guaranteed, and the data cannot be lost or corrupted.<sup>3</sup> Furthermore, any changes are visible to all users. Patients can access their data at any time, understand who accessed it and how they used it. The Blockchain helps to meet these requirements through strong cryptographic protocols and smart contracts between two parties, in order to use the private data to a third party. Furthermore, a decentralized management system that allows healthcare facilities to access the data of the same patient represents a real breakthrough in terms of resource and data management. In a decentralized system, the patient's medical record could be unique and updated by the various structures the patient visits, all connected via Blockchain. In this sense, the repercussions could affect any phase of the patient's health, allowing an exchange of health data in a safe, authorized, verifiable, and mediated way by the patient.<sup>4</sup> This could include the booking of an appointment, medical treatment with the prescription of drugs (involving in the Blockchain network all the interested parties, doctors, patients, and pharmacists), surgical treatment, rehabilitation, and remote monitoring of patients (telemedicine and telerehabilitation) by transmitting securely and encrypted patient data.<sup>4</sup> Even in medical research, the Blockchain system could make a difference, expanding patient participation in clinical trials and allowing sensitive data to be made anonymous and secure. Furthermore, the fact that the data on the Blockchain is immutable would certify the integrity of the data collected.<sup>5</sup>

### **Blockchain and orthopaedic register**

The first nationwide orthopedic registry was established in Sweden in 1975 to collect data on Total Knee Arthroplasty (TKA). Since then, several countries have established registries to gather descriptive information on joint replacement outcomes.<sup>6</sup> Registries are designed to collect information about the number and characteristics of implants, surgical approaches (access type, side, cementation, etc.), and the causes that led to prosthetic implant failure. Only the surgeon who implanted the prosthesis should be authorized to write and fill in the surgical register. Current management systems are implemented on web 2.0 and require a significant investment of time and money, with problems of source independence and content ownership. Furthermore, managing these sensitive data to make them easily usable and prevent any type of alteration represents a significant problem for the orthopedics community.

The reliable, permanent, and widely distributed characteristics of blockchain technology make it a promising innovation to overcome these problems. This is possible because blockchains are constitutionally difficult to access without authorization. Through the use of blocks, it is possible to allow "access authorization" only for relevant stakeholders

using a combination of public and private keys (held by patients), which are used to encrypt/send and decrypt/receive data. This allows access only to authorized subjects, who are always easily traceable. Moreover, access key holders could maintain safe data access in every part of the world, which could also aid research purposes and make it more transparent and objective. In addition, all new changes written in a new block leave traces of the previous data, providing assurance in terms of the originality of the data and immutability of the sources.

This system looks very different from the public "permissionless" common Web 2.0 systems.<sup>7</sup> Through the use of smart contracts, it is possible to automate some electronic medical data access requests, speeding up the data upload process. Smart contracts are programs stored on the blockchain that run only when specific conditions have been fulfilled, without requiring the main user or other authorization. This could greatly simplify the number of digital transactions that surgeons must supervise, ultimately speeding up the data loading process.<sup>8</sup>

Specifically, when a patient provides consent for institutional access to their electronic medical information, it is possible to start the smart contract, which runs automatically and distributes only selected records that can be sourced from all the authorized hospitals where the patient provided consent. In a simplified model, the surgeon, after obtaining consent to deposit data in an institutional platform, starts the smart contract that runs automatically and distributes only selected and appropriate information, allowing for the upload of new data on a specific orthopedic treatment for a specific patient ID in a single and immutable block.

Implementing blockchain technology in orthopedic registers presents several potential challenges and drawbacks, which can broadly be categorized into technical, regulatory, financial, and practical domains. Here's an elaboration on each of these areas.

### **Technical challenges**

Blockchain networks, especially those that use proof-of-work (PoW) consensus mechanisms, can face scalability issues. Orthopedic registers require processing and storing large volumes of data efficiently, but blockchain can struggle with high transaction volumes and speed.

Different healthcare providers may use different blockchain systems, leading to challenges in interoperability. Ensuring seamless data exchange and compatibility across various blockchain platforms is crucial for the comprehensive integration of orthopedic registers.

While blockchain offers enhanced security, the immutable nature of blockchain poses privacy concerns. Modifying or deleting data, when necessary, is complicated, potentially conflicting with laws that allow patients to have their information corrected or deleted.

### **Regulatory and compliance issues**

Adhering to data protection laws such as the General Data Protection Regulation (GDPR) in the European Union poses a significant challenge. Blockchain's decentralized

and immutable characteristics may conflict with regulations that require data to be editable or deletable.

The lack of standardization in blockchain technologies can hinder regulatory compliance. Regulatory bodies may find it challenging to establish guidelines that accommodate the diverse nature of blockchain implementations.

### **Financial impediments**

Implementing blockchain technology requires significant initial investment in infrastructure, training, and system integration. The cost can be prohibitive for many healthcare providers, especially smaller clinics or hospitals. Ongoing Maintenance Costs: Blockchain systems necessitate continuous maintenance, updates, and security measures, which entail ongoing costs. The need for specialized personnel to manage and operate blockchain systems further adds to the expense.

### **Practical concerns**

Convincing all stakeholders, including healthcare providers, patients, and insurers, to adopt blockchain technology can be challenging. The benefits of blockchain must be clearly demonstrated to overcome resistance to change.

There is a shortage of professionals with the requisite blockchain expertise. Training existing staff or hiring new talent is necessary, which can be time-consuming and costly.

Orthopedic registers contain complex and voluminous data, including images, surgery reports, and patient outcomes. Blockchain's current capabilities may not suffice for efficiently handling such data types and volumes.

### **Blockchain and medical imaging**

Medical imaging plays a crucial role in the diagnosis and treatment of diseases. Most of the time, this valuable data is stored in multiple centralized servers, whether public or private.<sup>9</sup> However, physical copies provided to patients can be easily lost, leading to the need for repeat exams that are costly in terms of time, money, and health. To address these issues, radiology could adopt easily accessible decentralized imaging management systems integrated with blockchain technology to cryptographically secure, time-stamp, and safely store electronic Medical Imaging Records (MIRs).<sup>10</sup> The MIRs could be encrypted and stored in an off-chain decentralized imaging sharing application. They can only be accessed with patients' consent using smart-contract technology via a private key.

Providers can deliver their services, such as writing reports, by adding a new block of data on a decentralized on-chain ledger, which secures and expands patients' electronic medical records (EMRs) chronologically. This system offers numerous advantages to both patients and healthcare institutions. All information entered in the system is encrypted using blockchain, making it tamper-proof.

Important clinical information, such as contrast allergy and the presence of implants in the body, can also be stored on patients' on-chain EMRs and easily shared, thus avoiding repeated form fill-outs. The decentralized MIR storage system can solve the problem of lost medical exam copies, creating a personalized record of all patients' medical imaging

accessible at any time and from any place. Only patients can dynamically give or revoke consent to access any medical exam by any requesting party, empowering them in their interactions with healthcare providers.<sup>11</sup> From healthcare providers' perspective, blockchain applications in MIRs can dramatically improve productivity and reduce wasted time and economic resources.

Additionally, it can accelerate the growth of teleradiology, addressing the emerging problem of radiologist shortages and expanding healthcare to remote and rural areas. This system can also speed up the development of Artificial Intelligence (AI) and application of ChatGPT, which requires a vast quantity of data to evolve rapidly and accurately.<sup>12</sup> Traditionally, centralized MIR storages lack the sheer amount of data required to do so. Furthermore, their multitude scattered across the entire healthcare environment complicates researchers' efforts to access them. A decentralized, diffuse MIR storage framework, in which patients' sensitive personal data are encrypted through blockchain technology, represents the perfect environment in which to implement supervised deep learning networks for AI algorithms.<sup>12</sup>

The ultimate goal is to achieve machine semi or full-automation in tackling complex clinical cases, reducing the workload of human counterparts, and vastly increasing diagnosis accuracy and precision. There are still many limitations before this model can see widespread implementation. Radiology is one of the most technologically advanced fields in medicine, but the adoption of new technologies in healthcare traditionally progresses at a much slower pace. Finally, the strength of this decentralized model lies in the willingness of each participant to share information, which represents a paradigm shift compared to the traditional healthcare attitude toward handling patients' sensitive data.

### **Blockchain and research data and clinical perspective**

Blockchain technology offers excellent protection for patients' data, thanks to its use of encryption and its decentralized nature. Moreover, storing health data in the blockchain could positively impact the quality of patient care.<sup>13</sup> Additionally, anonymizing data can incentivize patients to participate and contribute more to research studies, potentially through a governance token reward. Data can be generated from multiple sources, including wearable devices (for prospective studies), medical images, and scoring scales.<sup>14</sup>

These data can also be accessed and utilized by both doctors and patients, enabling researchers to reduce data collection time and more easily select inclusion criteria, resulting in a more standardized database. By automatically introducing data from a patient's device, such as knee range of motion or step length, biases can be eliminated, thus improving the validity of research. Over time, doctors can utilize this data to track a patient's clinical progression, providing evidence of therapy effectiveness.

Additionally, a remote monitoring system and continuous interaction between patient and doctor can be envisioned. Smart contracts can facilitate the sharing of this data on an orthopedic blockchain, which researchers worldwide can



utilize to promote multi-center studies, create a broader database, and obtain more reliable results.<sup>15</sup> In the field of orthopedics and traumatology, plates, screws, or prosthetic implants can be tracked from production to implantation, recording each step (production lot, transport, etc.) on the blockchain.

Integration with AI enables tracking their entire life cycle, aiding in decisions regarding implant removal or replacement, and providing valuable information to manufacturers to enhance the development of future implants. Furthermore, the blockchain can serve as a secure means to manage legal relationships between patients and healthcare facilities, both for obtaining consent for surgical treatment and verifying compensation transactions.<sup>16</sup> Lastly, the blockchain can be utilized to monitor educational content, validating the source to improve the training path of medical staff.

Blockchain technology's potential to revolutionize patient data protection and its application in medical research, especially when combined with the innovative concept of incentivizing participation through governance tokens, presents a significant shift in how healthcare data can be managed and utilized. Here are some practical applications and potential case studies that illustrate how these concepts could be implemented in real-world scenarios:

### ***Secure patient data sharing***

Imagine a blockchain-based platform that enables patients to securely share their orthopedic health data with researchers or pharmaceutical companies working on new treatments. Each patient is given governance tokens as a reward for their data contribution. These tokens can be used to vote on future research directions or to access premium services within the platform. This approach not only empowers patients by giving them control over their data but also incentivizes their participation in medical research.

### ***Improved clinical trials***

A blockchain system could be used to streamline the process of patient recruitment for clinical trials. By allowing patients to register their health profiles on a blockchain, researchers can easily identify potential participants who meet the criteria for their studies. Patients who agree to participate are rewarded with governance tokens, which could be used to receive health services or access to exclusive medical insights. This system ensures transparency in patient selection and enhances trust in clinical research.

### ***Enhanced data integrity and transparency in research***

A research institution implements a blockchain to log all data related to a multi-year study on the effectiveness of a new orthopedic surgery technique. Each data entry is time-stamped and immutable, ensuring the integrity of the research data. Patients who contribute their post-operative outcomes to the study receive governance tokens, fostering a sense of ownership and participation in the research process. This approach not only secures the data but also promotes transparency and accountability in medical research.

### ***Decentralized health data marketplaces***

A decentralized marketplace where individuals can securely sell access to their anonymized health data to researchers or pharmaceutical companies. The use of blockchain ensures that transactions are secure and that patients retain control over who has access to their data. Patients are compensated with governance tokens for each transaction, which can be used within the ecosystem for various services or cashed out. This marketplace democratizes access to valuable health data while providing a direct benefit to the data providers—the patients themselves.

### ***Patient-driven research initiatives***

A patient advocacy group for a rare orthopedic condition uses blockchain to create a research fund. Patients contribute data and receive governance tokens in return. These tokens grant them voting rights on which research projects should be funded. This model not only incentivizes data sharing but also puts research priorities in the hands of those most affected by the outcomes, ensuring that the research is aligned with patient needs.

### ***Internet of things - internet of medical things in orthopaedics and blockchain***

The use of connected devices controlled and identified through the Internet of Things (IoT) has rapidly increased in recent years.<sup>17</sup> IoT integrates physical and virtual elements to enhance the quality of human life and provide better services. Physical objects have the ability to receive stimuli from the surrounding world, while virtual objects can be stored and processed.

IoT has gained significant interest in various fields, particularly in healthcare, where it is often referred to as the Internet of Medical Things (IoMT).<sup>18</sup> It aims to improve traditional communication between doctors and patients, ensuring better healthcare services. This technology seeks to shift medicine from a centralized to a decentralized model, similar to what cryptocurrencies are doing in the financial world. Wearable IoT devices are utilized in medicine as sensors attached to the body to monitor patients' health.<sup>19</sup>

They can measure various parameters, with the wrist being the most commonly used body part, followed by the chest. However, sensors can be applied or implanted anywhere, such as on external fixators and prosthetic components implanted directly into the bone. Most sensors are accelerometers and can record multiple data points that are stored in the cloud and then secured on a blockchain system. Recent advancements in the integration of IoT and cloud computing have led to the development of numerous medical systems that enable continuous patient monitoring.

These systems can store data, communicate with each other, and with other devices, thanks to various communication protocols, including 3G, 4G, and recently 5G cellular networks, RFID, NFC, Bluetooth, Wi-Fi, GPS, 6LoWPAN, Z-Wave, and Zigbee.<sup>20,21</sup> In orthopedics, for instance, IoT can bring benefits in evaluating patients' rehabilitation phase after surgeries such as arthroplasty or fracture fixation.

By making fixation devices or prosthetic components part of the IoT network, these devices can directly provide in-

formation about any deformities, consolidation state, bone pain, blood pressure, and frequency of rehabilitation exercises. Hip or knee prostheses can provide information about the patient's daily activity, gait cycle, and range of motion achieved. All this information can be obtained by bringing the doctor's phone close to the device, enabling them to receive all the information via NFC, for example. Alternatively, this process can happen automatically via the 5G network, and the doctor will simply receive a notification on their smartphone.

All these data can be stored on a blockchain, improving the understanding of patients' healthcare, enhancing their treatment, and ensuring timeliness.

The integration of Internet of Things (IoT) with blockchain technology in the field of orthopedics represents a pioneering approach to healthcare management, patient care, and medical research. This convergence aims to enhance data accuracy, security, and interoperability across various devices and systems, facilitating real-time monitoring, personalized treatment plans, and improved clinical outcomes. Here's a detailed exploration of this integration and the potential challenges or risks associated with it.

### *Internet of things and blockchain integration in orthopedics: an overview*

IoT devices in orthopedics include wearable sensors, implanted devices, and other connected medical instruments that monitor patients' health status, movement patterns, and rehabilitation progress. These devices generate vast amounts of data, providing insights into patient recovery, the effectiveness of treatments, and potential complications.

Blockchain technology offers a decentralized and secure platform for storing and sharing the data collected by IoT devices. By leveraging blockchain, healthcare providers can ensure data integrity, patient privacy, and secure access to medical records. This technology enables the creation of a tamper-proof ledger of patient data, enhancing trust among all stakeholders involved.

### *Practical application scenario*

Imagine a scenario where a patient recovering from knee surgery wears IoT-enabled braces that monitor their range of motion, activity levels, and healing progress. This data is automatically uploaded to a blockchain, where it is securely stored and made accessible to authorized healthcare providers. The patient's progress can be tracked in real-time, allowing for timely adjustments to their rehabilitation plan. Additionally, the data collected can contribute to broader research studies on orthopedic recovery, with patients incentivized to share their data through blockchain-based tokens.

### *Benefits of internet of things and blockchain integration in orthopedics*

IoT devices can monitor patient health in real-time, offering personalized care based on the data collected. This is particularly beneficial for post-operative monitoring in orthopedics, where early detection of complications can significantly improve outcomes.

Blockchain provides a secure and immutable ledger for storing data collected by IoT devices. This ensures the integrity of medical records and protects against unauthorized access, making it ideal for sensitive health information.

The integration facilitates the collection of large volumes of data, which can be anonymized and used for research. This can accelerate advancements in orthopedic treatments and the development of new medical devices.

### **Challenges and risks**

While the integration of IoT and blockchain in orthopedics holds promise, several challenges and risks must be addressed.

#### ***Technical and operational challenges***

Both IoT and blockchain technologies face scalability issues. As the number of IoT devices increases, the volume of data generated can overwhelm current blockchain networks, leading to delays and increased costs.

There is a lack of standardization across different IoT devices and blockchain platforms. This can hinder the seamless exchange of data among healthcare providers, patients, and researchers.

Implementing and maintaining an integrated IoT-blockchain system can be complex and costly. It requires significant investment in infrastructure, as well as ongoing operational costs.

#### ***Security and privacy concerns***

Despite the security advantages of blockchain, the integration with IoT devices raises privacy concerns. There's a risk that sensitive health data could be exposed if not properly encrypted or if the blockchain is not configured to comply with privacy regulations.

IoT devices are known for their security vulnerabilities. If a device is compromised, it could potentially expose the blockchain to fraudulent data, undermining the integrity of the entire system.

Ensuring that the integrated system complies with healthcare regulations, such as HIPAA in the United States or GDPR in Europe, is challenging. The immutable nature of blockchain can conflict with regulations that require the ability to alter or delete personal data.

#### ***Ethical and social implications***

There are ethical considerations regarding patient consent and the ownership of the data collected by IoT devices. Patients must be fully informed about how their data will be used and must retain control over it.

The reliance on advanced technologies like IoT and blockchain could exacerbate healthcare disparities. Patients without access to the latest technologies or those who are not tech-savvy may be left behind.

### **Artificial intelligence, machine learning and deep learning**

Artificial Intelligence (AI) refers to the application of algorithms that enable machines to solve problems that traditionally required human intelligence.<sup>22</sup> The term was coined

by John McCarthy in 1955, based on the theory that computers could learn to perform tasks through pattern recognition without human involvement. AI is a branch of computer science that focuses on developing hardware and software systems capable of possessing human-like abilities and autonomously pursuing defined objectives by making decisions that were previously entrusted to humans.

These abilities include understanding and processing natural language (NLP - Natural Language Processing) and images (Image Processing), learning, reasoning, and the ability to plan and interact with people, machines, and the environment. The distinguishing feature of AI, from a technological and methodological perspective, is the learning model or method through which intelligence becomes proficient in a task or action.

Deep Learning is a learning model inspired by the structure and functioning of the human brain. It emulates the human mind and was introduced in 2012. Deep Learning requires specialized artificial neural networks (deep artificial neural networks) and powerful computational capacity capable of supporting different layers of calculation and analysis, similar to neural connections in the human brain.<sup>23,24</sup>

Integrating AI in healthcare, including orthopedics, brings transformative potential, such as improved diagnostic accuracy, personalized treatment plans, and operational efficiencies. However, the implementation of AI also faces significant challenges and limitations. To make these concepts more tangible, let's discuss some real-world applications and the obstacles encountered in the healthcare sector.

### **Real-world applications of AI in healthcare**

#### *Predictive analytics for patient outcomes*

AI models can analyze vast datasets from Electronic Health Records (EHRs), imaging, and wearables to predict patient outcomes, identify high-risk patients, and tailor treatment plans. For example, AI algorithms can predict the risk of osteoporosis-related fractures by analyzing bone density scans and patient medical histories.

#### *Diagnostic assistance*

AI-powered imaging analysis tools are being used to assist in the diagnosis of conditions like fractures, osteoarthritis, and spinal disorders. These tools can help radiologists and orthopedic surgeons by highlighting areas of interest and suggesting preliminary diagnoses.

#### *Robotic surgery*

In orthopedics, robotic-assisted surgery systems use AI to enhance the precision of procedures such as joint replacements. These systems can analyze pre-operative imaging to plan the surgery and assist surgeons in executing the plan with high precision, potentially improving patient outcomes.

#### *Virtual health assistants*

AI-driven chatbots and virtual health assistants provide patients with personalized advice, reminders for medication, and answers to health-related questions, improving patient engagement and adherence to treatment plans.

### **Challenges and limitations in implementing AI in healthcare**

#### *Data privacy and security*

One of the primary concerns with AI in healthcare is the protection of patient data. AI systems require access to vast amounts of sensitive health information, raising privacy and security concerns. Ensuring compliance with regulations like HIPAA in the U.S. and GDPR in Europe is crucial.

#### *Bias and ethical concerns*

AI systems can inherit biases present in their training data, leading to biased predictions and decisions. For instance, if an AI model is trained primarily on data from one demographic group, its accuracy may be lower for other groups. Addressing these biases is essential to ensure equitable healthcare outcomes.

#### *Integration with existing systems*

Integrating AI tools with existing healthcare IT systems can be challenging due to compatibility issues, data silos, and the diverse nature of healthcare data. Ensuring seamless integration is crucial for the effective use of AI in clinical settings.

#### *Reliability and accountability*

The reliability of AI systems and the accountability for their decisions remain significant concerns. Errors in diagnosis or treatment recommendations can have serious implications for patient care. Establishing clear guidelines on the use of AI and responsibility in case of errors is crucial.

#### *Resistance to change*

Healthcare professionals may be skeptical of AI tools, fearing they might replace human judgment or lead to a depersonalization of care. Educating and training healthcare workers on the benefits and limitations of AI can help mitigate these concerns.

### **A case scenario**

We present a possible scenario that could be observed in the future when all these technologies are combined with each other, with inputs and outputs entered into the blockchain. Let's take an example of a patient who falls with a knee prosthesis implanted. The smartwatch worn by the patient detects the fall and alerts emergency services. At the same time, the smartwatch communicates via IoT with the prosthetic components implanted at the patient's knee. Through sensors that detect the distance, the prosthetic components communicate to the smartwatch that their mobilization has likely occurred. The smartwatch, in addition to calling for help, also notifies that the patient's knee prosthesis has probably been mobilized, possibly due to a fracture from the fall. Furthermore, based on the operating register data entered in the blockchain, the emergency number operator is aware of the type of prosthesis and the operating surgeon.



The patient is transferred to a hospital where an expert knee surgeon works, and an X-ray is performed. The X-ray images can be compared to those previously taken by the patient. The radiologist's hardware is equipped with a neural chip (Neural Processing Unit). The software, over time, has learned to discriminate between normal and pathological images based on the initial data provided by the radiologist and subsequent deep learning. The radiology report states that there is a tibial plateau fracture and prosthetic loosening.

Additionally, through deep learning, a classification is made. The machine sends a request for advice to the operating surgeon who is currently on duty, based on the cloud data in the hospital system. The doctor visits the patient, reviews the radiographic images, and sees on the tablet that the patient had previously undergone medical examinations for knee pain, classified as unspecified knee pain, as indicated in the blockchain.

Based on all this information, the AI suggests to the doctor that it is likely an acute-on-chronic prosthetic loosening and requests confirmation to organize the surgery. The first available slot in the operating room is the next day, and the transfusion center and anesthesia department are automatically notified. Based on the data stored in the blockchain, the prosthesis company is also contacted to prepare the instruments and the new implant required for the case. The surgery is successfully performed, and the new orthopedic register is written.

The physiotherapist is alerted for the rehabilitation process, which will be recorded and archived in the blockchain along with the patient's entire medical history. All the information remains archived, decentralized, and immutable. This represents just one explanatory example of how blockchain, IoT, Deep Learning, and AI can meet health needs, specifically in orthopedics. The possibilities are big, and the continuous development and integration of these systems in the health sector can open a world of opportunities to improve healthcare and make it more efficient.

In a comprehensive data-sharing system, particularly one that integrates advanced technologies like AI, IoT, and blockchain within healthcare settings such as orthopedics, the promise of enhanced patient care, improved efficiencies, and groundbreaking research is significant. However, this scenario also brings to light important ethical and privacy concerns that must be carefully navigated. Simplifying the complex technical aspects can help broaden understanding for all stakeholders involved.

### Ethical and privacy concerns

#### *Patient consent and autonomy*

One of the core ethical concerns revolves around patient consent and autonomy. Patients must be fully informed about how their data will be used, who will have access to it, and for what purposes. Simplified, this means ensuring that patients understand they have the right to decide whether their personal health information can be shared and used for purposes beyond their immediate medical care, such as research.

#### *Data privacy and security*

The integration of technologies like AI and IoT in healthcare raises significant privacy concerns. Essentially, this is about ensuring that patient data, which includes sensitive health information, is kept secure from unauthorized access or breaches. With data being shared across platforms and organizations, safeguarding this information becomes a complex challenge.

#### *Bias and fairness*

AI systems, which may be used to analyze patient data or assist in diagnosis, can inherit biases present in their training data. This could lead to unfair treatment recommendations or outcomes for certain groups of patients. In simpler terms, it's crucial that these systems are designed and trained to treat all patients fairly, regardless of their background.

#### *Accountability and transparency*

When technology makes decisions or recommendations that affect patient care, it's important to have clear accountability. This means being able to trace decisions back to the data or algorithms that generated them and ensuring that there is transparency in how these technological systems operate.

#### *Simplifying Complex technical terms*

To make the discussion more accessible, let's break down some of the technical terms.

*AI (Artificial Intelligence):* computers programmed to think and learn like humans, used to analyze data or assist in making decisions.

*IoT (Internet of Things):* devices connected to the internet that collect and exchange data, like wearable health monitors.

*Blockchain:* a secure, decentralized way of recording transactions that ensures data integrity and transparency.

*Addressing the concerns:* to address these ethical and privacy concerns, a comprehensive data-sharing system in healthcare should.

*Ensure informed consent:* make the consent process more understandable and transparent, allowing patients to make informed decisions about their data.

*Enhance data security:* Implement strong encryption and security measures to protect patient data from unauthorized access.

*Mitigate bias:* regularly review and update AI systems to ensure they are fair and unbiased, using diverse datasets for training.

*Clarify accountability:* Establish clear guidelines on who is responsible for decisions made with the assistance of technology, ensuring there is always a human in the loop.

By addressing these concerns head-on and simplifying the complexities of the technology involved, we can move towards a future where healthcare is both innovative and respectful of the ethical and privacy rights of patients.

## List of abbreviations

IoT, Internet of Things  
AI, artificial intelligence  
DLT, Distributed Ledger Technology  
TKA, Total Knee Arthroplasty  
IoMT, Internet of Medical Things  
EHRs, Electronic Health Records  
NLP, Natural Language Processing

## Conflict of interest

The authors declare that they have no conflict of interest that could inappropriately influence this work.

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## Ethics approval and consent to participate

All patients gave the informed consent prior being included into the study. All procedures involving human participants were in accordance with the 1964 Helsinki declaration and its later amendments. For this type of study, any statement relating to studies on animals is required.

## Consent for publication

Not applicable.

## Availability of data and material

The dataset used and/or analysed during the current study are available from the corresponding author on reasonable request.

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## Adoption of blockchain in orthopedic practice

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