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STRAIN SENSOR-BASED MONITORING OF SMART ORTHOPEDIC DEVICES IN LOWER LIMB FRACTURE HEALING: A REVIEW

Vladimir Antic[1], Dragan Misic[2†], Miodrag Manic[2]

[1]Center of Applied Mathematics and Electronics, Belgrade, Serbia
[2]University of Nis, Faculty for Mechanical Engineering, Nis, Serbia

Abstract. *Self-Monitoring Analysis and Reporting Technology (SMART) implants provide significant improvements in diagnostic and post-operative patient treatment by using the measurement data regarding physical parameters such as pressure, force, strain, displacement, and other physical stimuli to improve bone healing. Strain sensors are widely used as a part of the SMART orthopedic devices because they can precisely monitor small changes in resistance in order to determine the strain. This characteristic helps in measuring subtle physical stimuli for enhancing fracture fixation during bone healing. The data set collected from the strain sensor can be processed by an active device to monitor the patient's health and provide the most beneficial assistance for the healing process. This paper complies with studies on internal and external SMART implants based on strain sensors technology in order to advance knowledge on the technical aspects of the healing of broken low extremities. The paper presents the current state-of-the-art in low extremity bone fracture fixation. It is shown that there is a lack of relevant information regarding both external and internal fixation devices. It also highlights the technical challenges of the innovation underlying SMART implants caused by advancements in applied wireless technology, power supply, dimensions, life-lasting, and utilization of customized devices.*

Key words: *Strain sensors, SMART orthopedic devices, Bone fractures, Bone healing, Fracture stiffness.*

1. INTRODUCTION

Although studies have demonstrated their utility in guiding surgical technique, postoperative rehabilitation, and confirming in vivo implant loading and performance, applications of bone implants have largely been academic and have not yet been fully

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Corresponding author: Vladimir Antic
Center for Applied Mathematics and Electronics, VojvodeStepe 445, Belgrade, Serbia
E-mail:avladimir@ptt.rs

evaluated clinically [1, 2]. Self-Monitoring Analysis and Reporting Technology (SMART) implants are medical devices with mechanical and electrical capabilities, which have the potential to enable personalized medicine and optimize the care of individual patients. They are used for both therapeutic and diagnostic purposes and opened the door to integrating electrical sensors on the bone scaffold to track implant performance [3]. SMART fracture fixation devices can provide objective data that can be used for getting diagnose and to guide patient rehabilitation strategy [4-7]. As diagnostic tools, SMART implants provide information about the environment in the body that cannot be obtained in any other way. Moreover, they continuously monitor critical intracorporeal parameters, allowing for real-time treatment guidance [1]. However, there is a lack of quantitative measurements which necessitates the use of objective measurements [1, 4, 8-10]. This quantitative data can be used to adjust treatments, initiate care transitions, and detect adverse events [11, 12]. The biomechanical properties and physical parameter measurements like bone deflection under loading, temperature, fracture stiffness (closure), fracture void geometry deformation, bending moment, and vibration properties, can all aid in bone healing [4, 7, 9, 13-16].

Early attempts to aid bone healing have been focused on direct and indirect measurement techniques in patients treated with external fixators, allowing direct measuring the stiffness of the recovered bone in the zone of fracture after removal of the connecting rod, or an indirect measurement through the non-invasive attachment of additional equipment, such as goniometers or a strain gauge transducer clamp [13, 17, 18]. By monitoring the mechanical response of the device, external fixation devices are used to indirectly measure fracture stiffness as a measure of bone union [19, 20]. External fixation now plays a minor role in fracture treatment, with internal fixation treating the vast majority of lower limb fractures. Although external fracture fixation devices were developed earlier than internal fixation devices, researchers continue to focus on external fixation because of the negative effects on patient comfort, prolonged recovery time, potential infections, higher mortality, and similar [21-24]. On the other hand, the implanted monitoring devices with an internal power supply and instrumented bone plate are commonly used to continuously and wirelessly monitor interfragmentary movement. At the bone fracture site, they also collect data about the patient’s activity. The raw data is statistically processed, allowing the influence of load fluctuations to be averaged, rendering an external load reference useless. The increased ease of use enabled remote monitoring, and the continuous acquisition of the fracture activity profile is thought to be a key differentiator between this concept and passive techniques. By incorporating intelligent software functions, microsensors and wireless charging have greatly increased the potential of orthopedic implants, in general. Recent advancements have enabled sophisticated and large-scale data transmission by utilizing secure data and communication networks, as well as embedded sensors.

This paper presents a systematic review of strain sensor technology methods for measuring bone healing parameters with SMART implants. External and internal fixator types are compared to gain a better understanding of sensor-based diagnostic. The paper also provides the state-of-the-art in lower extremity fracture fixation, specifically the femur, tibia, and fibula, because they have the highest dislocation rates and force the patient to remain immobile for an extended period of time, resulting in long-term discomfort and a low quality of life [25]. Since the significant technical challenges of the innovation underlying SMART implants are relayed to implant materials, the timeline of material development is presented to show improvements in implant safety, design, and efficacy of implants used in fracture fixation. The studies presented here span the years 1984 to 2022. It has been demonstrated that there is a significant lack of clinical practice data. It should be noted that some additional data are available to the researchers, but the results of animal and cadaver experimental tests are not included in this review due to ethical reasons.

2. SMART ORTHOPEDIC IMPLANTS

In general, orthopedic implants are mechanical devices that are surgically implanted inside the body to restore function to a damaged structure. An implant is attached to the bone both proximal and distal to the fracture to act as a support. The implants help stabilize the bone fragments, allowing for faster healing. Fracture plates, intramedullary rods and external fixators are available for fracture fixation. Loads are transmitted through both the bone and the fixator when a bone is loaded. Since the fracture cannot withstand loads in the acute postoperative period, when the limb is loaded, the forces are transmitted exclusively to the fixator and not to the bone. As the fracture heals and a bone callus is being formed the bone can carry some load reducing the force on the fixator. In addition, as a bony bridge, the fracture can carry more load while less force is transmitted through the fixator.

A bone fracture can be described as a partial or complete fracture of the bone, which can be open (compound) when the bone pushes through the skin and is visible or closed (simple) when the bone is broken but the skin remains intact. A significant proportion of bone fractures are caused by high force or stress. In addition, certain medical conditions, such as osteoporosis and cancer, can lead to a fracture. According to [26] there are 14 different types of fractures, described in Table 1.

Table 1 Bone fractures

Fracture type	Description
Avulsion fracture	Occurs when a muscle or ligament pulls on the bone.
Comminuted fracture	Occurs when an impact breaks the bone into many pieces.
Compression fracture	Occurs in the spongy bone of the spine.
Dislocation	Occurs when a joint dislocates and one of the joint's bones fractures
Greenstick fracture	A bone fractures on one side but does not completely break because the remaining bone can bend
Impacted fracture	Occurs when a piece of the bone impacts another bone.
Intra-articular fracture	Occurs when a fracture extends into the surface of a joint.
Longitudinal fracture	The fracture extends along the length of the bone.
Oblique fracture	Occurs opposite to a bone's long axis.
Pathological fracture	Occurs when an underlying condition weakens the bone and causes a fracture
Spiral fracture	Occurs when at least one part of the bone twists during a break.
Stress fracture	Occurs when stress and strain are applied repeatedly.
Transverse fracture	A straight break across the bone.

(Source: [26])

The fracture must be reduced to allow the natural healing process to begin which involves aligning the broken bone ends. For smaller fractures, the affected area can be manipulated from the outside. However, in some cases, surgery may be required. Casts or clamps, metal plates and screws, intramedullary nails or rods placed in bone cavities, and external fixations are all methods of doing this. Several clinical studies discovered that, when compared to the standard clinical assessment, decisions based on monitoring mechanical properties of healing bone could reduce refracture rates while shortening the meantime to hardware removal [19, 20, 25].

The ability to integrate sensor technology in orthopedic SMART implant applications drives many innovations and developments that result in early detection of infections, shorten recovery times, and improve patient comfort during the healing process [27]. SMART orthopedic implants are typically miniaturized and compact electrically active systems used for diagnosis, monitoring, and treatment [28]. They can measure pressure, force, strain, displacement, proximity, and temperature, as well as other physical stimuli that can aid with knee arthroplasty, hip arthroplasty, spinal fusion, fracture fixation, and other procedures that incorporate application-specific technology into the implant [1].

External fixators detect relative translation and rotation of the external fixation pins in order to determine bone healing status [25]. When the bone is subjected to external load, the external fixator deforms. The studies [4, 7, 9, 13-15], focused on assessing the mechanical performance of the implant as a function of frame configurations and bone deformation. Telemetric solutions transmit data from within the body and use electrical induction as the energy source [29, 30]. Examples include an implantable and autonomously working electronic unit for continuous recording of fracture movement through real-time sensor data processing, a miniature, wireless, telemetric, low-power tire pressure sensor for measuring stress and deflection for future use in orthopedic applications, and others [8, 31]. Researchers have also proposed methods for measuring strain on orthopedic devices non-invasively using ultrasound [32], implanted magnetoelastic wireless electronic devices [33], and analysis of vibrations through bone [34]. Moreover, data on sensor packages instrumentation in orthopedic implants has long been a challenge due to the sensor package size constraints, the need for wireless telemetry, and low power consumption [12, 35]. The main issue is that sensor packages are too large to be built into smaller orthopedic components such as fracture fixation plates, microcontroller units, and internal battery sources with limited lifetime [8, 36-38].

Internal fixation devices are self-contained electronic units that transmit data from inside the body using a sensor-based inductive-capacitive-resistive oscillating circuit and telemetric solutions, allowing for short-term measurement of implant deformations and long-term measurements of a variety of biomechanical parameters [29, 30, 39]. Microprocessors for real-time data processing are frequently used in internal fixation devices, as are wireless, telemetric, low-power, sensors embedded within a deformable enclosure for measuring load and deformation [8, 31]. IoT allows for remote monitoring and emergency notification systems, as well as the collection of a variety of data [40, 41]. The issue is dealing with large datasets [42].

3. SMART ORTHOPEDIC IMPLANT SENSOR SYSTEMS

Since Rydell conducted the first research on the implantation of SMART sensors in orthopedic devices in 1966, various research aimed at the further development of SMART implant technologies [1, 11, 27, 43-46]. The research has also significantly improved the understanding of biomechanics, which has been crucial for the development of novel next-generation surgical techniques and implant technologies [1, 47].

3.1 SMART orthopedic implant system structure

Despite decades of research, SMART implants have yet to enter daily clinical practice largely due to significant technical modification required to integrate current sensor technology before SMART orthopedic devices can be used in routine health care. Recent advances in wireless sensors and medical telemetry, on the other hand, are opening up previously untapped opportunities in orthopedic implants. Fig. 1 depicts a SMART orthopedic implant system with a wireless data transmission and processing link between the system and the bone-loss monitoring devices. A sensor chip, sensor readout unit, reader unit, and battery are all part of the implant system. Microelectrodes on the sensor chip allow for electrochemical monitoring. An application-specific integrated circuit serves as the basis for the sensor readout unit. For bone characterization, an on-chip sensor measures amperometric, potentiometric, and impedance parameters (sensor chip). A microcontroller in the reader unit enables the sensor reading and bi-directional data transmission between the implant and the interface. All components must be designed for low-power operation.

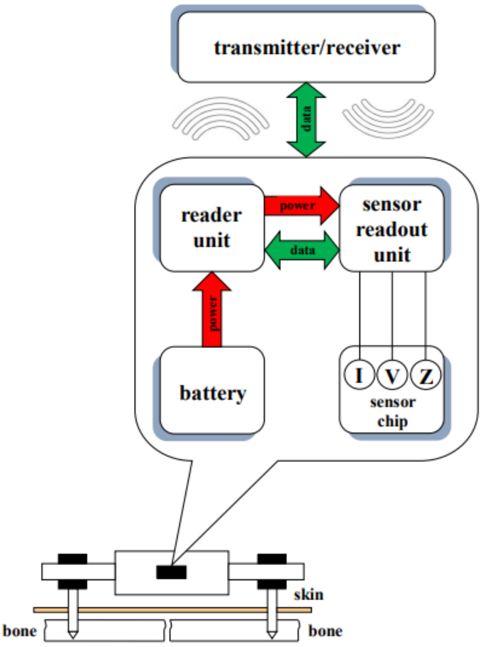

Fig.1 SMART orthopedic implant system with wireless link

One of the SMART orthopedic implant systems with a wireless link between the implanted electronics circuit and an external reader unit was recently developed by the SMART IMPLANT consortium in the Spitzencluster microTEC Südwest [48]. Sensors in the implant system measure the oxygen concentration, pH value, and impedance in the implant's environment. In conjunction with the high integration density, the electronic circuits are designed for maximum energy efficiency, allowing for as small and wireless active implants as possible. This refers to small, unobtrusive sensors that are implanted alongside the orthopedic device and used to wirelessly communicate information to exterior monitoring/control equipment.

The implant system is made up of an application specific integrated circuit (ASIC) and a microcontroller, which enable sensor and inductive energy readout, as well as bidirectional data transfer between the implant and an external unit via an inductive interface [48]. The link allows for data transfer for implant parametrization, sensor uplink transmission of measured data, and implementation of a closed loop power control. Fig. 2 depicts a molded interconnected device (MID) board assembly for the SMART implant system.

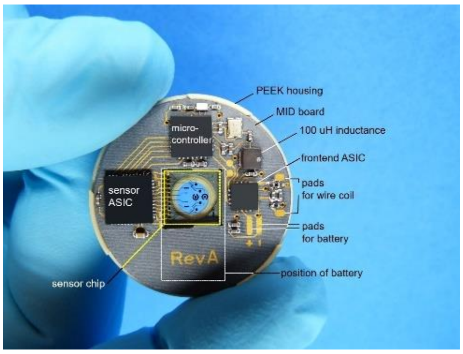

Fig.2 MID board assembly (Source: [48])

The board and battery are mechanically protected by a two-part rigid polyether-ether-ketone (PEEK) capsule, a chemically resistant building material. PEEK is coated with Parylene-C before being integrated into the capsule because alone is insufficient as a barrier to water vapor and thus moisture to protect the MID board and electronic components from moisture ingress. Because of its rechargeable battery, the implant can function independently.

3.2 SMART implants materials

Although the technology underlying SMART implants such as sensing, energy transfer, energy storage, wireless communication has evolved significantly over the years, a number of technical challenges remain to overcome before SMART implants can be used in routine health care. Implant failure mechanisms, infection, toxicity, muscle reattachment, oxidative or galvanic corrosion of metal implants, polymer degradation by hydrolysis or erosion, and other factors all have impact on the safety, design, and efficacy of implants used in fracture fixation [49].

Metals have unique and useful bulk surface areas and biological properties, including biocompatible loading and heat transfer. Due to the high mechanical stress and fracture toughness of iron, cobalt, nickel, and titanium, they were the first and are still widely used materials for implants [50, 51]. To obtain certain properties (elasticity, strength, corrosion resistance), metal alloys such as stainless steel, cobalt, titanium and magnesium alloys are also often used for implants [52, 53]. Stainless steel (chromium-nickel alloy) is the most common material among metallic implants (often used for fracture plates and hip screws) due to its low cost and ease of manufacture. The presence of chromium allows chromium III oxide (C_2O_3) to form a healing side effect [54]. It has high stiffness (10 times greater than bone) which can lead to bone resorption due to stress shielding. Stainless steel can stimulate an inflammatory response in which the oxide of stainless steel becomes conductive [55]. Cobalt-based alloys are superior to stainless steel in terms of strength, corrosion resistance and biocompatibility, but are more expensive to manufacture [56-58]. Titanium and titanium alloys exhibit low density, high biocompatibility, and an oxide layer to which bone progenitor cells can firmly attach [59-61]. Known for its common orthodontic wire and vascular stent applications, nickel-titanium (nitinol) has the lowest elastic modulus of any biocompatible metal and possesses bone-like biomechanical properties such as low elastic modulus and superelastic behavior. It may also offer the additional properties of shape memory, fatigue resistance, thermal deployment and MRI compatibility [62]. Titanium-based materials are very expensive, so they are only used in patients with hypersensitivity reactions to stainless steel or cobalt-based alloys. Magnesium is slightly less dense than bone and can function as an osteoconductive and biodegradable implant material in load-bearing applications. It is important to control the high corrosion rate to make it applicable for biomedical applications [53, 63, 64]. Table 2 summarizes the properties of metal materials used for implants.

Table 2 Characteristics of metal-based alloys

Authors	Alloys	Advantages	Disadvantages
Brogini et al. (2021) [57] Solanke et al. (2021) [58] Aherwar et al. (2016) [56] Williams (2008) [65]	Cobalt-based	Biocompatible; strength; corrosion resistance;	Expensive; difficult fabrication; implant loosening rate;
Findik (2020) [58] Shekhawat et al. (2021) [53] Lin et al. (2022) [64]	Magnesium-based	Osteoconductive and biodegradable material;	Fast degradation; less dense than bone – low mechanical strength;
Filip et al. (2022) [51] Shekhawat et al. (2021) [53] Wall et al. (2008) [54] Jacobs et al. (1998) [55]	Stainless steel	Low cost; easy to manufacture;	High stiffness; stimulate inflammatory response and allergic reactions; stress shielding effects;
Anene et al. (2021) [61] Xu et al. (2020) [60] Andani et al. (2014) [62] Thomas et al. (2012) [59] Williams (2008) [65]	Titanium-based	Corrosion resistance; low modulus of elasticity; biocompatible; bone-like mechanical properties; osteointegration;	Highly expensive; potentially toxic; bone resorption; causes allergic reactions;

The only metallic implant alloys currently proven to be long-term biocompatible are cobalt-chromium and titanium alloys. But there is no long-term benefit for any of these alloys. Bone adheres faster to titanium alloys than to cobalt-chromium alloys. The surface texture can enhance implant incorporation due to its roughness and porosity [65].

Over time, synthetic materials have evolved from biocompatible and biodegradable materials to today's bioactive materials, such as bone-like calcium phosphate. By manipulating the composition, polymeric compounds can simulate the structure of various tissues while maintaining their mechanical properties [66]. Among synthetic compounds, polyurethane stands out as one of the most versatile materials that can be used as orthopedic implants [67]. The increasing use of polymers is dictated by low production costs and high versatility. In orthopedics, the use of polymers is steadily increasing due to the unlimited possibilities to manipulate their biomechanical properties [68, 69]. First-generation polymer biomaterials include polyethylene (PE), polymethyl methacrylate (PMMA) and polyurethane (PU). The main advantages of using PE are low friction resistance, abrasion and impact resistance, and good biocompatibility [70, 71]. The advantages of PMMA are good tensile properties, tensile strength and good flexural rigidity. The disadvantages are the release of heat and methyl methacrylate monomer in the in-situ polymerization process [72, 73]. PU is a very versatile and inexpensive material that offers specific properties depending on the intended use of the implanted device. It can mimic bone biological structures and be made fully biocompatible and biodegradable [10, 51, 74].

Due to the increasing life expectancy of the population and the number of surgical procedures, it is expected that the implants will be very reliable and resistant to breakage. Bioceramics are biocompatible, very wear-resistant and have a high fracture toughness. They are divided into three types: bioinert, which do not interact with living tissue and are non-toxic (zirconia, alumina); biodegradable substances that are absorbed and dissolved by the body (calcium phosphate and hydroxyapatite); and bioactive, which can form bioactive glass [53]. Alumina-zirconia ceramic composites exhibit remarkable stability and mechanical properties but have high production costs [75]. Calcium phosphate coatings have been used in orthopedics for their resemblance to the mineral, the bone phase, and offer the advantage of significant biocompatibility and osseointegration with host tissue. Plasma-sprayed calcium phosphate coatings are not uniform and there is little control over the thickness and surface topography, which can lead to implant inflammation if particles are released from them [51, 76]. Table 3 summarizes research on the properties of non-metallic materials used for bone healing purposes.

Table 3 Characteristics of non-metal materials for SMART implants

Authors	Non-metallic	Advantages	Disadvantages
Polymers			
Jefferis (2021) [71] Boschetto et al. (2020) [70]	Polyethylene	Poor resistance to friction, abrasion or impact; biocompatibility;	Limited heat stability;
Allizond et al. (2022) [73] Shirvan et al. (2021) [67]	Polymethyl methacrylate	Good tensile strength and flexural rigidity;	Release of heat and methyl methacrylate monomer upon in-situ polymerization;
Fillip et al. (2022) [72] Ong et al. (2015) [10] Calvert et al. (2010) [74]	Polyurethane	Versatile; inexpensive; mimic the biological structure of bone; biocompatible; biodegradable;	Infections; premature failure;
Ceramics			
Fillip et al. (2022) [51] Piconi (2017) [75]	Bioinert (zirconia, alumina)	Do not interact with living tissue; non-toxic; Alumina-zirconia composites have high stability and mechanical properties;	High production costs;
Fillip et al. (2022) [51] Wang et al. (2011) [76]	Biodegradable (calcium phosphates, hidroxyapatite)	Absorbed and dissolved in the body; calcium phosphate similar to the mineral, shows high osteointegration with host tissues;	Implant inflammation;
Shekhwat et al. (2021) [53]	Bone-like calcium phosphate	Form bioactive glass;	Brittle; low fracture toughness; mechanical weakness;

The findings indicate that extensive research on non-metallic materials has been conducted in recent years. Polymers are of particular interest due to their biocompatibility, high tensile strength, low friction resistance, biodegradability, and other properties. Ceramic materials are also of interest because they are non-toxic, do not integrate with tissue, have high stability, and exhibit high osteointegration.

3.3 Strain sensors

Understanding how an object responds to different forces is required for real-time patient monitoring systems, which are commonly used to measure a variety of parameters such as skin conductance, temperature, heart rate, and blood pressure. The most well-known examples of medical sensors are electrocardiograms, electroencephalograms, accelerometers, blood pressure monitors, thermometers, and other types of sensors.

The main components of the sensor system are excitation control, amplifiers, converters, analog filters and compensation. The sensor can also be made an integral part of a computer. The actuators of the sensor nodes (pacemaker, insulin pump, various alarms) are placed inside the sensors to collect, process, store, transmit and use all received data before further action is taken [77, 78].

Strain sensors convert mechanical stimuli into electrical or optical signals and other responses to strain, i.e. the degree of material deformation caused by an applied force/moment (mechanical strain) or by thermal expansion (with temperature change) [79]. Mechanical strain is determined as the ratio of a changed length of material to its original, unaffected length and can be either positive (extension) or negative (contraction) depending on whether an object is tensioned or compressed.

Resistive and capacitive strain sensors are the most researched stretchable strain sensors used for bone healing, joint replacement, multifunctional prostheses [80, 81]. Capacitive strain sensors are made by sandwiching an insulating foil (dielectric layer) between two stretchable electrodes [82]. The capacitance of strain sensors increases independently of the resistance value of the electrodes when strained due to the geometric changes in the capacitive region. Metal foil-based resistive strain sensors have been used since the 1940s to detect small deformations in rigid bodies [83, 84]. Today, the structure of resistive strain sensors has changed from a brittle to a stretchable format. When stretching or compressing, the electrical resistance of the conductive network changes depending on the mechanical stress applied. Resistance variations arise from geometric changes, separation mechanisms, etc.

The strain gauge, with a sensor that measures changes in force, weight, or tension, is the most commonly used method of measuring strain in SMART orthopedic devices. The basic principle of electrical resistance in a strain gauge, which varies in direct proportion to the strain level, was described by Kelvin in 1856 [3]. The metallic strain gauge consists of a very small wire or, more commonly, metallic foil, arranged in a grid pattern that maximizes the amount of metal wire or foil subjected to strain in a parallel direction. The grid is bonded to a thin support (carrier) that is attached to the test specimen. As a result, the strain of the specimen is passed on the strain gauge, which reacts with a linear change in its electrical resistance (See Fig. 3) [85].

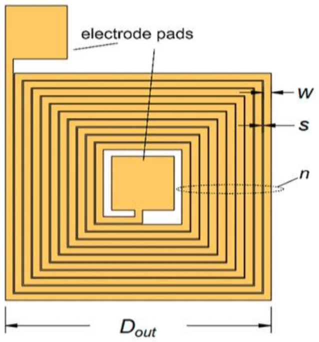

Fig. 3 A square spiral thin-film sensor (Source: [85])

D_{out}, S, W, and n represent diameter, turn width, spacing between turns, and number of turns, respectively. The metal layer used in manufacturing should be as thin as possible to achieve optimal sensor quality. In practice, strain measurements rarely involve magnitudes greater than a few millistrains (10^{-3}) [86]. For that reason, it is necessary to closely monitor small changes in resistance to determine the strain. This property helps measure subtle physical stimuli to improve fracture fixation during bone healing. The data set collected by the strain sensor is processed by an active device and can be analyzed by the orthopedist or surgeon who monitors the patient and optimally supports the healing process.

4. SMART ORTHOPEDIC FIXATION: TECHNICAL SOLUTIONS

In orthopedics, fracture healing is generally viewed as restoring biomechanical function, particularly for measures of alignment, strength, and stiffness. As a fracture heals, the fracture callus stiffens and the load to failure increases, with the two properties increasing proportionally in the early stages [13]. The time frame for healing depends on patient-specific factors, fracture patterns, treatment modalities, hardware loosening, or implant-associated infections [9]. Currently, most fracture healing techniques are subjective for the physician and only indirectly assess the healing stage [4]. The lack of quantitative measurements leads to a well-recognized need for objective measurements [9].

4.1 SMART orthopedic fixation devices

SMART fracture fixation devices can provide objective data to guide patient rehabilitation strategies at different stages of treatment, e.g. to determine when weight-bearing is acceptable to determine if a patient is progressing toward nonunion, to direct patients to the most effective weight-bearing exercises that can stimulate bone formation and diagnosis when a patient is adequately healed [4], [5], [6], [7]. Monitoring loads on a SMART fracture fixation device during weight-bearing is frequently used to indicate fracture consolidation and healing. While premature weight-bearing can increase the complication rate, unnecessarily delayed weight-bearing leads to indirect lost wage costs and additional burdens on the healthcare system. Strain sensor technology can aid in the intraoperative assessment and postoperative monitoring of orthopedic patients, and can help modify and improve implant design to achieve better patient outcomes.

4.1.1 SMART external orthopedic fixation devices

Mechanical frames of external fixation devices stabilize the bone and soft tissue remote from the surgical or injury site. They allow forfast positioning and dynamic adjustment of the mechanical flexibility of the implant during the healing process [25, 77]. In addition to mechanical frames, sensors and processing devices are fundamental components of SMART external fixation devices (See Fig. 4).

The sensor system collects environmental and physiological data. That can meaningfully interpret different sets of data from different sources, potentially affecting human health. An active device not only makes intelligent decisions but also controls actuators by those decisions. An external fixation device allows for axial micromotion at the fracture site that efficiently induces callus development, aiding in the gradual closure and healing of fractures while maintaining alignment of comminuted bone surfaces and bone length. Such a strategy is called dynamization [77]. It should be noted that complications such as pint-track infection, pin loosening, malunion, nonunion, etc. may occur during the application of the device to bone. According to [87], healing problems in lower extremity fractures still occur in 5–10% of cases and are associated with significantly poorer patient quality of life, higher morbidity, high health care expenditures and socioeconomic burden.

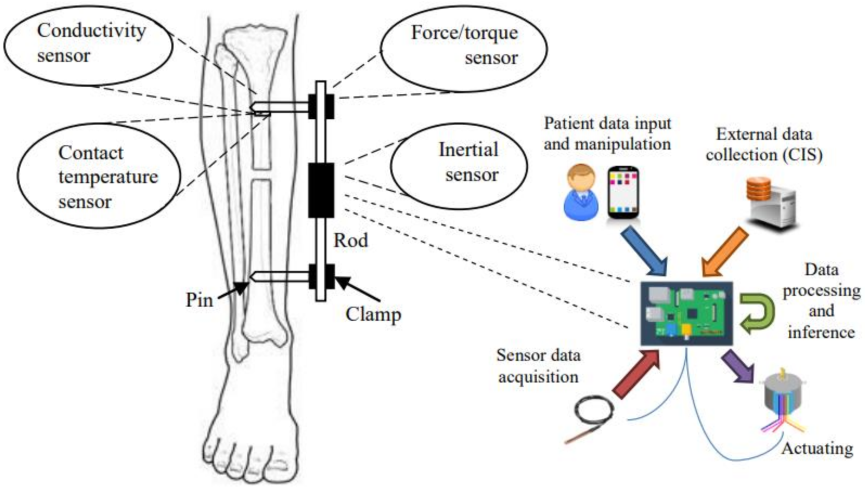

Fig. 4 Components of external fixation devices (Source: [77])

In addition, although magnetic resonance imaging (MRI), computed thermography (CT), X-rays, and other radiographic methods can monitor the problem and provide a better diagnosis, they have limited practical applications due to their high cost and radiation dose [88, 89]. Moreover, the MRI magnetic field has the power to heat up and violently displace ferromagnetic materials [90]. Misic et al. (2018) proposed an improvement in a fixation device design that incorporates aware, sensing, SMART, and active device paradigms that allow for real-time monitoring of bone fracture healing [91]. Their design is said to be an IoT gateway capable of classifying events and milestones in the patient’s recovery process based on data from various sensors and reporting them to specialists or connected healthcare information systems. The concept is demonstrated by classifying patients' compliance with prescribed behaviors in the postoperative treatment of bone fractures. In addition, external fixation devices are manufactured in specific sizes affecting patient comfort and recovery [92]. As a result, additive manufacturing can be used to manufacture custom medical implants, creating custom, lightweight, and efficient external fixation devices [21, 93-95]. Table 4 summarizes the findings of studies on external orthopedic fixation devices.

Studies also show that the successful use of an external fixator depends heavily on determining the best time for its removal. Premature removal of the fixator can result in bone refraction, requiring further surgery and a longer hospital stay. On the other hand, delaying the removal of the implant can affect bone metabolism, cause infections, and prolong treatment time [25, 96].

Table 4 A review of studies on external orthopedic fixation devices

Authors	Description
Zdravkovic et al. (2016) [77] Soriento et al. (2021) [25]	Positioning and dynamic adjustment of the implant mechanical flexibility.
Algahtani et al. (2021) [21] Parvizi and Kim (2010) [23] Friis (2017) [23] Sellei et al. (2015) [24]	Drawbacks (discomfort, delayed recovery time, infection).
Ekegren et al. (2018) [87]	Lower limb fracture complications.
Mišić et al. (2018) [91]	IoT gateway design.
Wu et al. (2020) [92] Murr (2020) [93] Salmi (2021) [94] Bikas (2016) [95] Alaghtani et al. (2021) [21] Mattei et al. (2017) [96] Sorriento et al. (2021) [25]	Selecting the time to remove external fixation device.

4.1.2 SMART internal orthopedic fixation devices

Internal fixations with bone plates have shown encouraging results compared to other surgical techniques [97]. In [64] the authors introduce SMART bone plates for fracture healing using microscale instrumented implants as a means of postoperative fracture monitoring and electrical impedance spectroscopy to track the healing tissue with great sensitivity. Electrical impedance is measured by recording the difference in length with two microelectrodes placed within the fracture gap. The results demonstrate the adaptability of electrical impedance spectroscopy to conventional fracture treatment methods. In [28] the authors describe the measurement of physical stimuli achieved through the application-specific technology of the implant. Fig. 5 presents the application in fracture fixation of long bone fracture affixed with the internal fixation devices.

Recent advances in wireless healthcare, microsensors and wireless charging have greatly enhanced the potential of orthopedic implants by integrating intelligent functions. However, other obstacles remain, such as the reliability of wireless communication links, downsizing, unobtrusive power supply, the ability to perform standalone operations without continuous monitoring, good measurement quality, affordability, low rate of associated complications, and so on [98]. Many of these prior-limitation have been addressed by new technologies, with advances in communications, data storage and digitalization opening the way for significant changes in orthopedic surgery and patient care [99-101].

Recent improvements have used secure data and communications networks and embedded physical sensors to enable sophisticated and large-scale data transmission [102]. These technologies have become increasingly centralized over the past two decades and are often served by mobile devices [78]. Traditional goniometry principles have been applied to mobile phone technologies to potentially increase precision and tests without the use of additional equipment. A summary of integrated orthopedic fixation device studies is given in Table 5.

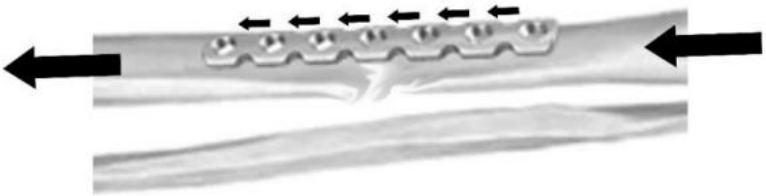

Fig. 5 Internal fixation of long bone (Source: [28])

Table 5 A review of studies on integrated orthopedic fixation devices

Authors	Description
Kareke and Nukala (2022) [98] Evans (2016) [99] Desai et al. (2011) [100]	Perform stand-alone operations without continual monitoring; good measuring quality; affordability; data storage. Obstacles: wireless communication link dependability, downsizing, unobtrusive powering,
Hima Padmaja and Sreenivasa (2013) [101]	Recent improvements: secure data and communications networks; embedded physical sensors to enable sophisticated and large-scale data transmission.
Shah et al. (2021) [102]	Mobile devices technology.

4.2 Data processing

Digital health is being explored for medical records, diagnostics and rehabilitation, the translation of wellness into healthcare, intraoperative monitoring, improvement in surgical technique, as well as some early-stage long-term monitoring projects with implantable devices. The Internet of Things (loT) is now being used to enable remote health monitoring and emergency notification systems [40-42]. Unfortunately, although sensors allow a variety of information from the environment to be accurately captured to record critical data, current sensor-based diagnostics and monitoring are nowhere near as mature as in the larger medical community when it comes to orthopedic trauma.

Indirect measurements of fracture stiffness are possible by monitoring the mechanical response of external fixation devices as the load is transferred from the fixator to the callus as the bone heals. Studies show quantified bone healing patterns by monitoring external fixator strain [19, 20]. In [25] the authors propose a low-cost and custom solution consisting of a 2D array of capacitive sensors that can detect both the relative translation and rotation of the external fixator pins as an index to determine bone healing status. Capacitive sensors are cheap and easily scalable to any irregular surface. In particular, the authors chose to record the displacement of the pins because of the advantage of being in direct contact with the bone fragments. When some movements occur at the bone level, they are directly transmitted outward through the pins.

In [25] and [29] the authors describe the telemetric solutions that transmit the data from inside the body and are based on electrical induction as the energy source. An induction coil positioned on the injured limb is required for data acquisition and transmission, which enables short-term measurement of implant deformations. In [31] the authors propose an alternative approach for long-term measurements of biomechanical parameters without an external power source. An implantable and autonomously working electronic unit was developed for the continuous recording of fracture movement. The system also includes a microprocessor for real-time processing of sensor data. In [8], the authors developed a miniature, wireless, telemetric, low power tirepressure sensor for measuring stress and deflection for future use in orthopedic applications. The capacitive transducer membrane is used and the transducer was subjected to compressive stress to determine the sensor signal value and internal resistance force. The sensor package is embedded in a deformable enclosure to illustrate possible applications of the sensor for load monitoring. In [39] the authors propose a design of a wireless and passive temperature sensor that can be embedded in an orthopedic implant. The sensor is based on an inductive-capacitive-resistive oscillating circuit that is fed inductively so that the temperature in the implant can be measured wirelessly. The sensor monitors internal wound temperature to diagnose local infection at the implantation site. Table 6 presents methods for sensor-based diagnostics for orthopedic trauma.

The findings suggest more research into internal sensors. The reason is that new technologies significantly aid in the development of embedded systems, which have compact long-lasting power sources and monitoring based on wireless sensors, data processing based on cloud and IoT. Another example of novel methods is medical applications for mobile phones. On the other hand, more recent research on external sensors is based on affordable, customized solutions that provide patients with greater comfort during the healing process.

4.3 SMART implants and strain sensors in lower limb fracture fixations

Tibial fractures are the most common long bone fracture (~one third of long bone fractures in adults) and the most common site of long bone nonunion [32], [103]. Patients with dislocations are more likely to experience additional (postoperative) complications such as infection or implant loosening during the recovery process [19]. They also require different types of hospital and surgical care during follow-up receive pain medication and seek outpatient physical therapy more often than patients with the right bony connection [104]. To avoid complications such as nonunion or malunion, refracture, and implant failure, physicians often limit weight-bearing for extended periods to allow for adequate bone growth [105]. External fixation systems extend beyond the skin of the fractured bone and are commonly required for comminuted fractures [106]. This makes them more susceptible to infection through contact with the outside world. Internal fixators are the more common and preferred option due to the lower risk of infection. Fixation systems support any loads applied to the limb that would normally be transmitted through the intact bone tissue while the fracture heals. The goal of the fixator is to provide increased stability that prevents micro movements within the fracture. The fixation implant must be designed to be stiff enough to provide support but flexible not to interfere with the bone union. Insertion of these implants typically requires extensive surgical procedures. Implant loosening, infection, and re-fracture from early weight bearing are common causes failure in these systems [107].

Table 6 Sensor-based diagnostic for orthopedic trauma

Authors	Fixator type	Description
Pelham et al. (2017) [19] Augat et al. (2014) [20]	External	Indirect measurement of fracture stiffness used as a measure of bone union and fracture healing. Measurements possible by monitoring the mechanical response of external fixation devices.
Sorriento et al. (2021) [25]	External	Low-cost customized solution consisting of 2D matrix of capacitive sensors. Detects relative translation and rotation of the external fixator pins as an index to determine bone healing status. Capacitive sensors are cheap and easily scalable to any irregular surface. The displacement record of the pins in direct contact with the bone fragments. The external fixator deforms when the bone is subjected to an external load. Deformation decreases as the stiffness of the bone callus increases.
Seide et al. (2012) [30] Wilson et al. (2009) [29]	Internal	Telemetric solutions that transmit the data from inside the body. Based on electric induction as the energy source. Induction coil positioned on the injured limb for data acquisition/transmission. Allow short-term measurement of implant deformations.
Windolf et al. (2014) [31]	Internal	Approach for long-term measurements of biomechanical parameters without an external power source. Implantable and autonomously working electronic unit for continuous recording of the fracture movement. Includes microprocessor for real-time data processing.
Anderson et al. (2022) [8]	Internal	Miniature, wireless, telemetric, low-power, tire-pressure sensor for measuring load and deformation. Capacitive transducer membrane used. Transducer subjected to the compression strain to determine the sensor signal and internal resistance force. Sensor package embedded within a deformable enclosure.
Karipott et al. (2017) [39]	Internal	Wireless, passive temperature sensor embedded in orthopedic implant. Sensor based on an inductive-capacitive-resistive oscillating circuit. Sensor monitors internal wound temperature to diagnose local infection at the implantation site.
Merle et al. (2022) [41] Cherid et al. (2020) [40] Dunn et al. (2018) [42]	Internal	IoT enables remote health monitoring and emergency notification systems. A variety of data captured. Problems of handling the large-size datasets.

Measuring stiffness (e.g., deflection or strain at a given load) is useful for tracking healing and risk of failure because it can be measured non-destructively. For long bone fractures repaired with external fixation (pins passed through the skin and connected to an external plate), fracture stiffness can be measured by applying a force across the bone and measuring the resulting pin deflection or plate deflection. Several clinical studies of external fixation devices found that compared to the standard clinical assessment, decisions based on mechanical stiffness dramatically reduced refracture rates while shortening the mean time to hardware removal [4, 13]. Vibration tests to evaluate the mechanical properties of the external and internal fixation systems to assess their resonant response are reported by [7, 10]. In [14, 15] the authors studied the deformation of frames during bone healing. The studies focused on evaluating the mechanical performance of the implant as a function of different frame configurations. Researchers have also proposed methods for non-invasively measuring strain on orthopedic devices using ultrasound [32], implanted magnetoelastic wireless electronic devices [33], and analysis of vibrations through bone [34]. In [108] the authors describe a fluidic X-ray visualized strain indicator under applied load. This sensor uses a liquid-level gauge with hydromechanical amplification and the results are visualized in simple X-ray images. Studies on the external fixation of long bones are presented in Table 7.

Instrumentation of sensor packages in orthopedic implants has long been a challenge due to package size requirements, the need for wireless telemetry, and low power consumption [12, 35]. Embedded sensors can be tasked with measuring load, strain, temperature, and acceleration, and monitoring implant wear and migration, tissue infection, bone fixation, and similarly. The main problem is that the sensor packages are too large to be built into smaller orthopedic components such as fracture fixation plates, which are not limited by the size of the sensor itself but by the size of the accompanying signal processing (functionalities related to microcontroller units), wireless telemetry (measurement and transmission of load, strain, displacement and similar) and aspects of power management (limited lifetime and size of internal battery sources) [8]. Most implantable electronic devices are powered by internal batteries whose lifespan limits long-term operation. Additional surgery intervention to change the battery is undesirable due to increased pain and risk to the patient. A sustainable energy source is therefore crucial for implantable devices. Piezoelectric materials are viable candidates for such implantable sensor systems as they can be used as self-powered, battery-free sensors with intrinsic mechano-electric energy harvesting capability [36].

Nagarajan (2014) has developed a novel strain sensor that is suitable for wireless monitoring of mechanical deformation in tension, compression or bending using high-frequency-based interrogation [37]. It is a multi-layer strain sensor that operates based on the relative deformations of metallic sensing elements with the potential for remote sensing and significant improvement in long-term performance. The technology differs from the rest with its wireless and passive structural integrity monitoring capabilities. In addition, it is inexpensive and efficient as it does not require a clear line of sight like most technologies do. This creates more accuracy and convenience in detecting tension, strain, compression and more [38]. An overview of research on internal fixation device technology is presented in Table 8.

Studies on both external and internal fixation devices reveal a lack of information from recent clinical studies. The studies on external fixation demonstrate technological advancement that enhance mechanical response and amplify visualization of the strain sensor. There are neither clear explanations of the experiments that were conducted nor data that are relevant to wider application of the suggested methodologies.

Table 7 External fixation of long bones

Authors	Description
Claes et al. (2009) [4] Richardson et al. (1992) [13]	Decisions based on mechanical stiffness reduces refracture rates and mean time to hardware removal
Ong et al. (2019) [10] Chiu et al. (2019) [7]	Vibration tests to evaluate the mechanical properties of the external and internal fixation systems to evaluate its resonant response.
Willie et al. (2009) [14] Un et al. (2007) [15]	Deformation of frames during the fracture healing. Mechanical performance of the implant as a function of different frame configurations.
Stoffel (2000) [32]	Non-invasively measuring strain on orthopedic devices using ultrasound.
Gattiker et al. (2008) [33]	Implanted magnetoelastic wireless electronic devices.
Melnikov (2010) [34]	Analysis of vibrations through bone.
Rajamanthrilage et al. (2021) [108]	Fluidic X-ray visualized strain indicator under applied load.
Seide et al. (2012) [30] Wilson et al. (2009) [29]	Telemetric solutions that transmit the data

Table 8 Internal fixation technology

Authors	Internal fixator technology
O'Connor, Kiourty (2017) [12] D'Lima et al. (2013) [35]	Embedded sensors tasked with: • measuring load, strain, temperature, and acceleration, • monitoring implant wear, implant migration, tissue infection.
Anderson et al. (2020) [8]	Large sensor packages to be built into smaller orthopedic components. Limitations: • sensor size • signal processing (microcontroller units), • wireless telemetry, • power management.
Sun et al. (2018) [36]	A sustainable power source for implantable devices. Piezoelectric materials for implantable sensor systems. Self-powered, battery-free sensors with intrinsic mechano-electric energy harvesting capability.
Umass Lowell (2014) [38]	Multi-layer strain sensor suitable for wireless monitoring of mechanical deformation using high frequencies. Based on the relative deformation of metallic sensing elements. Wireless and passive capabilities are used to monitor structural integrity. Inexpensive. Does not require a clear line of sight.
Windolf et al. (2014) [31]	Implanted monitoring device with an internal power supply. Monitored interfragmentary motion continuously and wirelessly.

The use of cutting-edge wireless telemetry and power management technologies, which are acknowledged as urgent for the continued development of implantable devices, is primarily related to research on internal strain sensors. However, it is also clear that there is a data gap. Clinical studies are typically only partially described, and there are no public datasets, which could serve as the foundation for experiments of a similar nature.

5. CHALLENGES AND FURTHER PERSPECTIVES

Power consumption, robustness, implant size and cost, wireless communication range, and data transfer rates have typically been barriers to the practical adoption of SMART implants in bone healing. For this reason, given the significant breakthroughs in wireless communication and implantable sensor technologies, it is reasonable to recommend the focus of future research to the clinical application of SMART implants and the integration of mobile platforms to enhance them. In recent years, SMART technology has been brought to the forefront of manufacturing by integrating the Internet of Things, artificial intelligence and cyber-physical systems [109]. It now focuses on customer requirements to meet the need for high-quality personalized instruments, implants and devices.

Long-term monitoring of implants and the (removable) embedded sensors that can go dormant until an anomaly is found will be made possible by future developments. Through wireless monitoring, cloud-based software could use abnormal sensors that show aseptic loosening of implants or a change in biochemical markers indicative of subclinical infection, allowing early detection of a complication and guiding appropriate treatment. A unique implant ID related to patient data may be used to generate long-term information for orthopedic implants. Sensor technology may also be extended to record implant survival rates.

In the future, intelligent implants will be able to keep track of how well a broken leg is healing and, if necessary, trigger specific movements of the implant to simulate healing at the fracture site. In order to stabilize the broken bone, the smart implants should also identify incorrect loads and provide details about how well the fracture is healed. The implant responds if a fracture does not heal properly.

Decision criteria and control in the medical field should target the surgeons and physicians by assisting them and providing suggestions modeled by the artificial intelligence tools with relevant benefit to the patient little-known diseases requiring suggestions or warnings of an automated system and could be a solid argument for a doctor. Numerous simple and routine procedures that time and are overwhelming for medical staff that could easily be carried out by a machine. In order to build intelligent tools that can recognize human functionality, the artificial intelligence field offers a variety of techniques, approaches and algorithms that call for intelligent behavior, i.e.an understanding of how humans think and behave.

6. CONCLUSIONS

SMART implants can be used for therapeutic and diagnostic purposes by integrating electrical sensors on the bone scaffold to track implant function to provide information about the internal environment that cannot be obtained in any other way. They can continuously monitor key intracorporal parameters, allowing for real-time therapeutic guidance. External SMART bone fixators stabilize the bone away from the surgical field, while internal SMART bone fixation devices incorporate bone plates to monitor fracture healing. External fixation devices allow for implant positioning and dynamic adjustment of mechanical flexibility. They also have disadvantages such as discomfort, delayed healing time, infections, and a large frame to handle. Internal fixators are advancements in the design of fixation devices that are commonly used in the treatment of fractured bones because they produce better results. Wireless technologies, microsensors, and innovation in computing have dramatically expanded the potential of these implants.

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