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Review Article

AN EVALUATION OF SMART IMPLANTS IN ORTHOPEDIC SURGERY THAT ENHANCE PATIENT OUTCOMES, BIHAR, INDIA: A NARRATIVE REVIEW.

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ABSTRACT

Background:
Smart implants, which provide real-time data for patient treatment and outcomes, could revolutionize healthcare. These devices are used in fracture fixation, spine fusion, and joint replacements. Smart implants have not been widely accepted in clinical practice due to the limitations of incorporating sensor technology into implant designs, despite decades of research and technological breakthroughs.

Objective:
This narrative review aims to provide an overview of the current state of smart implants in orthopedic surgery, highlighting their potential benefits, technological challenges, and the need for sensor technology advancements.

Summary:
Smart orthopedic implants have the capability to measure various physical parameters within the body, such as pressure, force, strain, displacement, proximity, and temperature, providing valuable data for patient care. These implants have led to advancements in implant design, surgical techniques, and postoperative care. However, their limited adoption in clinical practice is primarily attributed to the significant modifications required to incorporate the latest sensor technology. The review emphasizes the need for future smart implants to feature compact, robust, and cost-effective sensors that can seamlessly integrate into current implant designs. The rapid pace of technological development holds the promise of widespread adoption of smart implants, provided that these obstacles are overcome.

Implications for Future Research:
To fully realize the potential benefits of smart implants, future research should focus on developing sensor technologies that minimize the need for extensive modifications to existing implants. By making these sensors compact, robust, and affordable, smart implants can become an integral part of routine clinical practice.

Policy Development:
Healthcare officials and regulators should work with academics and manufacturers to develop smart implant guidelines and standards for safe and effective use, which might reduce healthcare costs and enhance patient outcomes. Further research can broaden smart implants' uses beyond orthopedic surgery, strengthening their position in modern medicine.

Keywords: Smart Implant, Knee, Force, Hip, Fracture
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INTRODUCTION

Smart implants are cutting-edge gadgets with therapeutic and diagnostic capabilities. They have the power to transform customized treatment, improve patient outcomes, and cut expenses [1]. As diagnostic instruments, they give distinct perspectives into the interior environment of the body, supplying accurate information to customize therapies, spot problems early, and direct care transitions. These implants enable real-time treatment adjustments by continuously monitoring vital bodily characteristics [2]. We can cut expenses by limiting problems, speeding up recovery, decreasing missed work following surgery, and lowering readmission and revision rates by incorporating smart implants into healthcare. The development of next-generation implants and surgical techniques has been fueled by research on smart implants, which has also enhanced our understanding of physiology, healing, implant-tissue interactions, and biomechanics.

Smart implant technology has advanced significantly, but before they are widely used in healthcare, there are still technical issues that need to be resolved [3]. These issues include sensing, power, energy storage, and wireless communication. The diagnostic technology in smart implant applications is carried by the implant itself. Particularly larger orthopedic implants provide plenty of room for combining sensors, electronics, and telemetry, which has resulted in creative advancements in this sector during the previous fifty years.

The key question identified for this review topic is: "What are the current advancements and challenges in smart implant technology, and how can these cutting-edge devices be seamlessly integrated into routine healthcare practices to improve patient outcomes and reduce healthcare expenses?" This question encompasses the need to assess the progress made in smart implant technology while addressing the technical challenges that still impede their widespread adoption in healthcare settings. Additionally, it highlights the potential benefits of incorporating smart implants, such as personalized treatment, early problem detection, and cost reduction, and underscores the importance of exploring ways to harness their full potential in healthcare.

METHODOLOGY

The literature search for this narrative review encompassed a broad range of years. This extended timeline was necessary to provide a comprehensive overview of the history and development of smart implants in orthopedic surgery. Multiple databases were utilized to conduct the literature search, ensuring a comprehensive collection of relevant sources. These databases may have included but were not limited to PubMed, IEEE Xplore, Google Scholar, and academic journals in the field of orthopedic surgery and biomedical engineering. The use of various databases contributed to the retrieval of a wide range of scholarly articles and sources related to smart implants in orthopedic surgery.

The review primarily focused on English-language literature, as indicated by the language used in the reviewed articles and references. While some studies and sources may have been published in languages other than English, the narrative review predominantly drew from English-language publications. The review included published articles, studies, and references that contributed to the understanding of smart implants in orthopedic surgery. Both peer-reviewed journal articles and relevant conference papers were considered, provided they contributed valuable insights into the topic. The review incorporated a variety of study designs, including experimental studies, clinical trials, observational studies, and technical reports. The inclusion of diverse study designs allowed for a comprehensive exploration of the subject matter, covering both technological advancements and clinical applications of smart implants.

TECHNOLOGY OVERVIEW

Strain gages, tiny foil arrays adhered to the implant's surface, are the basis for smart implants, which have been in use since the 1960s [1]. These gauges distort together with the implant, changing resistance in a way that indicates strain. This adjustment yields an output voltage after processing [4].

It can be difficult to shield strain gauges from biological fluids, but this problem is frequently resolved by altering the implant to provide room for the gauges and signal circuitry. After that, a lid is placed over the cavity and lead wires or an antenna are extended for data transmission.

Percutaneous lead wires were utilized in the early smart implants, however they had drawbacks such as infection risk and patient movement problems. Although not appropriate for therapeutic application, they are useful for research. While they addressed certain problems, second-generation smart implants were limited in size and battery life and relied on battery-operated telemetry transmitters [5]. In order to overcome these constraints, inductively powered smart implants that operate wirelessly and rely on electromagnetic energy transmission were created.

As technology developed, inductively powered systems became more dependable and compact, replacing their initial bulkiness. Strain gauges, power coils, antennas, signal conditioning circuits, and telemetry systems are frequently found in these systems. They are calibrated in a lab environment by external readers. The main physical parameters that smart orthopedic implants measure include pressure, force, strain, displacement, proximity, and temperature. Applications include spine fusion, hip and knee replacements, fracture fixation, and more.

APPLICATIONS IN THE KNEE

Total knee arthroplasty (TKA) is the preferred course of treatment for knee osteoarthritis when conservative measures are ineffective. In the USA, 3.48 million TKA treatments are anticipated to be performed by 2030 because to rising demand [6].

During total knee arthroplasty (TKA), metal pieces and high molecular weight polyethylene (UHMWPE) implants are used to replace certain knee components. Understanding knee biomechanics is essential for improving postoperative outcomes, and smart knee implants play a major part in this.

Knee forces are dynamic and dependent on a number of variables. Tibiofemoral joint forces have been measured using smart implants equipped with strain gauges, demonstrating the wide variations in forces experienced during different activities. Because of the patellofemoral joint's small size, sensor integration is difficult. A smart patellar implant was developed recently that may find application *in vivo*. Though largely used for research purposes, permanent smart knee implants have improved both implant design and surgical methods. Improved results and ligament balance have been attained by the use of trial implants for intraoperative assessments.

During surgery, real-time force data is provided via OrthoSensor's smart tibial trial components. Despite the fact that they cost about $500, the results are worth it [7]. All things considered, smart knee implants have enhanced patient care and deepened our understanding of knee biomechanics.

APPLICATIONS IN THE HIP

Hip osteoarthritis is a common condition for which total hip arthroplasty (THA) is the recommended treatment when conservative measures fail. It is projected that the primary THA demand in the United States will reach 572,000 operations by 2030 [6].

During total hip arthroplasty (THA), metal pieces and ceramic or ultra-high molecular weight polyethylene (UHMWPE) implants are used to replace certain hip components. For the purpose of bettering outcomes and comprehending hip biomechanics, smart hip implants are essential.

In 1966, the first smart THA was carried out, and nearly ten years later, wireless systems followed [8]. These systems used inductive or battery power, signal circuitry, and strain gauges. Their lifetime was constrained, though. With amazing accuracy, modern smart hip implants measure loads and bending moments. The titanium stem houses all the electronics, which are also used to measure force and temperature.

Different stresses are detected during different activities, such as running (4.3 x BW) and one-leg standing (3.6 × BW), according to data from smart hip implants. Hip forces can reach up to 2.6 × BW when climbing stairs, and they are approximately 1.0 × BW when in a double-leg stance. 18 MPa of pressure has been measured during dynamic exercises [9]. Walking forces are not considerably impacted by footwear selection. Crutches lessen hip forces, particularly in the first four weeks following surgery.

Additionally, data indicate that when walking, hip temperatures can rise above 43°C, with lower temperatures in joints that have ceramic cups. The prevalent issue of prosthesis loosening has led to the development of smart hip implants that can detect it. These implants detect loosening during simulations using telemetry and vibration-sensitive lock-in amplifiers.

Though their primary application has been in research, smart hip implants have addressed pertinent clinical issues, directed rehabilitation, and offered important insights on implant performance under load for future designs.

APPLICATIONS IN THE SPINE

Two of the main causes of disability in the world are neck and low back pain. Spinal fusion surgery is a common treatment after conservative measures are exhausted; in the United States, approximately 450,000 such procedures are carried out each year [10].

The purpose of spinal fusion surgery is to support the spine by fused adjacent vertebrae. Both biology and biomechanics are necessary for the success of spinal fusion, although spinal biomechanics is still not well understood.

Since 1966, researchers have studied spine biomechanics with smart implants. Harrington rods with strain gauges were employed in early systems to measure forces; in later systems, telemetry devices were attached to the rods. These systems had drawbacks but also offered information [11].

More sophisticated smart implants, such as parts for the hips and knees, that mimic signal electronics, telemetry systems in big fixators, and strain gauges. In the event of vomiting, 363 N while coughing, and 421 N during twisting and raising, posterior spinal fixators have recorded forces as high as 676 N. The stresses exerted on the spine varied depending on the activity.

Implants for interbody and corpectomy load sequentially with the spine. Strain gauges have been utilized in smart interbody implants, but because of their small size, they needed lead wires or external telemetry systems. Spinal forces are directly related to muscular contraction and can be greater than 4.7 times body weight (BW) [5]. These implants' mechanical characteristics affect fusion rates and load sharing.

Given that stresses vary during bone growth, smart implants may be useful in monitoring the course of fusion following spine fusion surgery. Correlating forces with the process of fusion shows promise, according to recent studies using interbody cages.

In general, data on spine biomechanics obtained from smart spine implants has been very helpful in guiding research and optimizing clinical care. Although they haven't been fully utilized, their ability to objectively diagnose fusion progression holds promise for customized patient therapy.

APPLICATIONS IN FRACTURE FIXATION

An implant is affixed to the bone above and below the fracture during surgical treatment of long bone fractures in order to stabilize and support the shattered pieces and promote healing. External fixators, intramedullary rods, and fracture plates are available for use in treating fractures.

Forces are transferred through the fixator and the bone when a bone is under load, such as the tibia when supporting weight on the lower limb. When a patient places weight on a fractured limb during the early stages of recovery, the fixator bears the full force of the weight instead of the shattered bone. Less force is transmitted through the fixator when the bone eventually gains the ability to support some weight as the fracture heals and a bony callus forms. As the fracture heals completely, the bone continues to bear more weight and the fixator bears less [12].

These loads during weight-bearing are monitored by smart fracture fixation devices, which act as an indicator of how effectively the fracture is consolidating and healing. The measured forces can offer useful, unbiased information to help direct rehabilitation at various treatment phases. For instance, they can assist in deciding when it's safe to permit weight-bearing, evaluate the patient's healing process, suggest beneficial weight-bearing exercises to encourage the production of new bone, and decide when the patient is well enough to resume regular activities.

For more than 40 years, smart fracture fixation devices have been utilized to learn more about the biomechanics of fracture healing. In order to measure stresses and bending moments, these devices—which can include strain gauges and telemetry systems—have been used with external fixators, femoral nail plates, big femur endoprostheses, fracture plates, and intramedullary rods.

Muscle activation is correlated with forces in the proximal femur, which can reach four times body weight. These findings indicate that muscle forces are important in loading fractures. Walking and elevating the pelvis from a supine position are two examples of activities that might cause bending moments in the proximal femur to exceed 20 Nm [13]. Walking and jumping can cause implant stresses to approach 3,000 N, while partial weight-bearing workouts can cause forces greater than 300 N to intramedullary rods in the femur. The distal femur may be subjected to stresses greater than 3.3 times body weight when jogging [14].

In clinical practice, stresses on fracture plates have been monitored using force data from smart implants to make sure they stay below the plate's mechanical endurance limit. In order to prevent implant failures, patients are recommended to minimize weight bearing on the wounded limb until the weights in the fracture plate are within safe bounds.

CHALLENGES AND EMERGING TECHNOLOGIES

Even after decades of development, smart implants are still not widely used in clinical settings. This is mostly due to the fact that there are still a number of issues and restrictions with smart implant technology that need to be resolved.

Power consumption, communication range, data transmission speeds, size, durability, and cost are a few major technical challenges. In an attempt to address issues with power consumption, research has been done on energy harvesting techniques and ultra-low power circuits. The goal of these techniques is to use sources like as rotations, deformations, and vibrations that occur when walking to produce energy inside the implant [15]. Nevertheless, the electronics cannot be sufficiently powered by the energy that has been captured thus far.

Smart implants have made use of List of abbreviations:

TKA- Total knee arthroplasty

UHMWPE- ultra-high molecular weight polyethylene

THA- total hip arthroplasty

BW- body weight

MEMS- microelectromechanical systems

(MEMS) based technologies to reduce the size of sensors and signal conditioning circuits. Materials frequently utilized in orthopedic implants as well as biocompatible materials can be employed to create these microscale components. Smaller sensors use less power, but because they function at higher frequencies, connecting with external electronics can present problems such tissue heating and signal attenuation.

The requirement to alter host implants to make room for sensors and circuitry has been one of the biggest obstacles to the practical implementation of smart implants. Implant performance may be impacted by the technically difficult, expensive, and potentially unstable process of creating chambers inside implants to house sophisticated electronics and strain gauges. Next-generation smart implants must have tiny, straightforward, durable, and reasonably priced sensors that require little to no alteration to current implant designs in order to be successfully used in clinical settings.

Recently, piezoresistive polymers have come to light as a potentially useful technique for intelligent orthopedic implants. These polymers are suited for use as force-sensing smart implants in applications such as knee, hip, and shoulder arthroplasty because they alter their electrical resistance in response to loads. As an alternative, force sensors embedded inside polyethylene inserts have also been produced [16].

Another method for creating smart implants is through passive resonator sensors. These sensors can be compact, straightforward, and made up of just a few parts. They also don't require power or signal conditioning electronics. When subjected to an RF field, they resonantly function, and the frequency at which they resonantly function signifies the sensor's condition. These sensors are capable of measuring target analytes as well as force, pressure, temperature, and pH. Their manufacturing costs are low, and with little alteration, they might be included into pre-made implants. Although this technology has demonstrated potential in in vitro experiments and simulated in vivo conditions, it has not yet been extensively utilized in real-world clinical settings.

CONCLUSION

Smart implants have been shown to be clinically useful, and there is great promise for the technology to improve patient care and facilitate individualized medicine. But as of now, the entrance obstacles have made using smart implants in routine clinical practice unfeasible. After fifty years of study, around one hundred individuals have received permanent smart orthopedic implants that are used in clinical settings. But with technology developing so quickly, the day when smart implants are widely used is almost here. The secret to integrating smart implants into routine clinical practice is new sensor technology that reduces the need to modify current implants.

LIMITATIONS

One of the primary limitations identified in the reviewed literature is the limited clinical implementation of smart implants despite decades of research. While the technology shows promise, most studies and applications have remained in the research and experimental phase, with relatively few permanent smart orthopedic implants used in clinical practice. The research acknowledges that several technical challenges still exist, including issues related to power consumption, communication range, data transmission speeds, size, durability, and cost. These challenges have hindered the widespread adoption of smart implants in routine clinical settings.

NEED FOR FUTURE RESEARCH

Future research should prioritize the development of compact, robust, and cost-effective sensor technologies that require minimal alterations to existing implant designs, enhancing their feasibility for clinical use. Additionally, collaboration among healthcare officials, regulators, academics, and manufacturers is crucial to establish guidelines and standards for safe smart implant utilization, potentially reducing healthcare costs and improving patient outcomes. Furthermore, research should explore expanding the applications of smart implants beyond orthopedic surgery, investigating their adaptability in diverse healthcare scenarios to maximize their impact on modern medicine.

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LIST OF ABBREVIATIONS

TKA- Total Knee Arthroplasty
UHMWPE- Ultra-High Molecular Weight Polyethylene
THA- Total Hip Arthroplasty
BW- Body Weight
MEMS- Microelectromechanical Systems

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CONFLICT OF INTEREST:

The authors have no competing interests to declare.

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