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Wireless Sensors for Smart Orthopedic Implants

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Abstract Orthopedic implants are medical devices which are surgically implanted inside the human body and widely used for replacing missing joints and bones or restoring function of a damaged structure. Examples include orthopedic implants for joint replacement (hip, elbow, knee, shoulder, etc.), implants that treat fractures (ulna, femur, etc.), and implants for fixation of the spine. Recent advances in wireless sensors and medical telemetry are promising new and hitherto unexplored opportunities in orthopedic implants. This implies miniature unobtrusive sensors that are implanted along with the orthopedic device and used to wirelessly communicate information to exterior monitoring/control equipment. This information may be related to the status of the medical device itself and/or the health status of the surrounding biological tissues. This paper provides a review of orthopedic implants with wireless communication capabilities. Example applications reported to date are discussed, along with challenges raised (biocompatibility, wireless interface, and powering), and future directions.

Keywords Biotelemetry · Orthopedic implants · Sensors · Wireless

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1 Introduction

Orthopedic implants are medical devices which are surgically placed inside the human body to replace missing joints and bones, or to restore function of a damaged structure. In terms of design and geometry, orthopedic implants can be as simple as screws and plates or more complex like telescopic devices that slowly increase in length to enforce and monitor bone growth. As such, applications of orthopedic implants are numerous and range from joint replacements (hip, elbow, knee, shoulder, etc.) to implants that treat fractures (ulna, femur, etc.) or implants for fixation of the spine. The market of orthopedic implants is one of the biggest in the medical arena, and it is expected to expand significantly in the future as a result of the continuously growing elderly population. In fact, a recent 'market research' study estimated the market value of orthopedic implants will increase from 29.2 billion USD in 2012 to 41.2 billion USD in 2019 [1]. As an example, total knee replacement (or arthroplasty) is currently considered a common medical operation, with over 600,000 cases per year in the USA alone [2].

Survival of the orthopedic implant and its impact on the surrounding biological tissues depend on several parameters, including the employed implant materials, surgical technique, implant geometry, physical activity of the patient, and age of the patient. Despite the increasing demand for orthopedic implants, their life cycle does not typically exceed 10–15 years [3]. Potential causes of failure include wear, loosening, and misalignment. With this in mind, the ability to unobtrusively monitor the implant's performance in real time could offer unprecedented capabilities in detecting early failures and eventually offering a much better quality of life for individuals with orthopedic implants.

As would be expected, wired solutions that connect implanted sensors to exterior equipment via tethered connections are highly problematic. Specifically, transcutaneous wires may cause infections and severely limit the individual's mobility. Therefore, the focus of this paper is on wireless sensors that are placed alongside the orthopedic implant during surgery and used to wirelessly transmit information to exterior monitoring/control equipment. This information may be related to the status of the medical device itself and/or the health status of the surrounding biological tissues.

In this paper, we provide a review of orthopedic implants with wireless communication capabilities. Section 2 will discuss example applications reported to date, including: (a) detection of loosening for hip implants, (b) force measurements in knee implants, (c) assessment of bone healing, (d) wireless correction of orthopedic structural deformities, (e) temperature measurements for hip implants, (f) measurement of contact forces and moments in the shoulder joint, (g) diagnosis of orthopedic implant failures, (h) spinal fusion monitoring, and (i) investigation of tribocorrosion of metallic implant materials. Section 3 will address two of the major challenges raised in designing wireless sensors for orthopedic implants, i.e., (a) biocompatibility, (b) wireless interface, and (c) powering. Section 4 will discuss future directions in the area of wireless sensors for orthopedic implants.

2 Applications of Orthopedic Implants with Wireless Biotelemetry Functionality

Several applications have already been reported in the literature for smart orthopedic implants integrated with wireless sensors. Some of the most promising applications are briefly outlined below.

2.1 Detection of Loosening for Hip Implants

The most common cause of hip disability and/or chronic hip pain is arthritis. For example, hip osteoarthritis implies the degeneration and finally the destruction of the cartilage in the hip joint. This leads to a complete failure of the hip joint [3]. In a total hip replacement surgery, also known as total hip arthroplasty, the damaged bone and cartilage are removed and replaced with prosthetic components. The latter entail metal, plastic and/or ceramic stems, balls, sockets, and spacers. Unfortunately, 5–10 years after total hip replacement, loosening of the stem tends to occur [3]. This is typically due to wear of the orthopedic implant surfaces over the years, which, in turn, weakens the surrounding bone. To date, symptoms of orthopedic implant loosening are not obvious to the patient or his medical provider. As a result, loosening is not detected until the very late stages when the hip implant has failed or is about to fail. To improve the patient's quality of life and reduce the chance of any medical complications, it is highly desired to achieve early, accurate, and unobtrusive diagnosis of hip implant loosening.

In [4], the concept of vibrometry was employed to unobtrusively detect hip implant loosening. The method was based on measuring the resonance frequency and dampening. Specifically, it indicated that an anchored hip implant exhibited linear acoustic behavior, while a loosened hip implant exhibited nonlinear acoustic behavior. In another study [5], a blood flow ultrasound probe was employed to detect vibrations of well-fixed versus loosened hip implants (see Fig. 1). A more recent technique used to detect loosening of hip implants employed mechanical magnetic sensors, i.e., 'oscillators' [6]. These oscillators were placed in the femoral stem and were excited by a coil that was placed outside the human body. When excited, these oscillators oscillate at a speed that is strongly dependent upon the anchorage of the hip implant. This speed was, in turn, detected by another external coil and post-processed to derive loosening-related parameters.

2.2 Force Measurements in Knee Implants

The most common cause of knee disability and/or chronic hip pain is arthritis, particularly osteoarthritis, rheumatoid arthritis, and post-traumatic arthritis. For example, obesity and extreme physical activity combined with age factors contribute to the appearance of knee osteoarthritis [7]. Total knee replacement, or total knee arthroplasty, is one of the most common surgeries in the field of orthopedic implants. Also known as 'resurfacing,' total knee replacement basically entails replacement of only the surface of

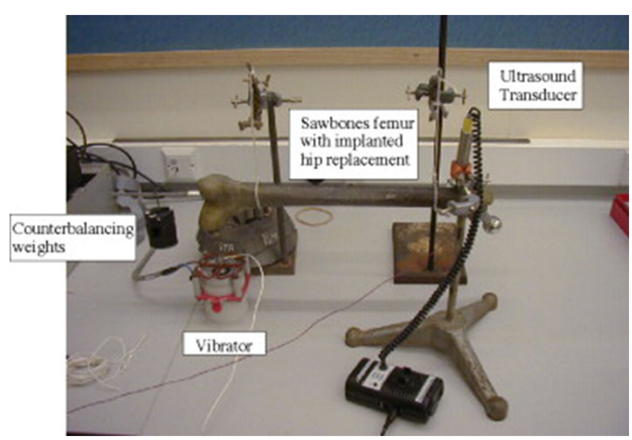

Fig. 1 Measurement setup used in [5] to detect loosening of hip implants

the bones. Specifically, the damaged cartilage surfaces at the ends of the femur and tibia are removed and replaced with metal components that recreate the surface of the joint. Concurrently, in some cases, the kneecap is cut and resurfaced with a plastic button. A plastic spacer is finally inserted between the metal components to create a smooth gliding surface. A major challenge during total knee replacement relates to balancing the forces of the surrounding soft tissues and eventually equilibrating the tension in the collateral ligaments. To date, the latter depends on the experience of the surgeon, and there is no way to precisely know the forces in the knee implant during or after surgery [7].

With this in mind, authors in [7] realized an instrumented insert for real-time force measurements in knee implants. As shown in Fig. 2, the insert included wireless piezoresistive strain sensors and was tested in a mechanical knee simulator that mimicked in vivo conditions. Specifically, two force sensing gauges were integrated in each condyle compartment of total condylar prosthesis. Results showed that the sensors were able to measure forces up to 1.5 times the body weight with adequate sensitivity. Importantly, dynamic testing indicated that the sensors could easily track changes in forces regardless of how quickly or slowly they occur.

2.3 Bone Healing Assessment

The current practice for monitoring bone healing entails a series of sequential radiographs and/or computed tomography (CT) scans. Unfortunately, comparison among various radiographs or CT scans is highly subjective. In other words, to date, there is no objective measure of quantifying and eventually assessing bone healing. Also, parameters related to the mechanical properties and performance of the bone structure cannot be derived via the aforementioned imaging techniques.

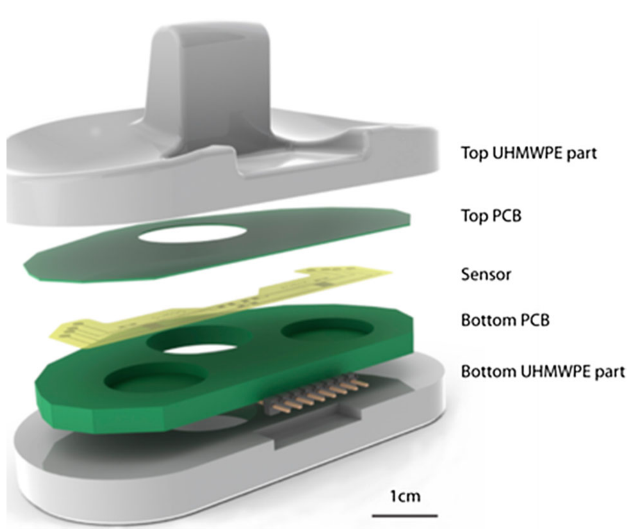

Fig. 2 Components of the instrumented prosthetics developed in [7]

To address this concern, authors in [8] proposed the integration of load measuring electronics into orthopedic implants as a promising option for assessing bone healing. Specifically, the study demonstrated a wireless telemetry system that was used to measure the bending load in a titanium internal femoral fixator. The key components of the implanted sensing system were the strain gauges that were designed to be highly sensitive to bending of the plate. A set of implanted and external coils was used for wireless energy and data transmission, and an implanted microprocessor was employed for data collection and processing. A dedicated external reader system was finally connected to a notebook PC.

2.4 Wireless Correction of Orthopedic Structural Deformities

Correction of structural deformities in orthopedics has seen many applications and advances over the past several years. One of the most well-known applications relates to limb lengthening. To date, the traditional way of enabling limb lengthening entails external fixation. Though successful in several medical cases, external fixation comes along with several drawbacks, including high risk of infection, mechanical failure, and reduced quality of life for individuals. The latter is attributed to the presence of external braces/rods and the requirement for repetitive surgeries needed to tune the fixation.

A wireless alternative to obtrusive external fixations for limb lengthening was presented in [9]. The proposed technology employed an implantable actuator and an exterior driver circuit that were designed to wirelessly communicate with each other using magnetic coupling. The implanted electronics could monitor: (a) the progress of the implanted telescoping rod, (b) the force applied by the implanted telescoping rod, and (c) potential procedural errors, such as magnetic decoupling between the implanted and exterior device. The system was shown to reliably deliver extension distances within 34 μm and maintain coupling out to 70 mm. The system was also able to measure torques as low as 0.12 mN m.

2.5 Wireless Temperature Measurements in Hip Implants

Temperature increase in the biological tissues surrounding the hip implant may cause increased polyethylene wear, decreased polyethylene strength, or loosening of the cup. Such an increase in temperature may be caused by intensive activities (walking long distances, exercising, etc.)

which, in turn, cause friction to the hip implant. The ability to monitor the temperature levels around a hip implant in real time could provide critical information related to the selection of implant materials and identification of patients who are at risk of implant loosening, implant failure, thermally induced bone necrosis, etc.

A proof-of-concept prototype for wirelessly measuring the temperature in hip implants was presented in [10] (see Fig. 3). The study demonstrated an instrumented hip implant in which a titanium hip endoprosthesis was modified to house wireless electronics inside its hollow neck. Specifically, a temperature sensor was placed inside the implant and used to trigger a timer circuit. The latter produced an inductive pulse train with temperature-dependent intervals which was eventually detected by a magneto-resistive sensor on the exterior side. Powering was performed via magnetic coupling between an external and implanted coil pair at 4 kHz. Overall, the implant temperature was measured with an accuracy of 0.1 µC in a range between 20 and 58 µC and at a sampling rate of 2–10 Hz.

2.6 Measurement of Contact Forces and Moments in the Shoulder Joint

The ability to measure the contact forces and contact moments in shoulder prosthesis may offer several advantages. Examples include providing guidance in implant design and fixation, giving indications to patients to avoid overloading the prosthesis, improving the physiotherapy process, and helping standardize mechanical tests for new implant devices.

Along these lines, authors in [11] developed an instrumented shoulder joint implant that was capable of measuring the contact forces and contact moments acting in the glenohumeral joint (see Fig. 4). The instrumented implant was based on a clinically tested BIOMET Biomodular

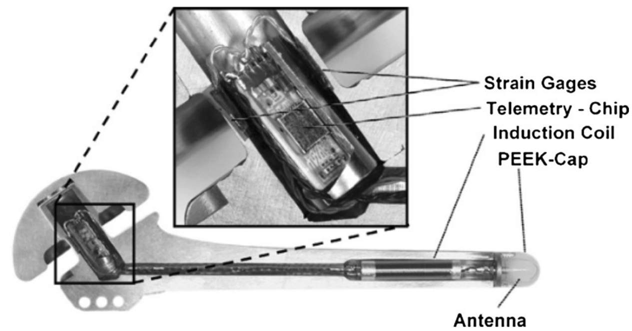

Fig. 4 Instrumented shoulder implant in [11]

shoulder replacement. The implanted electronics included six load sensors (strain gages), a nine-channel wireless telemetry unit, and an inductive power supply. An average measuring precision of approximately 2% was demonstrated.

2.7 Diagnosing Orthopedic Implant Failures

Authors in [12] demonstrated an implanted magneto-elastic microsensor for diagnosing failing orthopedic implants. The reported microsensor employed a MetGlas-2826 film, 30 µm in thickness, along with a sensing coil that was placed 30 mm away from the film. The sensor's magneto-elastic response strongly depends on the implant loading and is detected as voltage by the coil. Therefore, by post-processing the collected magneto-elastic response, one can derive critical conclusion as to the health status of the orthopedic implant. To do so, filtering was performed to de-noise the data, and a decision-making module was employed for final data assessment. The sensor was successfully validated in vitro on an external fixation system and a hip prosthesis implant, respectively.

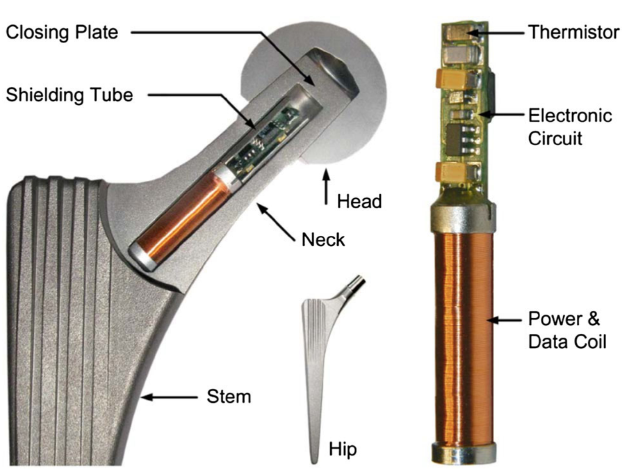

Fig. 3 Cross section of the modified hip implant presented in [10]

Fig. 5 Spinal fusion fixation instrumentation reported in [13]

2.8 Spinal Fusion Monitoring

Strain sensors for use in spinal fusion monitoring were reported in [13] (see Fig. 5). The strain sensors were microelectromechanical system (MEMS) capacitive-based pure bending sensors, and exhibited a cantilever structure consisting of two parallel plates with a narrow gap and a conjoint end. Wireless communication was made feasible via a wireless and batteryless telemetry system. All implanted electronics, including the sensors and telemetry unit, were eventually attached to spinal fusion rods. Experimental results demonstrated nine permutations of the design with different metal coverage areas (14, 9.3 and 4.7 mm^2) and gaps (3, 6 and 7.4 µm). The nominal capacitances ranged from 7.6 to 42 pF. Simulation versus experimental results showed an average difference of 5% for all nine designs explored.

2.9 Investigation of Tribocorrosion of Metallic Implant Materials

The science of tribocorrosion can be defined as a degradation process of the surface of materials resulting from the combined action of mechanical wear and chemical/electrochemical reactions [14]. To date, there are no wireless sensors reported for unobtrusively monitoring the tribocorrosion levels in live tissue in real time. However, there are several sensors reported for assessing tribocorrosion in in vitro environments. For example, the study in [15] reported an apparatus that employs an electrochemical cell for controlling the surface chemistry of the metal in contact and for studying the role of anodic oxidation. A computer-based data acquisition system was used to capture the most relevant mechanical and electrochemical parameters. In another case [16], a Modular Universal Surface Tester was employed to provide fretting motion and to control the normal load applied upon two alloys, and in situ electrochemical measurements were conducted including open-circuit potential and potentiostatic current measurements. Given the current state of the art, usage of wireless sensors to monitor tribocorrosion effects in vivo is anticipated to have a great impact in the area of medical implants.

3 Challenges Related to Wireless Sensors for Smart Orthopedic Implants

Design of wireless sensors for orthopedic implants is associated with several challenges. Some of these challenges are shared by the designers of orthopedic implants, while others are specific to implanted sensor design. Three of the most critical challenges entail biocompatibility, wireless interface design, and powering. These challenges are discussed in detail in the following.

3.1 Biocompatibility

As is well known [17], materials for orthopedic implants range from metals [CoCrMo alloys, titanium (Ti) and its alloys, and stainless steel], ceramics (alumina, zirconia, titania, and hydroxyapatite), ultrahigh molecular weight polymers [polyethylene, polyurethane, and poly-lactic-co-glycolic acid (PLGA)], titanium oxides, to biologically synthesized substances (such as mineralized complexes of collagens, calcium, and phosphate). Similar biocompatible and tissue-friendly materials need to be used for the integrated smart sensors as well. Insulating the implants with a thin layer of low-loss biocompatible coating is another reported approach. Example materials proposed for biocompatible encapsulation include zirconia, PEEK, and Silastic MDX-4210 Biomedical-Grade Base Elastomer. Even with this encapsulation, the body eventually wraps devices in a fibrous cocoon and pushes them out. As such, design of long-term biomedical implants is an area of very high scientific significance.

3.2 Wireless Interface

In the literature, several ways of realizing the wireless interface between a wireless sensor implanted next to an orthopedic prosthesis and the exterior monitoring/control unit have been reported.

- *Inductive Coupling* Inductive coupling has traditionally been one of the most popular methods of enabling wireless communication for implanted sensors [18]. In this case, a coil implanted inside the human body communicates with a coil placed right outside the human body via magnetic coupling. Though unobtrusive and widely used, this approach is highly sensitive to the distance and alignment between the two coils.
- *Wireless Antennas* To address the aforementioned concerns related to inductive coupling, wireless antenna transmission/reception has been reported for implanted sensors communicating with an external monitoring/control unit. Compared to inductive coupling, antenna communication is less sensitive to distance and misalignment considerations. Nevertheless, design of implantable antennas is associated with several challenges related to miniaturization, frequency selection, biocompatibility, patient safety, communication performance, operation inside a lossy biological tissue environment, etc. Such challenges have been extensively addressed in [19–21]. Nevertheless, it is worth noting that antenna design for orthopedic implants

brings forward some application-specific considerations: (a) permittivity of the bone is much lower than that of other biological tissues, implying that miniaturization of the antenna design turns out to be more demanding; (b) size of the orthopedic implants is relatively large and, if conformal, the antenna may occupy such size. In fact, antennas that are specifically designed for smart orthopedic implants have been reported in [22] and [23]. For example, in [22], a slotted waveguide antenna was proposed for bone fixation at 20 GHz. The antenna was conformal to the body of the Echidna Pin and used the pin as a waveguide. In [23], a flexible loop antenna was proposed for integration into cylindrical bone implants and operation in the MedRadio (401–406 MHz) and ISM (433–434.8 MHz) bands.

- *Ultrasound Communication* Ultrasound communication between implanted sensors and exterior equipment has also been reported. For example, authors in [24] proposed a load-monitoring concept in which a passive load sensor communicated with an external ultrasound-based unit. The measurement principle was based on modifying an external force into a varying amount of fluid in a microchannel integrated into the sensor. To determine the amount of fluid in the microchannel, an ultrasound read-out method was proposed that was based on an integral evaluation of C scans of the microchannel. In addition, reference reflectors inside the sensor were used to calibrate the ultrasound echoes.

3.3 Powering

Power requirements of wireless sensors for smart orthopedic implants may vary from a few microwatts to a few milliwatts. As would be expected, powering these sensors in an unobtrusive and reliable manner is of utmost significance. In the literature, a number of ways have been reported for powering implanted sensors, the most well known of which are summarized below.

- *Batteries* Batteries are one of the most reliable forms of powering for wireless implants. Nevertheless, long battery life comes along with increased size, which is highly undesirable. Also, batteries require frequent replacement which, in turn, implies multiple invasive surgical operations. As an alternative, batteries can be recharged using wireless powering schemes. These will be discussed next.
- *Inductive Coupling Using Two Coils* Power transfer via inductive coupling [25, 26] requires two coils: (a) one that is implanted inside the human body and (b) one that is placed right outside the human body. Similar to the case of inductive coupling for data transfer, power transfer efficiency in this case strongly depends on the coupling between the two coils as well as their quality factor. In other words, power transfer efficiency depends on numerous parameters, including the coil geometry (size, structure, etc.), distance between the coils, alignment between the coils, and properties of the environment that surrounds the coils. For example, when the coils are slightly misaligned, efficiency may significantly decrease. Providing high power at low efficiency requires the existence of strong alternating magnetic fields. This is highly undesirable in the case of implanted sensors as it may increase the temperature in the surrounding tissues and violate patient safety requirements imposed by national and international regulations.
- *Resonant-Based Power Delivery Using Four Coils* To address low efficiencies that are typically associated with inductive coupling, the resonant-based power delivery has recently been reported. This technique typically employs four coils, namely the driver, primary, secondary, and load coils. Such a four-coil system can be optimized to provide maximum efficiency at a given operating distance. Compared to its two-coil counterpart, efficiency in this case is less sensitive to changes in inter-coil distance. A proof-of-concept prototype system was reported in [27]. In this example, a wireless power link at 700 kHz was considered. Power transfer efficiency using resonant-based power delivery was shown to be higher than 80%. For comparison, power transfer efficiency using the traditional two-coil coupling technique was approximately 40%.
- *Power Harvesting* Power harvesting entails capturing power acquired from external sources (e.g., radio frequency, motion, thermal, etc.) and using that power to turn 'on' low-power electronics, such as implanted sensors. Authors in [28] extensively discussed RF power harvesting. Importantly, they demonstrated a thermometer that turned 'on' simply by harvesting RF power that was readily available in the surrounding environment. In another case [29], authors demonstrated piezoelectric materials used to convert human motion into electrical energy. Specifically, zirconate titanate (PZT) and its power generation capabilities were explored. Application of these PZT elements in powering wireless sensors for total knee replacement implants was also discussed.

4 Future Directions

Extensive research is currently being carried out in the area of smart wireless sensors for orthopedic implants. The utmost goal is smart, miniaturized, biocompatible, and unobtrusive wireless sensors to realize intelligent implants. In doing so, new and hitherto unexplored opportunities are opening up in the field of orthopedics, promising a much higher quality of life for individuals.

Example applications that are currently being investigated for wireless sensors in orthopedic implants include: developing novel diagnostics of hip implant loosening, monitoring the load applied during physiotherapy to avoid harming the implant or the surrounding biological tissues, finding safe alternatives to existing imaging techniques that often require exposure to ionizing radiation, developing closed-loop systems that generate alarm signals when a failure is detected, coupling on-demand drug delivery capabilities to the implant, sensing bone formation, etc. Currently, several challenges still remain to be resolved, including: reliability of the wireless communication link, miniaturization, unobtrusive powering, 'reliability' and eventually the ability to achieve stand-alone operation without requiring constant supervision by a medical provider, good measuring accuracy, low-cost, low rates of implant failures, animal testing, etc.

5 Conclusion

Orthopedic implants are rising as one of the most commonly performed surgeries in the area of orthopedics. Recent advances in wireless health care, miniaturized sensors, and wireless powering are promising to significantly uplift the capabilities of orthopedic implants by integrating all sorts of smart functionalities. The utmost goal is a much better quality of life for individuals with orthopedic implants. This paper presented a review of the current status in the field, discussing existing applications and challenges, and providing directions for future research.

Compliance with ethical standards

Conflict of interest On behalf of all authors, the corresponding author states that there is no conflict of interest.

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