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Review on Monitoring the Flexibility of Orthopeadic Implants

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ABSTRACT - Bone is a unique tissue that is capable of repairing itself after damage. However, there are certain instances of fractures and defects that require clinical intervention for proper alignment and healing. As with any implant, careful consideration of the material used to create the implants to treat these problems is needed. If the incorrect material is chosen, the implants themselves can lead to bone fractures or defects, or bone healing may not take place at all. All three classes of biomaterials–metals, ceramics, and polymers–have been used in the treatment of both bone fractures and bone defects, and each has its own unique benefits and limitations for its applications. Furthermore, composites of these different materials have also been created to try to take advantage of all the different benefits offered by each different material. This review highlights different materials that have been used for the development of internal fixators and bone graft substitutes to treat fracture and bone defects as well as their limitations and needed future research

Key Words: Bone scaffold, Bone fracture, Bone defect, Orthopedic implant, Orthopedic device

I. INTRODUCTION

Over the past decades, internal fixation of bone fractures has evolved into a well managed procedure and has transformed the incident of a skeletal fracture from a disabling and sometimes life-threatening event into an, for most of the cases, inconvenient but manageable episode. Still, significant rates of severe complications related to internal fixations persist, including hardware failures and non- and delayed-unions of 5–10% [1]. The risk factors for healing disturbances are many fold, including open fractures, impaired blood supply, infections, diabetes, smoking, alcohol abuse and inadequate fixation stability, to name the most important [2,3]. Emphasis for improvements to prevent complications has been put mainly on surgical procedures and implant development.

This is surprising, since after-treatment builds an essential pillar of the patient journey, potentially determining its success. Advances in aftercare and rehabilitation lack behind and follow decades-old protocols based on generalized beliefs and conventions. Individualized and evidence-based rehabilitation, particularly in the early healing phase, [1] may prevent complications in the first place through patient-tailored physiotherapy and mobilization or [2] may enable early diagnosis of complications for taking timely counteractions. These include adapting physiotherapy or applying therapeutic noninvasive (e.g., shock wave or ultrasound therapies) or invasive treatments. The timely detection of healing disturbances is regarded as essential puzzle piece for fast recovery. The FDA defines a nonunion as a fracture that remains un united after 9 months [2]. This convention is, however, under debate within the medical community towards shortening the period to 6 months [4]. Regardless, the approach creates unproductive waiting time for the patient and obviously forms a social-economic burden [1].

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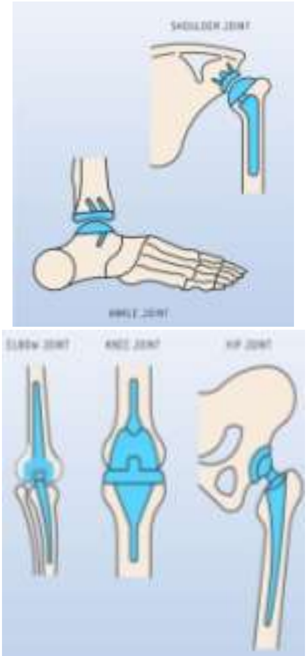

Fig. 1: Orthopedic joints

The aim of this study was to systematically investigate the device safety and performance in a large animal experiment to provide evidence for interpret ability of the sensor output with regards to the bone healing status on the path to clinical introduction.

II. LITERATURE REVIEW

[5] The clinical application of smart implants has been conclusively tested, and the potential of the technology to have an effect on clinical care and allow personalized medication is huge. but, so far, the barriers to entry have made using smart implants in daily clinical practice prohibitive. In five decades of studies, the whole wide variety of permanent clever orthopedic implants applied clinically in all applications is ~a hundred patients. but, with rapidly advancing technology, the huge implementation of smart implants is close to. New sensor technology that minimizes modifications to current implants is the important thing to allowing smart implants into day by day clinical exercise .

[6] A simple and low-cost fiber-optic curvature sensor based on intensity modulation together with its application in the human joint angle monitoring is presented. The proposed sensor is suitable for the medical and sports applications, and it is wearable, non-invasive, nonintrusive and completely harmless. Here conclude that SMS based frame work will reduce the time delay in collection and transferring the data to Doctor by using mobile. This system is more efficient and it can be extended for World wide. Wireless communication electronics based on GSM standard, by which the sensing part of the system communicates with a Mobile Station, is developed for this sensor.

[7] In this work, we demonstrated a polyimide-based MEMS strain-sensing device for monitoring Orthopeadiac implants. Throughout the design process, FEA modeling results were used to optimize device placement inside an artificial Orthopeadiac component (UHMWPE). The PI-based technology is well suited for biomedical applications and can provide a significant cost advantage since it does not implies changes on current prosthesis. The device was subjected to tests in a mechanical Orthopeadiac simulator using static and dynamic axial load conditions similar to those encountered in vivo. Results indicated the measured strain is in accordance with simulated strain and that the applied forces can be estimated from measured strain. The experimental data demonstrates the sensor is capable of measuring the strain associated to the total axial forces in the range of approximately 4 times body weight with a good sensitivity and accuracy for events happening within 1 s time window.

[8] Tibial forces are directly related to the transmission of stresses in the implant. These include contact stresses generated at the bearing surface and subsurface, stresses at the implant–cement–bone interface, and stresses transmitted to underlying bone. Stresses at the bearing surface are a major factor in generating wear and fatigue, which determine the life of the implant. Stresses at the implant–cement interface are correlated with aseptic loosening, migration, and generation of third-body wear particles. Stresses transmitted to underlying bone result in remodeling, stress shielding, and osteoporosis. Accurate measurement of these forces could yield insight into the stresses generated during common activities of daily living. The tibiofemoral force data can be used to develop bio-mechanical Orthopeadiac models and in vitro wear tests and to evaluate the effect of improvements in implant design and bearing surfaces, rehabilitation protocols, and orthopedics.

[9] The new torque transducer of the non-contact type employing stress-sensitive amorphous ribbons has been established. By this torque transducer, it is possible to detect instantaneous torque as well as static torque. A high frequency ac bias of 20 kHz or higher can be used, so the cutoff frequency of the dynamic response is expected to be beyond 2a3 kHz. In addition to the features mentioned above, the torque transducer is

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characterized by its simple structure and high sensitivity, so various applications of this torque transducer are expected.

[10] A simple and low-cost fiber-optic curvature sensor based on intensity modulation together with its application in the human joint angle monitoring is presented. The proposed sensor is suitable for the medical and sports applications, and it is wearable, non-invasive, non intrusive and completely harmless. Here conclude that SMS based frame work will reduce the time delay in collection and transferring the data to Doctor by using mobile. This system is more efficient and it can be extended for World wide.Wireless communication electronics based on GSM standard, by which the sensing part of the system communicates with a Mobile Station, is developed for this sensor. By carefully guiding the lead-in and lead-out fiber sections to the box with the electronics we have avoided the errors that can cause losses in the light transmission.

[11] In major cases, the knee implantation is failing because of lack of care after knee implantation. Here we can overcome this failure with our proposed system which helps to monitor the patient's implant continuously with multiple sensors like Flexibility, Temperature & Pressure sensors. In our proposed hardware, we are using GSM modules for long distance communication so that we can send the alert notifications to the concerned caretaker and physician for instant help/treatment. With this equipment, we can reduce the problems of knee implantation .

[12] This paper described a magnetic-based detection method in which amorphous ribbons were used to determine the stress levels in knee implants. Wear can be related with increased loading on the UHMWPE tibial insert, and this resulted in a proportionate drop in the magnetizing winding inductance as the ribbon permeability changed. The method employed is passive, non-invasive and requires minimal modification to existing insert designs. More importantly, this approach eliminates need for secondary windings; hence it can be used for in-vivo observation even without additional circuitry. Effective and timely monitoring of implant stress can prolong their longevity, thereby reducing the associated replacement costs.

[13] The clinical utility of smart implants has been conclusively demonstrated, and the potential of the technology to affect clinical care and enable personalized medicine is vast. However, to date, the barriers to entry have made the use of smart implants in daily clinical practice prohibitive. In 5 decades of research, the total number of permanent smart orthopedic implants utilized clinically in all applications is ~100 patients. However, with rapidly advancing technology, the widespread implementation of smart implants is near. New sensor technology that minimizes modifications to existing implants is the key to enabling smart implants into daily clinical practice.

[14] This instrumented tibial prosthesis opens exciting possibilities for use in measuring forces during activities of daily living. We will continue to monitor tibial forces during these activities. In addition, we are currently collecting data during more strenuous and athletic activities.We plan to include fluoroscopic gait analysis to relate accurate tibio femoral position and orientation with instantaneous tibial force measurement. Future applications include the ability to validate mathematical models, potential improvements in total knee arthroplasty design, and the capability to study the effect of postoperative physical therapy, overall rehabilitation, bracing, and the use of corrective orthotics.

[15] The most probable cause of premature implant failure is aseptic loosening, which is a severe physiological response to foreign debris in the joint. This debris is generated from abrasive wear in the ultra-high molecular weight polyethylene (UHMWPE) of the tibial insert, due to malpositioning of the articular surfaces and the high forces acting in the joint. Therefore, effective monitoring of the temperature, force and flex within the UHMWPE insert can provide real-time caution on the condition of the knee implant to the patient.

[16] A simple and low-cost fiber-optic curvature sensor based on intensity modulation together with its application in the human joint angle monitoring is presented. The proposed sensor is suitable for the medical and sports applications, and it is wearable, non-invasive, nonintrusive and completely harmless. Here conclude that SMS based frame work will reduce the time delay in collection and transferring the data to Doctor by using mobile. This system is more efficient and it can be extended for World wide. Wireless communication electronics based on GSM standard, by which the sensing part of the system communicates with a Mobile Station, is developed for this sensor.

[17] In this work, an instrumented prosthesis for knee implants monitoring was presented. Sensor system, including magnetic measurement system and

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strain gauges, was designed, configured and validated toward reference systems to provide needed information for functionality evaluation of the prosthetic knee. The electronic system to fulfill all the needs of sensing, powering and communication of the instrumented knee prosthesis is under study. However, some components of electronic system in read out unit and remote powering were designed and the simulation results showed their efficiencies. The proposed instrumentation and electronics can be inserted into the polyethylene part without any changes in the overall prosthesis design, representing a promising new system for monitoring medical implants with the help of new electronic systems. It allows in-vivo monitoring and can provide information on the biomechanics of the knee -including force and kinematic- also to early detect problems due to knee imbalance and wearing. Furthermore, it can be used for improving patient's treatment during follow up. The system can also be adapted to other kind of prostheses, i.e. shoulder, hip and ankle, broadening the application for similar instrumented devices.

[18] The image-based measurement technique appears uniquely well suited for performing accurate measurements of knee prosthesis kinematics during dynamic activities. The information gained from the study of prosthetic kinematics will dramatically increase the understanding of how these devices are functioning in vivo, and will permit quantitative functional comparisons between different prosthetic designs. Quantitative comparison data will permit the design of improved devices based on positive performance and measured mechanics, rather than design based on compensation for observed clinical failures.

[19] This work proposed a system architecture based on the five design principles addressed in the Introduction. We performed small scale data collection during the pre-operative and post-operative TKA period. The obtained knee ROM data is analyzed with respect to the knee ROM recovery progress by the factors of EPCA, BMI, and hemostatic agents. The results showed that the three factors were truly related with the recovery progress of TKA knee ROM. In the future work, large scale clinical trials should be able to provide more solid results for statistical analysis. Other external calibration approaches instead of the robotic arms will be required when considering the monitoring in the home environment. The improved sensor-worn methods also require further experiments for verification. Furthermore, there are still many puzzles requiring novel and intelligent solutions to complete the whole research road map.

[20] Several limitations in this study should be mentioned. First, this study lacked a concise control group. We found that for the first few patients with a severe osseous deficit of the bilateral condyle or plateau the computer-recommended osseous cut would be excessive, so we routinely used the preoperative templating to modify the osseous cut. For ethical concerns, we could not perform the osseous cut using the navigation system alone. Second, of the 3 patients with fair knee scores, 2 were moderately obese (body mass index were 27.7 and 34.6) and the other had advanced rheumatoid arthritis and L2 compressive fracture, so we could not completely exclude the negative effect of underlying medical condition with the outcomes of this procedure. Third, for a novel technique that is under development, a limited follow-up period and patient numbers are always concerns. This preliminary report revealed a promising alternative technique that requires longer follow-up and larger patient numbers to reach statistical significance. Nevertheless, our modification of bony cuts using a novel preoperative templating technique could lead to consistently beneficial results for most patients with valgus deformity

[21] A specially designed integrated circuit was developed for the instrumentation of small orthopedic implants (Graichen et al., 1995). The most important requirements like multi channel, low power consumption, small size and long-term function are realized with a bipolar transistor array (B1000A, AEG, Germany) of 4.2×5.0 mm. A full bridge rectifier, voltage regulator, eight input channels, and a pulse interval modulator (PIM) are integrated on this circuit. Prior to implantation, the accuracy of force and MEMS measurements is investigated. In the force accuracy tests, the implant is held at different constant levels of power and MEMS

[22] In the present study, the patients reported a high level of pain during the first postoperative night and the next day, but the level of pain fell sharply thereafter. Andersen et al. (2009) reported that 40% of patients had moderate or severe pain when walking, 1 month after TKA, while none of the patients in the present study reported severe pain and only 14% reported moderate pain during walking 1 month after UKA. Our results confirm that fast-track Oxford UKA with discharge on the day after surgery is a safe procedure (Reilly et al. 2005, Essving et al. 2009). A pressure bandage need not be used for more

than 24 h unless in patients with increased risk of intra-articular bleeding. Due to the high level of pain and use of strong opioids in the initial period after surgery, we would not recommend Oxford UKA as an outpatient procedure unless analgesia is improved. In this context, a preoperative dose of methylprednisolone may be an option, as shown in TKA (Lunn et al. 2011). We found rapid recovery as assessed by the Oxford knee score, and the lack of supervised physiotherapy does not appear to have been a disadvantage to the patients regarding early knee flexion and knee function.

[23] This study demonstrates that there is no difference in survivor ship and radiological alignment or OKS between navigated and non-navigated UKAs at an average of 6.9 years and 8.9 years, respectively. Long-term follow-up with larger patient groups will be required to establish whether component alignment is a predictor for a successful clinical outcome and to justify the routine use of computer navigation in UKAs.

[24] In this article, a novel method for IOP monitoring (based on a CLS containing a passive telemetry system, allowing the measurement of the evolution of IOP and the transmission of this information in a wireless way) has been tested on nucleated pig eyes to demonstrate the functionality of this new device under simplified physiological conditions. The results presented in this article show that the device is sufficiently sensitive to measure a signal equivalent to the human ocular pulsation and follows IOP variations in a reproducible way, in static and dynamic mode. The very wide sensitivity range is probably caused by many parameters. The size, and so keratometry, of the pig eye was different. The lens curvature has been calculated to fit optimally on the average human cornea, not to the radius of curvature of a pig eye, which is larger. So the fitting of the lens is not optimal. Finally, the global biomechanics of each pig eye is already diverse in vivo, and even more so ex vivo.

[25] In this article, the autonomous sensor proposed for force measurements in human knee implants was presented. The experimental results showed that the sensor represents a promising new system for medical implants in vivo force monitoring. Some authors have suggested that contact areas and pressures within TKA prosthesis (Total Knee Arthoplastic) can be predictors of wear and failure of the tibial inserts made by ultra-high molecular weight polyethylene (UHMWPE). Since the proposed device permits the in vivo measurements, it is possible to have information on the mechanical insert behavior. The autonomous sensor could lead to an improvement regarding the knee implant function and the treatment of patients with total knee implants. Furthermore, the hysteresis phenomenon that has been analyzed in this manuscript could in part explain the variability of the results. However, this variability can still achieve a good accuracy in the force measurement. In a possible future development it is expected to adopt fabrication techniques and design strategies that can reduce or completely mitigate the hysteresis phenomenon.

III. CONCLUSION

In major cases, the knee implantation is failing because of lack of care after knee implantation. Here we can overcome this failure with our proposed system which helps to monitor the patient's implant continuously with multiple sensors like Flexibility, MEMS & Pressure sensors. The most probable cause of premature implant failure is aseptic loosening, which is a severe physiological response to foreign debris in the joint.

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