Design and integration of an instrumented knee prosthesis

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Abstract

Total knee arthroplasty is nowadays one of the most important orthopedic surgeries. It consists of a procedure in which parts of the knee joint are replaced by a prosthesis. The largest indication for total knee arthroplasty is osteoarthritis, a knee disease that can cause the cartilage of the femur and tibia to wear away, so that the bones rub together with use. The major risk factors for osteoarthritis are aging and obesity. Both the life expectancy and the obesity rate are increasing in the developed countries, thus the number of estimated total knee arthroplasties is growing over the years.

Although over one million of prosthetic joints are implanted every year in the developed countries, none of them contains sensors to help the orthopedic surgeons in improving the precision of the replacement surgery. The goal of this study is to design an electronic system to be embedded inside a total knee prosthesis, in order to measure the force applied to it and its kinematics. Providing the orthopedic surgeons with quantitative data on the biomechanics of the prosthetic knee can help them in improving the implant precision and, as a consequence, could reduce the risk of an early revision surgery.

In the frame of this thesis, we worked with the F.I.R.S.T. prosthesis by Symbios Orthopedie SA, that was instrumented with sensors and electronics to measure, process and transmit force and kinematics data to an external reader. The constraints in the design have been established by the medical doctors and the prosthesis manufacturer and the technical solutions adopted are presented. In order to simplify a future approval for human tests, we decided not to modify the shape of the knee artificial joint. To achieve that, we put all the sensors and the electronics inside the middle part of the prosthesis, constituted of a polyethylene insert located between the metallic parts of the artificial joint and whose function is to reduce the rubbing.

An original encapsulation was designed to guarantee the bio-compatibility of the instrumented prosthesis and to avoid a potentially dangerous contact between the electronics and the human body. This should be ensured even in case of extreme wearing of the polyethylene insert, that can occur some years after the prosthesis implant and is one of the main indications for a revision surgery.

The sensors were tested by using mechanical simulators of the knee joint and validated by means of reference sensors. Different demonstrators have been designed, from the first, with

only the sensors located inside the prosthesis and all the electronics fabricated in a large-scale outside of it, to the last miniaturized versions, that can be entirely embedded inside the prosthesis.

Moreover, an autonomous sensor for balancing the ligaments tension during the knee replacement surgery was designed, fabricated and tested. Such a device could be an important help for the medical doctors during the surgery to improve the precision of the implant and, being non-implantable, could easily obtain an approval for human clinical trials.

Key words: Total knee arthroplasty, osteoarthritis, knee joint, instrumented prosthesis, biomechanics, force and kinematics measurements, electronic implantable system, mechanical knee simulator, ligaments balancing.

Résumé

L'arthroplastie totale du genou est de nos jours une opération orthopédique des plus courantes. Elle consiste à remplacer des parties du genou par une prothèse. La principale pathologie qui détermine la nécessité d'une arthroplastie totale du genou est l'ostéoarthrose, une maladie du genou qui peut provoquer une usure des cartilages du fémur et du tibia, d'une façon telle que les os frottent l'un sur l'autre. Les principaux facteurs de risque pour l'arthrose sont le vieillissement et l'obésité. L'espérance de vie ainsi que le taux d'obésité étant à la hausse dans les pays développés, le nombre estimé d'arthroplasties totales du genou croît de ce fait d'année en année.

Bien que plus d'un million de prothèses soient implantées chaque année dans les pays développés, aucune d'elles ne contient des capteurs qui puissent aider les chirurgiens orthopédiques à accroître la précision de l'opération de remplacement de l'articulation. Le but de cette étude est de concevoir un système électronique qui puisse être inséré à l'intérieur d'une prothèse totale du genou, afin de mesurer la force appliquée sur cette dernière et sa cinématique. Fournir aux chirurgiens orthopédistes des mesures quantitatives sur la biomécanique de la prothèse de genou peut aider à améliorer la précision de l'implantation et, par conséquent, à réduire le risque d'une opération de remplacement précoce de prothèse.

Dans le cadre de cette thèse, nous avons travaillé avec la prothèse F.I.R.S.T. de Symbios Orthopédie SA, à laquelle nous avons ajouté des capteurs et une électronique capable de traiter et transmettre des données relatives à la force et la cinématique à un lecteur externe. Les contraintes du projet ont été établies par les médecins et par le fabricant de la prothèse et les solutions techniques adoptées sont présentées. Pour simplifier une future approbation en vue de tester la prothèse sur l'homme, nous avons décidé de maintenir inchangée sa forme. Pour obtenir ce résultat, nous avons placé tous les capteurs et l'électronique dans la partie centrale de la prothèse, constituée d'un insert en polyéthylène placée entre les parties métalliques de l'implant et dont la fonction est de réduire la friction.

Une encapsulation originale a été conçue pour assurer la biocompatibilité de la prothèse instrumentée et pour éviter le risque d'un contact, potentiellement dangereux, entre les composants électroniques et les fluides corporels. Cette caractéristique doit être garantie même en cas d'usure extrême de l'insert en polyéthylène. Ce phénomène pourrait se manifester des années après l'implantation de la prothèse et cette usure prématurée est l'une des raisons

principales qui conduisent à une opération de substitution de la prothèse.

Les capteurs ont été testés à l'aide de simulateurs mécaniques du genou et validés par comparaison à des capteurs de référence. Plusieurs démonstrateurs ont été conçus, à partir de la première version, avec seulement les capteurs placés à l'intérieur de la prothèse et toute l'électronique fabriquée à grande échelle en dehors, jusqu'à la dernière itération miniaturisée, qui peut être insérée entièrement dans la prothèse.

De plus, nous avons conçu, fabriqué et testé un capteur autonome pour équilibrer la tension des ligaments pendant l'opération de remplacement du genou. Un tel dispositif pourrait être d'un grand secours pour les médecins lors de l'opération afin d'en améliorer la précision. N'étant pas implantable, cet insert pourrait facilement obtenir l'approbation pour les essais sur l'homme.

Mots clefs : Arthroplastie totale du genou, ostéarthrose, articulation du genou, prothèse instrumentée, biomécanique, mesures de force et cinématique, système électronique implantable, simulateur mécanique du genou, équilibre des ligaments.

Riassunto

L'artroplastica totale di ginocchio è oggigiorno una delle più importanti operazioni ortopediche. Consiste nella sostituzione di parti del ginocchio con una protesi. La principale causa che determina la necessità di un'artoplastica totale di ginocchio è l'osteoartrite, una patologia del ginocchio che può causare un consumo delle cartilagini di femore e tibia, così che le ossa si trovano a sfregare una sull'altra. I principali fattori di rischio per l'osteoartrite sono l'invecchiamento e l'obesità. Sia l'aspettativa di vita che il tasso di obesità sono in crescita nei paesi sviluppati, dunque il numero stimato di artroplastiche totali di ginocchio sta crescendo di anno in anno.

Sebbene oltre un milione di protesi siano impiantate ogni anno nei paesi sviluppati, nessuna di esse contiene sensori che possano aiutare i chirurghi ortopedici a migliorare la precisione dell'operazione di sostituzione dell'articolazione. Lo scopo di questo studio è progettare un sistema elettronico che possa essere inserito all'interno di una protesi totale di ginocchio, per misurare la forza applicata su di essa e la sua cinematica. Fornire ai chirurghi ortopedici delle misure quantitative sulla biomeccanica della protesi di ginocchio può aiutare a migliorare la precisione dell'impianto e, di conseguenza, a ridurre il rischio di una precoce operazione di sostituzione della protesi stessa.

Nell'ambito di questa tesi, abbiamo lavorato con la protesi F.I.R.S.T. di Symbios Orthopedie SA, alla quale abbiamo aggiunto dei sensori e un'elettronica in grado di elaborare e trasmettere dati relativi alla forza e alla cinematica ad un lettore esterno. I vincoli di progetto sono stati stabiliti dai medici e dal fabbricante della protesi e le soluzione tecniche adottate sono presentate. Per semplificare una futura approvazione per testare la protesi sull'uomo, abbiamo deciso di mantenere inalterata la sua forma esterna. Per ottenere tale risultato, abbiamo collocato tutti i sensori e l'elettronica nella parte centrale della protesi, costituita da un inserto in polietilene collocato tra le parti metalliche dell'impianto e la cui funzione è ridurre la frizione.

Una incapsulazione originale è stata progettata per garantire la bio-compatibilità della protesi instrumentata e per evitare il rischio di un contatto, potenzialmente pericoloso, tra i componenti elettronici e i fluidi corporei. Questa caratteristica deve essere garantita anche in caso di estrema usura dell'inserto in polietilene. Questo fenomeno potrebbe manifestarsi alcuni anni dopo l'impianto della protesi e questa usura prematura è uno dei motivi principali che portano ad una operazione di sostituzione della protesi stessa.

Riassunto

I sensori sono stati testati utilizzando dei simulatori meccanici del ginocchio e validati attraverso un confronto con dei sensori di riferimento. Diversi dimostratori sono stati progettati, dal primo, con solo i sensori piazzati all'interno della protesi e tutta l'elettronica fabbricata in larga-scala fuori di essa, fino all'ultima versione miniaturizzata, che può essere inserita interamente nella protesi.

Inoltre, abbiamo progettato, fabbricato e testato un sensore autonomo per equilibrare la tensione dei legamenti durante l'operazione di sostituzione del ginocchio. Un tale dispositivo potrebbe essere di enorme aiuto per i medici durante l'operazione per migliorarne la precisione. Essendo non impiantabile, questo inserto potrebbe facilmente ottenere un'approvazione per effettuare dei test sull'uomo.

Parole chiave: Artroplastica totale di ginocchio, osteoartrite, articolazione del ginocchio, protesi instrumentata, biomeccanica, misure di forza e cinematica, sistema elettronico impiantabile, simulatore meccanico del ginocchio, equilibrio dei legamenti.

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List of acronyms

- **ADC**: Analog-to-digital converter

- **AFE**: Analog front-end

- **DAC**: Digital-to-analog converter

- **FRAM**: Ferroelectric random-access memory

- **HF**: High frequency

- **I2C**: Inter Integrated Circuit

- **IC**: Integrated circuit

- **LF**: Low-frequency

- **PCB**: Printed circuit board

- **PE**: Polyethylene

- **RFID**: Radio-frequency identification

- **RX**: Receiver

- **SG**: Strain gauges

- **SPI**: Serial peripheral interface

- **TKA**: Total knee arthroplasty

- **TX**: Transmitter

- **UHMW**: Ultra-high molecular weight

- **USB**: Universal serial bus

1 Introduction to total knee arthroplasty

This introduction describes the procedure of total knee arthroplasty and its increasing importance in orthopedic surgery. Basic information of the anatomy of the knee and its kinematics is briefly presented. Finally, the concept of knee prosthesis and knee replacement are introduced.

1.1 Knee arthroplasty

Total Knee Arthroplasty (TKA) is one of the most common and successful orthopedic procedures performed [1]. It is a surgical procedure in which parts of the knee joint are replaced with a prosthesis, as shown in Figure 1.1. It relieves pain and improves knee function in people with advanced arthritis of the joint [2].

Figure 1.1: Human knee joint before and after total knee arthroplasty. Reprinted from [3].

The largest indication for TKA is osteoarthritis, a form of arthritis that can cause the cartilage to wear away virtually completely, so that the adjacent bones in the joint rub together with use

(see Figure 1.2). Table 1.1 lists the main reasons for the primary procedures in England, Wales and Northern Ireland in 2012 [5]. Osteoarthritis was recorded as the surgery reason in 98% of the surgeries.
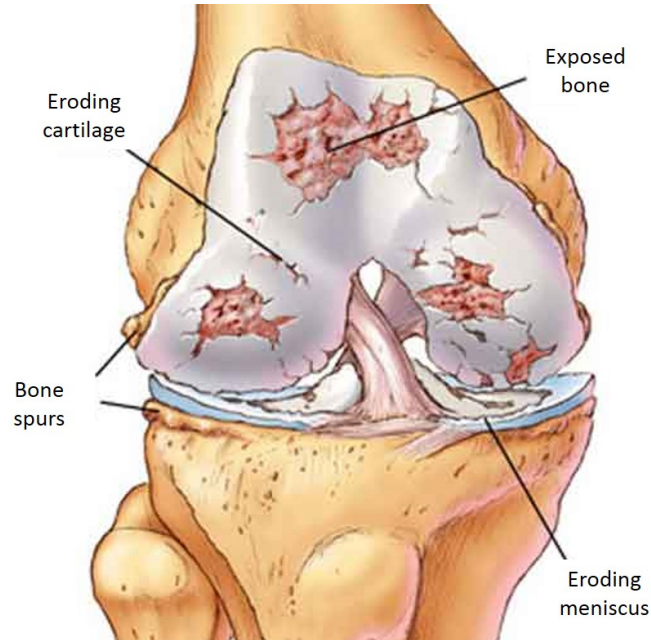
Figure 1.2: Human knee affected by osteoarthritis. Reprinted from [4].

Table 1.1: Indications for TKA. Data taken from [5].

Indications for surgery	Percentage
Osteoarthritis	98%
Avascular necrosis	<1%
Inflammatory arthropathy	<1%
Previous infection	<1%
Rheumatoid arthritis	1%
Previous trauma	<1%
Other	<1%

Aging and obesity are the major risk factors for ostheoarthritis [7]. Since life expectancy in developed countries is increasing and the rate of obesity is rising, the rates of knee osteoarthritis are expected to increase in the upcoming years.

As of 2010, more than 650,000 total knee replacements were performed annually in the United States [6].

The number of TKAs has been increasing every year in the developed countries. For instance, Figure 1.3 shows the number of knee prostheses implanted per 100,000 persons per year in the UK from 1991 to 2006. In other countries, data are similar: in the USA, the rate of implanted

prostheses has risen from 31.2 per 100,000 persons in the years 1971-76 to 220.9 per 100,000 persons in 2008 [9].
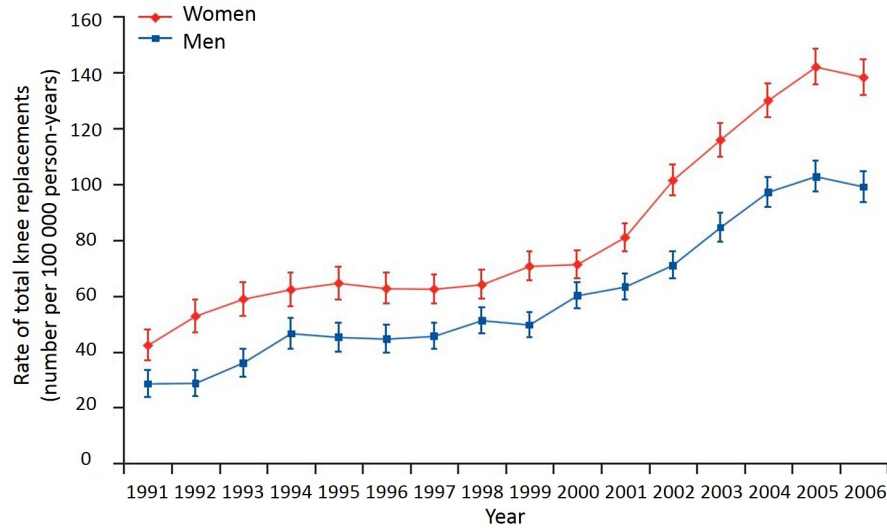
Figure 1.3: TKAs per 100,000 persons per year in the UK from 1991 to 2006. Bars show 95% Cls. Reprinted from [2].

The rate of TKAs per person per year is expected to increase in the upcoming years. A study by Kurtz et al. [10] estimated an exponential rising of the number of primary TKA procedures in the USA from 2005 to 2030, as depicted in Figure 1.4, where the increment of primary TKAs and Total Hip Arthroplasty (THA) procedures are compared.
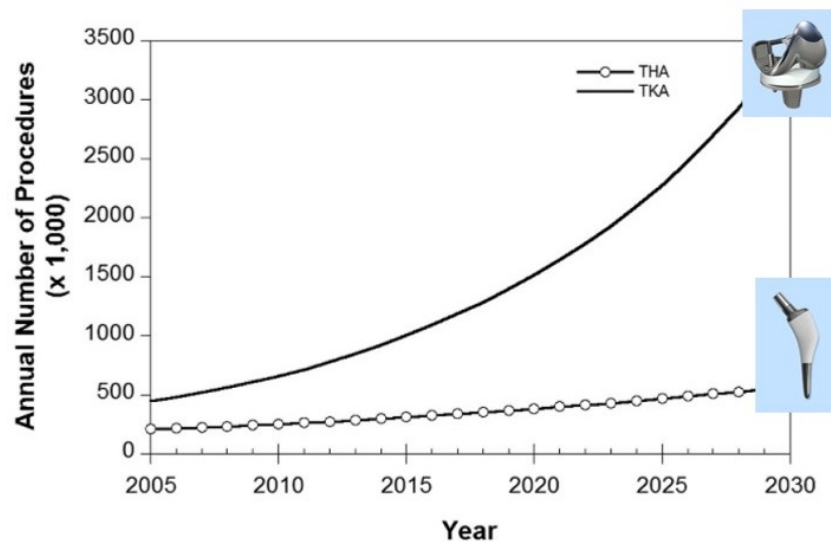
Figure 1.4: Projected number of THA and TKA procedures in the United States from 2005 to 2030. Reprinted from [10].

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1.2   Revision surgery

The life expectancy of a knee prosthesis inside the human body is around 15-20 years. This period strongly depends on the health, lifestyle and activity level of the patient. A recent study by Bae at al. [11] on 224 patients that needed a revision surgery from 1999 to 2009 reported that the survival rates prior to any revisions being necessary are 97% after 5 years, 92% after 8 years, and 86% after 10 years.

The main reasons for a TKA revision surgery are listed in table 1.2. Aseptic loosening, usually caused by implant wear, is the most common and is the origin of more than 30% of revision surgeries. The rate of wear is a product of both time and activity, and that is why it represents a concern more in young and active patients [12]. Figure 1.5 shows another interesting point: between 1975 and 1994, the mean age of a patient receiving a primary TKA has increased from around 65 to almost 72. The main reason was the relatively large increase in number of operations for the elderly people, related to the improvements in the anesthetic techniques as well as a changed age distribution of the population [13].

Since 1994, the trend has changed and the mean age for the primary TKA started to decrease. In 2012, it was around 69. This change in the curve could appear strange, but it is justified, in consideration of the fact that obesity, one of the biggest reasons for knee arthroplasty, is increasing in the new generations in the developed countries. Moreover, the increasing number of people practicing sport at high level is also increasing the injury rate and the necessity of a knee prosthesis at young age.

Table 1.2: Indications for TKA revision surgery. Data taken from [5].

Indications for surgery	Percentage
Aseptic loosening	32%
Pain	15%
Lysis	8%
Wear of polyethylene component	10%
Instability	14%
Infection	22%
Malalignment	6%
Stiffness	5%
Progressive arthritis remaining	9%
Dislocation/subluxation	3%
Periprosthetic fracture	3%
Component dissociation	2%
Implant fracture	<1%
Other	10%

This explains also why it is so important to have an improved surgical technique, to reduce
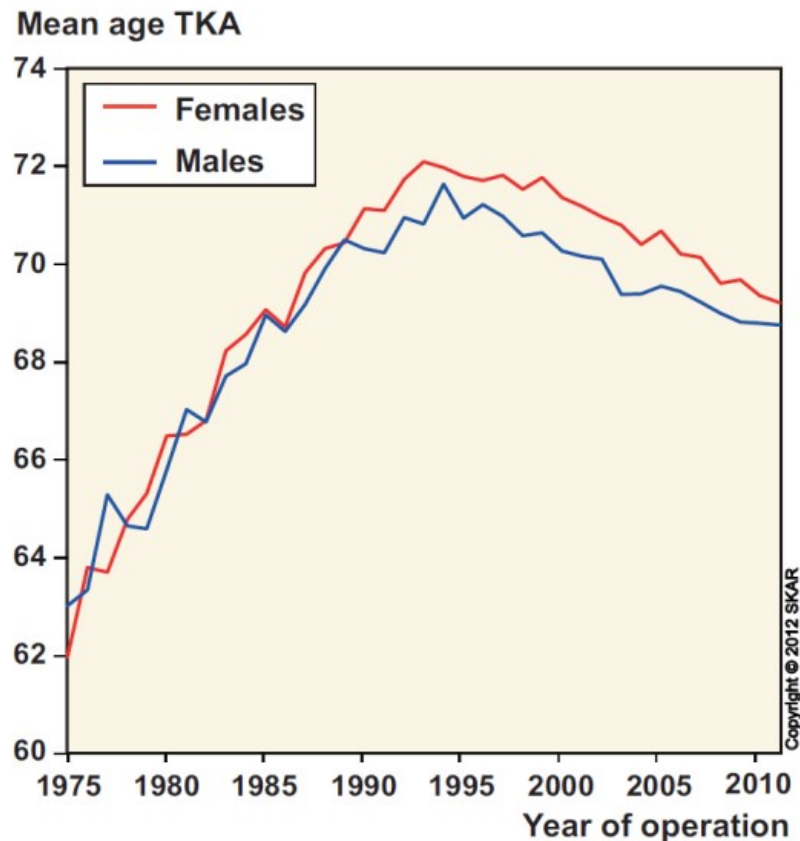
Figure 1.5: Mean age of the primary TKS. Reprinted from [13].

the risk of an early revision surgery. In fact, a revision is more complex for the surgeon, the rehabilitation is longer for the patient and the whole treatment is more expensive for the national health service or insurance. Considering the mean age of the first implant 69, the average life expectancy of the prosthesis 15 years and the life expectancy at birth which is now around 80 years in the developed countries (82.8 in Switzerland by 2013 [14]), the probability of a second revision surgery for a patient with a prosthesis implanted in young age is not negligible.

1.3 Surgery precision

Nowadays, the precision of the implant depends on the ability and the experience of the surgeon. When the knee has been closed at the end of the operation, the only feedback can be given by a patient that goes back to consult the orthopedic doctor because he feels pain. If it happens some months (or few years) after the surgery, the only solution is to open the knee again and replace the prosthesis.

All the prostheses presently implanted in patients do not contain any sensor. Having a system

that could help the orthopaedics during the surgery for increasing the precision of the implant positioning (but also the physiotherapists during the rehabilitation) could be very helpful in order to reduce the rate of revision surgeries due to an error in the prosthesis placement.

A prosthesis instrumented with sensors could also reduce the risk of having patients that need a third implant during their life.

1.4 Knee anatomy

In order to understand the complex problems related to the knee joint and why a prosthesis can be necessary, it is important to have a basic knowledge of the anatomy of the knee. The knee is one of the largest and most complex joints in the body. It it constituted of three parts: the tighbone (femur), the shinbone (tibia) and the patella (or kneecap), that sits in front of the knee. It is a synovial joint, i.e. a joint that is enclosed by a ligament capsule and contain a fluid (synovial fluid) that lubrificates it.

The bottom part of the femur joins the top part of the tibia to create the knee joint. The two round knobs that are at the end of the femur are called condyles. They are in contact with the top surface of the tibia, called tibial plateau. The patella glides in the front part of the knee through a special groove formed by the two femoral condyles and called the patello-femoral groove.

The end of the bones of the joints is covered by the articular cartilage, a slippery substance that allows the surfaces to slide without damage to either surface. The function of articular cartilage is to absorb the shocks and to provide an extremely smooth surface to facilitate motion. In the knee, articular cartilage covers the ends of the femur, the top of the tibia, and the back of the patella. Figure 1.6 shows the anatomy of the knee, with the description of all the structures mentioned.

The menisci, not displayed in Figure 1.6, are shown in Figure 1.7. They are two fibro-cartilaginous structures (medial and lateral meniscus), whose main function is to reduce the frictions when the upper condyles of the tibia and the condyles of the femur meet in the knee joint.

1.5 Knee rotations

The kinematics of the knee is governed by a complex combination of rotation and translations, that will not be detailed here. For the purpose of this study, it is however important to have some knowledge on the knee rotations: the flexion-extension, abduction-adduction and intra-extra rotations, all shown in Figure 1.8.
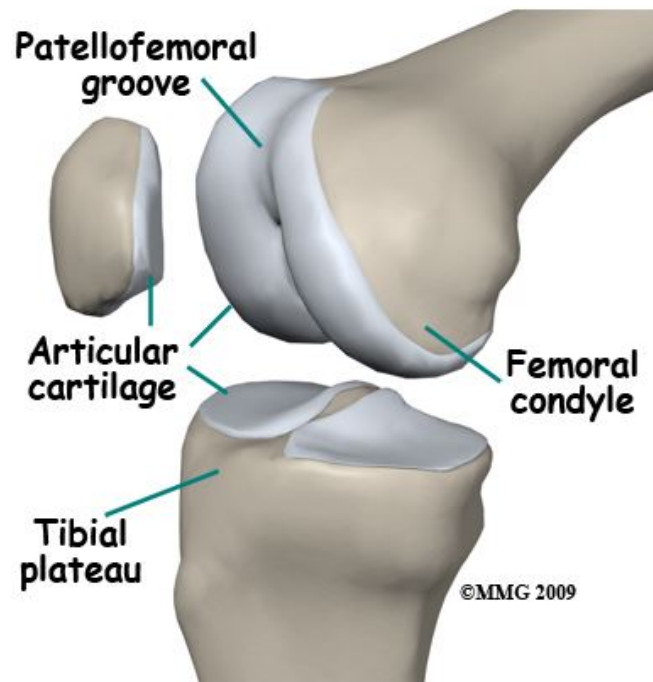
Figure 1.6: Anatomy of the knee. Reprinted from [15].
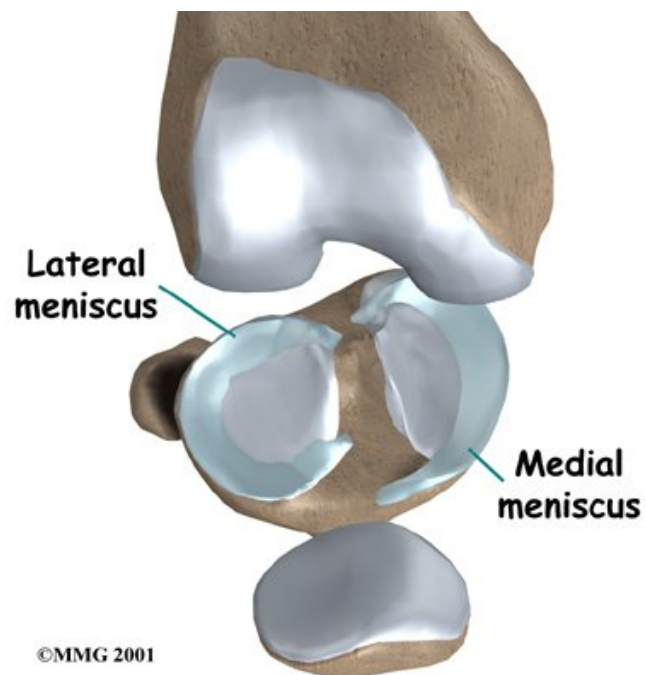
Figure 1.7: Meniscus. Reprinted from [15].

1.6 Total knee prosthesis

A total knee prosthesis is made up of three main parts: the tibial component (bottom part) replaces the top surface of the tibia. The femoral component (top part) replaces the bottom
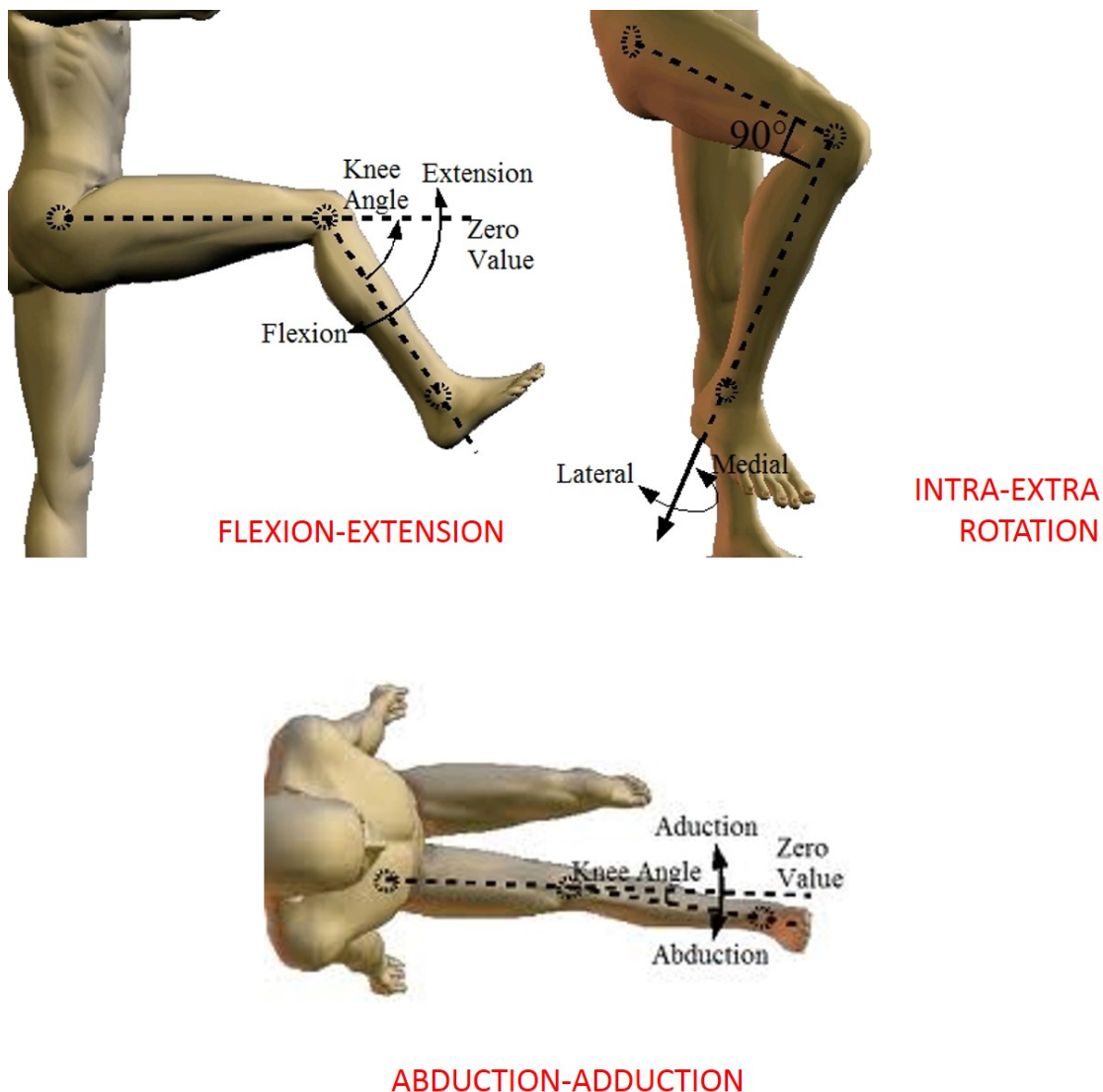
Figure 1.8: Knee rotations. Reprinted from [16].

surface of the femur. The middle insert replaces the menisci, that are removed during the surgery. The patellar component (kneecap portion) can be used to replace the surface of the patella where it glides in the groove on the femur. Figure 1.9 shows a typical structure of a total knee prosthesis (the patellar component is not displayed).

The tibial and femoral components are usually made of metal, while the middle insert and the patellar component are usually made of plastic. In particular, metal components are typically made of titanium or cobalt-chrome alloys. Both these materials are bio-compatible, they are known for their durability and have stable chemical properties, such that they do not interact with the human body [17].
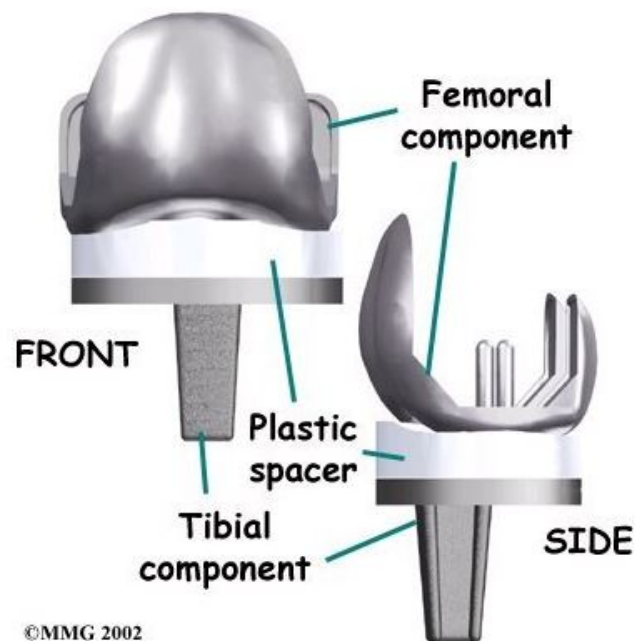
Figure 1.9: Knee prosthesis components. Reprinted from [15].

Bio-compatibility is essential, to prevent the body from rejecting the prosthesis.

The plastic used for the middle insert and the patellar component is usually Ultra High Molecular Weight (UHMW) Polyethylene (PE), a material widely used in medical devices for its bio-compatibility and its ability to glide smoothly within the mechanical joints.

There are mainly two types of artificial total knee joints: Fixed-Bearing and Mobile-bearing knee prostheses. In the Fixed-bearing knee prosthesis, the PE insert is attached to the metallic tibial component and the femoral component rolls on it. The Mobile-bearing knee prosthesis allows also the PE insert to horizontally rotate few degrees on the tibial tray, adding an additional degree of freedom. The two configurations are shown in Figure 1.10.

Both are widely used. Orthopedics surgeons often prefer to use the Fixed-bearing prosthesis with older patients, who are expected to be less active, while the Mobile-bearing prosthesis is preferred for younger subjects, whose lifestyle is usually more active.

1.7 Total knee arthroplasy procedure

The surgery for total knee replacement consists of different steps, described in Figure 1.11. First of all, the surgeon makes an incision in the frontal part of the knee and opens it. When the knee has been opened, a cutting guide is placed on the lower part of the femur and several parts of the bone are cut in a way that fits with the shape of the metallic part of the prosthesis (femoral component) that will replace it (a). The following step is the tibia surface preparation:
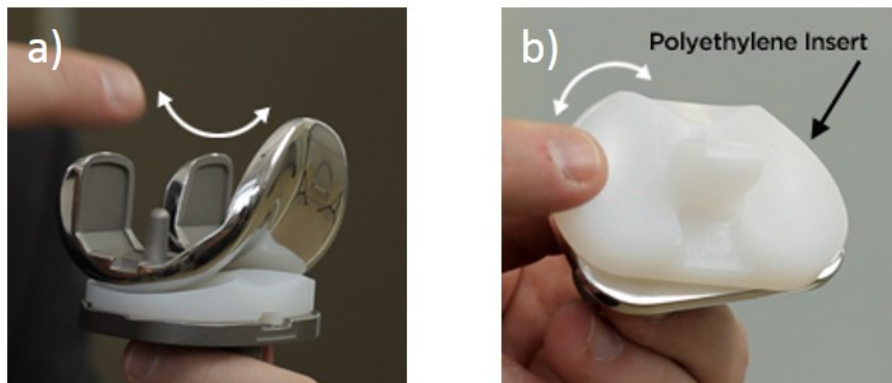
Figure 1.10: a) Fixed-bearing prosthesis and b) Mobile-bearing prosthesis (femoral component not shown). Reprinted from [17].

the tibia is cut with the help of another cutting guide, in order to have the correct alignment (b). The third step is the removal of the patella articular surface, that will be replaced by a plastic piece (c). The fourth step consists in the placement of the femoral metallic component on the lower part of the femur previously cut: the piece can be held in place by friction if the prosthesis is not cemented, or glued using an epoxy cement if the prosthesis is cemented (d). Then, the tibial tray is attached to the top of the tibia, whose surface was prepared in step b. Similarly to the femoral component, it can be cemented or attached to the bone with a screw. The PE middle component is then attached to the tibial tray in case of a fixed-bearing prosthesis or simply placed on top of it in the case of a mobile-bearing prosthesis (e). The patellar component is then put into place behind the patella. It is usually cemented (f). Finally, the knee is closed and the post operative phase begins.

1.8 Conclusion

In this chapter, we introduced total knee arthroplasty, one of the the most common surgery of the knee joint.

We presented the reasons that can lead to the decision to implant a knee prosthesis into a patient and we explained why the number of these surgeries is increasing year after year, while the average age of the first implant is decreasing.

Moreover, we described the risks related to the revision surgery, necessary when the first implanted prosthesis fails and has to be replaced.

We gave some basic information on the knee anatomy and kinematics and finally we described the components of a knee prosthesis and how the surgical procedure to implant it in the body of the patient is.

We explained that, until now, all the total knee prostheses available on the market do not
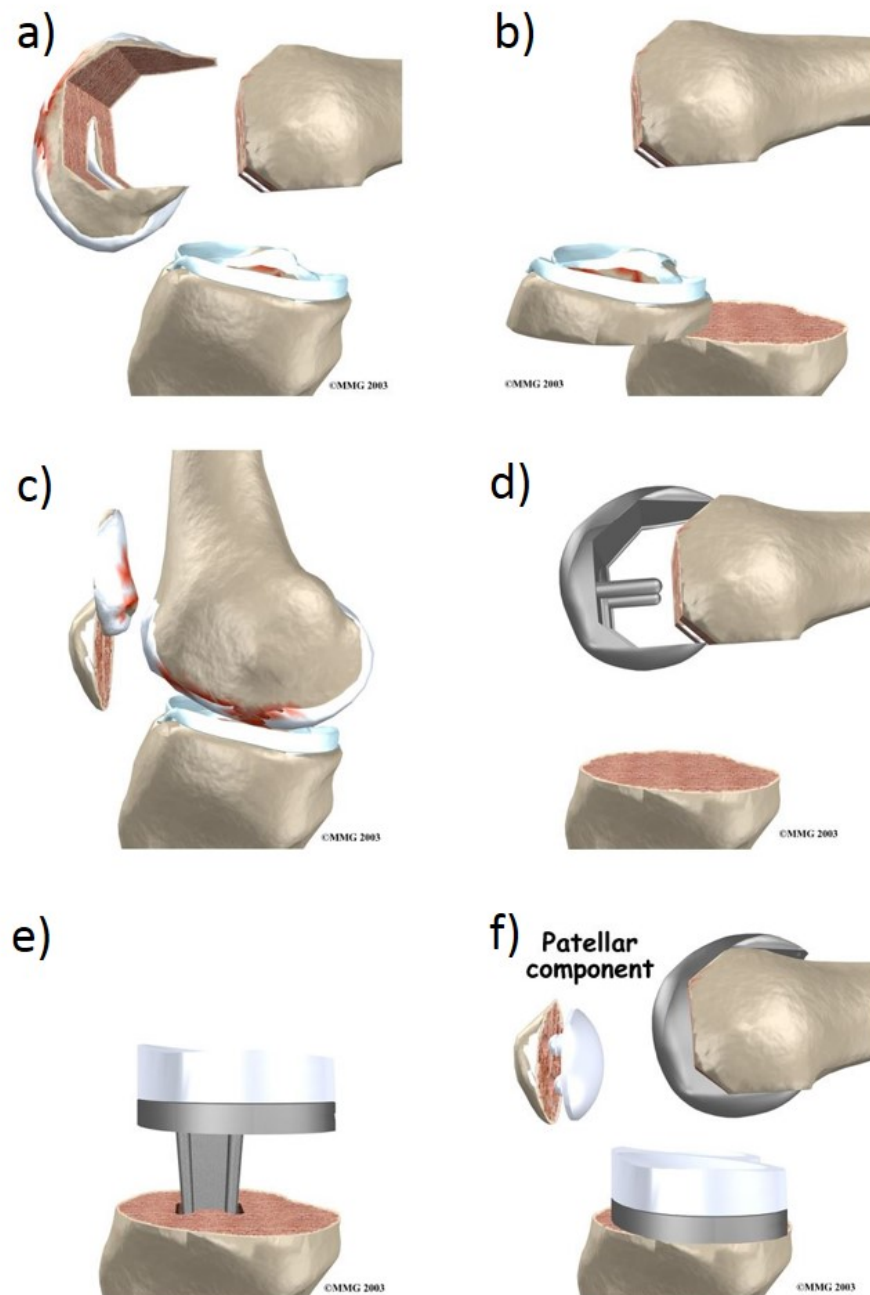
Figure 1.11: Different steps of the TKA procedure: a) Femur preparation, b) Tibia preparation, c) Patella preparation, d) Placement of femoral part, e) Placement of tibial part and PE insert, f) Placement of the patellar component. Reprinted from [15].

contain any sensor, that could help the orthopedic doctors during the surgery, to increase the precision of the implant positioning and thus reduce the risk of an early revision surgery.

The next chapter will introduce the goal of this thesis and will detail the contribution of the

author within the SImOS project, that financed this work.

2 Goal of the thesis

The work presented in this thesis was carried out in the context of the Nano-Tera SImOS project (Swiss National Foundation SNF20NAN1_123630). Its goal is to design an innovative instrumented knee prosthesis, in order to measure *in vivo* bio-mechanical parameters of the prosthetic joint. In particular, the aim of the project is to measure the force applied to the implant and its kinematics. The prosthesis used was the F.I.R.S.T. by Symbios Orthopedie SA, Yverdon, Switzerland. The contribution of the author of this thesis within the project, that will be detailed in the following chapters, is introduced hereafter.

2.1 Author contribution to SImOS project

In the frame of SImOS project, the author of this work was in charge of the system integration and packaging. In particular, the objectives of the work presented in this thesis, were:

- To propose a packaging method offering key innovative features: minimum achievable footprint, high flexibility and modularity, suitable for microsystems like force sensors as well as electronics, able to communicate with an external reader.

- To develop a hermetic encapsulation method to protect the implanted electronics from the environment while taking care of sensor interconnections.

- To enable the validation of the overall system in a real environment (*in vitro* and *in vivo*).

Most of the objectives of this work can be achieved only some years after the beginning of a research project. For instance, the design, fabrication and testing of integrated circuits (IC) by two of the project partners takes time and this development cannot be integrated in a miniaturized system at the early beginning of the project. For this reason, the contribution of the author to the project was not limited to the three important points listed above. The following subsections describe the work that has been carried out in the different phases of the project and constitute the core of this thesis.

2.1.1 Contribution to the definition of the system architecture

The requirements for an instrumented knee prosthesis have been driven by the clinicians involved in the SImOS project and the engineers of Symbios Orthopedie SA, the prosthesis manufacturer, in the first year of the project.

These requirements have led the author to define a set of specifications which have determined the implant architecture and its mechanical footprint as well as the interconnections between the sensors and the implanted electronics which controls them.

This set of specifications includes the type of sensors (for force and kinematics measurements), a microcontroller for managing the data acquisition and transmission, a local data storage, a power management system, an RF harvesting system and an RF transceiver. The chosen microcontroller incorporates the peripherals necessary to control all the subsystems (Analog to Digital Converters, SPI and I2C buses, digital input/output and timers to synchronize the implant with the external system). Also, commercially available components matching project requirements have been selected.

The most difficult part of this task was the definition of the optimal footprint of the implant to be integrated in a non intrusive way to the prosthesis and the way to connect the sensors outputs to the rest of the electronics.

2.1.2 Contribution to the packaging of large-scale demonstrator

Several large-scale evaluation platforms, not focusing on miniaturization aspects but on the functionality defined with the help of medical doctors and prosthesis manufacturer, have been designed and fabricated by the author of this thesis.

These functional demonstrators have offered an ideal environment to prove the concept of data acquisition, storage and transmission from force and kinematics sensors. Moreover, they were used to develop and test the firmware that controls the sensors, the power management and the communication subsystems. Finally, they were exploited to devise encapsulation strategies in view of the extreme miniaturization.

2.1.3 Contribution to the design of a miniaturized system

The author has realized the high-density three-dimensional (3D) packaging and interconnection of the implantable electronic components and sensors. The smallest achievable footprint for the implanted electronics has been obtained by using a sandwich structure made of printed circuit boards and combining flexible and rigid substrates. The author always kept in mind the requirements of power consumption and high-reliability, bio-compatibility and mechanical resistance.

2.1.4 Contribution to the hardware reliability

While designing the system, the author focused on a reliable hardware, that could lead to further adaptations and modifications both of the implant electronics and firmware. The final system could easily be modified and adapted to other knee prosthesis fabricated by other manufacturers than Symbios Orthopedie SA and to other kind of prosthesis (for instance ankle prostheses) based on a similar mechanical structure.

2.2 Conclusion

In this chapter we introduced the goal of this thesis and we detailed the specific contributions of the author in the frame of Nano-Tera SImOS project, that funded this work. More details about the project will be provided in chapter 4.

In the next chapter, we will present the state of the art on the instrumented knee prostheses. Even though a commercial instrumented knee prosthesis does not exist nowadays, some examples of studies that brought to the design of customized devices, based on passive knee prostheses modified to put sensors inside, are known in literature. An overview of these devices, that could deeply transform the total knee arthroplasty procedure, will be provided.

3 State of the art on instrumented knee prosthesis

Although more than one million of prosthetic joints are implanted every year in EU and USA, none of them contains any sensor, that could be helpful for the prosthesis monitoring. The orthopedics could be helped by such a system during the surgery to increase the precision of the implant, by improving the balance of the ligaments tension and reaching an optimal mobility. The physiotherapists could be helped during the rehabilitation, receiving objective data on the improvement of the patient performance. Both for the patients and the clinician, but also for the medical insurances, reducing the number of revision surgeries would be a great improvement. Finally, having sensors implanted giving a feedback on the status of the prosthesis, could provide information that can lead to modifications of existing prostheses, and also provides more knowledge about the bio-mechanics of joints. In order to gather such information, the implants must be instrumented not only with sensors, but also with a telemetry system to transmit data from inside the prosthesis to an external readout unit.

Even if total knee arthroplasty is a very common surgical procedure, there are only a few research groups working in the field of instrumentation of prostheses and implants and their works mainly focused on measuring the forces applied to the prosthesis during different movements. This section describes the state of the art on those instrumented prostheses, from the earlier works, to the most recent devices.

3.1 Instrumented prosthesis by Charité-Universitatsmedizin

One of the early instrumented prosthesis was proposed and implanted in 1993 by Bergmann et al. [18] for the hip joint. They measured the resulting hip joint force, its orientation and the moments in two patients during walking and running, using a telemetry system in a total hip prostheses. The joint loading was observed over the first 18 and 30 months, respectively, following implantation.

They also implemented a tibial tray for measuring the six load components in total knee arthroplasty [19]. Their design is based on the INNEX total knee system (Zimmer GmbH,

Winterthur, Switzerland) with an ultra-congruent tibial insert and a standard femoral component. They modified the tibial part of the prosthesis, using two plates with hollow stems made from titanium alloy. These plates are separated by a small gap. They used six semiconductor strain gauges for measuring the load-dependent deformation of the inner hollow stem. The proposed instrumented prosthesis is shown in Figure 3.1
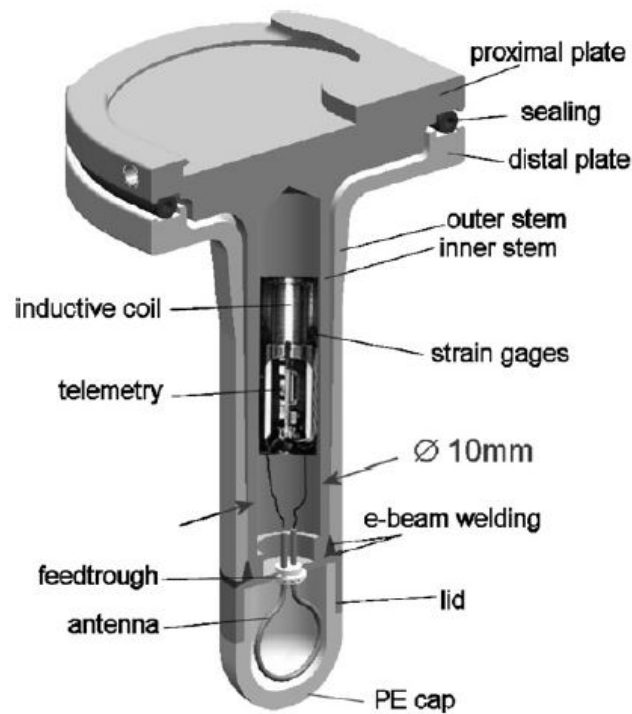
Figure 3.1: Section of the instrumented tibial tray proposed by Heinlein et al. Reprinted from [19].

They encapsulated a telemetry unit with a radio-frequency transmitter in the cavity of the prosthesis. The telemetry is powered inductively and strain gauges signals are transmitted via a small antenna placed at the tip of the implant. The mean sampling rate is 125 Hz. They calibrated the force sensors, obtaining a mean error of 2%. Figure 3.2 shows the tibial tray instrumented to measure the force applied.

In particular, it is well visible the UHMWPE tip, that contains the antenna for the system powering and the data communication. The material of the tip has to be modified for the antenna communication, impossible with a standard metallic tip, that would act as a shield.

In a later work [20], their custom-made telemetry tibial tray was implanted in two patients, to measure the three forces and three moments acting in the implant. In particular, it was used for the measurement of joint loading in level walking and stair climbing in 6-10 months follow up. The prosthesis that was implanted, with the instrumented tibial tray, is shown in Figure 3.3.
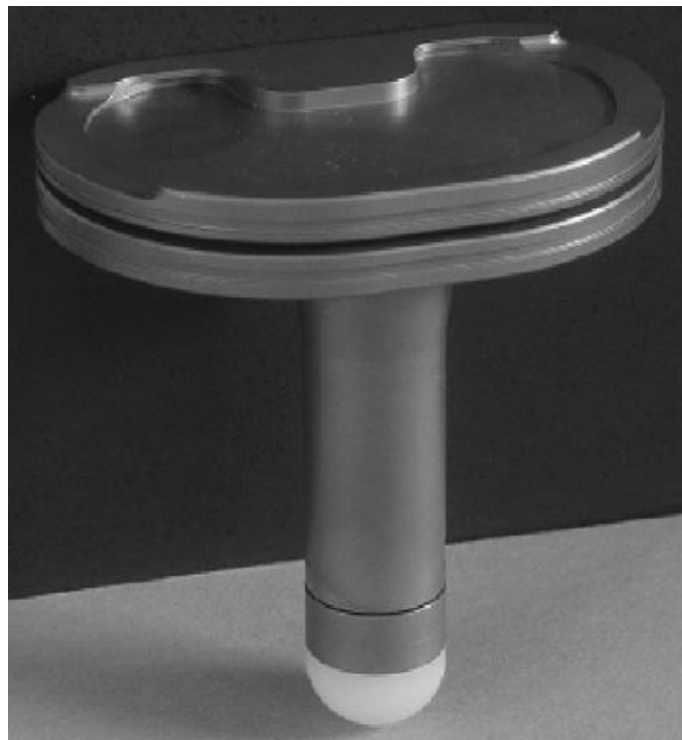
Figure 3.2: Instrumented tibial tray by Heinlein et al. Reprinted from [19].
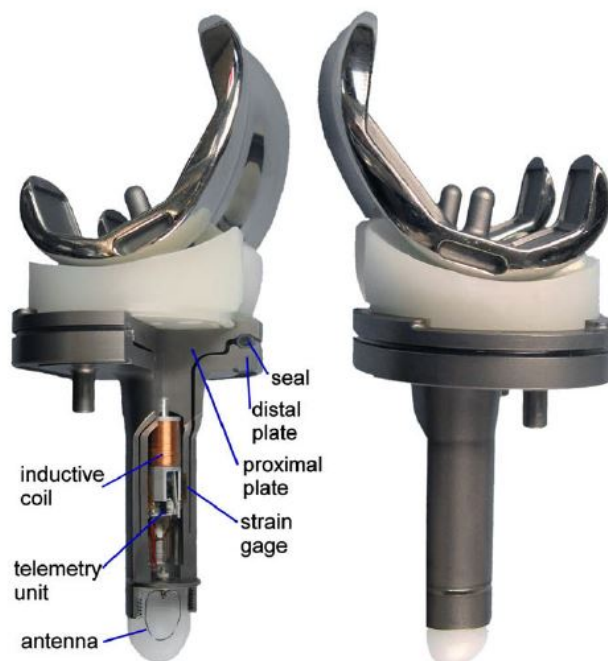
Figure 3.3: Instrumented tibial tray by Heinlein et al. Reprinted from [20].

They also studied the components of contact forces and moments of prosthetic knee joint in five subjects performing eight different activities of daily life [21].

The limitation of this study consists in the fact that the proposed prosthesis is significantly different from the original passive one; thus it requires an orthopedic doctor to modify the protocol for the surgery. Moreover, obtaining a validation for a human massive implantation is more complicated.

3.2 Instrumented prosthesis by Scripps Clinic Center for Orthopaedic Research and Education

Another early instrumented knee prosthesis for measurement of tibial forces was designed by the group of Prof. D'Lima, from the Scripps Clinic Center for Orthopaedic Research and Education, CA, USA. Similarly to what was done by the German group of Prof. Bergmann, they placed the strain gauges in the tibial part of the prosthesis [22, 23, 26]. In particular, they measured the tibio-femoral contact forces by placing the strain gauges in the tibial plate, as shown in figure 3.4
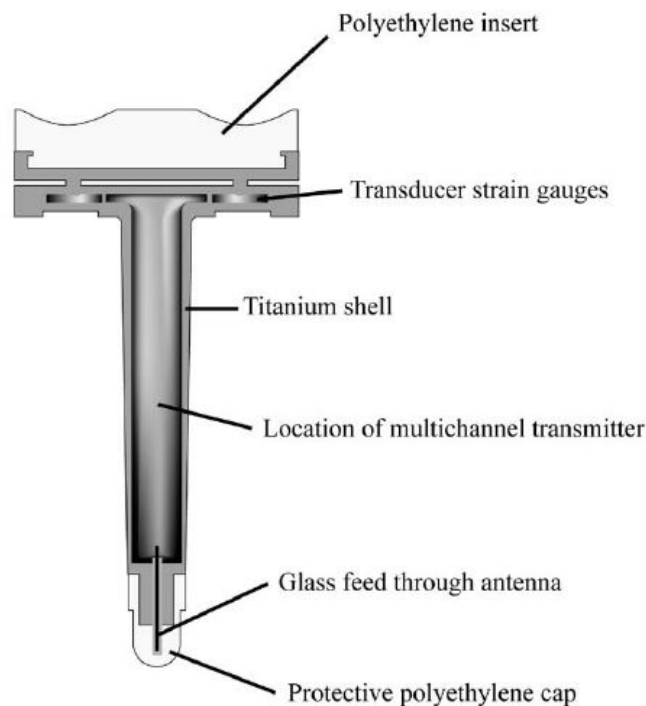
Figure 3.4: Cross section of the implant designed by DLima et al. Reprinted from [23].

They used a telemetry system, whose block diagram is shown in Figure 3.5. The analog signals from the four load transducers are converted to a multiplexed digital signal. Their design includes a microprocessor that generates a pulse code modulated RF signal, which is

transmitted through an antenna [23].

Figure 3.5: Telemetry system by DLima et al. Reprinted from [23].

Similarly to what the German group did, the transmitting antenna is located at the distal tip of the stem and is connected to the micro-transmitter. This choice has to be done because the RF signals do not pass through the titanium, the material of the prosthesis, but it requires a modification of the prosthesis. In particular, the distal part of the tibial tip, that contains the antenna, is covered by a polyethylene cap. Figure 3.6 shows the prosthesis with the telemetry system assembled (a) and a close view of the electronic system and the antenna (b).

Their device was implanted in a patient and the tibial forces were measured *in vivo* during the first year after total knee arthroplasty [24, 25]. Forces were measured during activities of daily living, such as rising from a chair, standing, walking and climbing stairs. In a later work [27], the instrumented prosthesis was implanted in three subjects, that were monitored during exercises and recreational activities. Figure 3.7 shows an X-ray image of the instrumented prosthesis implanted in one of the subjects that participated in the clinical trials.

Figure 3.6: (a) Implanted prosthesis with the telemetry system and (b) closed view of the electronics with the antenna. Reprinted from [26].

It is possible to recognize the different parts of the implant, already described in Figure 3.4.

Similarly to the work presented in 3.1, the limitation of this prosthesis is the significant modification of the instrumented prosthesis from the original one, resulting in an increased complication for the orthopedic doctors during surgery and a longer and more difficult approval from a hospital medical advisory board for massive implantation.

3.3 Instrumented prosthesis by University of Brescia

Another group working in the field of the instrumented knee prostheses is the one of Prof. Crescini, from the University of Brescia (Italy). In 2009, they designed an autonomous sensor to perform force measurements in a knee prosthesis and transmit the data to an external unit [28].

The autonomous sensor consists of magneto-resistive sensors for strain measurements, a low-power microcontroller with an A/D converter and a transceiver. It provides signal transmission via electromagnetic coupling at 125 kHz through the coil antenna of the transponder interface. The electronic system can be supplied by the same electromagnetic field.

A permanent magnet is located at the front face of the magneto-resistive element. The variation in the density of the magnetic flux, correlated to the strain applied, is measured as a

Figure 3.7: X-ray image of the instrumented prosthesis by DLima et al. implanted in a patient. Antero-posterior (A) and Lateral (B) views. Reprinted from [25].

resistance change.

This work differs from the others already described for two main reasons: as already explained, the sensors used for force measurement are not strain gauges, but magneto-resistors. Moreover, all the sensors and the electronics are not located in the tibial part of the prosthesis, but in the middle polyethylene insert. This second characteristics is innovative, because the proposed instrumented prosthesis is externally identical to the original one. This feature is very important, because the orthopedic surgeons would not be asked to change the surgery technique. Moreover, an acceptance for massive human implantation would be easier to be obtained. Figure 3.8 shows the proposed system.

The system was tested by calibrating the magneto-resistors at different levels of load.

The limitation of this work is the fact that in case of strong wearing of the polyethylene insert of the prosthesis, highly likely some years after the implant surgery, there is no protection to isolate the electronics from a very dangerous contact with the biological fluids and tissues.

In a later work [29], the system was tested *in vitro* with an automatic mechanical simulator INSTRON 8501 (see Figure 3.9), simulating the real knee forces and movements.
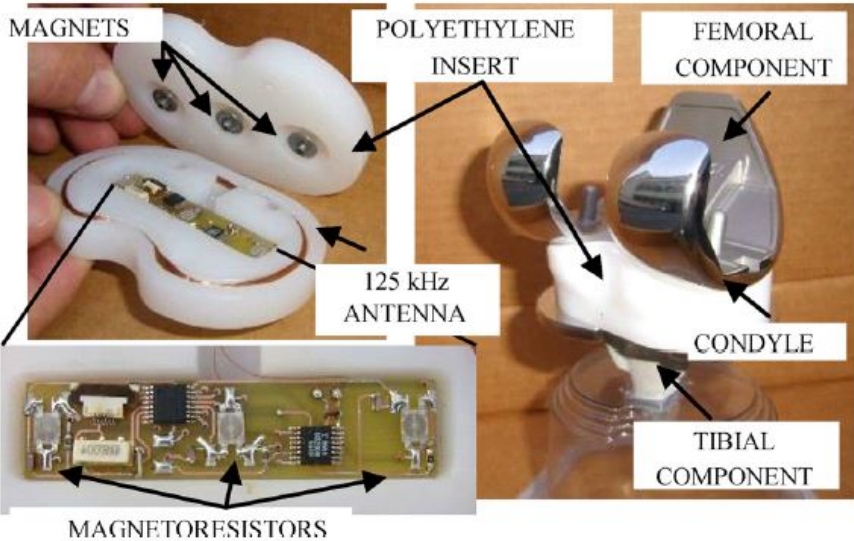
Figure 3.8: Instrumented prosthesis proposed by Crescini et al. Reprinted from [29].

Figure 3.9: Automatic mechanical simulator INSTRON 8501. Reprinted from [30].

Again, the electronics are not isolated and the problem of polyethylene wearing was not mentioned. Moreover, the remote powering efficiency analysis is not stated. That is why this system is not suitable for *in vivo* tests.

3.4 Instrumented prosthesis by University of Minnesota

Another similar work is the one of Holmberg et al. in 2013 [31]. The tibial insert is modified to measure the load applied to the knee, in a battery-less configuration.

In order to measure the load applied to the knee prosthesis, a capacitance sensor is proposed. A detail of the proposed force measurement system is shown in Figure 3.10.
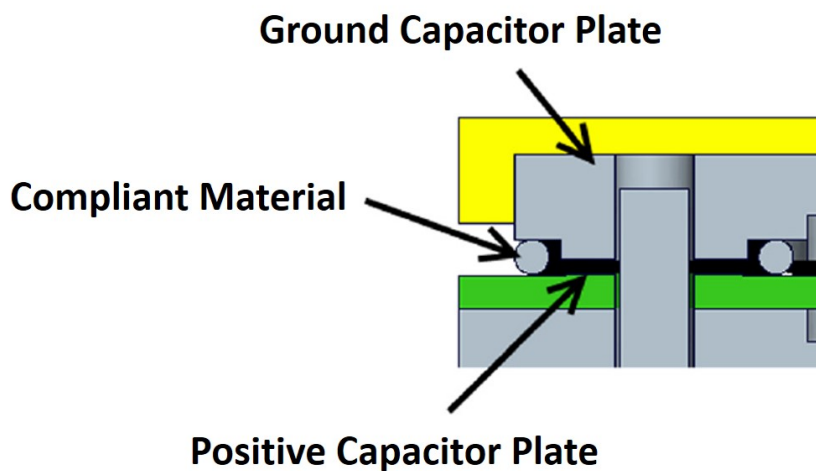
Figure 3.10: Layout of instrumented tibial tray by Holmberg et al. Reprinted from [31].

The system is powered internally, by a piezoelectric energy harvesting system. The energy is harvested during the walking of the patient, when forces are exerted on the tibial component (see Figure 3.11). This energy harvesting system provides all the energy required by the autonomous sensor and the wireless electronics, that are entirely powered by it.

The real system, shown in Figure 3.12, has the electronics exposed and thus this instrumented prosthesis, similarly to the one proposed by the group of Prof. Crescini, is not suitable for human implantation, due to the risk of contact between the biological fluids and the electronics in case of wearing of the polyethylene.

The fact that the system has a custom-made tibial tray, is also a potential problem not only for the surgeons, that should change the surgery procedure, but also for getting the approval for human implantation from a hospital medical advisory board.
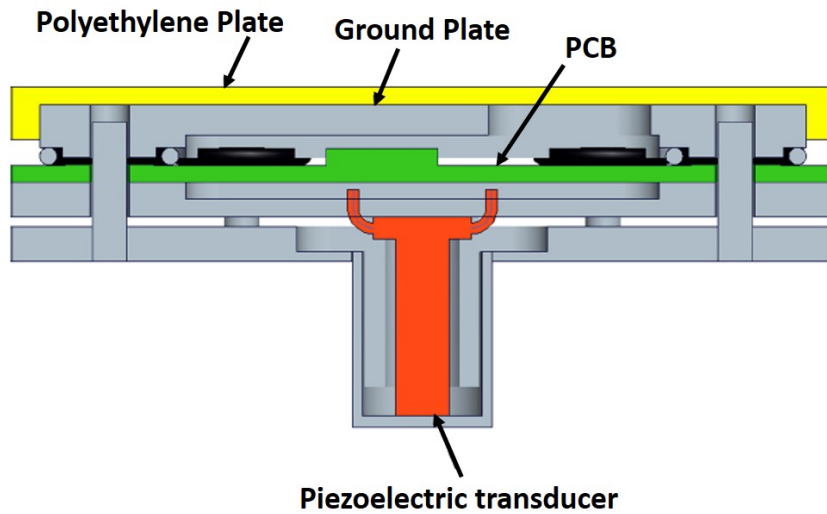
Figure 3.11: Layout of instrumented tibial tray by Holmberg et al. Reprinted from [31].
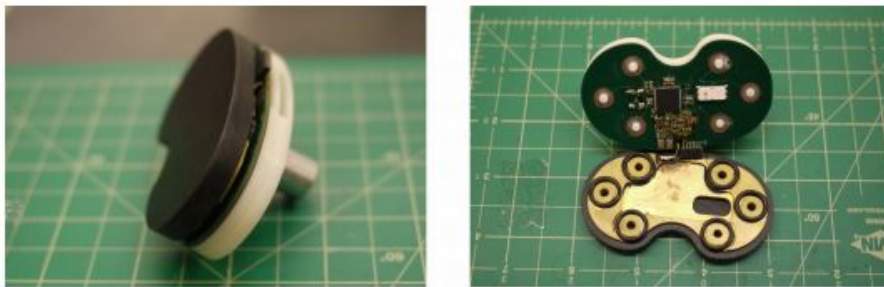
Figure 3.12: Instrumented tibial component by Holmberg at al. Reprinted from [31].

3.5   Single-use autonomous sensors

Some other devices exist, in which sensors and electronics are in the middle part of the prosthesis. These systems are not thought to be permanently implanted in the body of the patient, but are interesting, because they target the same application as this thesis.

3.5.1   Autonomous sensor by EPFL and University of Bern

The first example of an autonomous sensor used for ligament balancing is the one designed by Crottet at al. [34]. They developed a device consisting of two sensitive plates, equipped with three deformable bridges instrumented with thick-film piezoresistive sensors. They allow to measure the forces and moments acting in a knee joint during TKA, in order to improve the ligament balancing procedure (see Figure 3.13).

Their device was tested with a plastic knee joint and, in a second phase, on a cadaver specimen
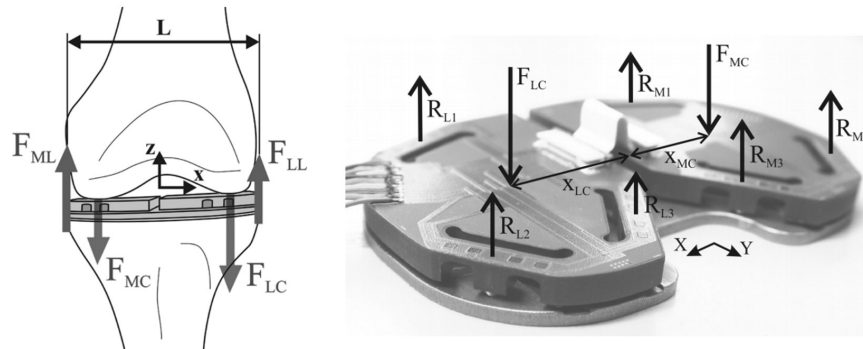
Figure 3.13: Autonomous sensor for ligament balancing designed by Crottet at al. Reprinted from [34].

and demonstrated an accuracy of 0.5% in a measurement range of 0-500 N.

As visible in Figure 3.13, the design does not include a wireless mode, thus the system requires a wire to collect sensors data.

3.5.2 Autonomous sensor by Tsinghua University

The group of Professor Wang, from Tsinghua University, Beijing, China, designed and fabricated a wireless system for the Ligament Balance Measuring in TKA [32] [33]. Their design includes two parts: the first one is a modified PE insert with four force sensors and a transmitting system (Figure 3.14); the second part is an external receiver (Figure 3.15).

They presented a calibration of the force sensors with a maximum relative error of 5%, but their work present strong limitations: the kind of force sensors used is not clearly detailed. Moreover, the sensors were calibrated in a force range going from 2.2 to 33.9 N, which are values completely unrealistic for a human knee, considering that when the surgeon manually applies varus-valgus loads during a standard TKA, the maximal contact force can reach 350–400 N [34].

3.5.3 Verasense by Orthosensors

Orthosensors SA, Florida, USA, developed a system for sensor-assisted knee replacement, called Verasense. It replaces the standard plastic tibial tray spacer used during knee replacement surgery and gives important information about the force applied on the implant to the medical doctors during surgery. In particular, it provides information on soft tissue balance, implant position and leg alignment. Figure 3.16 shows the Verasense autonomous sensor.

This system is meant to be single-use: the orthopedic surgeon can use it during surgery as shown in Figure 3.17 and, after verifying that the knee prosthesis is well aligned and the
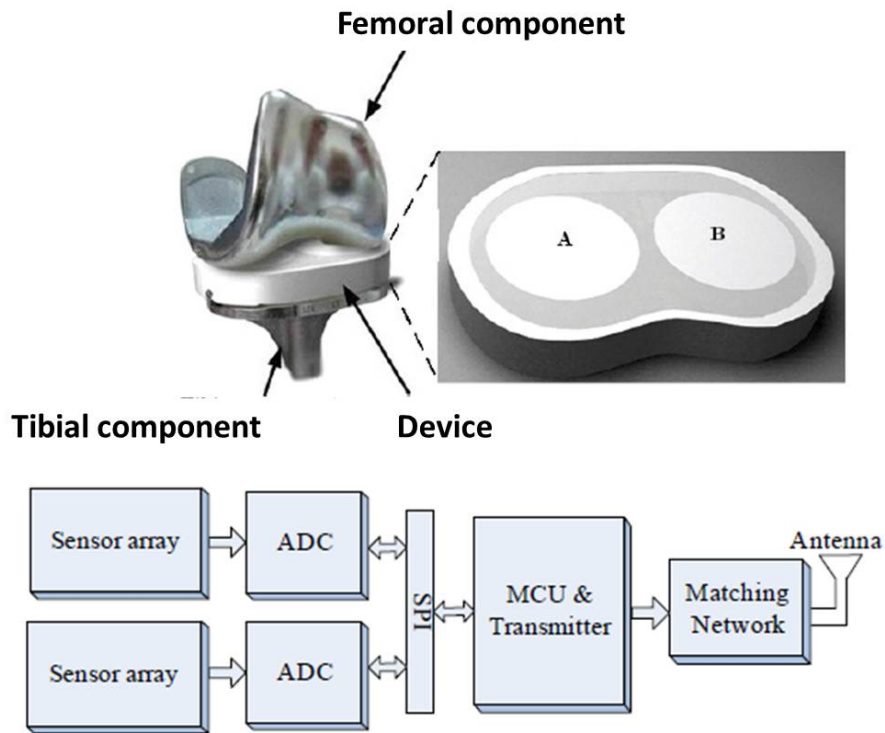
Figure 3.14: System and block diagram of the force measurement device proposed by the group of Professor Wang. Reprinted from [32] and [33].
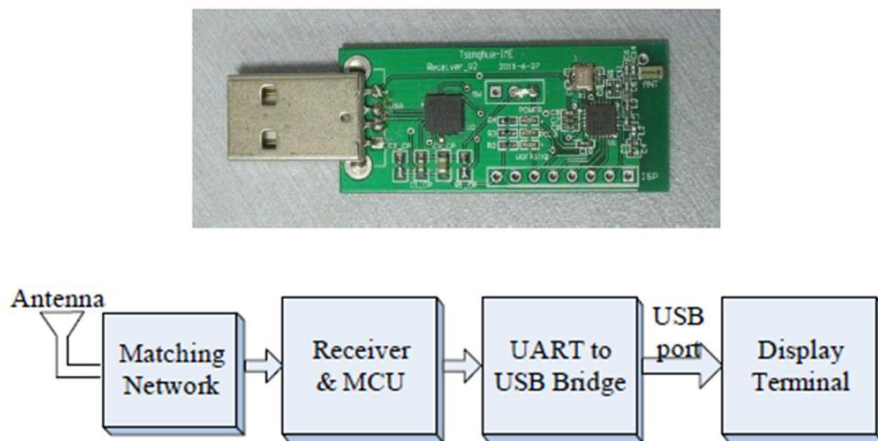
Figure 3.15: Receiver proposed by the group of Professor Wang. Reprinted from [33].

ligament tensions are well balanced, they replace it with the standard PE insert. Thus, the measurements can be done only when the knee is open and the system cannot provide any feedback after the implant, that could be used by the physiotherapists during rehabilitation or to verify the wearing of the prosthesis some years after the surgery.

Moreover, although this device could be very interesting for the surgeons to increase the

Figure 3.16: Verasense autonomous system. Reprinted from [36].

Figure 3.17: Use of Orthosensor autonomous system. Reprinted from [36].

precision of the implant positioning, the technology is not well described (only a few technical specifications are available), thus it is very difficult to compare it with other existing devices. Finally, it is intended for use only with a kind of prostheses: the Complete Knee System by Vanguard. This fact represents a strong limitation for this device, drastically reducing its application field.

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3.5.4 eLIBRA Dynamic Knee Balancing System

Another device, the eLIBRA Dynamic Knee Balancing System (see Figure 3.18), can help the orthopedic surgeon during surgery for the tendons balancing.

Figure 3.18: eLIBRA Dynamic Knee Balancing System. Reprinted from [37].

It provides an objective measurement of the forces across the medial and lateral compartments of the knee, when it is deflected by 90 degrees. According to the result of the force measurement, the surgeon can adjust the rotational position of the femoral component of the prosthesis in order to find the optimal position that balances the forces between the two compartments.

When the sensor is active and in place, the surgeon has to return the knee to 90 degrees of flexion and check the compartment forces on an external reader. If the forces in the two compartments are not equal, the femoral component of the prosthesis can be turned by using a specific instrument (the green wrench in Figure 3.19), until the two compartments forces are balanced.

Similarly to the Verasense system, this system is not an implantable device. It has to be taken out of the knee before the knee is closed at the end of the surgery.

3.6 Conclusion

In this chapter, we presented the state of the art on instrumented knee prostheses.

We described the works of the group of Prof. Bergmann from the Charité-Universitatsmedizin in Berlin (Germany) and the one of the group of Prof. D'Lima from the Cripps Clinic Center for Orthopaedic Research and Education in California (USA). Both this groups designed an instrumented knee prosthesis for measuring the load on the tibial tray, by modifying the tibial part of the prosthesis.

Figure 3.19: Adjustment of the femoral component of the prosthesis by using the eLIBRA Dynamic Knee Balancing System. Reprinted from [37].

In particular, they both modified the the distal section of the tibial part of the prosthesis by putting a PE tip, to host the antenna communicating with an external reader.

The group of Prof. Crescini from the university of Brescia (Italy) designed an instrumented knee prosthesis by modifying only the PE insert, but they did not design an encapsulation system to prevent the contact between the human body and the electronics in case of PE wearing.

A more recent work, by the group of Prof. Bechtold from the university of Minnesota (USA), designed a modified tibial tray to measure the load over it, but their design is based on a strong modification of the prosthesis as well.

The technical and medical issues related to these works have been listed.

Moreover, some single-use autonomous sensors for measuring the load applied on the knee prosthetic joint during the surgery have been introduced. They are not implantable devices, but they target the same application as the instrumented knee prostheses and can be an important support for the orthopedic surgeons during the ligament balancing.

In the next chapter, we will present the SImOS project, that aims to design an instrumented knee prosthesis that could solve the issues that we introduced in this chapter.

4 Project overview

In this chapter, we will describe in details the Nano-Tera SImOS project, that was briefly presented in chapter 2. The F.I.R.S.T. prosthesis by Symbios Orthopedie SA, that was used in the frame of this work, will be introduced. We will explain the kind of measurements that are interesting for such an implant and the methodology used to perform them. The constraints that have to be respected when designing an electronic system that has to be embedded in a medical device like a prosthesis, subject to wearing, will be listed. The innovative contribution of this project compared to the state of the art will be detailed. Finally, the consortium that contributed in the realization of the project will be presented.

4.1 Objectives

As explained in Chapter 3, although over one million of artificial joints are implanted every year in the developed countries, there are only few works in the field of instrumented prostheses. As far as the author knows, none of them led to a commercial product regularly implanted in patients, even though such a device could drastically reduce the number of early revision surgeries, that nowadays are about 8% in retired people and 20% in younger than 50 years, that are usually more active.

The goal of this thesis is to design innovative tools to measure *in vivo* bio-mechanical parameters of a knee prosthetic joint, but also to design a system that could be used, with only few modifications, with other kind of prostheses, such as ankle prostheses, that are based on the same principle as the knee prosthesis: plastic spacer between two metallic parts (see Figure 4.1).

These tools should be partly implanted inside the prosthesis and partly external. They must record medical information on the status of a knee prosthesis, in order to improve the treatments.

They should be used in all the different stages of the knee prosthesis implant:
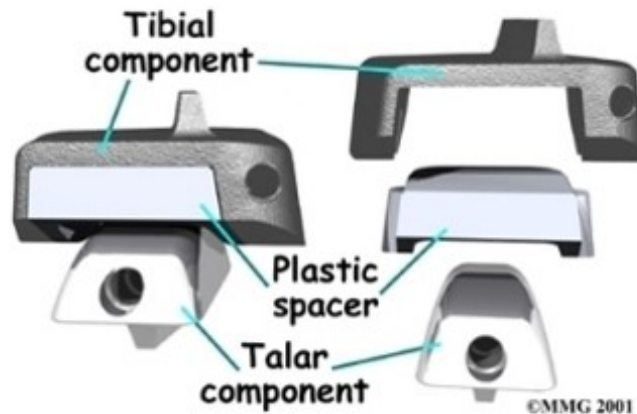
Figure 4.1: Ankle prosthesis presenting a plastic spacer between two metallic parts. Reprinted from [15].

- During surgery, they can help the surgeon in the precision of the implant positioning and to balance the tension of the ligaments and have the same amount of force applied on the two sides of the prosthesis. Moreover, they could help in the placements of the different parts of the prosthesis, in order to reach an optimal range of rotations.

- After surgery, it will allow to detect early migration of the prosthesis and potentially avoid later failure.

- During rehabilitation, they can help the physiotherapist in the evaluation of the mobility of the patient and to adapt the exercises accordingly.

- Over the years, they can provide the medical doctors with excessive wear and micro-motion information about the prosthesis, in particular in the case of a patient presenting a reduced mobility or feeling pain.

4.2 F.I.R.S.T. knee prosthesis

The overall objective of this thesis is to design a system that could be ideally used with any existing knee artificial joint, but in the frame of this work, we used the F.I.R.S.T. (Free Insert in Rotation Stabilized in Translation) knee prosthesis by Symbios Orthopedie SA. This prosthesis, shown in Figure 4.2, was designed in 2002 and is the result of a collaboration between Symbios Orthopedie SA and the University Hospital of Lausanne (CHUV).

It is an ultra congruent, postero-stabilized total knee prosthesis with a mobile bearing. It is designed to significantly reduce the wear of the polyethylene insert and to improve the range

Figure 4.2: F.I.R.S.T. knee prosthesis by Symbios Orthopedie SA.

of motion and the overall stability of the knee. For these reasons, it is particularly adapted to be implanted in young patients. Nowadays it is regularly implanted in Europe [38].

It is composed of thee main parts (Figure 4.3): the femoral (upper) and the tibial (lower) parts are made of a metallic cobalt and chrome alloy, while the middle insert is made of Ultra High Molecular Weight Polyethylene (UHMWPE– ISO 5834-2). The patellar component, not visible in Figure 4.3, is also made of UHMWPE and is placed in the front of the prosthesis.
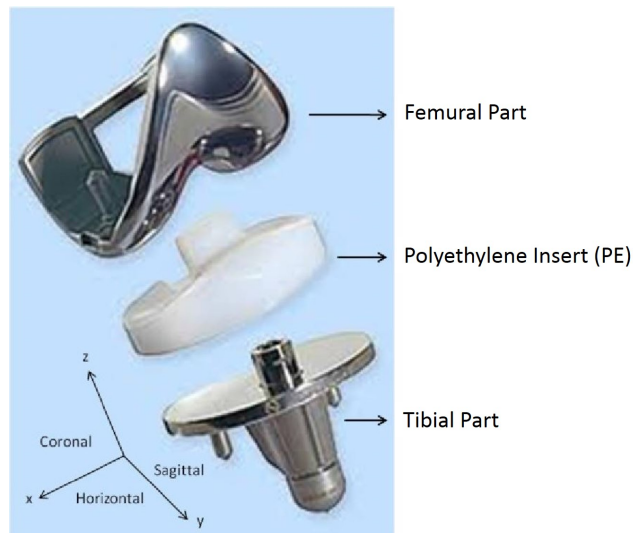
Figure 4.3: Three parts of the F.I.R.S.T. instrumented knee prosthesis.

All these three parts are available in a large range of sizes, to be adapted to every kind of knee, as shown in figure 4.4

For this work, only one size of the polyethylene insert was used, in particular the B12, having
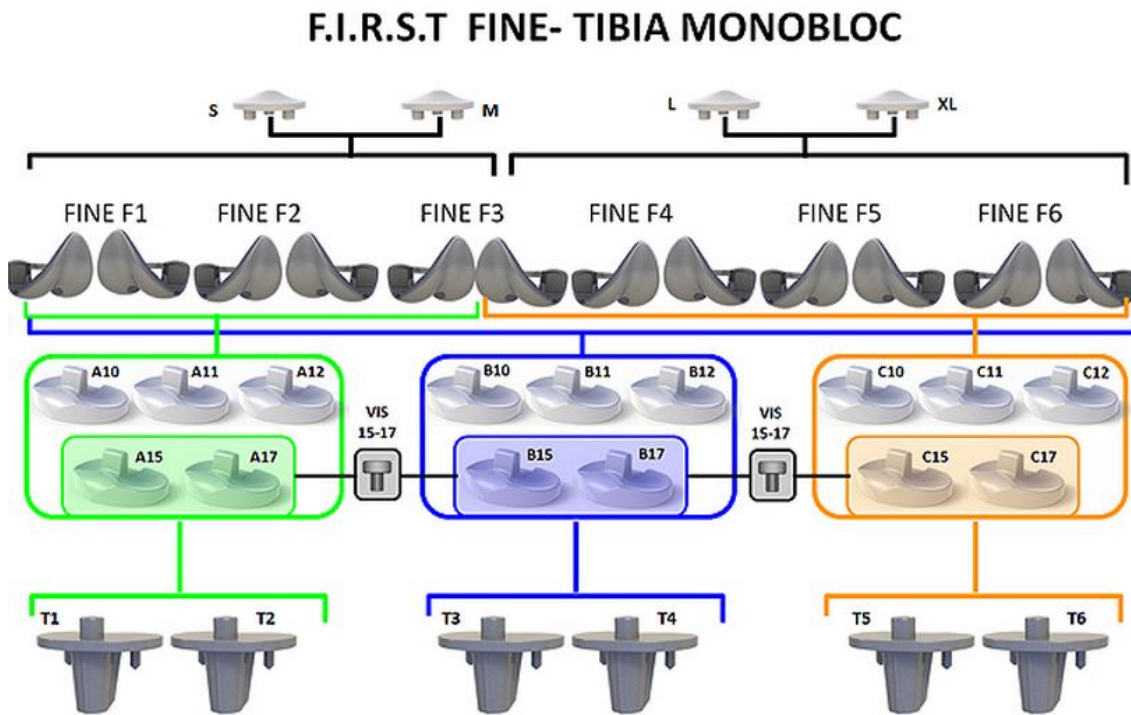
Figure 4.4: Available sizes of the F.I.R.S.T. knee prosthesis.

the middle planar dimensions and a thickness of 12 mm.

4.3 Type of measurements required

The biomechanical parameters that can be interesting in the evaluation of the status of a prosthetic knee joint are several, such as the force applied on the prosthesis, the joint rotational angles, the translational movements or the micro-motions between the prosthesis and the bone to which the prosthesis is fixed.

In this thesis we focused on the measurements of the vertical force applied on the prosthesis, both the total force and the force balance between the two femoral condyles, and the 3D rotational angles of the joint, that can be fused with the data obtained by using skin-mounted sensors to evaluate the prosthetic knee kinematics.

These parameters measured *in vivo* can help the medical doctor in making an objective evaluation of the knee joint. For instance, an unbalanced vertical force between the two sides of the prosthesis is usually related to the wearing of the PE insert (see Figure 4.5) and results in a pain felt by the patient.

The amount of the wear depends on multiple factors, such as the age, the sex, the weight, the way of life and the activity of the patient [41]. Nowadays, when the patient goes to the medical office, the exam typically used to confirm the hypothesis of PE wearing is an X-ray bio-image.
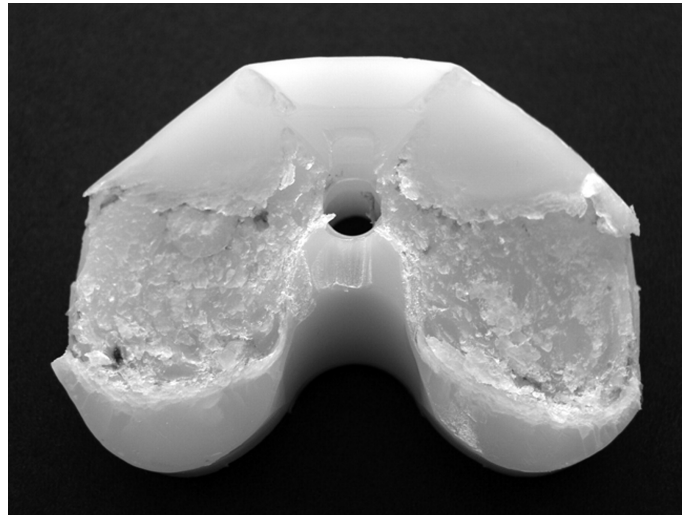
Figure 4.5: Worn polyethylene insert. Reprinted from [39].

Having embedded sensors to measure the vertical force could help in having a quantitative evaluation of the wear.

Knee mobility is related to the joint function. For instance, a limited range in the knee rotation angles can be caused by a wrong position of the implanted parts or a conflict with the surrounding anatomical structures, such as ligaments or muscles.

Force sensors

In order to measure the total force applied to the prosthesis and the lateral-medial imbalance, strain gauges were designed and fabricated by EPFL-LMIS4 in the Center of Micronanotechnology cleanroom available in EPFL (EPFL-CMI) [42]. The designed force sensors were arranged in a Wheatstone bridge topology containing 4 strain gauges, as shown in figure Figure 4.6.
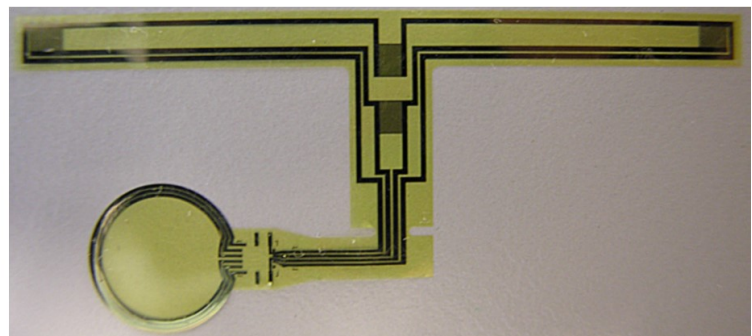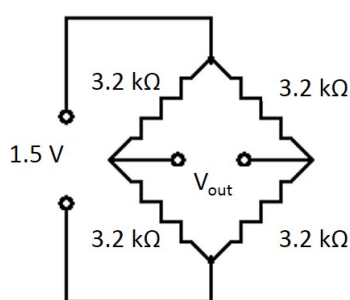
Figure 4.6: Strain gauges designed for the measurement of the vertical force applied to the prosthesis.

The specifications of the strain gauges are listed in table 4.1.

Table 4.1: Specifications of the strain gauges.

Strain Gauges specifications	
Excitation	1.5 V
Bridge impedance	3.2 $k\Omega$
Power	0.7 mW
Dimensions	4x2x0.03 mm
Volume	0.24 mm^3

The optimal position of the strain gauges inside the polyethylene insert corresponds to the point of maximum strain when a vertical force is applied on it. It was determined by means of a Finite Elements Analysis (see Figure 4.7), simulating a vertical force ranging from 50 N to 2500 N, performed in collaboration with the EPFL-LBO laboratory.

Kinematics sensors

For kinematics measurements, and in particular for the detection of the 3D rotational angles of the knee (flexion-extension, abduction-adduction, and intra-extra rotation), it was decided to use magnetic sensors.

The traditional measurement of the 3D knee kinematics is based on skin-mounted sensors (reflective markers), whose movements are detected by a system of infra-red cameras in a gait analysis lab (see Figure 4.8). This measurement is affected by the presence of soft tissues, because the markers are not directly in contact with the bones or, in the case of a prosthetic knee, with the femoral and tibial parts of it.

In this work, we decided to use a sensor system embedded inside the PE insert of the prosthesis. At least three Anisotropic Magnetic Resistors, connected in a Wheatstone Bridge configuration, have to be placed in the PE insert. Two magnets are connected to the femoral and tibial parts of the prosthesis, as shown in Figure 4.9. The movements of the two magnets are detected by the magnetic sensors and correlated with the rotations of the different parts of the prosthesis [43].

The data obtained with these sensors embedded inside the polyethylene can be validated by using a traditional system with skin mounted sensors.

4.4 Specifications for the SImOS instrumented prosthesis

In order to provide the orthopedic surgeons with a knee prosthesis almost identical to the one that they presently implant, it was decided that, except the small magnets required for the kinematics measurements, all the components implanted have to be placed inside the PE insert. This means that all the sensors, the electronics required for data acquisition and
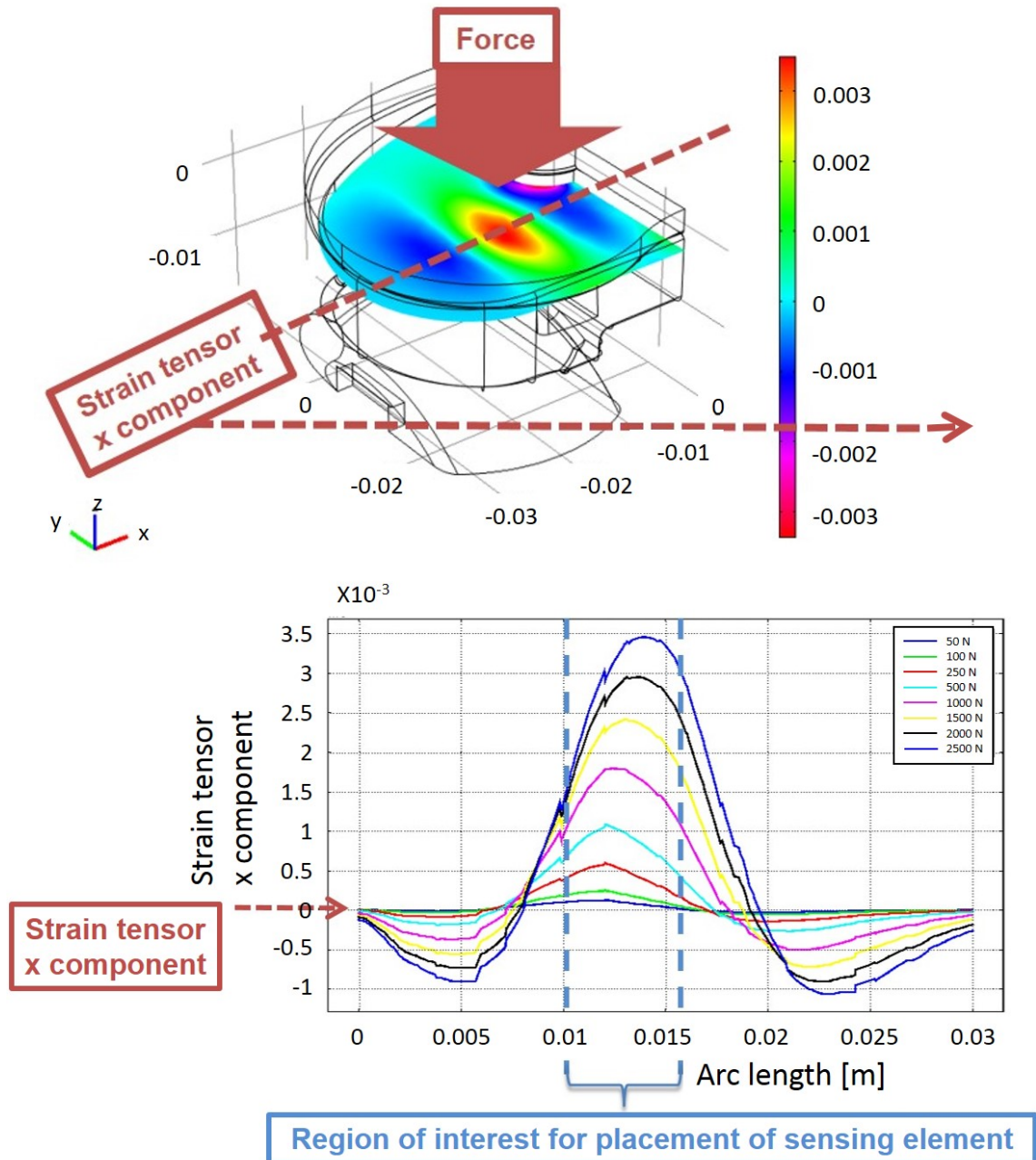
Figure 4.7: Finite Elements Analysis performed to determine the point of maximum strain when a vertical force (ranging from 50 N to 2500 N) is applied on the PE insert. Courtesy of EPFL-LBO.

transmission, the antenna used for powering the system and collecting data are embedded inside the middle part of the prosthesis.
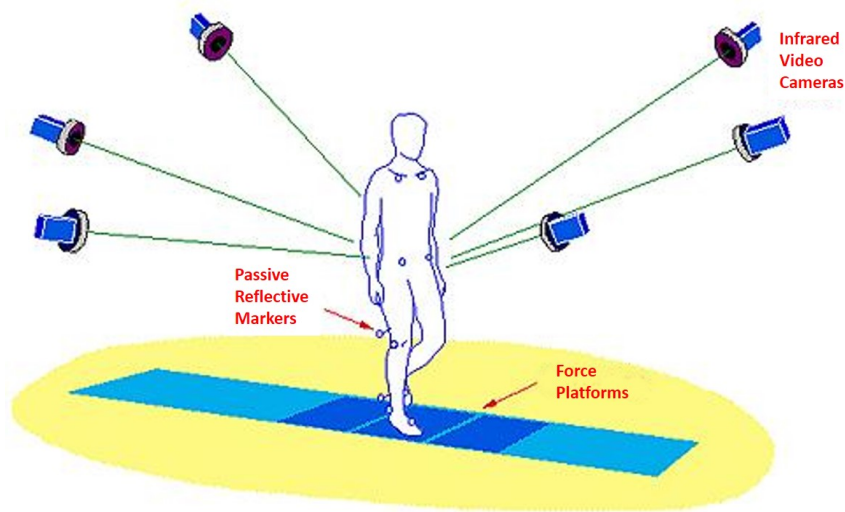
Figure 4.8: Kinematics measurement performed in a Gait Analysis Lab. Reprinted from [40].
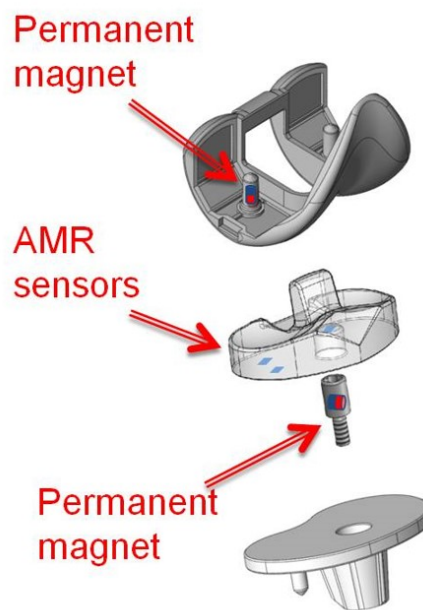
Figure 4.9: Anisotropic Magnetic Resistors and magnets used for kinematics measurements.

This choice results from two main reasons: first of all, obtaining an approval from an hospital medical advisory board for human tests would be much easier. Secondly, the clinicians are not required to change the surgery protocol, except for that fact that, when the prosthesis is in place, they can use an external reader to check if the ligaments tension is well balanced or the knee motion range is correct, adopting corrective measures if necessary.

One of the main issues with an instrumented knee prosthesis is to avoid the contact between

biological tissues and fluids and the electronics in case of extreme wearing of the PE insert of the prosthesis. It is reported that few years after the implant, the PE can be very worn. Using a traditional printed circuit board (PCB), with the electronic components soldered on the surface, this fact could represent a problem for the health of the patient. For this reason, in order to satisfy the regulations, the prosthesis manufacturers asked to place all the electronic components at not less than 3 mm below the PE surface. Unfortunately, in case of extreme wearing this could be insufficient. It is thus necessary to design a sealed electronic system, a sort of shell, with all the components inside and none of them soldered on the external surface.

Another important requirement that has to be respected in view of a future human implantation is the bio-compatibility, that has to be guaranteed during the whole life of the prosthesis. The PE insert that contains the shell with the electronics is bio-compatible, but the risk is once again the wearing. In chapter 5 the approach followed will be explained.

4.5   Innovative contribution

As all the instrumented knee prostheses described in the state of the art, the instrumented knee prosthesis proposed by the SImOS project can help the clinicians in the different steps of the implant life: during the surgery, to increase the precision of the positioning and the ligament tension balance, thus reducing the risk of an early revision; during rehabilitation, to evaluate the performance of the patients during the different exercises; when a patient reports some issues, to understand the source of the problem.

The SimOS instrumented prosthesis presents some very innovative features, that differentiate it from the other works and make it more attractive for a clinician or a patient.

- All the components are placed inside the PE insert. This means that the external shape of the prosthesis does not change and it is easier to obtain an ethical committee approval for human implantation.

- The surgery procedure does not require to be changed, thus no additional efforts are asked to the orthopedic surgeons.

- If the electronics inside the prosthesis is damaged, the prosthesis, being identical to the one already implanted, can stay in place and work as a traditional passive one.

- The SImOS prosthesis design does not include a battery, that would be difficult to be recharged. Moreover, it is potentially very dangerous in case of leaking for the human body.

- In case of extreme wearing of the polyethylene insert, the designed package (see chapter 5) avoids the risk of contact between the electronics and the biological tissues and fluids and the bio-compatibility is guaranteed.

- This instrumented prosthesis can acquire data from different kind of sensors at the same time, namely force and kinematics sensors. This is particularly useful for the medical doctors, which could be helped in the diagnosis if a patient presents some issues with the implant. For instance, the PE wearing can be detected by using the force sensors, while a limited mobility in rotation can be detected by using magnetic sensors for kinematics measurements.

4.6 Consortium

Such a project requires high-level competencies in different domains. The consortium that contributed in the realization of this work is constituted of five laboratories of the Ecole Polytechnique Fédérale de Lausanne (EPFL), a laboratory of the University Hospital of Lausanne (CHUV) and Symbios Orthopedie SA, the company that designed and provided the passive knee prosthesis under study.
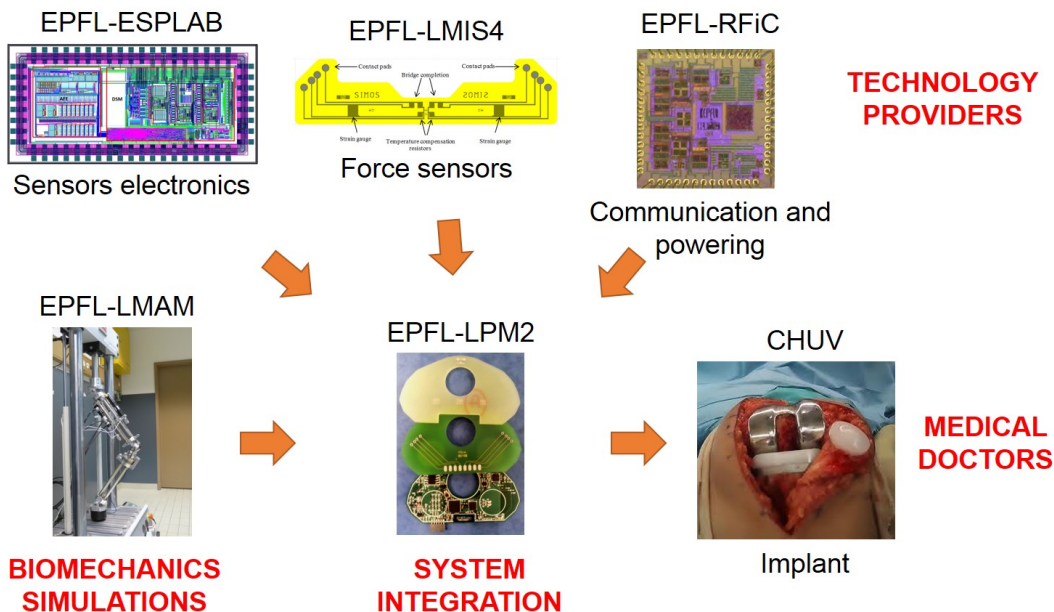
Figure 4.10: Consortium of partners working in SImOS project.

As shown in figure 4.10, the different groups worked together to provide the medical doctors with a prosthesis identical to the one that they are already implanting daily, but instrumented with sensors and electronics for data acquisition and transmission. The force sensors were developed by the Microsystems Laboratory (LMIS4) of EPFL. The Electronics and Signal Processing Laboratory (ESPLAB) and the The Radio Frequency Integrated Circuit (RFIC) Group designed the analog front-end (AFE) for interfacing the sensors and the IC for powering the system and data communication respectively. The Laboratory of Movement Analysis and Measurement (LMAM) was in charge of the kinematics measurements and the biomechanics

simulation. The Laboratory of Microengineering for manufacturing was in charge of system integration and encapsulation and, finally, the CHUV helped all the partners during the project providing medical advices.

4.7 Conclusion

In this chapter, we presented the SImOS project, that aims to design an innovative instrumented prosthesis to measure force and kinematics signals of a total knee artificial joint.

The prosthesis used for this work, the F.I.R.S.T. total knee prosthesis by Symbios Orthopedie SA, was presented and the kind of sensors used in the frame of this thesis were introduced.

The constraints that the medical doctor and the prosthesis manufacturer fixed in order to have an implant innovative compared to the ones presented in the previous chapter have been listed.

The next chapters will present the technical solutions adopted in order to achieve these objectives. In particular, chapter 5 will introduce the encapsulation of the electronic system inside the PE insert of the prosthesis and we will be detail how the proposed solution allows the respect of the design constraints.

5 System encapsulation

In this chapter, we describe the encapsulation proposed for the SImOS electronic system. In the first part, the specifications established by the medical doctors and the prosthesis manufacturers for an electronic system implantable into the F.I.R.S.T. knee prosthesis will be detailed. Then, the solution adopted will be presented, explaining how it respects the design constraints.

5.1 Instrumented prosthesis packaging requirements

The design of an implantable medical device is a very difficult challenge. The limitations in the design are due to the fact that these devices are meant to stay in the human body, a very harsh environment, from few hours, it is for instance the case for a capsule for endoscopy [50], to years, like a Pacemaker, that is expected to last in the body of the patient at least 10 years [51].

A knee prosthesis has to respect some general specifications, common to all the implantable medical devices, and some others specific to this kind of implant.

The discussions with the medical doctors and the engineers of Symbios Orthopedie SA led to a set of specifications that we fixed and had to respect while designing the miniaturized version of the instrumented prosthesis.

These requirements and specifications and the solution adopted are described in the following sub-sections.

5.1.1 Electronics inside the polyethylene insert

As already mentioned in section 4.4, one of the most important innovative contribution in the packaging of the proposed instrumented knee prosthesis, compared to the state of the art, is the fact that all the components are placed in the polyethylene insert of the prosthesis (see

Figure 5.1).
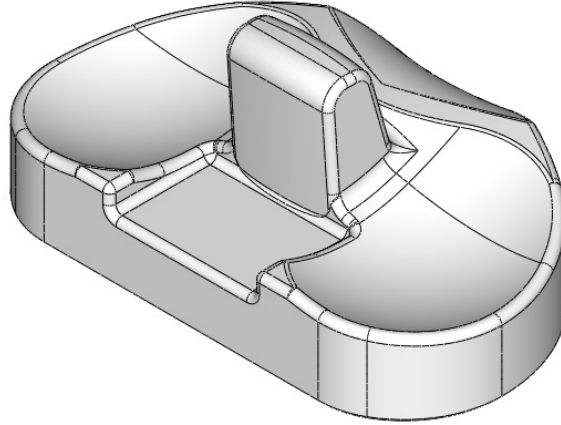
Figure 5.1: Polyethylene insert of the F.I.R.S.T. knee prosthesis by Symbios Orthopedie SA.

The only work present in literature that proposed a similar approach is the one of the group of Professor Crescini, from the University of Brescia, Italy, presented in Section 3.3.

This choice was made after discussing with both the orthopedic doctors and the prosthesis manufacturers and has multiple reasons.

Having an instrumented prosthesis with all the components inside the PE means that, externally, it cannot be distinguished from a passive one, except for the fact that the sensors and the electronics could be visible by looking at the instrumented PE, which is partially transparent, with a light behind.

From the medical point of view this is an undeniable advantage, because it means that the surgical procedure does not require to be modified and adapted to a different prosthesis shape. Changing the surgery protocol means that all the clinicians (surgeons, anesthetists, nurses, technicians, etc.) require a training, which could be long, expensive and not always well accepted, especially for implanting only few knee prostheses, during the preliminary clinical trials.

Another advantage of this approach is the fact that every new medical device, before being implanted in a patient, needs to get an approval from a hospital medical advisory board, in charge of evaluating its safety for the patients [52]. This has to be done regardless of the fact that this device is instrumented with electronics or not.

The decision-making process for approving medical devices is very complex, because it is subject to many constraints, and, very often, it requires years to make the final decision. Although it is difficult to find in literature concrete data regarding cost or time, it has been estimated that the time from concept to market for medical devices is between 3 to 7 years

[53].

Figure 5.2 shows the decision-making process for medical devices approval by the US Food and Drug Administration (FDA).
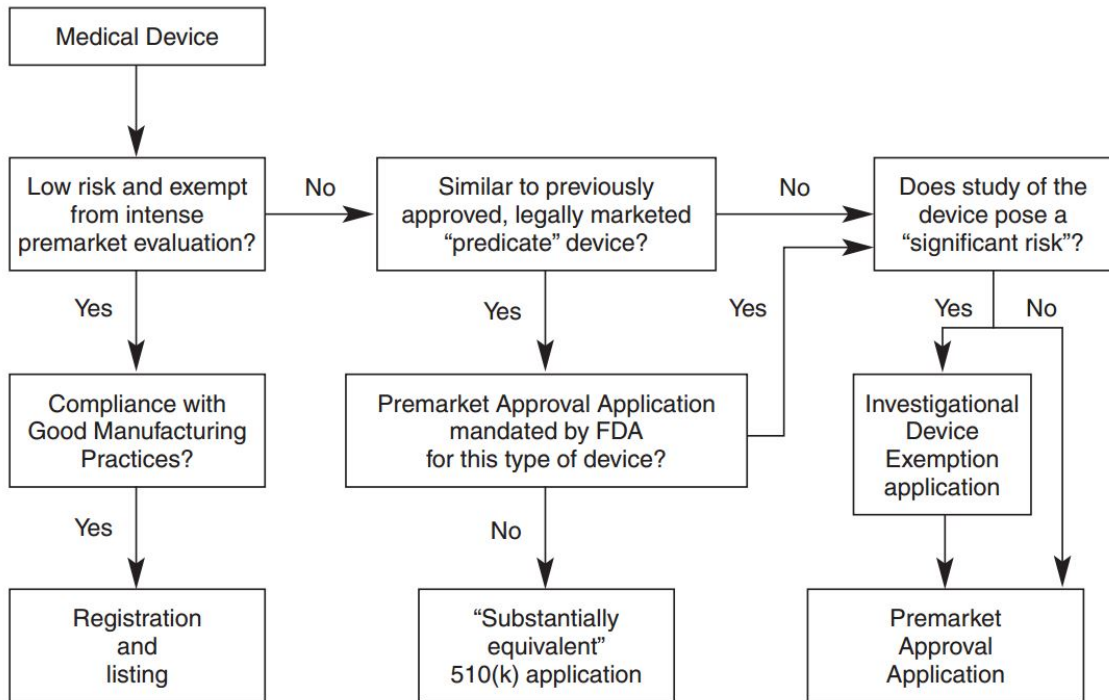
Figure 5.2: Overview of the FDA medical device approval process. Reprinted from [54].

The decision-making process is not necessarily the same in the European hospitals and institutions, but the block diagram clearly shows that getting an approval when a new device is *similar to previously approved, legally marketed "predicate" device* is much easier than for a totally new one.

5.1.2 Isolated electronics

The electronics embedded inside an instrumented knee prosthesis is constituted of multiple sub-systems:

- Sensors subsystem:
  for force and 3D kinematics measurements, at least a strain gauge per side and three bi-dimensional magnetic sensors are required.

- Analog front-end:
  for interfacing the analog sensors with a microcontroller, that controls the sensors data acquisition, storage and communication.

- Communication and powering subsystem:
  for powering the system by using an external reader and transmit the sensors data to it.

- Memory:
  an optional memory can be used to store the sensors data inside the implant before sending them to the external reader.

Such a complex system requires a lot of components, thus a lot of available space on the surface of the PCB that will be embedded inside the PE insert. A crucial element in the design of an implantable medical device is to avoid the contact between the electronic components and the human body. As it was explained before, a total knee prosthesis, and in particular its middle PE insert, is subject to wearing. To put a PCB directly inside the PE is potentially a risk, because some years after the implant the piece could be very worn and the electronic system could be exposed.

In section 5.2 the solution adopted to avoid this risk will be presented.

5.1.3   Power supply and data transmission

An instrumented prosthesis, like every medical implantable device, needs an energy source to be powered and a communication system to transmit sensors data to an external reader, that could be connected to a PC, a Tablet, a Smartphone or simply a display that can provide the clinicians with information on the status of the prosthesis (i.e. the force balance between the medial and lateral sides, the rotation angles, etc.).

Some medical devices are powered by a battery. For instance, the pacemaker has a battery, which is contained in a hermetically sealed casing. Unfortunately, this is not an applicable solution for an instrumented knee prosthesis, especially if one of the constraints of the design is to put all the electrical components (thus also the battery), inside the PE insert, which is strongly subjected to wear. In case of extreme wearing of the PE, the risk of battery leakage would prevent every hospital advisory board from giving an approval for an human implant.

Some technologies exist in which an electronic implantable device can be powered by an external reader, that is used both to transmit the required power to the implant and to collect sensors data.

Radio frequency inductive links are becoming more and more used for telemetry and wireless powering in the field of implanted medical devices and RFID implants [56].

The limitation of this approach is the amount of total energy that can be delivered through the RF-link, that depends on the frequency and the distance between transmitting and receiving coil. It is often limited, requiring a low-power design of the electronic implantable system and of the firmware of the microcontroller.

The kind of the receiving antenna and its placement in the implant are two other critical points in the design. This is particularly important if the antenna is placed inside the PE insert of a knee prosthesis, which is located between two metallic parts (the femoral and tibial parts) that can act as a shield, resulting in a loss of most of the transmitted energy.

For this reason, a PCB antenna, like the one shown in Figure 5.3 is not a suitable solution, because it would be located in the middle of the two metallic parts.
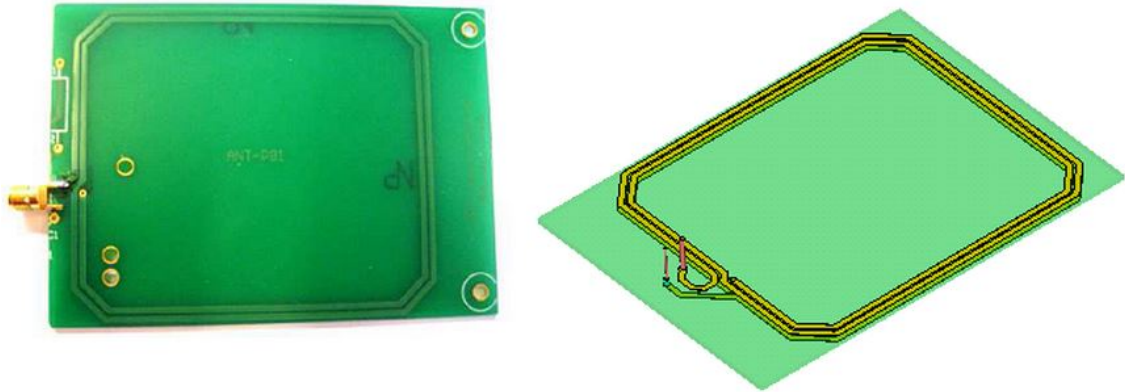
Figure 5.3: Example of a PCB coil. Reprinted from [57].

For a knee prosthesis a suitable solution could be an SMD RFID coil, like the one shown in Figure 5.4 as an example.
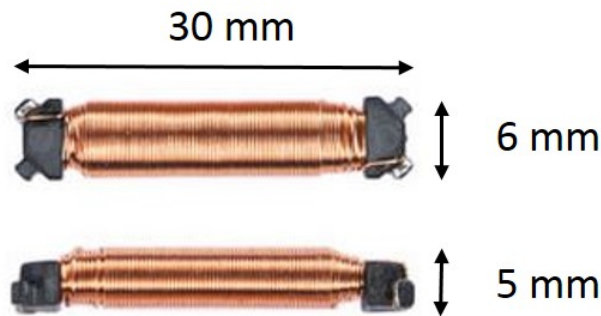
Figure 5.4: Example of an SMD RFID coil. Reprinted from [58].

5.1.4 Bio-compatibility

One of the most important requirement for an implantable medical device is understandably its bio-compatibility, in order to avoid a rejection by the human body. The materials of the F.I.R.S.T. knee prosthesis (cobalt-chrome alloy for the metallic parts and polyethylene for the

middle insert) are obviously bio-compatible. A modification of the existing prosthesis must guarantee that this bio-compatibility is kept.

Since the goal of this project is to keep the same external shape of the prosthesis, without modifications, at the moment of the surgery the bio-compatibility is guaranteed.

The problems can occur some time after the total knee arthroplasty, when the PE insert containing the sensors and the electronics begins to wear.

In case of extreme wearing, the PCB embedded inside the PE can be exposed and in contact with the human body. The substrates used in the PCB standard technology, under some limitations, can be bio-compatible, but are subject to lamination and since the materials typically used for the connections and wires (for instance copper) are not bio-compatible, an isolation is required [55].

5.1.5 Waterproof

The problem of having a waterproof system is conceptually similar to the one of guaranteeing the bio-compatibility. The PE insert is waterproof at the moment of the implant, but an extreme wear can put in contact the electronics and the biological fluids, with a possibly very dangerous effect for the patient.

This hypothetical source of risk must be avoided in the packaging design.

5.1.6 MRI compatibility

Another constraint in the design of an instrumented knee prosthesis is the fact that the Magnetic Resonance Imaging (MRI) compatibility, guaranteed with the passive prosthesis, should be kept. The information provided by the MRI (Magnetic Resonance Imaging) is significantly different than the other imaging methods. The MRI images are very efficient for showing the soft tissues and for this reason are used to observe the spinal cord, as well as the tendons and ligaments, especially around the knee and the shoulder. Furthermore, an MRI scan permits to distinguish between different tissues and thus it is used to detect pathological tissues (for instance brain tumor) from normal ones.

Although MRI scan will not be used for showing the knee in patients with a prosthesis, it will be still very useful for showing other parts of the body.

For these reasons, in order to get an approval from an medical advisory board for an instrumented prosthesis implantation, design a system with a full MRI-compatibility would be an important advantage.

5.2 Proposed solution

This section describes the design of the encapsulation of the instrumented version of the F.I.R.S.T. total knee prosthesis. All the technical solutions that were found to satisfy the requirements presented in the previous section will be detailed.

5.2.1 Dimensions of the electronic system

In Section 5.1.1, it was explained that, in order to obtain an approval for human implantation from an hospital advisory medical board, designing an instrumented prosthesis that is externally identical to one that is already implanted highly simplifies the task.

Moreover, in that case, the surgical procedure is identical to the original one, with a huge advantage for the clinicians.

For this reasons, the engineers of Symbios Orthopedie SA asked us to respect this strict constraint and put all the instrumentation inside the PE insert, in order to reduce the amount of documentation that has to be provided to the advisory committee and consequently the time-to-market for the new device.

Obviously, the most evident consequence of this choice is the fact that the space available for the electronics inside the PE insert is very limited. The size of the PE insert used in the frame of the thesis is shown in Figure 5.5.
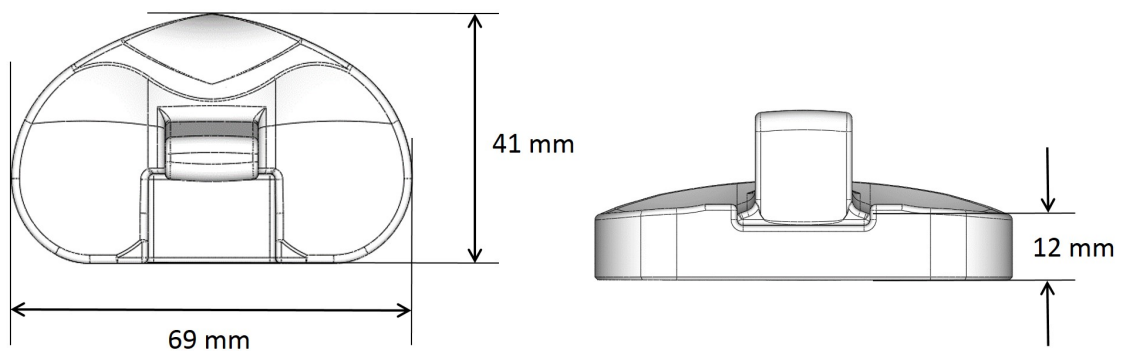
Figure 5.5: Size of the B12 PE insert used in the frame of this work. Top and lateral view.

The PE insert of the prosthesis, in the bottom part, has a hole (see Figure 5.6). The function of this hole is to host the head of the screw fixing the tibial part of the prosthesis to the pin that is inserted into the bone during the replacement surgery. Understandably, this space cannot be used for the electronic system.

Moreover, the prosthesis manufacturers, to keep the mechanical properties of the prosthesis, asked us to keep at least 3 mm of PE between the edge of the PE insert and the electronics embedded inside it. This space has to be kept both close to the external edge of the piece and
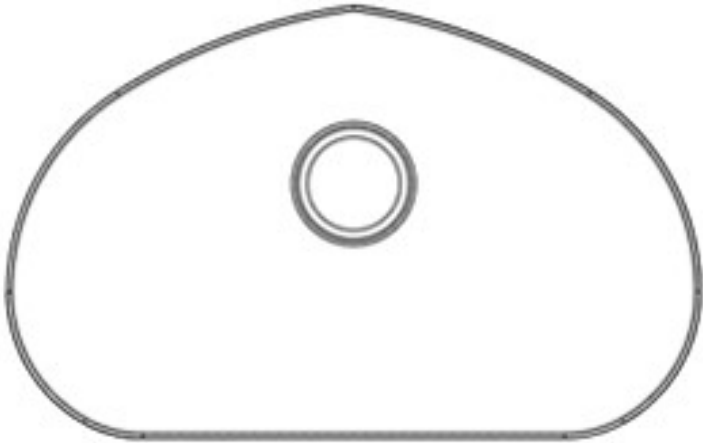
Figure 5.6: Bottom view of the PE insert.

close to the central hole, further reducing the available space for the electronics.

In conclusion, the available space for a Printed Circuit Board (PCB) containing the sensors and the electronics is very limited. The final dimensions of the PCB fitting the PE dimensions are depicted in 5.7. The estimated available area on the surface of the PE insert is $\sim 26\,cm^2$.
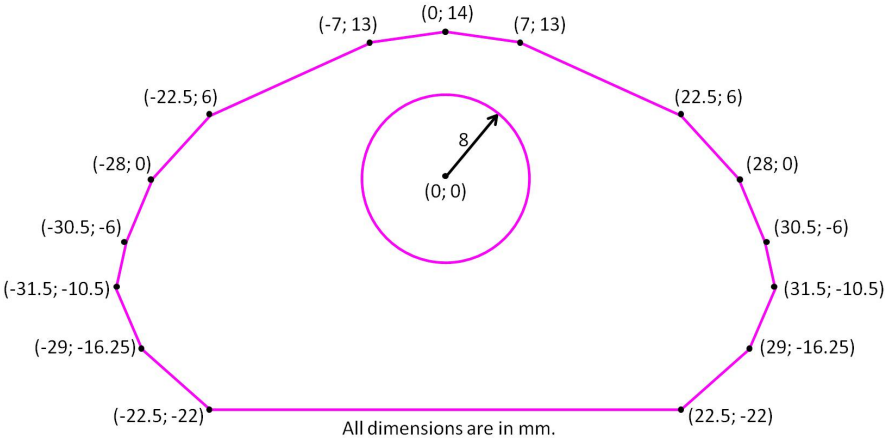
Figure 5.7: Dimensions of the PCB fitting the prosthesis available surface.

5.2.2   Isolation of the electronics

In section 3.3 we presented the instrumented knee prosthesis designed by the group of Professor Crescini, the only work known in literature in which all the electronic components (sensors, microcontroller, telemetry system, antenna) are located inside the PE insert of the prosthesis.

As explained in the previous section, this is also one of the goals of this thesis.

The main problem with the approach of the Crescini group is the fact that the electronics is not isolated and, in case of extreme wearing of the PE insert, it could be in contact with the human body. This limitation prevents this prosthesis to be tested *in vivo*.

In this work, a different approach is presented: the electronic system will be constituted of three PCBs, in a "sandwich" configuration, as shown in Figure 5.8.
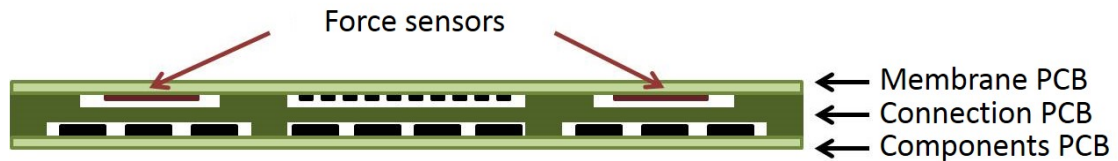
Figure 5.8: Sandwich PCB structure containing all the electronics of the SImOS instrumented prosthesis.

The PCB sandwich is organized as follows:

- Membrane PCB
  It is the upper of the three PCBs, the one on the side of the tibial part of the prosthesis. It contains the force sensors, one per side, glued to it in the internal part. Some electrical components could also be placed in the central part of it, if necessary. The thickness of the membrane PCB is 0.3 mm.

- Connection PCB
  The middle PCB has two functions: electrical connection between the upper and lower PCBs and mechanical support of the whole structure. Two cavities are opened in its top layer below the position of the strain gauges glued to the top PCB, in order to increase their deformation when a vertical force is applied to the prosthesis by the two femoral condyles. More cavities are opened where the electronic components are located, to have a final closed structure. The thickness of the connection PCB is 3.2 mm.

- Components PCB
  It is the PCB that contains most of the components required by the electronic system to acquire sensors data and transmit them to the external reader. All the components must be placed on its top face. The thickness of the components PCB is 0.8 mm, but it can also be reduced if necessary.

The height of the whole structure is 4.3 mm, but since the thickness of the components PCB can be reduced (in a limit case to a 0.1 mm flexible PCB) it could be of 3.6 mm. The thickness of the connection PCB depends on the height of the components soldered on the lower PCB, thus it could also be reduced, for instance by using the naked die version of the chips.

Figure 5.9 shown an exploded view of the resulting structure.
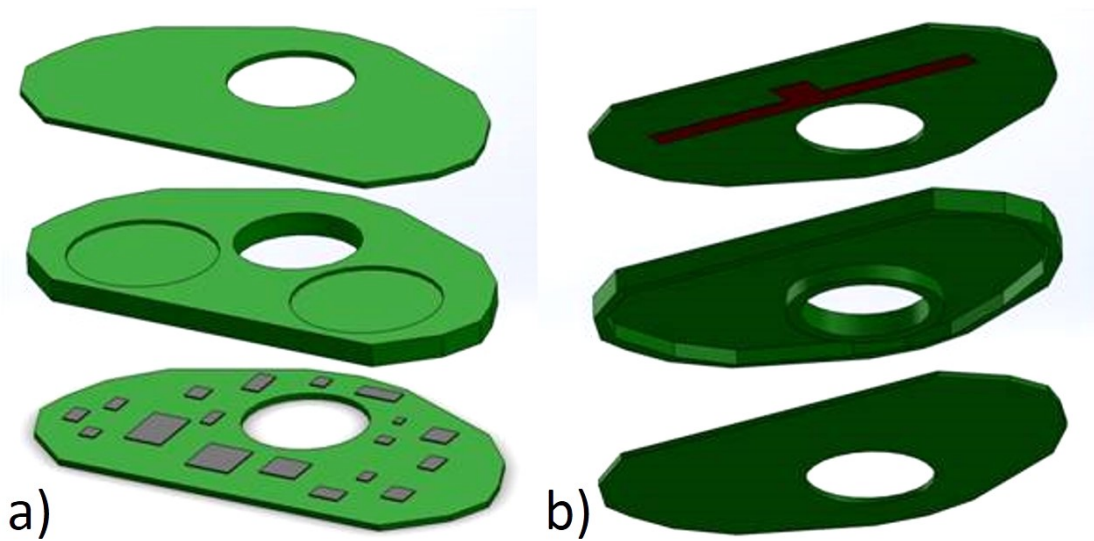
Figure 5.9: Exploded view of the PCB sandwich structure. a) Top view and b) Bottom view.

The three PCBs that form one of the electronic capsules realized during the project are shown in Figure 5.10. The yellow PCB is the Membrane PCB. The strain gauges are not visible, because they are glued on the bottom size of it. In the middle PCB, the two cavities opened to accentuate the deformation of the strain gauges when a force is applied are visible. In this case, all the components were placed in top face of the bottom PCB and none of them in the central part of the bottom face of the Membrane PCB.

The original middle insert of the F.I.R.S.T. knee prosthesis is fabricated by molding the PE in two phases. In the first phase, only the lower flat part is fabricated. In the second phase, the upper, with the concave structures in contact with the femoral condyles and the central pin is molded.

In order to fabricate the instrumented PE insert, three steps can be followed:

1. The lower part of the PE insert is molded;

2. The electronic capsule is put over it;

3. The upper part is fabricated.

Figure 5.11 schematically describes this fabrication protocol.

There are two main problems with this approach: the positioning of the electronic capsule inside the PE insert is very critical, because the strain gauges must be located as close as
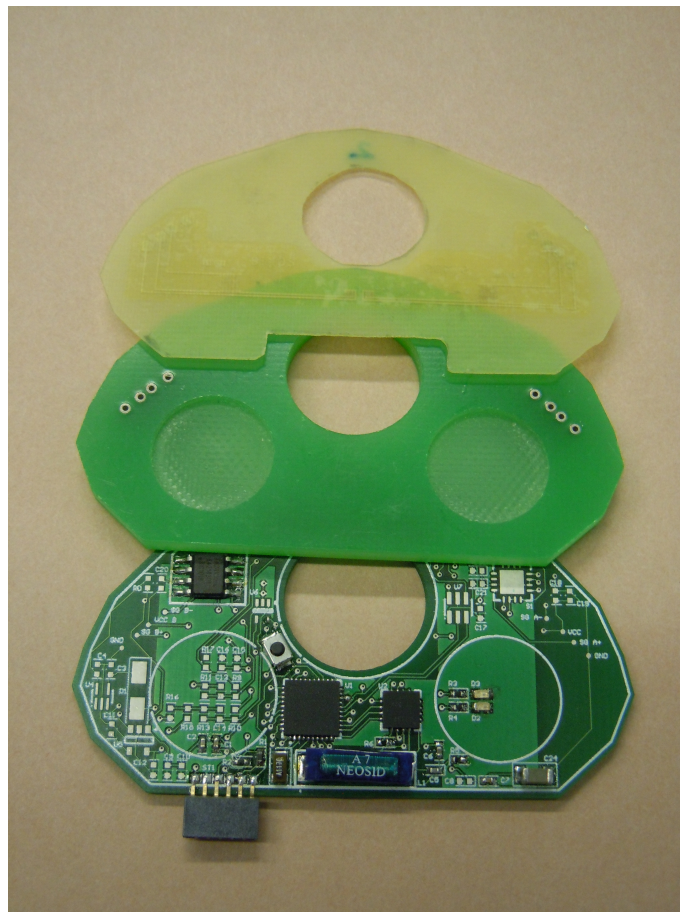
Figure 5.10: Membrane, connection and components PCBs of one of the electronic capsules designed during the project.

possible to the region of maximum strain (see section 4.3). Furthermore, the molding is done at a pressure of 120 bar, thus the risk of damage of the strain gauges is not negligible.

Luckly, Symbios Orthopedie SA recently developed a new fabrication process for the PE insert based on 3D printing, wich semplifies the task of putting the electronic capsule inside it. More details will be provided in the final section of this chapter.

The first issue with a structure like this capsule is to design an electronics, with all the subsystems described in section 5.1.2, in which all the components required can be placed in the limited space available in the components PCB. The different steps in the electronic design will be described in chapter 6.

Another very difficult challenge with such a structure is to guarantee the electrical connection between the three PCBs that constitute the capsule. In particular, the strain gauges glued to the Membrane (upper) PCB must be connected to the Components (lower) PCB through the
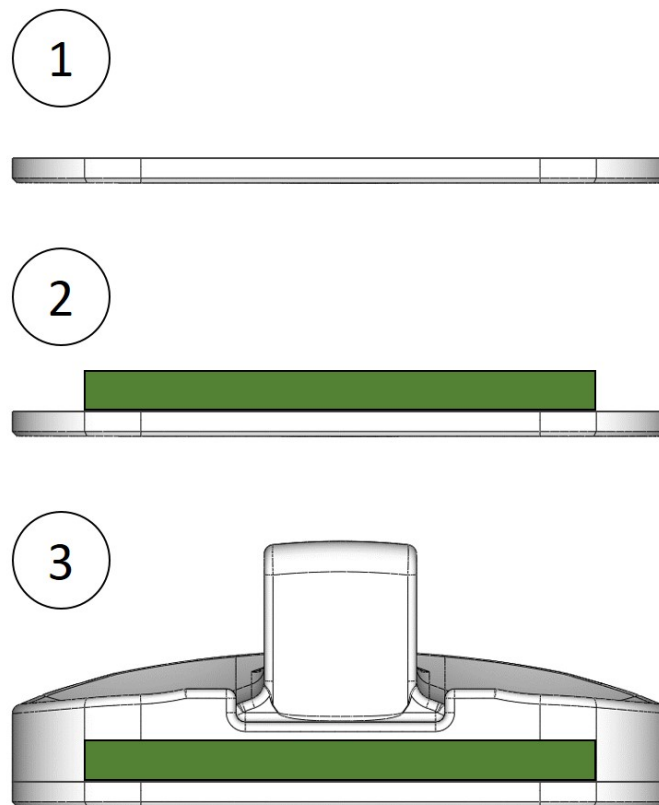
Figure 5.11: Fabrication steps in the fabrication of the instrumented PE insert.

connection (middle) PCB.

The critical point is having a good alignment between the three PCBs.

In section 4.3, it was explained that the design of the force sensors and their positioning inside the PE insert were based on a finite elements analysis. These simulations showed that the strain gauges have to be placed in the center of the two lateral purple circles in Figure 5.12 and the area around them should be free of other components. If, for instance, the space available in the bottom PCB is not enough for all the components required by the electronic system, some of them can be placed in the bottom face of the upper PCB. In particular, the optimal area for their positioning in the membrane PCB is its central part, above and below the hole in the upper view of the PE insert. As shown in Figure 4.5, this part is almost not subject to deformation and wearing. As a consequence, the presence of electronic components would not affect the force measurements.

The two force sensors are connected in a Wheatstone Bridge configuration, thus the pads that must be electrically connected are four per sensor: the power supply, the ground and the positive and negative outputs of the bridge. In total, eight pads must be aligned along the three PCBs.
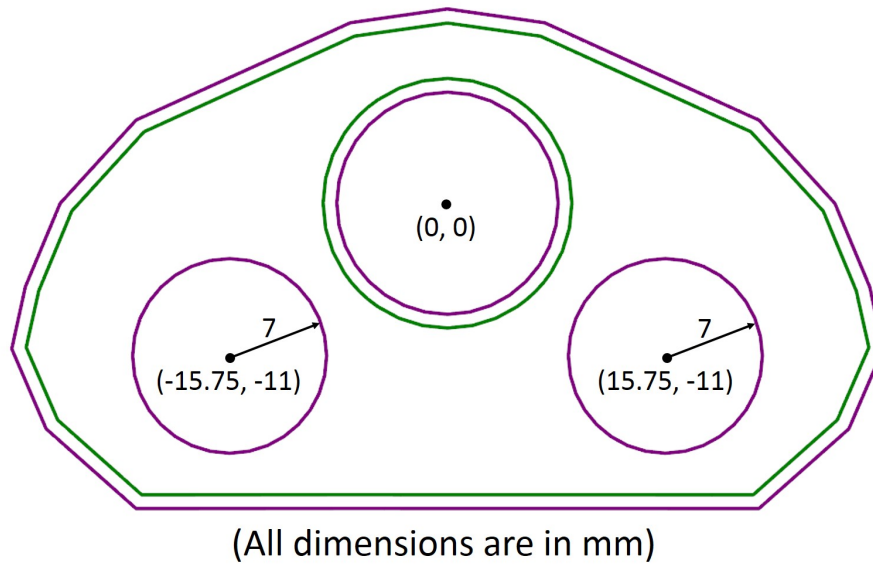
Figure 5.12: Positioning of the strain gauges in the PE insert.

The exact position of the contact points was defined and kept in the three PCBs (Figure 5.13).
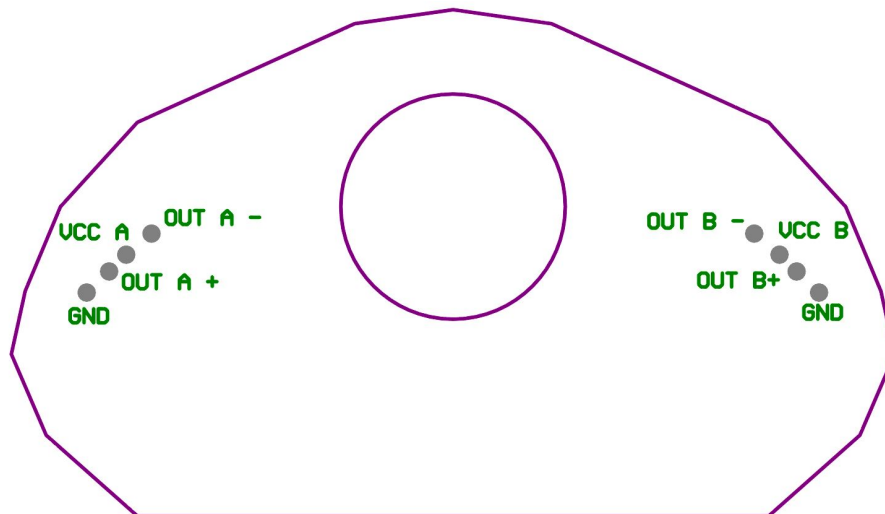
Figure 5.13: Position of the pads that connect the strain gauges in the upper PCB with the rest of the electronics in the lower PCB.

The strain gauges were designed accordingly, as shown in Figure 5.14.

For the good positioning of the thin film strain gauges on the Membrane PCB, some reference symbols are put on the bottom face of it, as shown in Figure 5.15. The reference symbols are also visible in the Figure 5.10 for the real system.

The membrane and components PCBs have pads with a diameter of 1 mm, while the middle
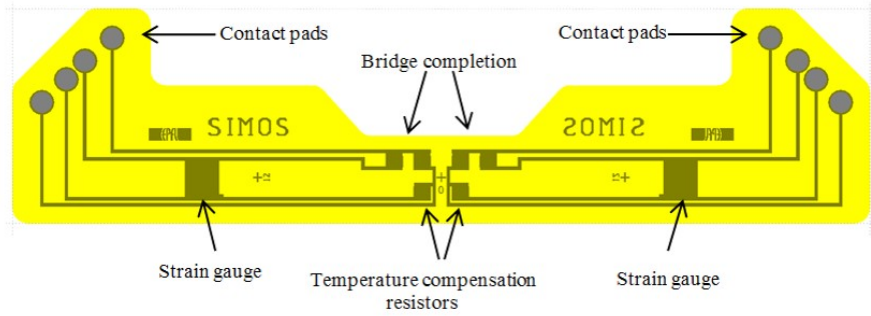
Figure 5.14: Strain gauges designed to be aligned with the connection pads in the electronic capsule.
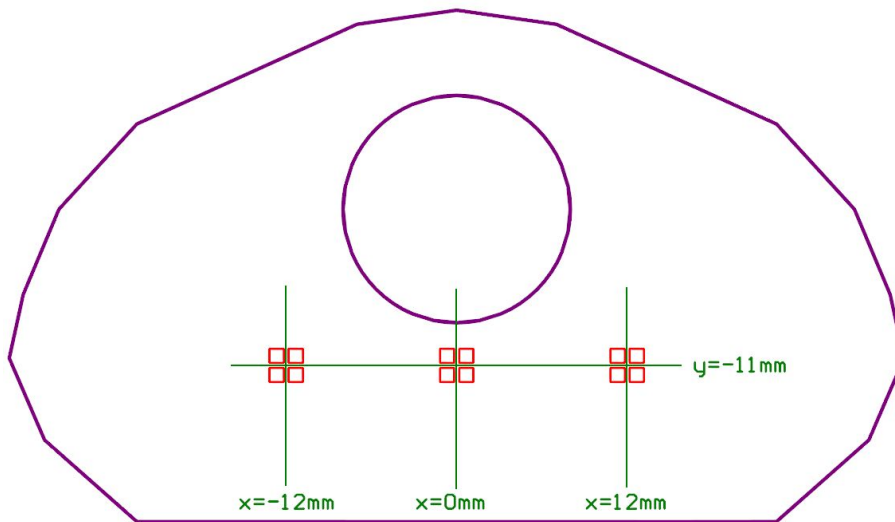
Figure 5.15: Reference symbols on the bottom surface of the Membrane PCB, used for the good alignment of the strain gauges on it.

PCB has vias, to connect the upper and lower PCBs together.

The alignment is not the only technical issue to electrically connect the strain gauges and the rest of the electronics. The pads on the membrane PCB must be soldered to the vias in the connection PCB and similarly, the vias on the connection PCB must be soldered to the pads in the connection PCB.

The main problem with it is the fact that, when the capsule is closed, the pads and the vias are not visible nor accessible with a soldering iron.

The solution that was found consists of two steps.

1. The membrane PCB with the glued force sensors is electrically connected to the connec-

tion PCB by using a conductive epoxy glue (H20E, Epotek, USA). The curing of the glue is performed at 60 degrees during 16 hours.

2. A solder paste (EDSYN CR11, 58 Bi - 42 Sn) is used to connect the two PCBs already glued together to the Components PCB. The solder paste is deposited on the pads of the bottom PCB with a dispenser. Then, the connection and membrane PCBs are put on top of it. The whole structure is put on an heating plate at 300 degrees during 15 seconds and then taken out.

5.2.3   Placement of the implanted coil

The placement of the coil in the PCB embedded inside the PE insert is very important. The implanted antenna has to be located as close as possible to the coil of the external reader, thus as far as possible from the center of the PCB. During the surgery, the orthopedic doctor can put the external reader close to the PE insert while the knee is open, for instance to evaluate the ligaments tension.

During total knee arthroplasty, the knee is opened in the front side, that is therefore more accessible. Moreover, in the back side there is much more fat, that could disturb the communication, than in the front. Thus, the ideal position of the antenna on the surface of the PCB embedded inside the PE insert is its front part.

During rehabilitation, the patient can be asked to put a protector knee belt, like the one in Figure 5.16, with the coil of the external reader that can be attached to it to read out the sensors data and provide the physiotherapists with objective values on the performance of the patient.

Figure 5.16: Placement of the antenna of the external reader.

5.2.4 Waterproof and bio-compatibility

As explained in sections 5.1.4 and 5.1.5, a fundamental requirement for a knee prosthesis is its bio-compatibility and the fact that it is waterproof.

Bio-compatibility is guaranteed at the moment of the knee replacement surgery also with the instrumented prosthesis, because the only materials in contact with the human body are the PE and the alloy of cobalt and chrome, both bio-compatibles. Moreover, PE is a waterproof material, thus the second feature also is not a concern at that time.

Both can become a concern some time after the surgery, if the wearing of the PE is excessive and the electronic capsule is exposed, thus in contact with the tissues and fluids of the body of the patient.

Most probably, the patient would feel pain before this happens, and would visit an orthopedic doctor, that could evaluate the risk thanks to the sensors embedded in the instrumented prosthesis, in particular the force sensors. Unfortunately, pain sensitivity is a very subjective experience and represents a challenging clinical problem [59]; for this reason, it cannot be used as an objective parameter in the design. Moreover, *in vivo* tests have not been performed in the frame of this study to try to correlate the risk of contact between electronics and human body with the pain felt by the patient. In any case, such a test would require years to be performed.

For all these reasons, in the packaging design, we cannot assume that the patient will go to the medical doctor before the risk of a dangerous contact is concrete. As a consequence, we must find some alternatives that could be considered safe by a medical advisory board, before human tests.

When the structure described in the previous section is closed, it looks like an isolated capsule, with all the components placed inside it (see Figure 5.17).
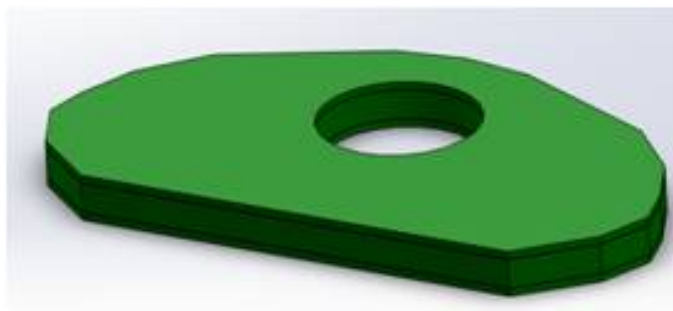
Figure 5.17: Closed electronic capsule, with all the components inside.

To avoid the risk that some fluids can enter into the electronic capsule in case of extreme wearing, the three PCBs that compose it must be glued together. The use of a bio-compatible glue is mandatory, since some parts of the glue could go out of the capsule. Bio-compatible

flexible epoxy glue is an optimal solution.

Regarding bio-compatibility, thanks to the chosen design, all the electronic components potentially dangerous are placed inside the PE insert and thus the risk of contact between them and the human body is limited. In case of extreme wearing, the body would be in contact only with the external part of the electronic capsule.

The main issue could be the fact that the typical PCB substrates (like FR4) laminates and since the conductive material typically used is copper, they cannot be considered fully bio-compatible.

A typical solution with medical implantable devices is to protect them with a polymer layer [60], like Poly-Para-Xylylen (Parylene C) , which offers a very good solution for covering the capsule of the instrumented prosthesis. Another solution would be the use of a substrate different from FR4, like Alumina (Al_2O_3), Polyimide and Pyralux, that can be considered fully bio-compatible [61].

Another advantage related to the choice of the described packaging is the fact that the upper part of the capsule is constituted of a PCB (Membrane PCB) that contains only a few copper in the bottom part of it for the connection pads. In fact, the strain gauges are glued to it with a bio-compatible glue and, moreover, their substrate is Polyimide, a fully bio-compatible material.

It is known that the wearing of a PE insert of a knee prosthesis is mainly located in its upper part, because the movement of the femoral part over it stresses the PE much more than the movement of the tibial part below it.

In conclusion, the proposed packaging is a very good from the point of view of bio-compatibility, because the combination of a closed electronic capsule, a Parylene protection and the presence of the force sensors that can detect the wearing *in vivo* largely reduces the risks for the patient.

5.2.5 MRI-compatibility

The importance of Magnetic Resonance Imaging (MRI) as diagnostic imaging modality has increased enormously in recent years [70]. As of 2013, there were approximately 25000 MRI machines worldwide and more than 2000 MRI units are sold every year [63]. The number of MRI scans in Europe increased of 14% from 2000 to 2010 (see Figure 5.18).

It is used to display soft tissues and, moreover, it allows to distinguish between different kinds of tissues. Thanks to this feature, it is a very useful technique in the detection of some kind of cancers. For instance, an MRI with contrast dye is the best way to see brain tumors [67].

Although MRI uses no ionizing radiations and thus is generally a very safe procedure, some problems can be encountered when the exam is made on a patient with a metallic implant,
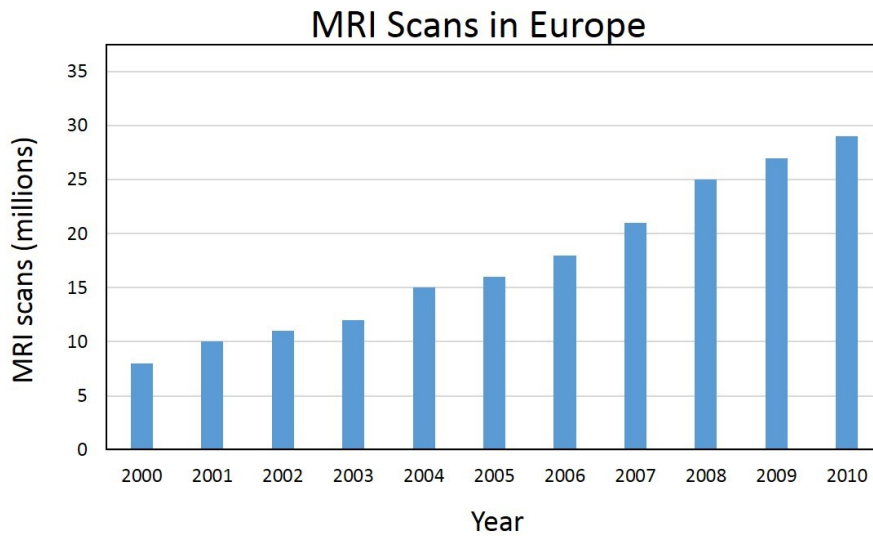
Figure 5.18: Number of MRI scans in Europe from 2000 to 2010. Data taken from [64].

such as pacemaker, a cochlear implant or an orthopedic prosthesis.

Nevertheless, for its importance in the diagnosis of some kind of tumors, it is crucial to guarantee that a patient with a knee prosthesis can perform an MRI scan.

In this section, we will provide some considerations on the MRI-compatibility of the instrumented prosthesis, that will require a deepened validation before a human implantation.

An MRI scan is not an adequate choice to represent an image of a prosthetic knee, because the presence of the metallic components would result in a distortion of the image, but it can be very useful to show other areas of the human body.

In literature we found papers demonstrating that the cobalt-chrome alloy used for the F.I.R.S.T. prosthesis is not ferromagnetic and can be safely used during an MRI scan [66][65]. The PE is not a ferromagnetic material, thus it does not represent an issue.

The problems can occur when some electronic components are embedded inside the PE insert. Their interaction with the MRI environment should be studied and, if necessary, some countermeasures should be taken.

In order to understand the kind of problems associated with an MRI scan, some basic knowledge on the technical aspects of it are required.

To create an image of a particular area of the human body by using an MRI machine, we need to acquire a signal generated by the resonating protons in this specific region. To achieve that, the MRI scanner applies a strong static magnetic field. Nowadays, most of the MRI scanners used for human studies range from a static magnetic field of 0.3 T to 3 T for commercial

devices (with the majority of them operating at 1.5 T), but in research we can find machines working at up to 10 T [69].

The hydrogen nuclei (protons) present in the human body are normally oriented in a random way. When placed in a strong magnetic field (B_0), they tend to align parallel or anti-parallel to the direction of the magnetic field. This generates a net magnetization within the human body in the MRI machine.

The protons align rotating at a predefined frequency, called Larmor frequency.

$$\omega_0 = \gamma B_0$$

Where:

ω_0: resonance frequency;
γ: gyromagnetic ratio = 42.56 MHz/Tesla for protons;
B_0: magnetic field [T].

A Radio Frequency (RF) pulse with the Larmor frequency is applied to bring the protons in resonance and flip the net longitudinal magnetization into the transverse plane.

The transverse magnetization induces a current in a receiver coil, placed on the body.

After switching off the RF pulse, the original situation (only net longitudinal magnetization within the body) is restored. The transverse magnetization will fade and a progressive increase in the longitudinal magnetization will occur.

This process of fading of transverse magnetization and increase in longitudinal magnetization is specific for different types of tissue and therefore allows the generation of image contrast between different structures.

Fast switching magnetic gradient fields are required for spatial encoding of the magnetic resonance signal. They enable the identification of proton position in 3D space.

All these components (strong static magnetic field, repeated RF pulses, fast switching magnetic gradient fields) can represent an issue for a patient with an implantable device, for instance a knee prosthesis.

- Mechanical effects:
  Implants containing ferromagnetic materials could be deflected or dislocated under the effect of the powerful magnetic field.

  The force of deflection can be calculated using the formula:

  $$F = mg \tan(\theta)$$

Where:

F: magnetic force vector in dynes (10^5 dynes = 1 Newton);
m: mass of the device in grams;
g: gravitational constant ($980\ cm\,s^{-2}$);
θ: angle of deflection from the vertical.

- Heating effects:
  A heating of the metallic components of the implant could be induced. In particular, the RF field may induce a current and thus an increase of the temperature potentially dangerous for the implant and the tissues around it.

- Effects on programmed devices:
  The electronic components (e.g. RAM, EEPROM, Flash memories, CPU function) could be destroyed or the programming settings could be changed by the RF field. This is a minor risk for a knee prosthesis, because even in case of a failure of the electronics, it can still be used as a passive artificial joint.

Most of the components inside the SImOS implant are MRI compatible, but a particular care is necessary in order to study the MRI effect on the antenna that will be used for data transmission and the magnet necessary for the magnetometers.

Both these devices have a very small mass. Moreover, the magnet is cemented to the tibial part and the antenna is soldered inside the sealed electronic capsule, closed inside the PE in turn. Thus, the risk of deflection or dislocation is negligible.

Concerning the issue of heating, the main risk with the instrumented prosthesis is represented by the antenna. The RF field may induce a current in it, resulting in an increase of temperature. Luckily, the antenna is embedded inside the PE insert and it is not directly in contact with the human body. Thus, an increase of the temperature of some degrees does not represent a real issue.

Concerning the problem of the programmed devices, like a microcontroller, this represents a minor risk for a knee prosthesis, because, even in case of a failure of the electronics, it can still be used as a passive artificial joint.

All this considerations are the result of a discussion, on the specific topic of MRI-compatibility of the instrumented prosthesis, that we had with a member the staff of the Biomedical Imaging Group of EPFL (EPFL-BIG).

Obviously, they should be validated with *in vitro* tests, that have not been performed in the frame of this work.

5.2.6 Discussion

The proposed packaging is constituted of an electronic sandwich structure, composed of three PCBs. The force sensors are glued to the upper one, used as a membrane to accentuate the strain effect. All the rest of the sensors and the electronics can be placed in the bottom PCB or, if necessary, in the same PCB that contains the force sensor, in an area of its bottom surface not subject to strain.

All the electronic components are placed in the internal part of the sandwich, in order to avoid any contact between them and the human body in case of extreme wearing of the PE insert.

A combined use of conductive glue and solder paste guarantees the electrical connection between the different parts of the insert.

Thanks to the use of bio-compatible glue and Parylene C, the system can be considered waterproof and almost fully bio-compatible.

Finally, such an encapsulation offers another advantage: even if, for unexpected reasons, the electronic system stops working properly, the prosthesis can still be used as a standard passive one and does not require any revision surgery, more complicated and expensive than the first replacement.

5.3   New polyethylene insert

Symbios Orthopedie SA recently designed a new kind of PE insert, that will be used in the future prostheses. This new insert presents a huge advantage in the design of an instrumented version of it, because it is used with a fixed-bearing knee prosthesis, thus it is fixed to the tibial part.

Being fixed, it does not require the screw head, present in the F.I.R.S.T. prosthesis, to stay in place on the tibial tray and consequently it does not present the middle hole, that largely reduces the space available for the electronic components.

The new PE insert is shown in Figure 5.19.

The same packaging presented in this chapter for PE insert of the F.I.R.S.T. prosthesis can be used with this new one. The big advantage of this new PE insert is the fact that the electronic capsule that can be put inside it does not require a middle hole, unlike the one of Figure 5.17.

That means that much more space can be used for the electronics placement, hugely simplifying the PCB design and routing.

A schematic draw of the capsule put inside this new PE insert is shown in Figure 5.20.

In chapter 7, a single-use autonomous sensors for ligament balancing during the surgery,
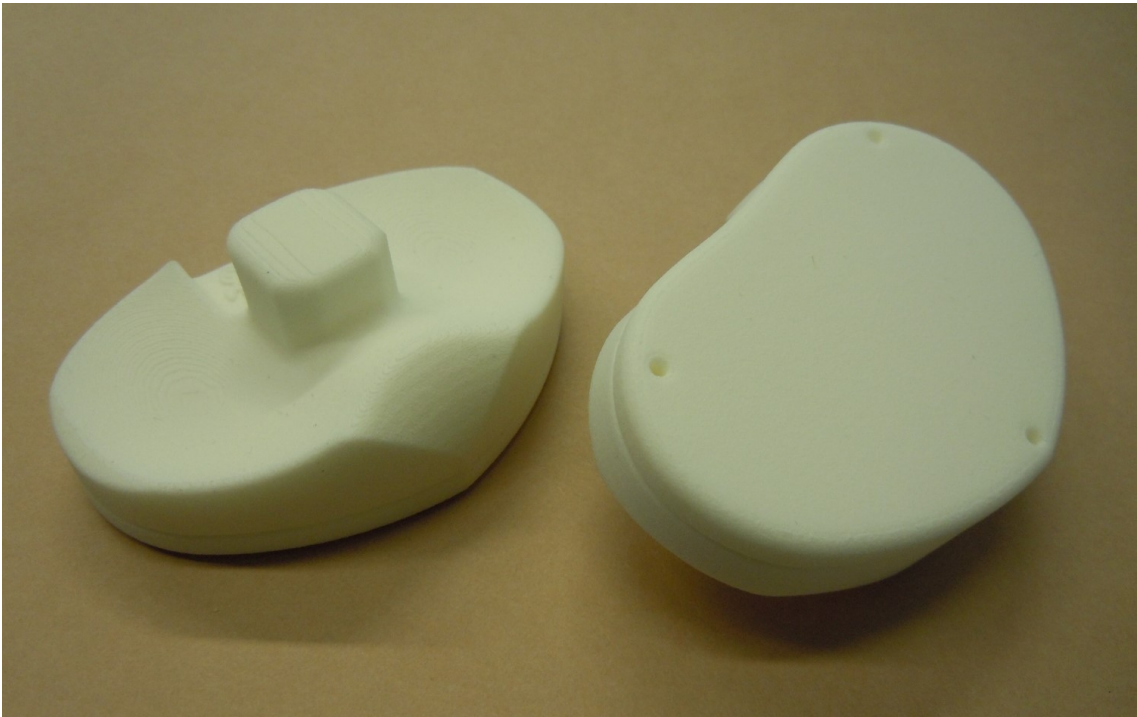
Figure 5.19: New PE insert by Symbios SA.

a)

b)
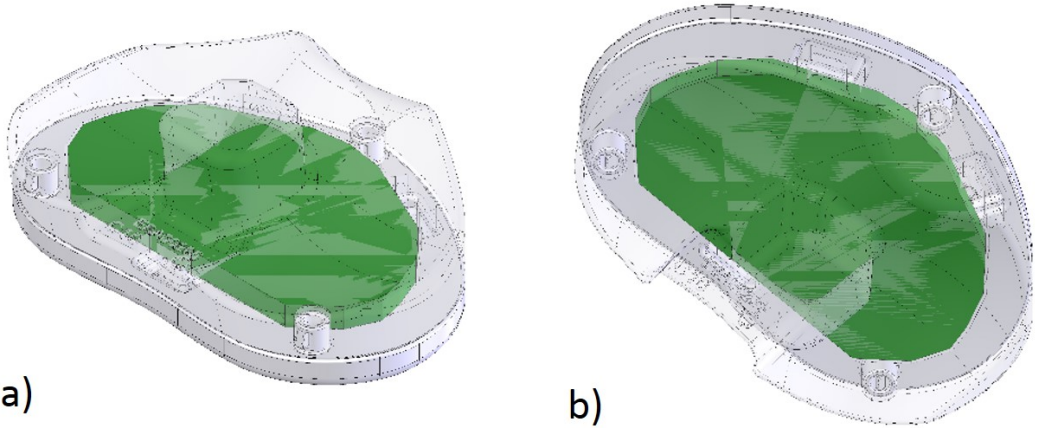
Figure 5.20: Draw of the new PE insert by Symbios SA with the electronic capsule embedded inside.

designed for this new PE insert, will be presented.

5.4 Conclusion

In this chapter, we presented the encapsulation proposed for the instrumented prosthesis.

We explained the motivations that brought to the the technical solution adopted, according to the constraints fixed by the orthopedic doctors and the prosthesis manufacturers.

Also, we introduces a new kind of PE insert and we briefly explained the advantage of using it in the design. This new PE insert has been used for the design of an autonomous sensor, that will be presented in chapter 7.

The following step in the system design is the definition of an electronic architecture that can manage the implanted sensors data acquisition and their communication to an external reader.

The different steps of this design will be detailed in the next chapter.

6 Steps in the electronic design

During the years of this thesis, we designed, fabricated and tested different functional demonstrators of the SImOS instrumented prosthesis.

At the beginning of the project, the architecture of the final SImOS system and all the interconnections between the different constitutive blocks were defined with the project partners.

We decided to use two force sensors and three magnetic sensors for kinematics measurements in the final system. An IC for the analog front-end was designed by EPFL-ESPLAB. The estimated power consumption of the whole system was $\sim 20mW$. EPFL-RFiC was in charge of the design of the IC for powering and communication able to deliver this amount of energy to the system, including the external reader and the implanted coil.

Both the analog front-end and the communication and powering ICs communicate with an embedded microcontroller through Serial Peripheral Interface (SPI) bus. In the communication, the microcontroller is the master, while the two other ICs are the slaves.

From the beginning, we were in charge of the choice of the microcontroller and the firmware implementation.

Figure 6.1 shows a schematic view of the architecture defined with our project partners.

The design, fabrication and test of an IC can require a very long time to be finalized. For this reason, in the first part of the work, we decided to design the electronics for the instrumented prosthesis by using commercially available devices. This choice allowed to prove the concept of the project before receiving the custom-designed components and, moreover, to have a backup solution in the case of an unlucky failure in the test of the ICs developed by our partners.

This chapter describes the different stages of the design of the instrumented knee prosthesis, from the first functional demonstrator, acquiring data from a single force sensor, to the latest one, integrating all the features required by the medical doctors and the prosthesis manufacturer at the beginning of the project.
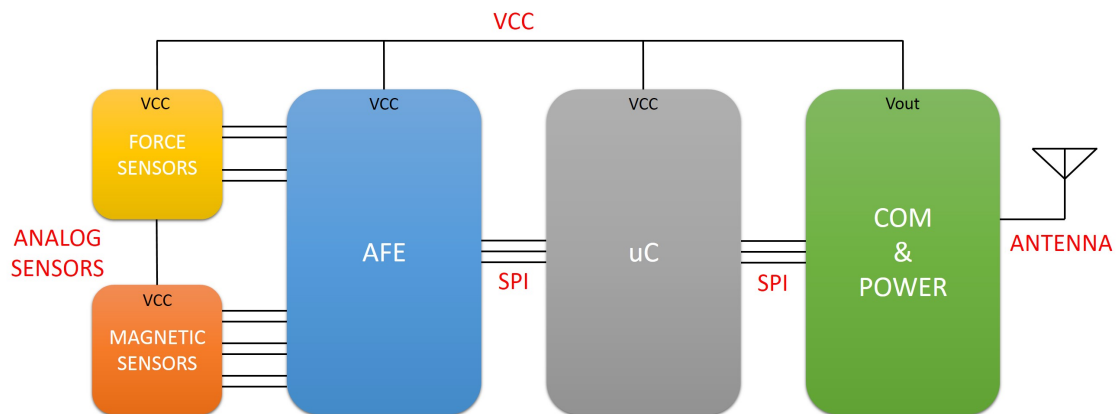
Figure 6.1: System architecture defined with the project partners at the beginning of the project.

In the first section, we will introduce the first SImOS demonstrator, used to prove the concept of an RFID Tag for data acquisition embedded inside the PE insert. Then, we will describe the first instrumented prosthesis acquiring simultaneously force and kinematics sensors data. We will show an example of electronic system fitting the dimensions of the instrumented prosthesis and used to proof the concept of the electronic capsule presented in the previous chapter.

Finally, we will describe the last SImOS demonstrator, integrating all the circuitry designed by our partners.

6.1 First large-scale demonstrator

The first SImOS demonstrator was developed in order to prove the concept of the SImOS instrumented prosthesis and in particular to test the use of an RFID Tag data acquisition system. At this stage, the objective was to acquire data from a force sensor and send it to an external reader, connected to a base station. A large-scale demonstrator, not focusing on miniaturization, was developed. It was composed of multiple Printed Circuit Boards (PCBs), that were placed out of the PE insert. Only the force sensors were placed inside it.

6.1.1 General description

The first functional demonstrator was based on a commercial device by Texas Instruments: the TMS37157, a device that combines a Low-Power 134.7 kHz transponder and an EEPROM for data storage. It has an SPI interface to communicate with a connected microcontroller. It can be used for powering sensors and read back data. Figure 6.2 shows the block diagram of the TMS37157.

The microcontroller and the sensors can be powered through the LF link. The microcontroller
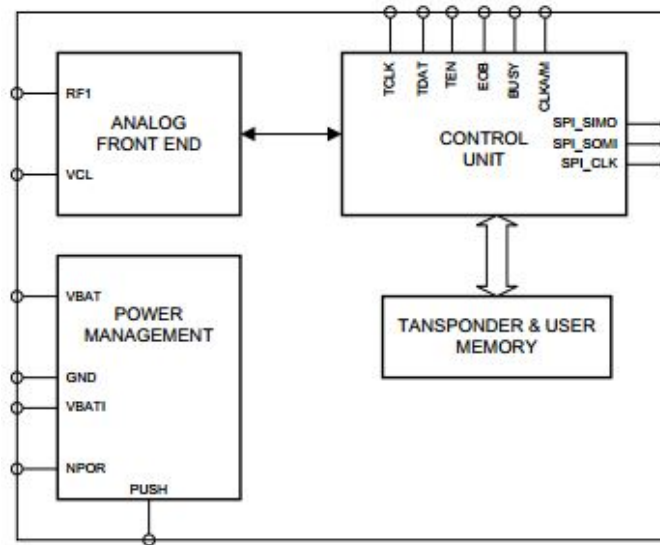
Figure 6.2: Block diagram of the TMS37157. Reprinted from [71].

can write the memory when powered through an external battery or the LF link. Data stored in the EEPROM can be accessible directly through the LF link from an external base station. The typical application system for sensor application is shown in Figure 6.3.
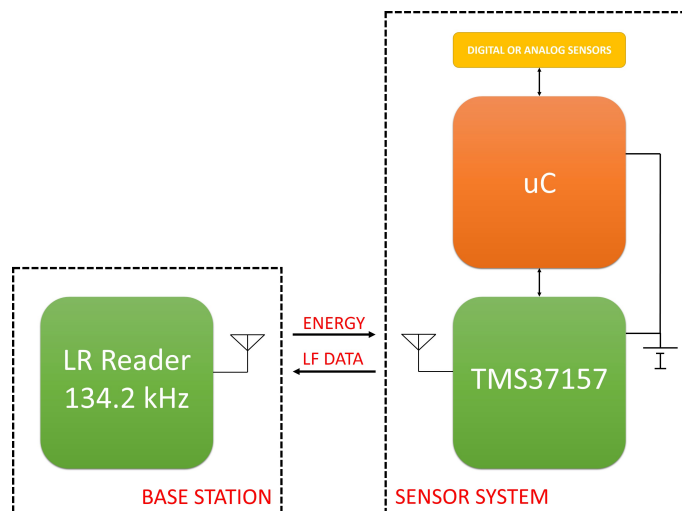
Figure 6.3: Typical application circuit of the TMS37147 for sensors applications.

We decided to use a Texas Instruments microcontroller: the MSP430F2274, an ultra low-power microcontroller (279 uA in Active mode at 1 MHz) having an SPI interface for the communication with the transponder and a 10-bit A/D converter with twelve multiplexed ports, that could be used to convert the analog sensors data to digital and store it into the TMS37157 EEPROM.

The basic architecture of the MSP430F22774 is shown in 6.4.

71
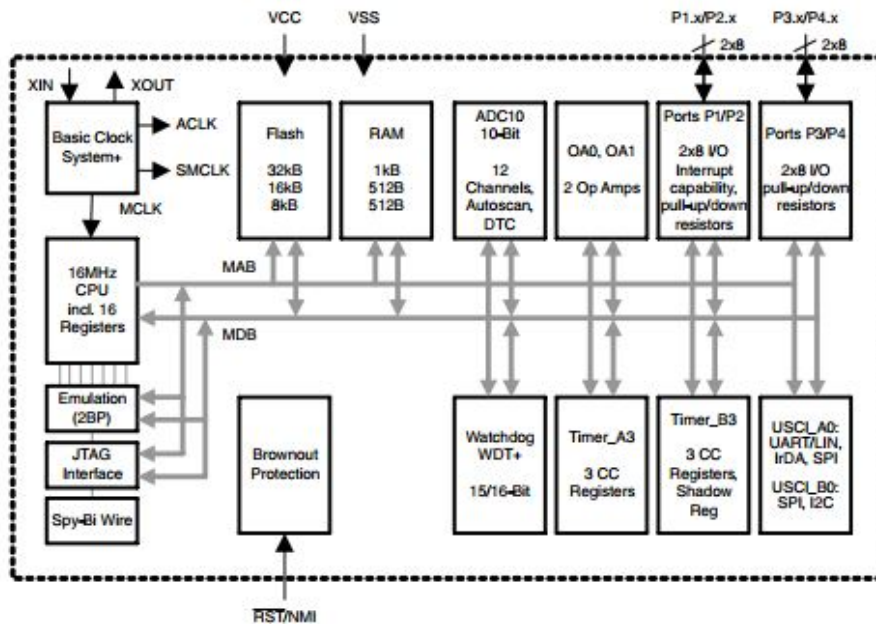
Figure 6.4: MSP430F2274 functional diagram. Reprinted from [72].

Two possible configurations have been tested. In the first one, the microcontroller was connected to a battery. It can wake up the TMS37157 to write data into its EEPROM. When the data are written, they can be read out through the LF Interface of the TMS37157. The second configuration can be used when the battery is not an applicable solution, for powering the microcontroller out of the RF Field. It is the case with the instrumented prosthesis, because the use of a battery inside the knee could be very dangerous in case of extreme wearing of the polyethylene, that could occur some years after the implant surgery. In this case, the battery has to be replaced by a big enough capacitor, which is used as a buffer during the LF communication. The typical application circuits are shown in Figure 6.5. Figure a) shows the configuration with the microcontroller connected to an external battery, while Figure b) shows the case of the microcontroller powered through the LF link by the pin VBATI of the TMS37157.

For the communication with the external reader, the Neosid Ms32ka transponder coil, shown in 6.6, was used. It is a small (11.6 x 3.2 x 2.5 mm) SMD antenna, working at 125 kHz, with an Inductance of 2.66 mH and a $Q \geq 55$.

In order to validate the system, in the first stage, only the analog signals from the strain gauges (force sensors) were acquired. The simplified architecture of the demonstrator is shown in 6.7.

6.1.2 Sensors system

This first functional demonstrator was meant to acquire data only from the first version of the strain gauges developed by EPFL-LMIS4 [44], connected in a Wheatstone bridge configuration.
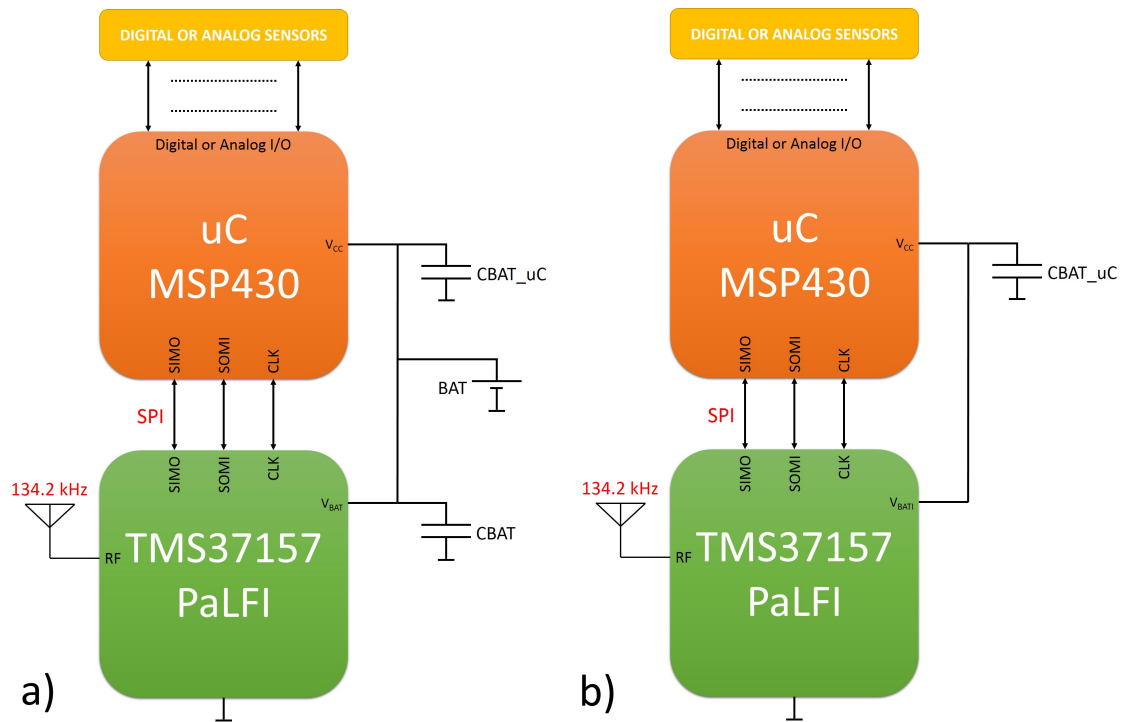
Figure 6.5: a) Application circuit of MSP430F2274 and TMS37157 with the microcontroller connected to a battery (a) and with the microcontroller powered be the VBATI pin of the TMS37157 through the LF link (b).
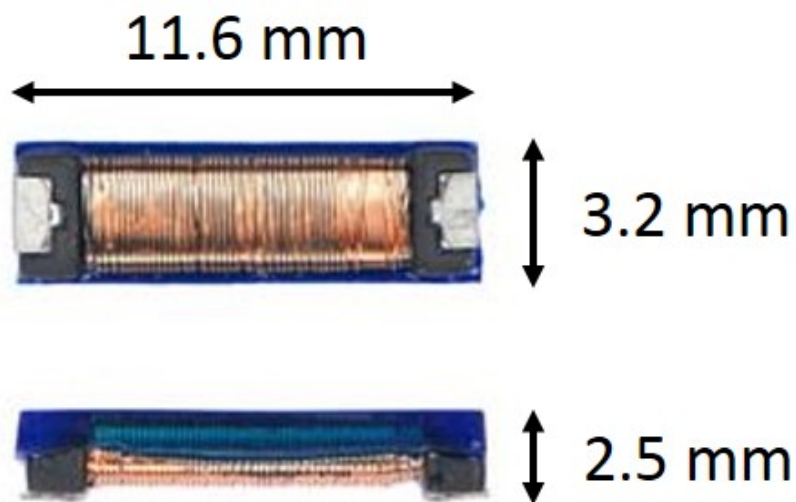
Figure 6.6: Antenna Neosid Ms32ka. Reprinted from [58].

Figure 6.7: First demonstrator architecture.

As explained in section 4.3, the design of the strain gauges and their positioning inside the PE insert were based on a finite elements analysis performed in collaboration with EPFL-LBO.

For this first test, a prosthesis PE insert was horizontally cut in order to put the strain gauges directly inside it, as shown in Figure 6.8.

Figure 6.8: Strain gauges embedded inside the PE insert for the first demonstrator.

Following the specifications provided by the prosthesis manufacturer, it was decided to keep 6 mm from the PE surface and the strain gauges. This means that for this test, the minimum thickness of the PE insert was 12 mm. Thus, the B12 prosthesis size was chosen.

A small connector (see figure 6.9) allowed the connection of the strain gauges to the rest of the electronics, located outside the PE insert.

6.1.3 Detailed schematics

A PCB with an analog front-end based on commercial devices (Figure 6.10), was designed and fabricated. The outputs of the sensors were amplified with a Low Power Amplifier LMV651 by
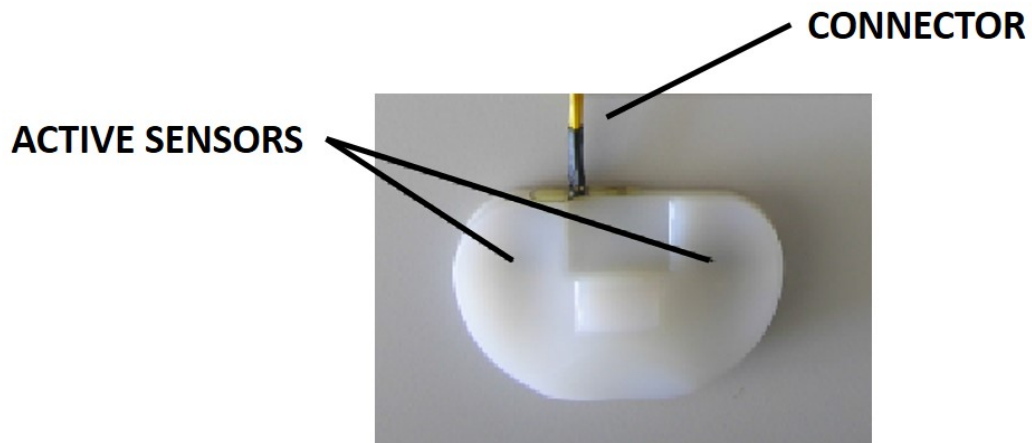
Figure 6.9: Connector used to connect the strain gauges embedded inside the PE insert with the external electronics.

National Semiconductors. As the strain gauges output is in the order of the mV, the amplifier gain was set to 1000. A 1 kOhm trimpot was used for balancing the input offset.
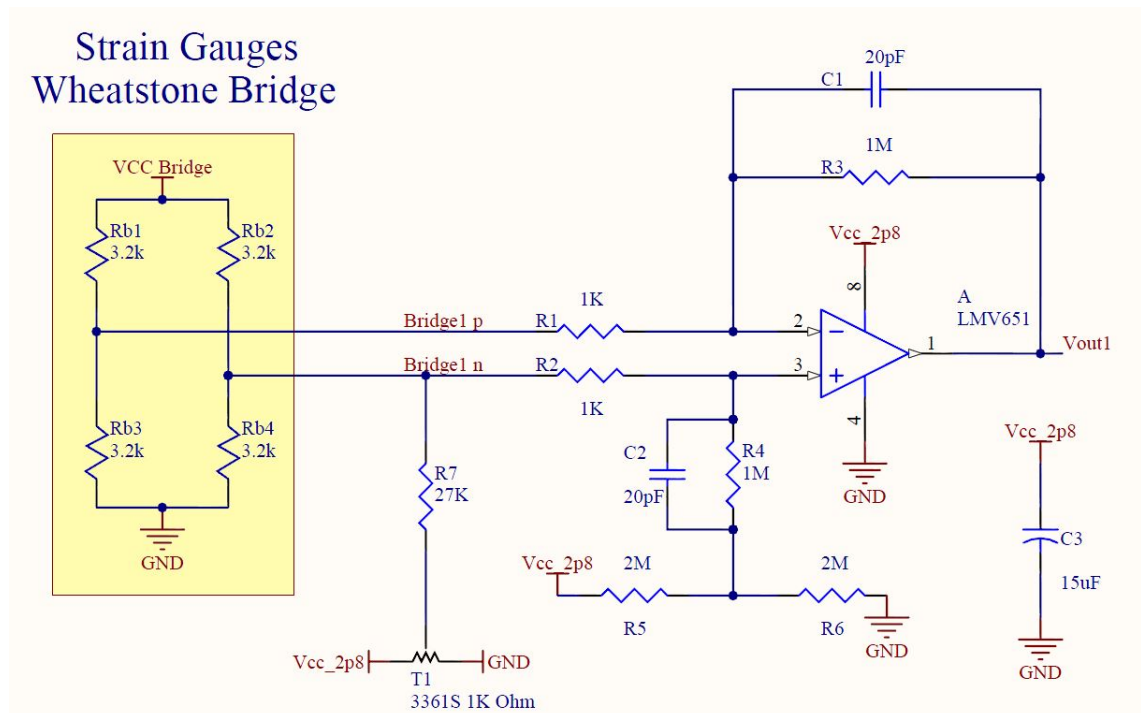
Figure 6.10: Analog front-end.

Then, the signals were sent to the evaluation kit eZ430-TMS37157 by Texas Instruments, which combines in a single PCB the MSP430F2274 microcontroller and the TMS37157 passive low-frequency interface (PaLFI) RFID transponder, operating at 134.2 kHz. One of the 10-bits A/D converters of the MSP430F2274 was used to convert the data acquired from the strain

gauges. The microcontroller was programmed for data acquisition and transmission with Code Composer Studio 4 by Texas Instruments, by using an USB debugging and programming dongle (Figure 6.11).

Figure 6.11: USB debugging and programming dongle. Reprinted from [73].

The data acquired was finally sent by the transponder interface to an external reader, connected to a PC by an USB cable (see Figure 6.12). A Labview interface was designed for post-processing and displaying.

Figure 6.12: eZ430-TMS37157. Reprinted from [73].

6.1.4 Experimental setup

In order to validate the system, we used a manual mechanical simulator of the knee, developed in EPFL by LMAM (see Figure 6.13). It can simulate different total contact forces and all three rotational movements, namely flexion-extension, abduction-adduction and internal-external rotations. A load cell is included in the demonstrator; it is located at the bottom of tibial part of the prosthesis, to measure the total compression force. It was also used to calibrate the strain gauges.

Figure 6.14 shows the experimental setup used for the measurement. The tests performed demonstrated that, using the TMS37157 to power the whole system, only few samples can be

Figure 6.13: Manual mechanical simulator of the knee.

acquired and sent to the base station. Thus, for this preliminary test, the system was used in a configuration with battery.

6.1.5   Results

The force sensors were calibrated by using the mechanical simulator described in section 6.1.4. Figure 6.15 shows the voltage output of the strain gauges Wheatstone bridge versus the voltage output of the load cell. The linear fitting is done based on least square error criteria (Rsquare: 0.81, Root Mean Square Error: 0.2).

The load cell integrated in the manual mechanical simulator provided the total contact force on the tibial part of the prosthesis, while the inserted bridge of strain gauges in the PE can only provide a portion of this force. Also due to the non-linear behavior of PE under different loads, a totally linear relation between those measurements was not expected. This was confirmed by the result depicted in Figure 6.15.

A LabView interface was developed in order to display the data received by the external reader.
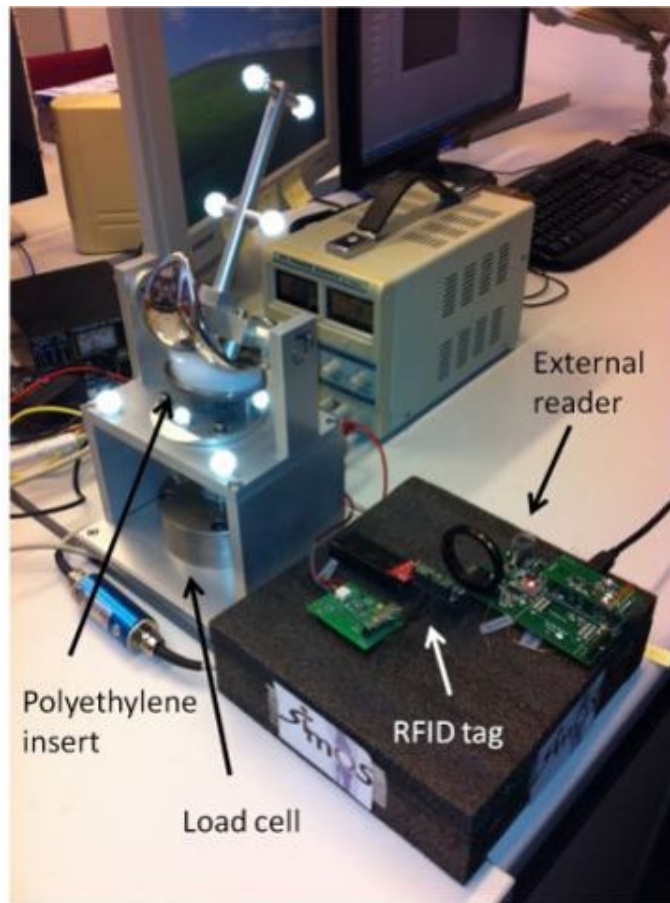
Figure 6.14: Experimental setup used for the first demonstrator.

It displays on a chart the output of the sensor over time. Figure 6.16 shows the interface during an acquisition from the strain gauges. The arrows show the voltage peaks corresponding to the application of a vertical force to the instrumented PE insert connected to the mechanical simulator.

6.1.6 Discussion

This first demonstrator was used to prove the concept of data acquisition and transmission from the strain gauges placed inside the PE insert of the prosthesis. The data acquisition, processing and transmission worked properly with the proposed system.

This test showed that only few samples can be acquired with the energy provided by the external reader, through the LF link, to the microcontroller and the sensors by using the TMS37157. For this reason, the only configuration used was the one with the microcontroller powered by an external power supply.
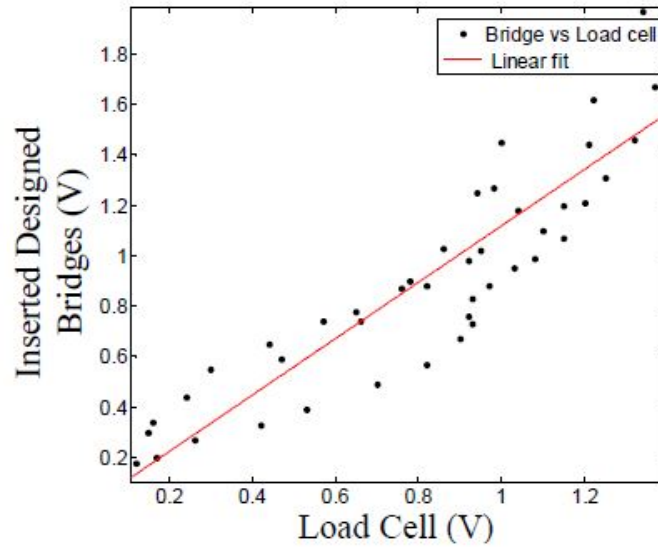
Figure 6.15: Voltage output of the force sensors bridge versus the voltage output of the load cell (sensitivity of load cell: 2.5mv/N) using the first functional demonstrator.
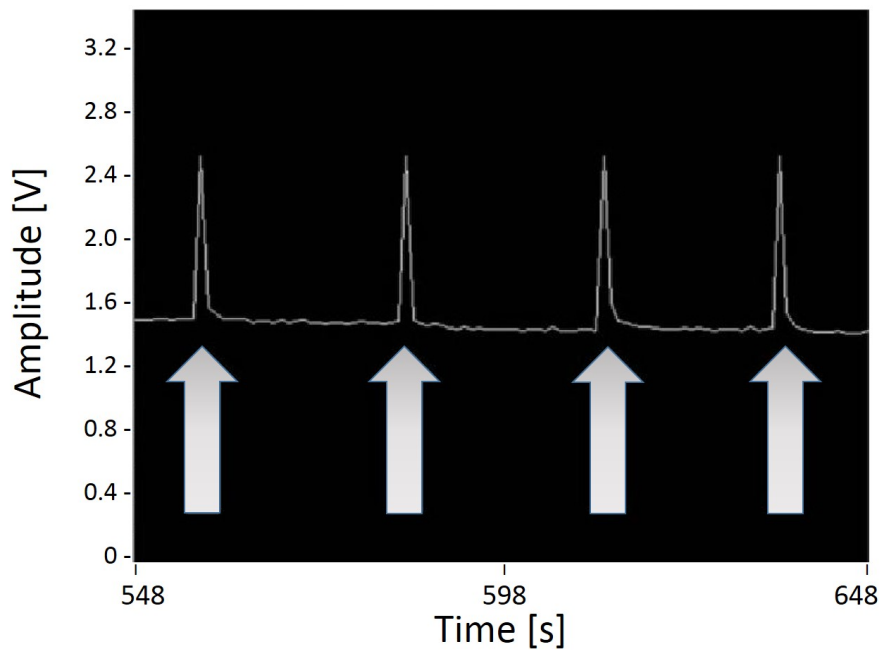
Figure 6.16: Peaks of force detected by the strain gauges while applying vertical force to the PE insert connected to the mechanical simulator.

6.2 Second large-scale demonstrator

At a later stage, it was decided to focus on the simultaneous acquisition of force and kinematics sensors data. A PE insert was modified to insert both the strain gauges for force measurements

and a magnetic sensor for kinematics measurements. The electronics was improved to allow the simultaneous acquisition of the two sensors. Again, at this stage of the project, only the sensors were embedded inside the PE insert, while the electronics for data acquisition and transmission was placed on an external PCB. Similarly to the first one, this demonstrator was fabricated and tested in a large-scale version, not focusing on miniaturization, but only on functionality.

6.2.1 General description

For this second test, it was decided to keep the components that were already used for the first demonstrator, thus the system including the microcontroller MSP430F2274 and the 134.2 kHz transponder interface TMS37157 from Texas Instruments was used.

Again, the sensors were placed inside a modified PE insert, while the rest of the electronics, similarly to the first demonstrator, was placed outside it.

The simplified architecture of the demonstrator is shown in 6.17.
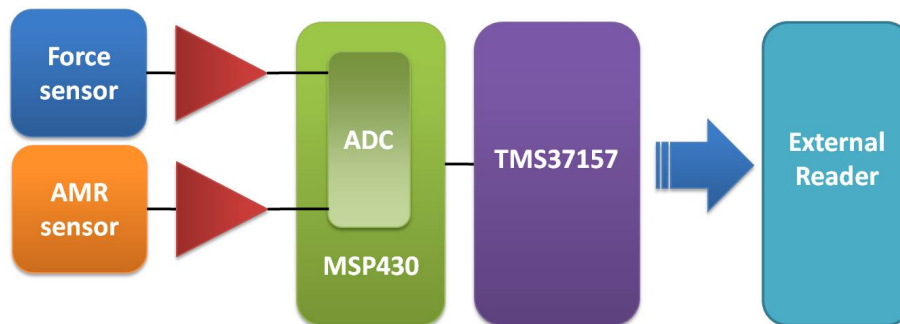
Figure 6.17: Second demonstrator architecture.

6.2.2 Sensors system

In order to measure the total force applied to the prosthesis and the balance between the forces applied to the medial and lateral condyles, an improved version of the system of strain gauges, developed by EPFL-LMIS4 and described in section 6.1.2, was used. Refer to that section for a more detailed description.

In order to measure the kinematics of the prosthetic knee, we used a magnetic measurement system consisting of a permanent magnet attached to the femoral part of the prosthesis and magnetic sensors located inside the PE insert.

The sensors used are the HMC1512 by Honeywell, based on Anisotropic Magnetoresistive (AMR) Technology. The anisotropic magneto resistance (AMR) sensors are preferred to the Hall-effect sensors due to their intrinsic sensitivity to the direction of the magnetic field, and

their higher resolution and low power consumption.

They have a resolution better than tenths of a degree or tenths of millimeters, thus they are suitable for measuring linear, angular, or rotary displacement. The HMC1512 contains two identical Wheatstone bridge elements. The Bridge B is physically rotated of 45° from Bridge A (see Figure 6.18). The sensor provides a range of angular displacements of ± 90°, with a <0.07° resolution.
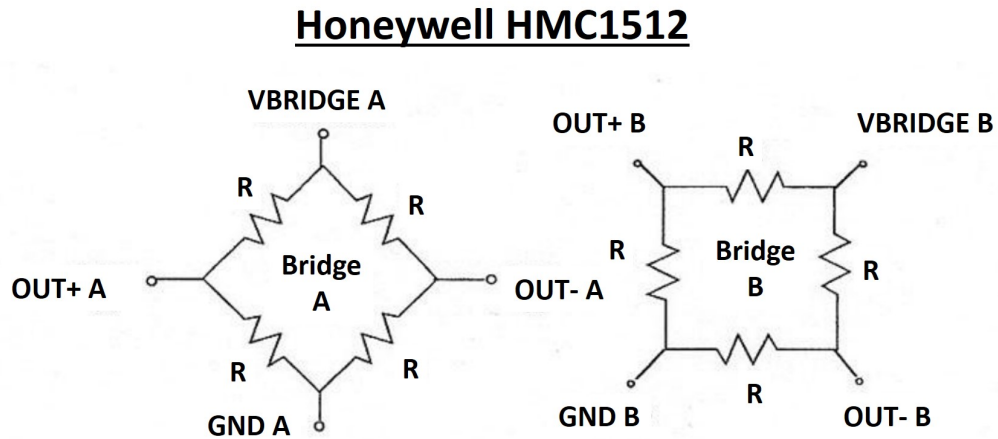
Honeywell HMC1512

Figure 6.18: Honeywell HMC1512 magnetic displacement sensors. Reprinted from [74].

With the bridges on the HMC1512 oriented 45° in rotation from each other, the differential output voltage for sensor bridge A is:

$$\Delta(V_A) = V_s \, S \, \sin(2\theta)$$

And for sensor bridge B, the differential output voltage is:

$$\Delta(V_B) = -V_s \, S \, \sin(2\theta)$$

Where:

V_s = Supply Voltage [V]
S = Material Constant (typically 12 mV/V for this sensor)
θ = Reference to magnetic Field Angle [degrees] (see Figure 6.19)

This designed sensor system was based on the assumption of the transparency of the human body to magnetic flux.

Moreover, it was assumed that the effect of the chromium-cobalt alloy-based prosthesis on
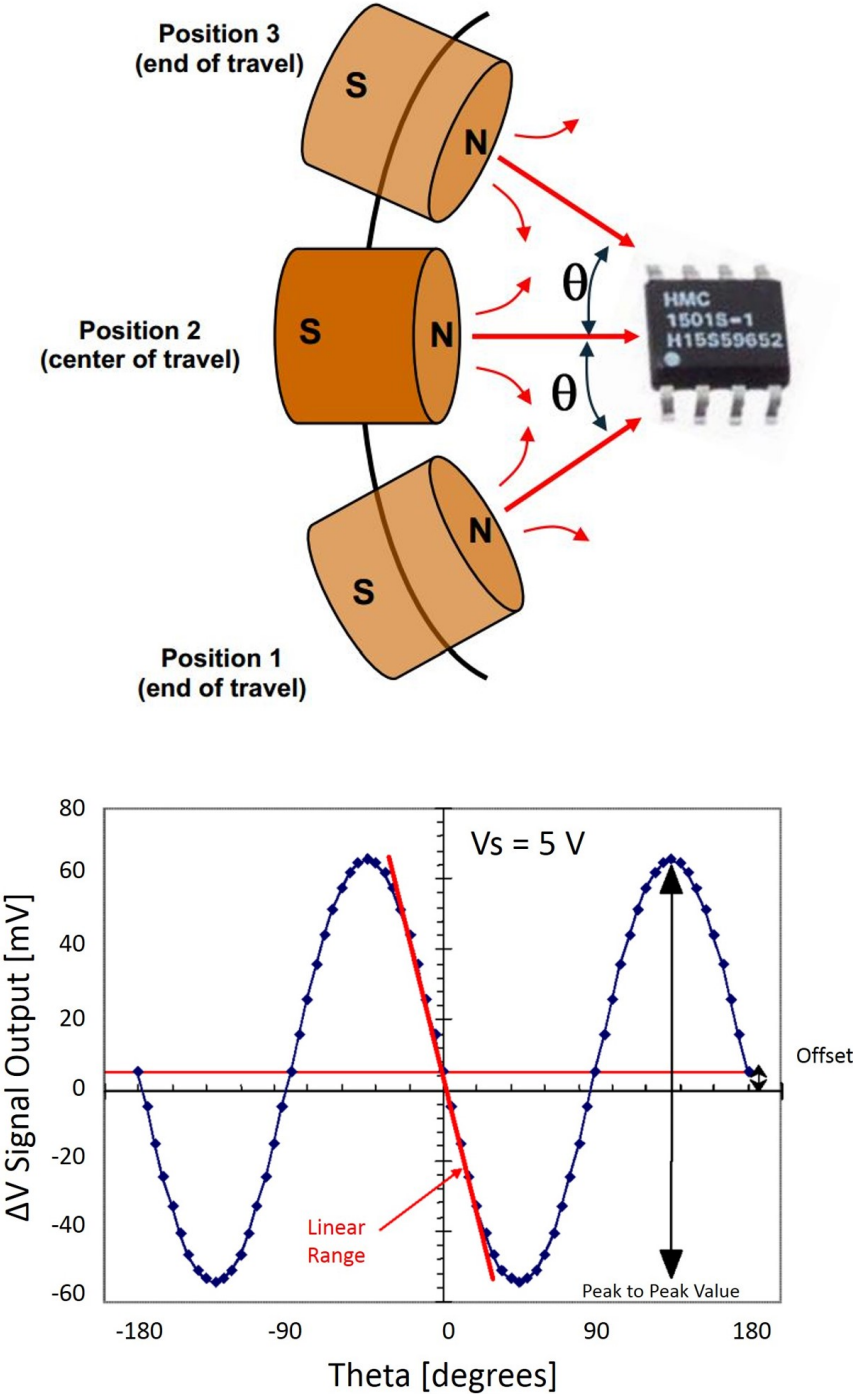
Figure 6.19: Mechanical orientation and electrical transfer function of the Honeywell HMC1512 magnetic displacement sensors. Reprinted from [74].

magnetic flux is negligible. This was practically tested by using a permanent magnet and a vector/magnitude gaussmeter (AlphaLab, US).

The magnet connected to the femoral part is oriented toward the PE insert, where the AMR sensors are embedded. They measure the direction of the magnetic flux. Consequently, the movements of the femur (and also of the femoral part of the prosthesis) above the PE insert result in changes of the magnetic flux direction which was measured by the sensors [45, 48]. The number of sensors was chosen based on an analytical approach of minimum needed sources of information for solving the problem of the geometry estimation of a magnet in a 3D space.

Figure 6.20 shows the placement of the AMR sensors inside the PE and the position of the magnet attached to the femoral Part of the prosthesis.
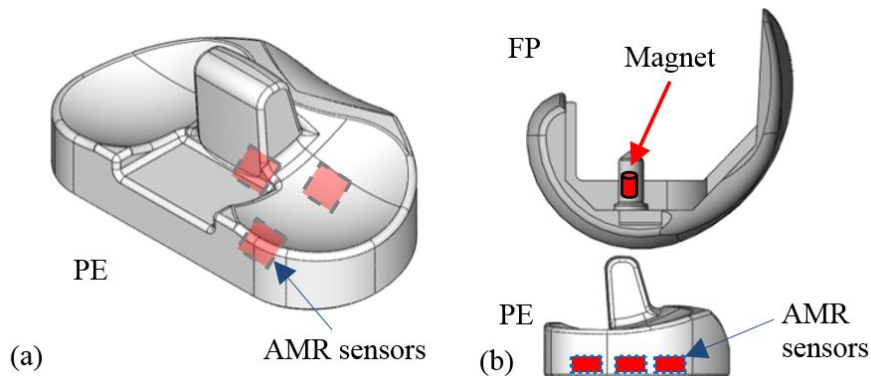
Figure 6.20: a) Placement of the AMR sensors inside the PE insert and b) of the magnet connected to femoral part.

The sensor data obtained by the internal sensors can be compared with the data obtained by using a system of skin-mounted sensors (reflective markers) for kinematics measurements, as explained in section 4.3.

In order to acquire sensors data both from the strain gauges and the AMR sensors, a PE insert was modified. It was horizontally cut twice. The first cut was made to put inside the strain gauges, similarly to what was explained in section 6.1.2 for the first demonstrator. Moreover, a small window has been opened in the lower part of the second cut, in order to add inside it a small PCB containing a 2-axes HMC1512 AMR sensor by Honeywell, as shown in Figure 6.21

Figure 6.22 shows the real system, with the strain gauges embedded inside the upper part of the PE insert and the PCB with the Honeywell HMC1512 AMR sensors placed in the small window that has been opened in the lower part of it.
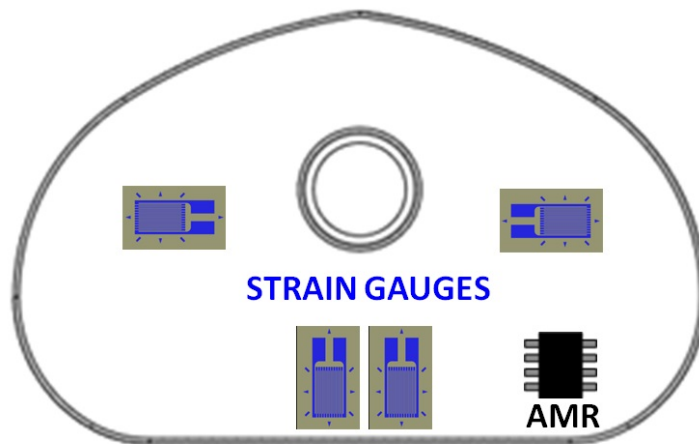
Figure 6.21: Sensors placement inside the PE insert of the prosthesis.

Figure 6.22: PE insert modified to embed the sensors.

6.2.3   Detailed schematics

The two different kind of sensors used in this second functional demonstrator are both connected in a Wheatstone Bridge configuration, thus a similar sensor interface can be used. The main difference is the amplification required: for the strain gauges, similarly to the sensors used in the first demonstrator, the order of magnitude of the useful signal is the mV, thus an Operational Amplifier gain of 1000 is required; for the anisotropic magnetic resistors, according to the reference design proposed by Honeywell, a gain of 22 is enough.

Consequently, as already shown in Figure 6.10, the output of the strain gauges was amplified with a Low Power Amplifier LMV651 by National Semiconductors (gain = 1000). The outputs of

the 2-channels AMR sensors were amplified with a Low Power Operational Amplifier MCP6002 by Microchip with a gain of 22 (see Figure 6.23).
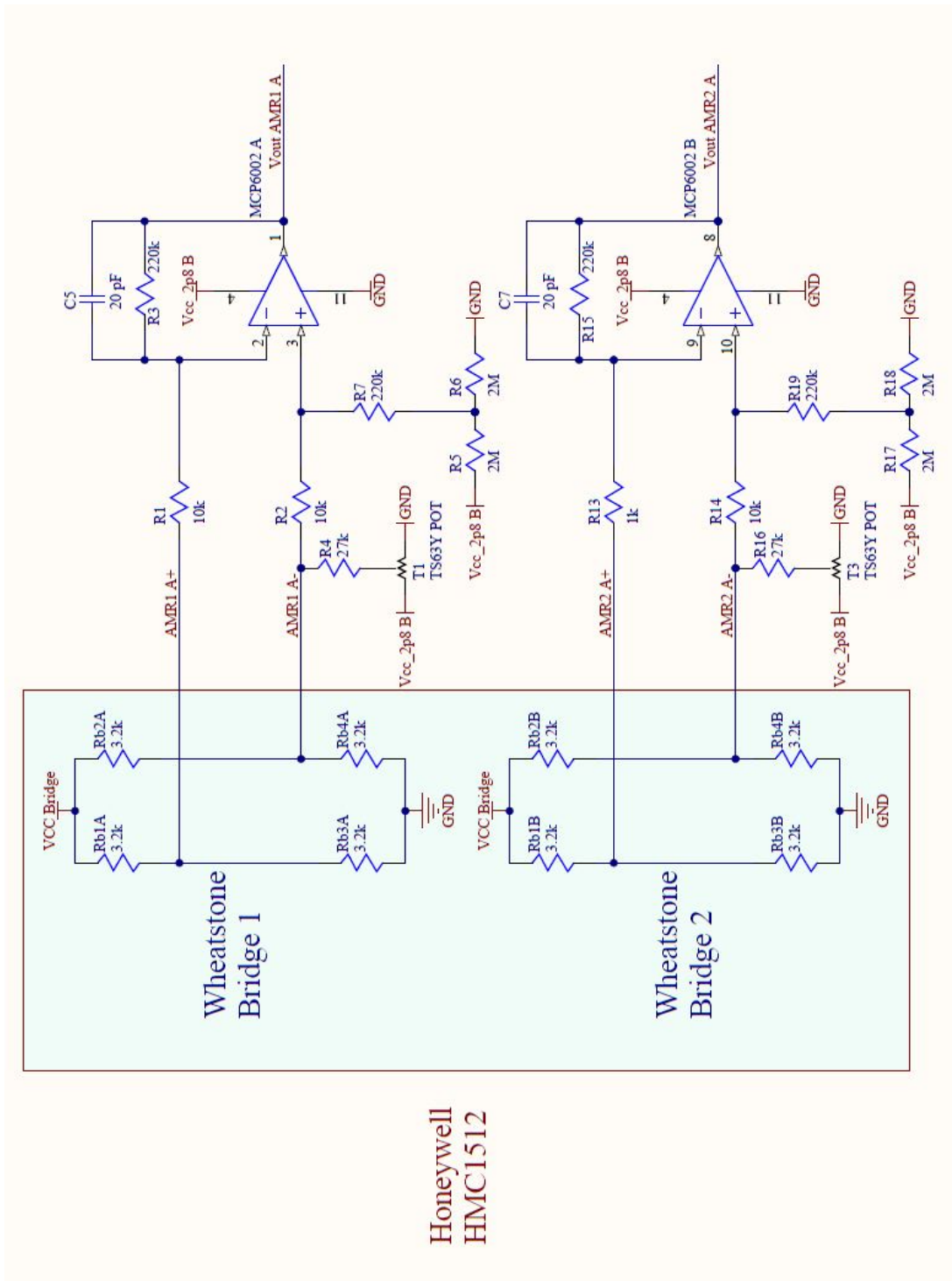
Figure 6.23: Analog front-end used for interfacing the AMR sensors in the second demonstrator.

Then, the signals were sent to the RFID Tag, containing the MSP430F2274 microcontroller by Texas Instruments. Three A/D converters ports were used to convert the output of the analog sensors. The Tag contains also the TMS37157 134.2 kHz passive low-frequency interface (PaLFI) RFID transponder, that is used to send data to the external reader. This external reader, connected by USB to a Personal Computer, is used both to power the system when used in a battery-less configuration and to receive sensors data. In this case, all the acquisitions were performed in a configuration with battery.

6.2.4   Experimental setup

As shown in figure 6.24, the knee mechanical simulator used to test this second demonstrator was the same used for the preliminary tests. The PE insert modified as explained in section 6.2.2 was connected to it to validate the measurement concept. The load cell located at the bottom of the tibial part of the knee simulator was used to calibrate the new strain gauges used. By acting on an adjustable screw placed between the load cell and the tibial part of the prosthesis, it was possible to simulate different body weights.
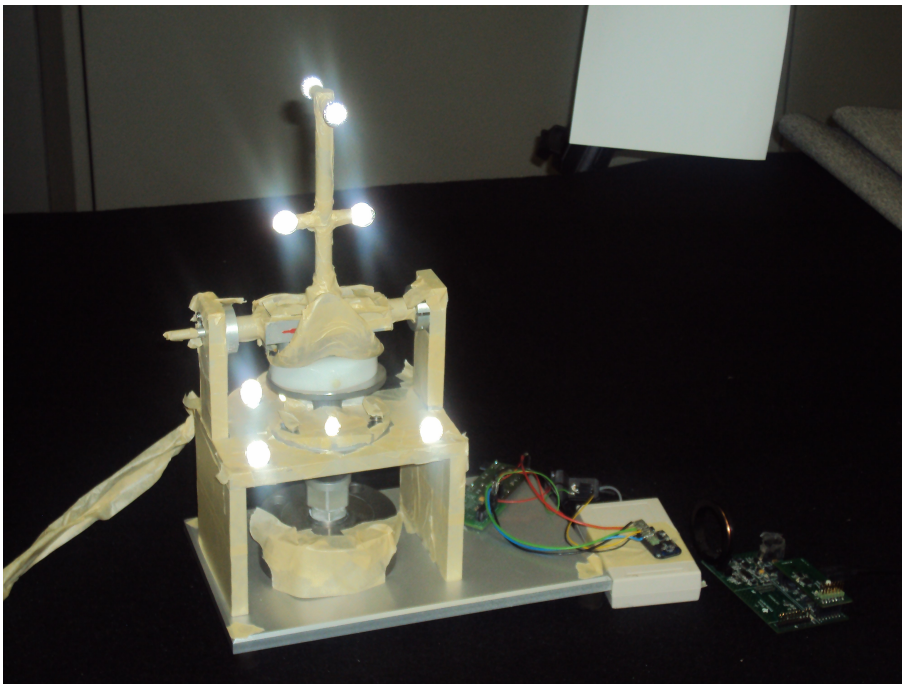
Figure 6.24: Experimental setup used for the second demonstrator.

The mechanical simulator has a set of infra-red markers (the reflecting balls in figure 6.24) located in known geometries of it, that can be used with an infra-red camera based system to track the exact kinematic of the prosthesis in the simulator and compare it with the results obtained with the magneto-resistors. The metallic parts of the mechanical simulator were covered by not reflective scotch tape, in order to reduce the noise in the measurement with the infra-red cameras.

Therefore, to evaluate the quality of the kinematics measurement based on the magnetic sensors placed inside the PE insert, an optical motion capture system (Vicon, UK), including seven cameras, was used as the gold standard (Figure 6.25).
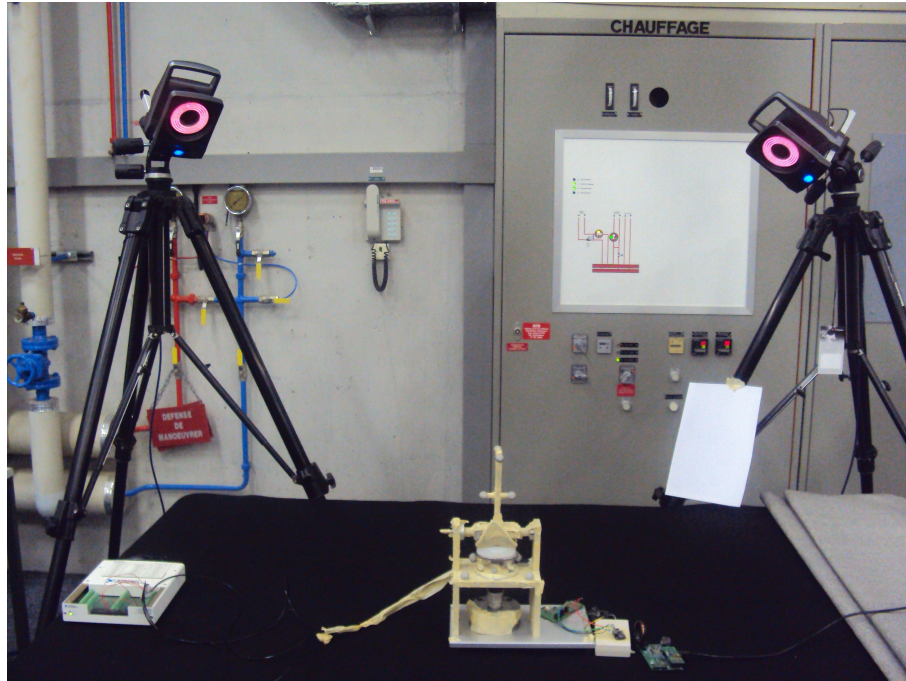
Figure 6.25: Experimental setup used for the second demonstrator with Vicon Motion Capture System.

6.2.5 Results

The mechanical simulator was used to calibrate this second version of the force sensors, similarly to the procedure adopted with the first demonstrator. Figure 6.26 shows the voltage output of the strain gauges Wheatstone bridge versus the voltage output of the load cell.

Although the behavior of the PE is not linear under different levels of load, a linear relation between the applied force and the sensor output can be employed to calibrate the sensors in the range of forces of interest for a human knee (from 0.3 kN to 1.6 kN).

Moreover, the Vicon cameras system was used by EPFL-LMAM to validate the concept of kinematics measurements with magnetic sensors placed inside the PE insert, by comparing the sensors data during 15 flexion-extensions and abduction-adductions, with a maximum absolute error of 3.64° [49].

The modified PE insert described in section 6.2.2 was also used in order to acquire simultaneously data from the strain gauges and the AMR. In particular, we acquired the total force applied to the prosthesis and the outputs of the two channels of the AMR sensor. A LabView interface was developed in order to display the data received by the external reader. It displays
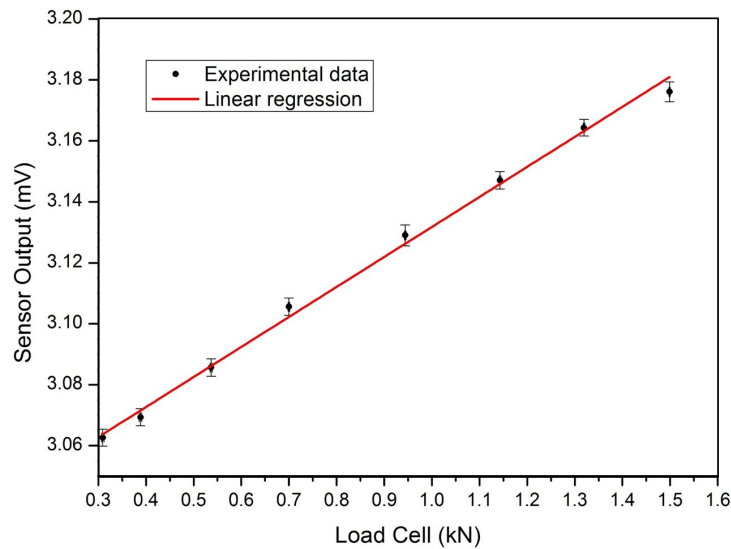
Figure 6.26: Voltage output of the force sensors bridge versus the voltage output of the load cell (sensitivity of load cell: 2.5 mV/N) using the second functional demonstrator.

on a chart the output of the sensors over time. Sensors data were obtained while applying an antero-posterior rotation of the manual mechanical simulator. In Figure 6.27, the first two charts show the outputs of the 2 channels of the AMR sensor, while the third shows the total force applied to the prosthesis.

A linear regression estimator, developed by EPFL-LMAM, was applied to the sensors data obtained to estimate the angles and the calibrated forces. The results are provided in Figure 6.28.

6.2.6 Discussion

This second demonstrator was used to prove the concept of data acquisition and transmission from both the strain gauges and the magnetic sensors placed inside the PE insert of the prosthesis. The data acquisition, processing and transmission worked properly with the proposed system. As expected, the telemetry system, that was already used for the first demonstrator, works properly for data communication, but cannot deliver enough energy to power the whole system; thus, the tests were performed in a configuration with an external power supply. As far as the we know, this second functional demonstrator represents the first example in literature of an instrumented prosthesis able to measure both the force applied to the prosthetic knee and its kinematics, in particular the Flexion-Extension and Abduction-Adduction angles.
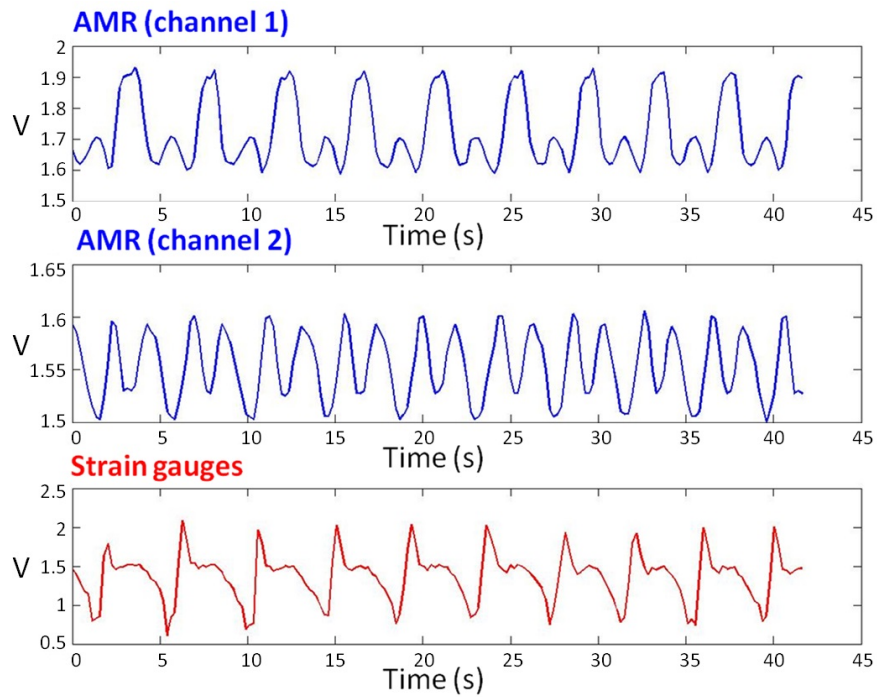
Figure 6.27: Concurrent voltage output of the AMR and force sensors during several flexion-extensions on the mechanical simulator.
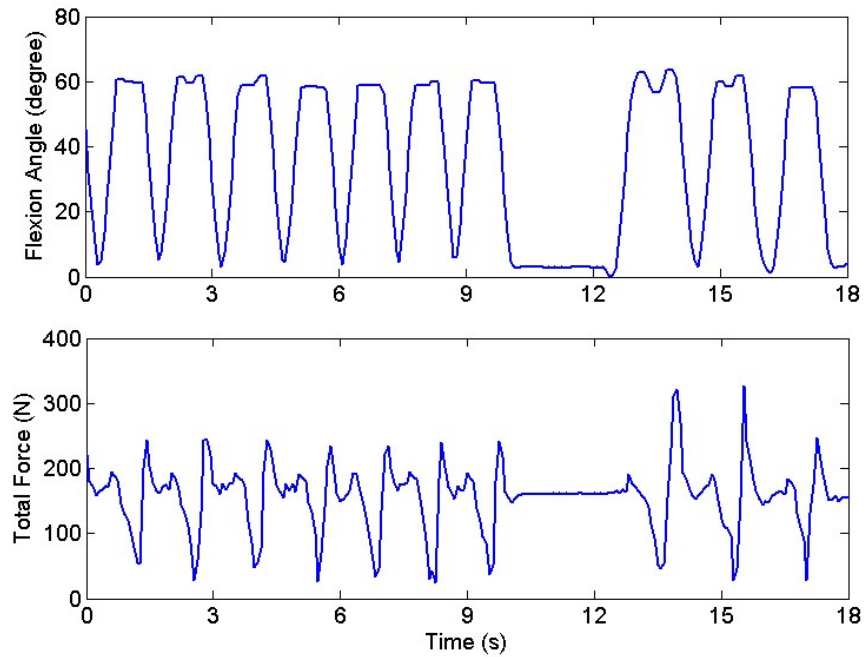
Figure 6.28: Flexion angle and force estimations based on separate linear regression models applied to the concurrent measurements of the sensors.

6.3 Miniaturized demonstrator

The following step was the design of a system fitting the dimension of the PE insert of the prosthesis, in order to demonstrate that it is possible to put the sensors and the electronics required for data acquisition, processing and transmission inside the PE insert of the prosthesis. At this stage, the system integration became and important concern, because the space available for the components was drastically reduced.

6.3.1 General description

The maximum dimensions of the PCB fitting the volume of the PE insert were presented in chapter 5, where all the constraints related to the design of the implantable device were listed.

The goal of this demonstrator was to show that it is possible have a complete system (sensors, microcontroller, memory, transponder, antenna) all embedded inside the PE.

One of the miniaturized realization designed and fabricated during the project is shown in figure 6.29.
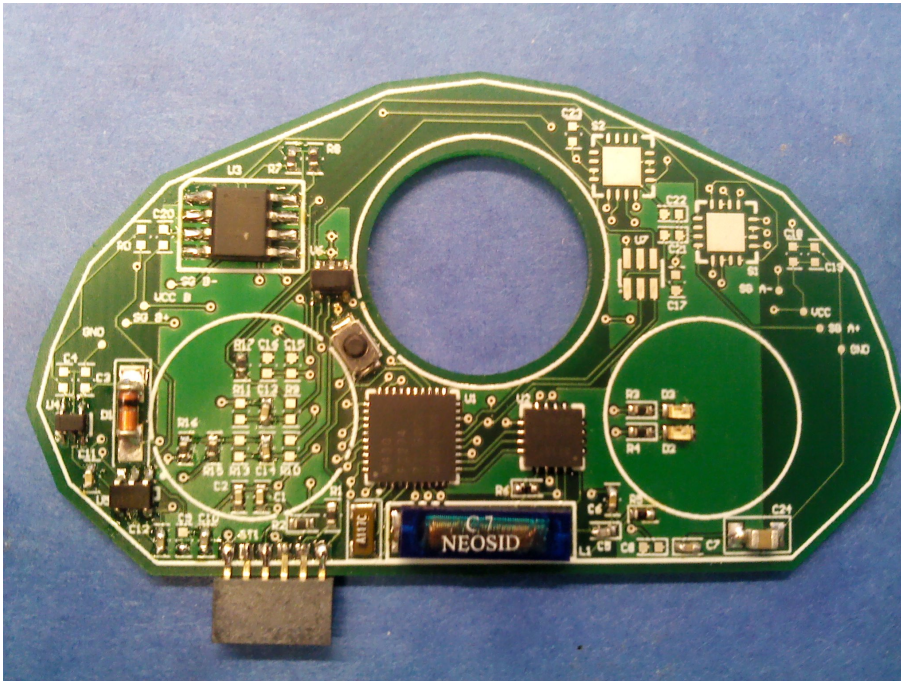
Figure 6.29: PCB fitting the PE insert dimensions.

For encapsulation reasons, all the electronic components must be placed in the top face of the Components (lower) PCB. Only the force sensors, with a limited number of other components, can be placed in the bottom face of the Membrane (upper PCB).

At this stage of the project, the ICs developed by our partners, in particular the one for the

system powering, were still under design. The research on new commercial devices able to provide wirelessy $\sim 20 mW$, the estimated power consumption of the whole system, did not provide good results, thus we had to test again the system with an external power supply.

However, these tests were very useful in order to validate the concept of electronic capsule presented in Section 5.2 as a possible solution to respect all the constraints fixed by the medical doctors and the prosthesis manufacturer in the design of an instrumented knee prosthesis.

6.3.2   Sensors system

The space available on the PCB fitting the dimensions of the prosthesis is very limited. Moreover, the ICs designed by our project partners, that could have allowed to save a lot of space, were not available yet. Thus, we were obliged to take the decision to acquire data only from the force sensors at this stage of the project. This choice was motivated by the big dimensions of the AMR sensors HMC1512 (the only available footprint is an 8-pin SOIC, measuring 4.9 x 6.0 x 1.5 mm). Putting three of them on the PCB means having not enough space for the other components.

Another reason for such a decision was the fact that the magnetic sensors are conceptually identical to the strain gauges (both are analog sensors connected in a Wheatstone Bridge configuration), thus, from the electronic point of view, adding them to the design in a later stage does not represent a major issue.

At this stage of the project, the last version of the strain gauges developed by EPFL-LMIS was already available and it was possible to add them to the design.

They are composed of a polyimide-metal-polyimide structure. The polyimide substrate allows the isolation and a flexible mechanical support for the sensors. Moreover, it is a bio-compatible material, thus suitable for implantable medical devices [46]. The piezoresistive material is a platinum layer embedded in the polyimide layers. The resistors of the Wheatstone bridge present a nominal resistance of 3.2 $k\Omega$. The force sensors present two full Wheatstone bridges, one per knee condyle. The sensor present dummy temperature compensation resistors, that, as the Wheatstone completion resistors, are placed in the middle part of the Membrane PCB, not subject to strain.

The shape of the force sensors is the same that was already presented in Figure 5.14.

6.3.3   Overview of the electronic system

Similarly to the previous system, the designed RFID Tag is based on the microcontroller MSP430F2274 and the PaLFI transponder TMS37157, both from Texas Instruments.

Its schematics is shown in Figure 6.30.

Figure 6.30: RFID Tag designed for the instrumented knee prosthesis.

The microcontroller can be programmed with a small connector (Sullins Connector Solutions LPPB061NFFN-RC). The problem with this connector is the fact that, to keep the shape of the

electronic system, it cannot stay connected to the PCB when the system is embedded inside the PE insert of the prosthesis. An easy solution is, while designing the PCB, to place the pads to solder it close to the border of the PCB. In this way, the PCB can be connected to the USB debugging and programming interface (Figure 6.11) and un-soldered before putting the PCB in the electronic capsule. Figure 6.31 shows the connector soldered to the PCB to program the microcontroller.
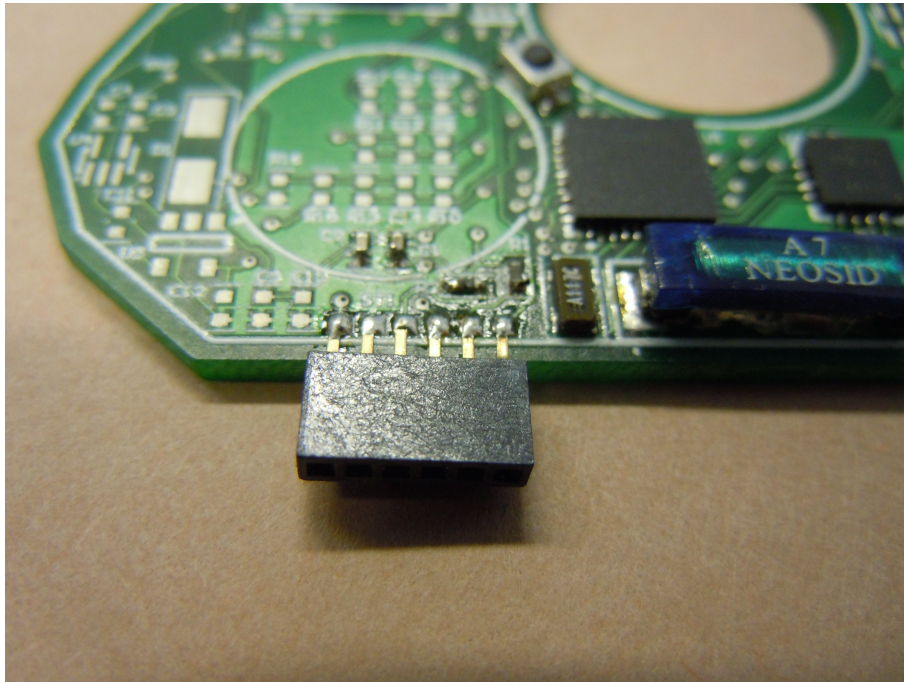
Figure 6.31: Connector for microcontroller programming.

A critical point in the design of a system that has to be embedded into a knee prosthesis is the positioning of the antenna on the PCB. As introduced in Section 5.2.3, the optimal position is the front part of the prosthesis, close to the patella. The coil Neosid Ms32ka is very small, but not enough to fit the space between the central hole and the front edge of the PCB. Consequently, waiting for a custom-designed antenna to be fabricated with the final communication and powering system, it was decided to put it in the back part of the PCB, even if for *in vivo* tests this would not be a valid solution, because the back of the knee presents much more fat, that could reduce the efficiency of the communication, than the front.

The analog front-end is conceptually similar to the ones already introduced for the first demonstrators.

A Ferroelectric Random-Access Memory (FRAM) was added to the design to store sensors data and upload them to the external reader only when the acquisition phase is over.

The FRAM was preferred to a FLASH, that could offer a larger storage capacity, for three main reasons:

- the lower power consumption;

- the faster writing time;

- the greater maximum number of write-erase cycles.

Figure 6.32 shows the different parts of the designed system.
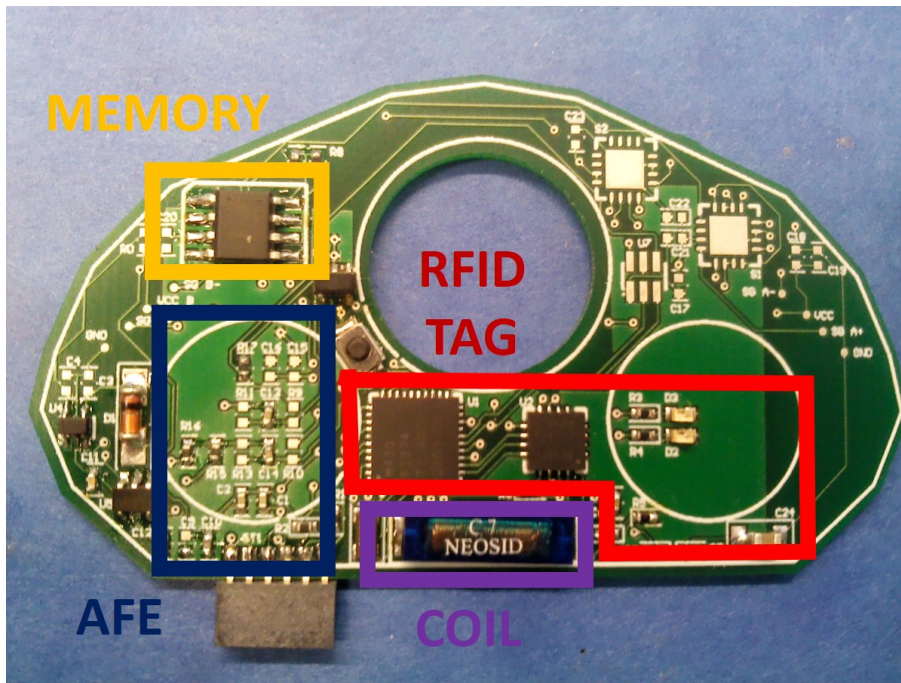
Figure 6.32: Positioning of the electronic subsystems on the PCB.

6.4   Sensors validation with the miniaturized system

In this section, the validation of the concept of the electronic capsule with the force sensors will be presented. The strain gauges designed and fabricated by EPFL-LMIS4 were embedded into a PE insert, by following the procedure explained in section 5.2.2. The force sensors were then validated by using a robotic knee simulator. The sensors calibration performed with the encapsulated system will be presented.

6.4.1   Experimental setup

The thin film strain gauges were glued to the membrane (upper) PCB of the capsule by using epoxy glue. Then, the resulting structure was aligned and glued with the connection (middle) PCB, presenting the two cavities below the force sensors to accentuate the strain effect (see figure 6.33).

Figure 6.33: Encapsulation of the Strain Gauges into the PE insert.

Figure 6.34 shows the real system. The signs used for the alignment of the sensors with the rest of the capsule are visible on the right picture, where the two rounded cavities below the sensors can be recognized.
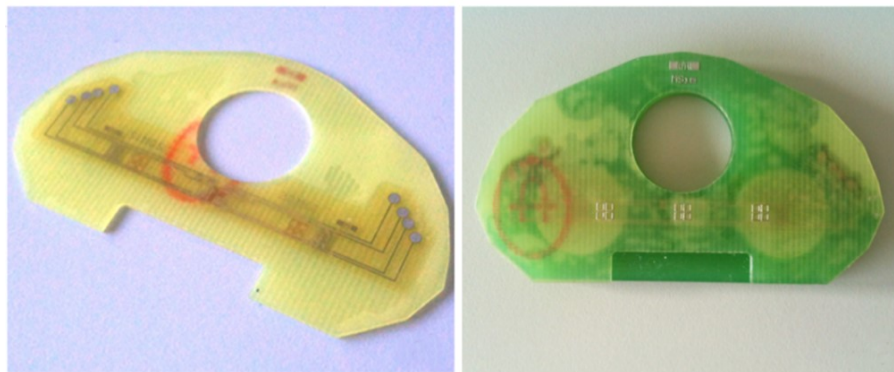
Figure 6.34: Encapsulation of the Strain Gauges into the PE insert. On the left, the strain gauges are glued to the Membrane PCB. On the right, the Membrane PCB is glued to the Connection PCB.

An 8-pin male to male connector was soldered to the back part of the connection PCB, in order to connect the four signals (Power supply, GND, Positive and Negative Outputs) of the two force sensors connected in a Wheatstone Bridge configuration to the external electronics. The resulting PE insert is shown in Figure 6.35.

The instrumented prosthesis just introduced was then tested in a robotic knee simulator,

Figure 6.35: PE insert instrumented with the Strain Gauges connected to the electronic capsule.

constituted of an artificial femur and tibia, that holds the knee prosthesis (see Figures 6.36 and 6.37). Multiple servo-hydraulic actuators, (MTS Bionix servo-hydraulic test system, MTS, USA and Custom Actuators, USA) were used to mimic the muscles acting on the knee [47]. A PID controller specifically designed for this actuator can simulate realistic patterns of knee forces.

The force sensors embedded inside the PE insert were characterized against the force component perpendicular to the tibial plate measured by a load cell (ATI Industrial Automation, USA) integrated in the artificial proximal tibia.

6.4.2   Results

The results of the characterization of the force sensors performed with the robotic knee simulator are presented hereafter.

Figures 6.38 and 6.39 represent the calibration curves of the sensors at 10° and 60° knee flexion respectively. The output voltages of the sensor channels were measured during a loading experiment using a quadriceps actuation.

The curves show a linear behavior of the sensors against the total force measured perpendicularly to the tibial plate of the prosthetic implant upon application of step forces ramping from 0 to 900N and back down.
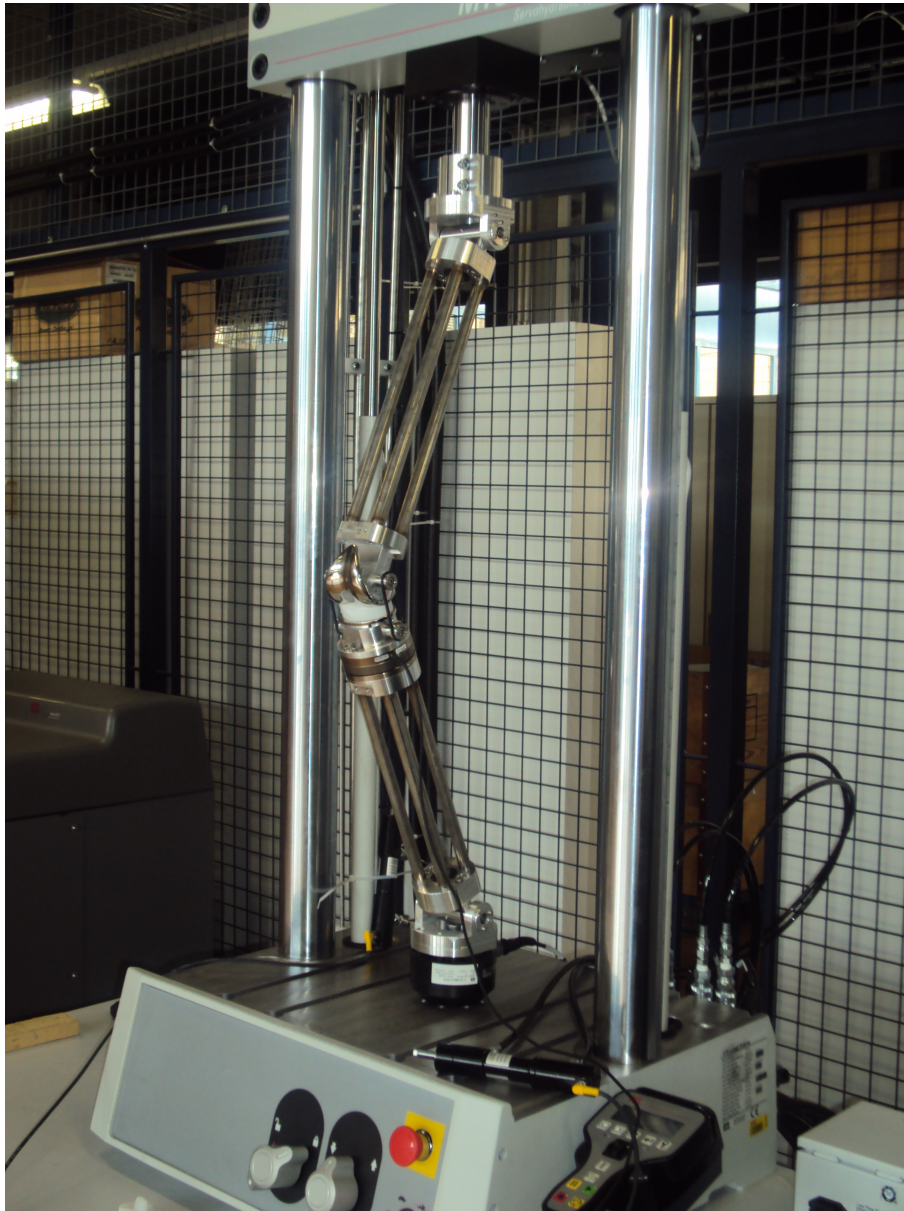
Figure 6.36: Robotic knee simulator used for force sensors characterization.

6.4.3   Discussion

The presented miniaturized system was the first step toward an electronic design fully contained in a PCB fitting the dimensions of the PE insert of the knee prosthesis. Due to the fact that the ICs for the analog front-end and the communication and powering system were still under design, the space on the PCB was limited and for this reason only the force sensors were used in the demonstrator. Another issue was the impossibility to wirelessy supply the system, because the available commercial components cannot provide enough energy. Nevertheless, the strain gauges were calibrated by using an automatic knee simulator and it was demon-

Figure 6.37: Detail of the F.I.R.S.T. knee prosthesis connected to the mechanical simulator.

strated that the concept of the electronic capsule was a good option for the SImOS system in order to respect the design constraints.

6.5 Final SImOS demonstrator

This section describes the final demonstrator designed for the SImOS project. The goal of this demonstrator was to test all the components developed by the project partners (force sensors, custom-designed analog front-end and communication and powering system) and integrate
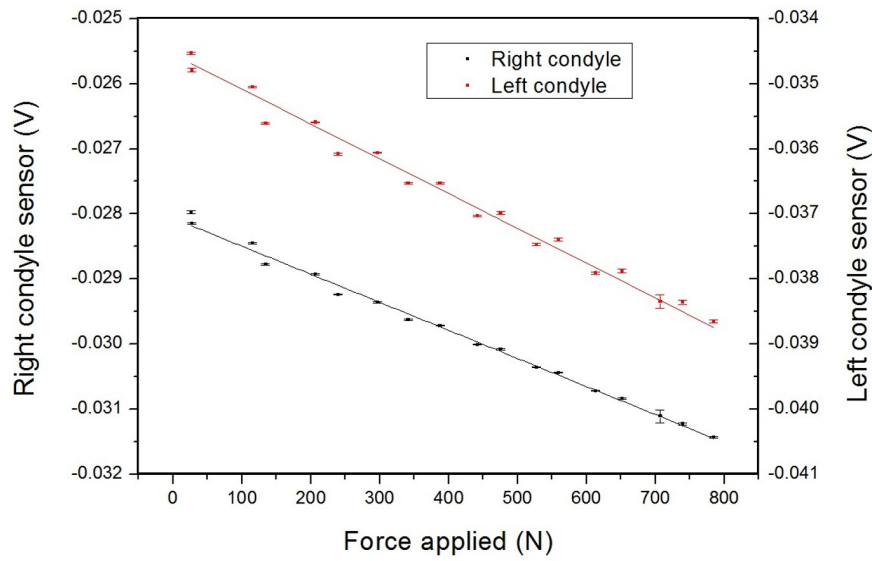
Figure 6.38: Calibration curve of the strain gauges at 10° knee flexion.
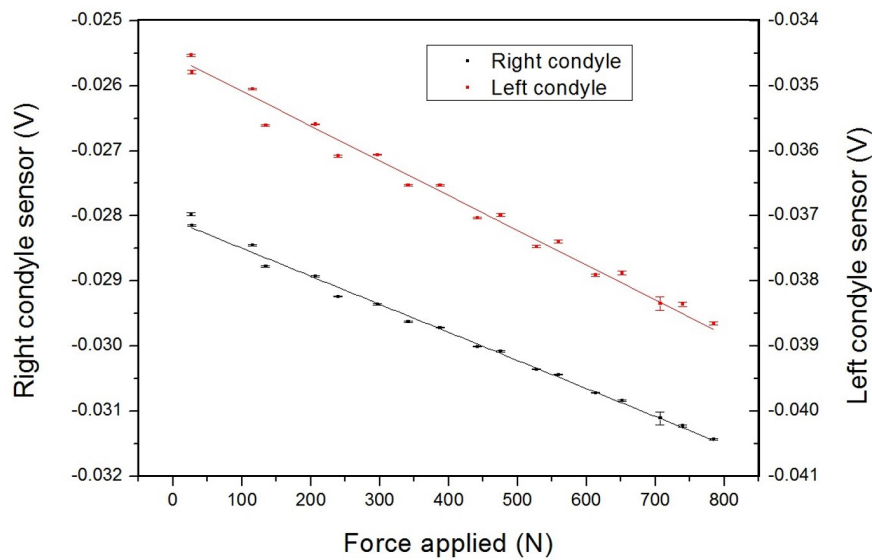
Figure 6.39: Calibration curve of the strain gauges at 60° knee flexion.

them with the microcontroller, that had to be programmed accordingly.

6.5.1 General description

To test the different subsystems separately, a modular large-scale demonstrator was designed.

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The architecture of the whole system is shown in Figure 6.40, where the left side represents the electronic system to be implanted inside the PE insert, while the right side represents the external components.

The external antenna, connected to the reader, can be attached to a protector knee belt, that is put on by the patient during the tests. For instance, the physiotherapist in charge of the rehabilitation can evaluate the performances of the knee by asking the patient to wear this non invasive tool.

Obviously, during the surgery, when the knee is open, a knee belt cannot be put on, but the clinicians can approach a display containing the external coil in order to read, for example, the balance of the tensions of the medial and lateral ligaments.
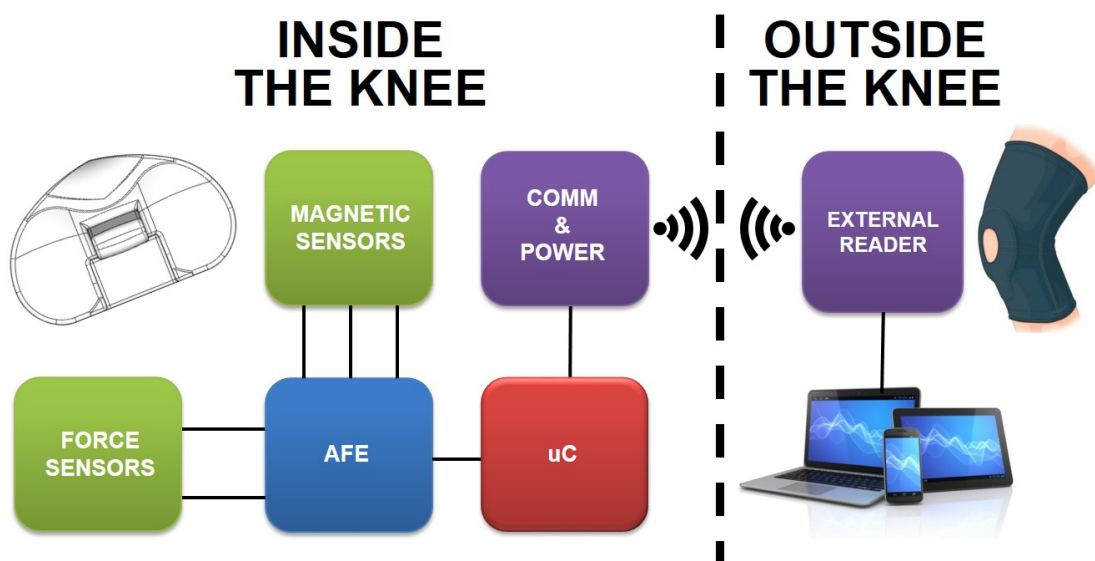
Figure 6.40: Architecture of the system that has to placed in the PCB fitting the shape of the prosthesis.

The microcontroller used was the MSP430F2274 already tested with the previous demonstrators. An external memory is added to the design to store the sensors data, that can be uploaded at a later stage. The analog front-end was designed by EPFL-ESPLAB. The communication and powering system was based on an IC and a coil developed by EPFL-RFiC, used to provide the energy required for the whole system (∼ 20 mW). They designed and fabricated also the external reader.

6.5.2 Sensors system

The sensors system for the final SImOS demonstrator included all the sensors for force and kinematics measurements.

As for the previous demonstrators, the force sensors used were the latest version of the thin

film strain gauges, connected in a Wheatstone bridge configuration, designed by EPFL-LMIS4. These sensors were fabricated in the clean-room of EPFL-CMI.

The kinematics sensors chosen for the last SImOS demonstrator are the Honeywell HMC1512 already tested with the second demonstrator. In this case, a configuration with three sensors was used, to guarantee an adequate sensitivity during flexion-extension and abduction-adduction [45].

6.5.3   Detailed schematics

For this final functional demonstrator, the analog front-end used was developed by EPFL-ESPLAB (see figure 6.41). It can manage the data acquisition from up to 8 sensors in a Wheatstone Bridge configuration.

It was used to acquire data from two strain gauges (one per side of the knee prosthesis) and three 2-channels AMR sensors. It is connected to the MSP430F2274 by SPI interface. The SPI port of the MSP430F2274 is also used to connect the transponder developed by EPFL-RFiC. This IC works at two different frequencies: 134.7 kHz for data transmission and 13.56 MHz for the system powering. Thus, it requires two coils. According to the specifications defined at the beginning of the project, this system is expected to deliver up to 20 mW through the external reader.

Figure 6.42 shows a simplified schematics of the analog front-end and the RFID Transponder connected to the microcontroller by the SPI bus.

Moreover, a memory is included in the design in order to store the data collected from the sensors and transmit them to the external reader after the acquisition phase, in order to save energy. The chosen memory was the Cypress FM24V10 FRAM, an 1 Mbit non-volatile memory employing a bi-directional I2C bus protocol. The MSP430F2274 has up to two SPI ports; one of this ports can also be used as an I2C port. In the proposed design, one of these two ports was connected to the SPI bus, as shown in figure 6.42, while the other one was connected to the I2C to communicate with the FRAM.

The typical configuration, with two 10 $k\Omega$ pull-up resistors connected to the CLK and DATA lines of the I2C bus, were used (see Figure 6.43).

A Large-Scale demonstrator of this final system was designed and tested. Figure 6.44 shows a picture of the system, where all the subsystems are highlighted with different colors.

The force sensors were embedded in the PE insert and directly connected to the Large-scale demonstrator, as shown in Figure 6.45.
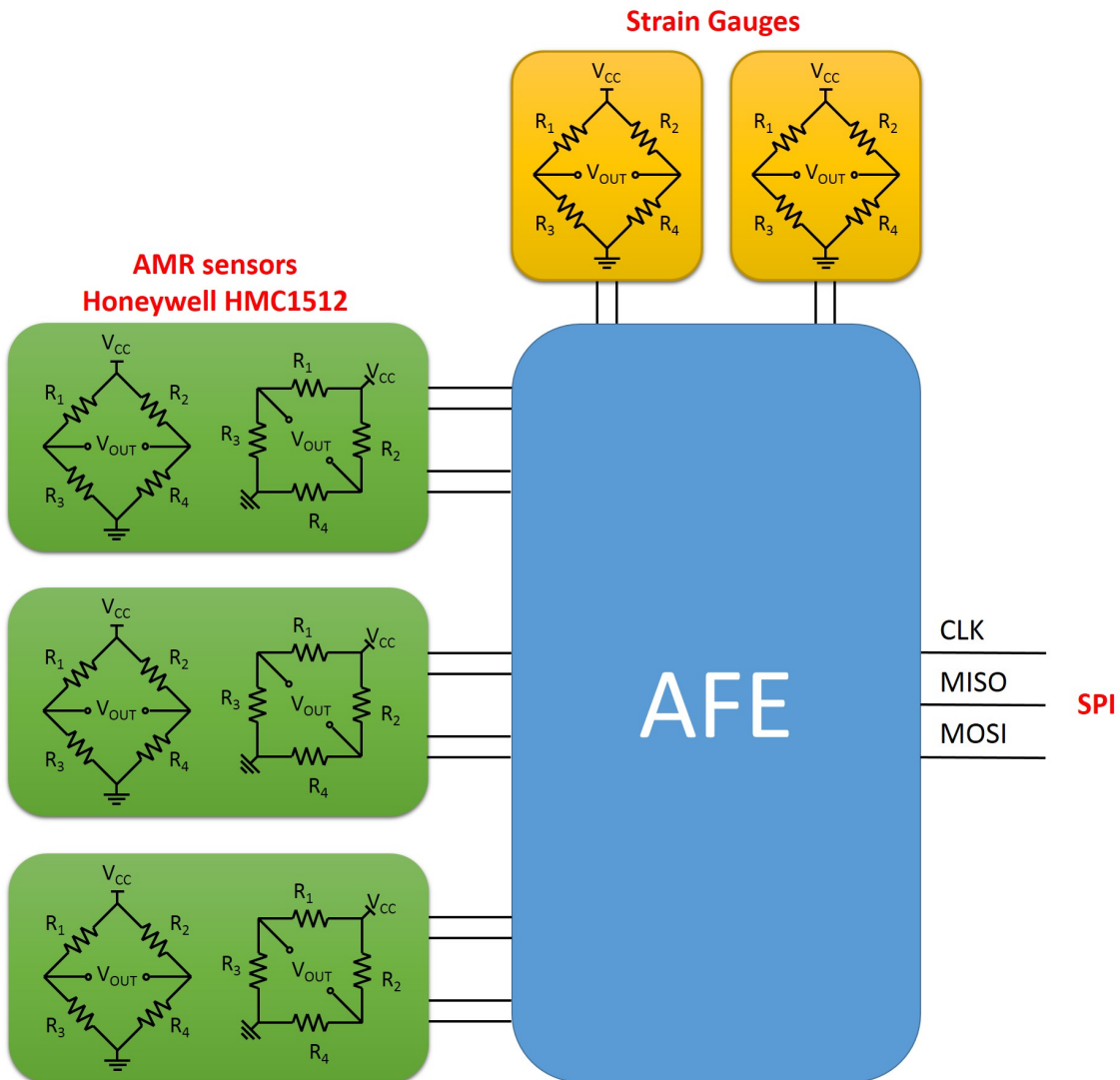
Figure 6.41: Analog front-end for the final SImOS functional demonstrator.

6.5.4 Discussion

The final system of the SImOS instrumented prosthesis was tested with a large-scale demonstrator.

The design of the last SImOS demonstrator, integrating all the ICs developed by the project partners, demonstrated that it is possible to realize a PCB fitting the dimensions of the PE insert of the F.I.R.S.T. prosthesis.

Unfortunately, this design presents an insurmountable issue. The integrated circuit for powering and data communication with the related custom-designed antennas, that was expected to deliver 20 mW through the external coil, does not work as expected. In particular, its SPI part, that we planned to use for the communication with the embedded microcontroller, cannot be
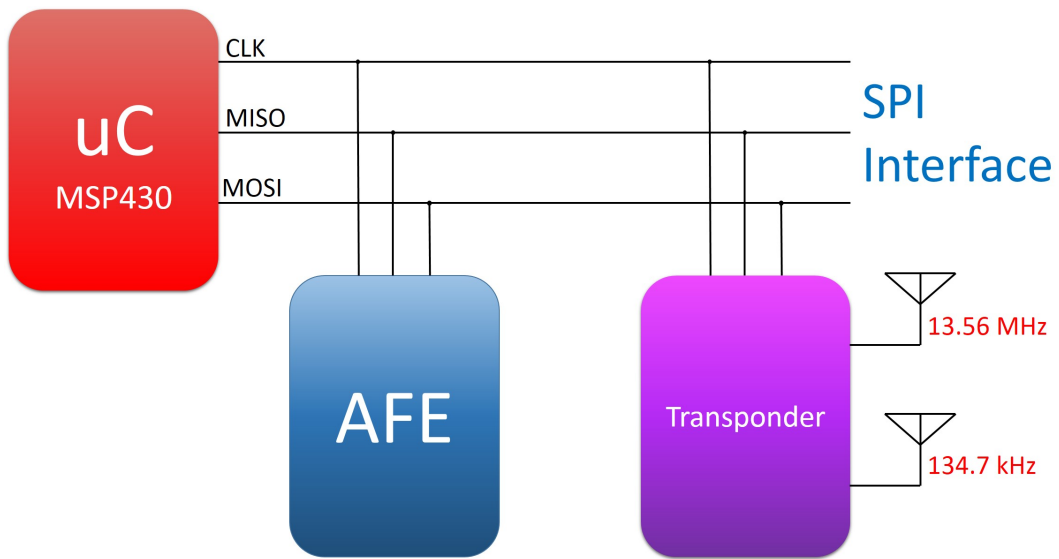
Figure 6.42: SPI bus with the analog front-end and the RFID transponder connected to the microcontroller.
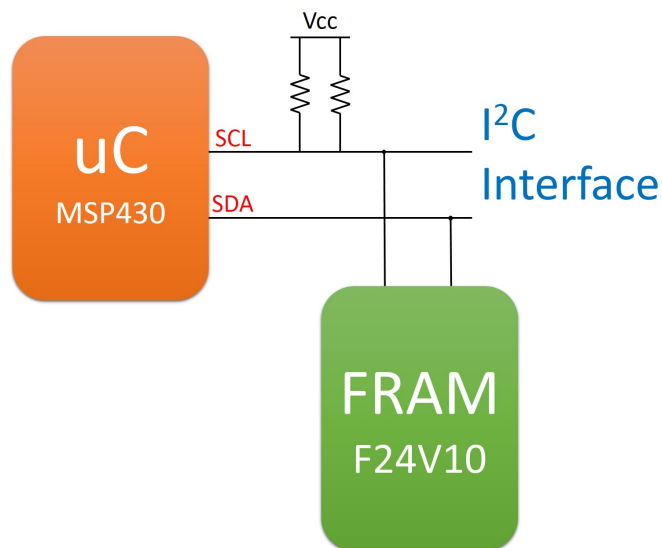
Figure 6.43: I2C bus with the FRAM Cypress FM24V10 connected to the microcontroller.

exploited.

In conclusion, this final SImOS demonstrator proved the feasibility of the instrumented prosthesis based on such a system, but these electronics cannot be integrated into a PE insert, because, without a properly working powering system, it cannot be used.
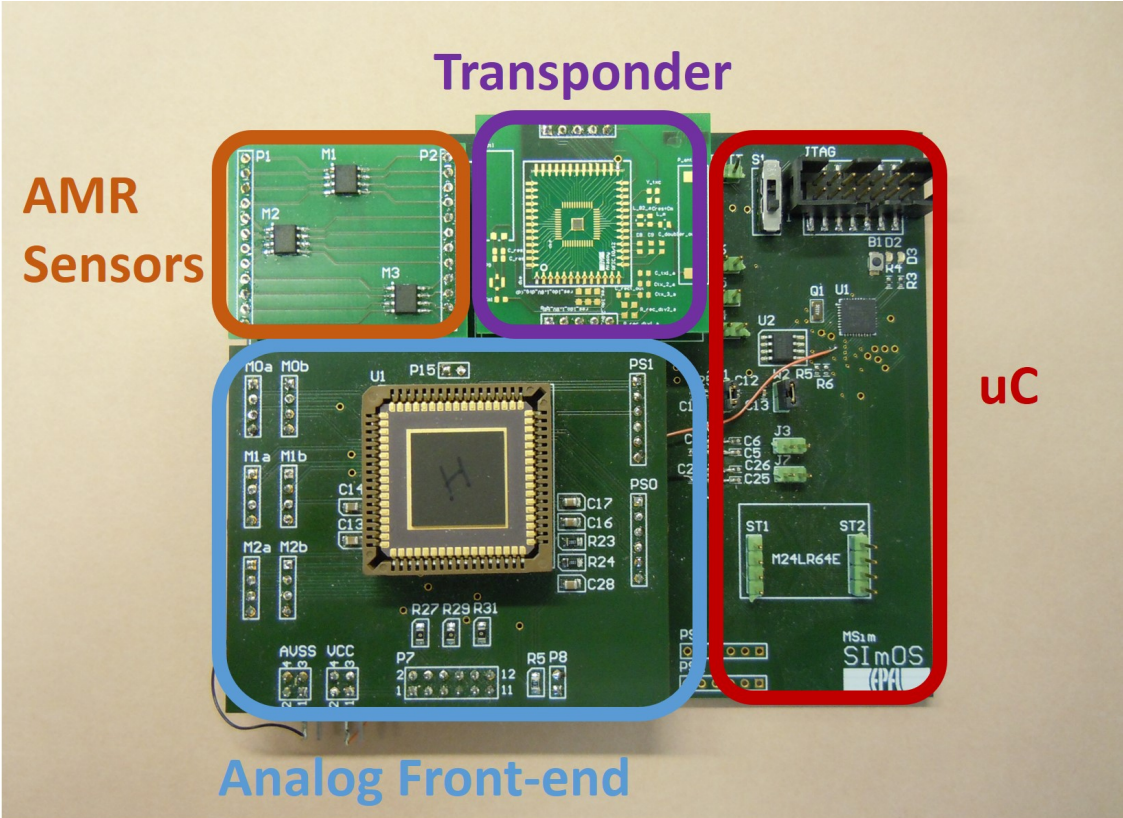
Figure 6.44: Final SImOS large-scale demonstrator.
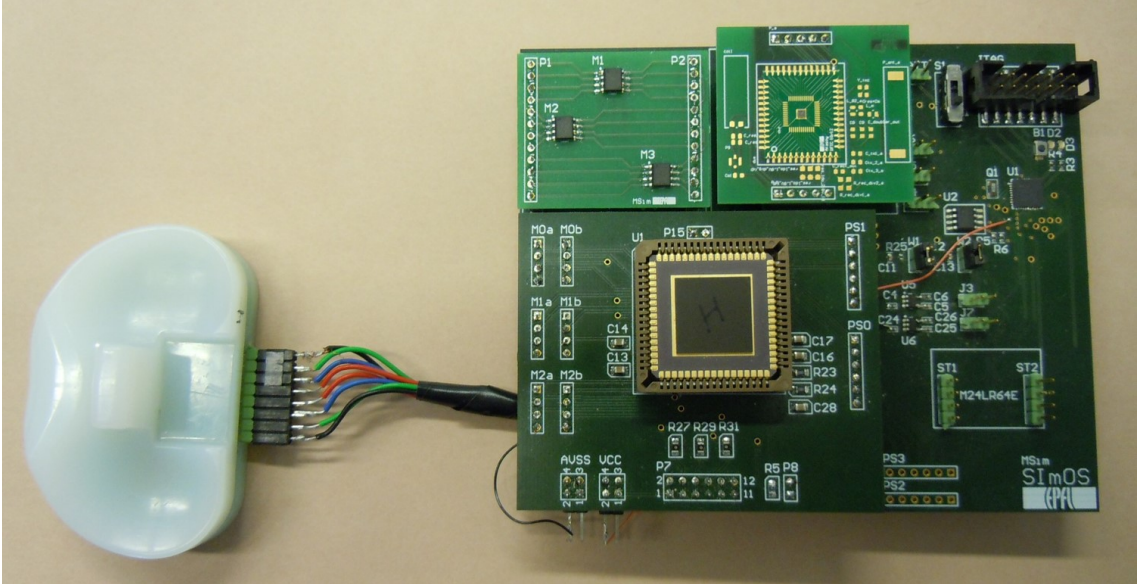
Figure 6.45: Strain Gauges embedded inside a PE insert and connected to the final SImOS large-scale demonstrator.

6.6 Conclusion

This chapter presented the different steps in the design of an instrumented version of the F.I.R.S.T. knee prosthesis by Symbios Orthopedie SA.

The first functional demonstrator was used to validate the concept of an RFID Tag used for data acquisition. It was used to acquire data from a single force sensor embedded inside the PE insert and validated with a manual mechanical simulator and demonstrated that the electronic system based on a microcontroller and an RFID transponder was a valid solution, even though the delivered energy was not sufficient to acquire more than few samples and an we had to use an external battery.

With the second demonstrator, we achieved the result of simultaneously acquiring data from both the strain gauges and the magnetic sensors: the system was validated again with a manual mechanical knee simulator and as far as we know, this is the first example present in literature of an instrumented prosthesis able to measure both the force applied to the prosthetic knee and its kinematics.

A miniaturized version, fitting the dimensions of the PE insert of the knee prosthesis, was designed and used to validate the force sensors acquisition with the electronic capsule, that was embedded into the PE.

Finally, the final demonstrator of the SImOS project was designed, by integrating all the ICs developed by our project partners. Unfortunately, the powering system was not working as expected, resulting in the impossibility of powering the system wirelessy.

In order to have a device with a telemetry system able to supply the power required by the whole system, we performed a research on new commercially available devices. Moreover, we had new discussions with the engineers of Symbios Orthopedie SA, that explained their new expectations in terms of instrumented prostheses.

These studies led to the idea of designing a new instrumented PE insert, to be used during the surgery in order to balance the tension of the medial and lateral ligaments. The design of this new device will be detailed in Chapter 7.

7 Autonomous sensor for ligament balance

The discussions with the engineers of Symbios Orthopedie SA brought us to the decision of designing a new instrumented PE insert, based on a similar concept but for a different application. The goal of this new system is to measure the force balance between the medial and lateral condyles of the knee prosthesis during the surgery. It is an autonomous sensors, that is taken out of the knee when the ligaments tensions are well balanced. It can be cleaned, sterilized and reused in a later surgery. The reason why the prosthesis manufacturer prefers such a system instead of a complete instrumented prosthesis is the fact that, not being an implantable device, it can be quickly accepted by a medical advisory board of a hospital for human trials and, keeping the same encapsulation used for the instrumented prosthesis, it could likely simplify the approval for a full implantable prosthesis afterwards.

The PE insert used for these tests is not the same used as for the functional demonstrators shown in chapter 6, but a new one, fabricated with a 3D printer and already introduced in section 5.3. The main advantage of this new PE insert is the fact that it is designed to be fixed to the tibial tray, thus it does not have the hole in the center of its bottom side to host the head of the screw that fixes the tibial part of the prosthesis to the bone.

This different design results in a increased available area of the PCB that is embedded inside it.

Not being able to use the communication and powering system designed specifically for the SImOS project, as explained in section 6.5.4, we had to find a different way to avoid the use of an external power supply.

The electronics used and some results on the measurements will be presented in this chapter.

7.1   General description

For this autonomous sensor, the PE insert adopted was the one used for the very last version of the knee prosthesis by Symbios Orthopedie, fabricated by 3D printing.

This new PE insert presents a main advantage: it does not have the hole in the middle, leaving much more space than the previous version for the capsule embedded inside it and, as a consequence, for the electronic system.

In order to host the electronic capsule, the PE insert was modified and a free space was left in its center, as shown in Figure 7.1. It can be opened to freely put in and take out the electronic system.
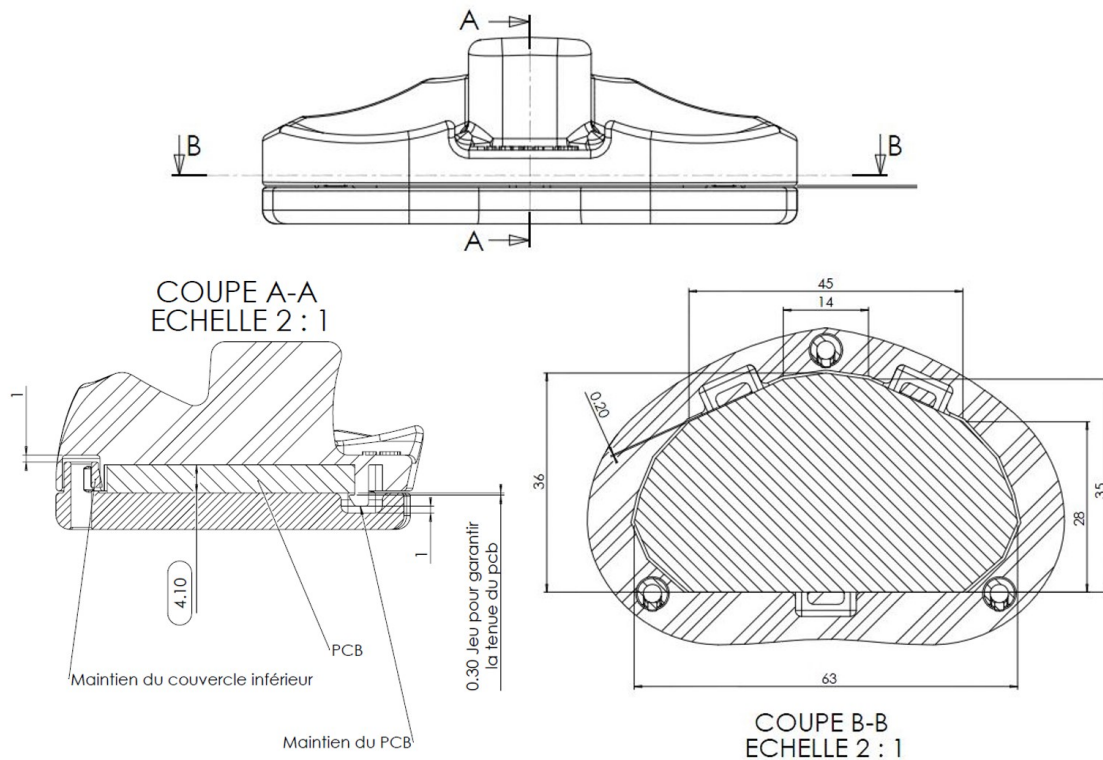
Figure 7.1: Design of the new PE insert modified to be instrumented.

The dimensions of the hole inside the PCB perfectly fits the dimensions of the electronic capsule, that can be embedded inside it. Figure 7.2 shows one of the PE insert fabricated to be instrumented.

7.2 Sensors system

The balance of the tensions of the medial and lateral ligaments of the knee allows to have an identical force applied to the PE insert by the two condyles of the prosthetic knee.

To verify the correct balance, only force sensors are required. To measure the balance of the
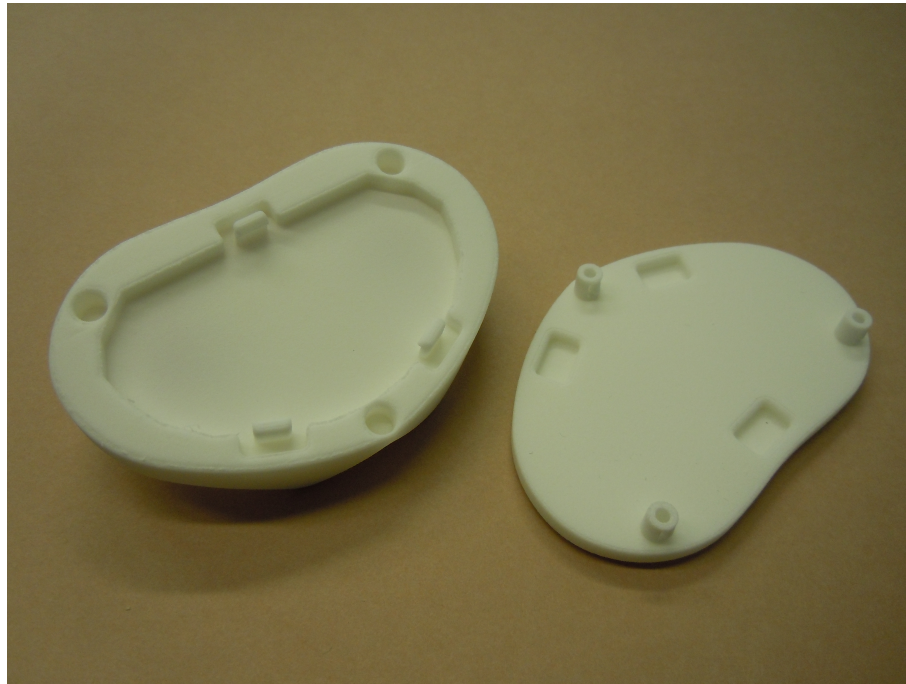
Figure 7.2: View of the upper and lower sections of the new PE insert.

medial and lateral forces, two Wheatstone bridges are necessary, one per side.

The latest version of the strain gauges designed by EPFL-LMIS4 showed a linear behavior in the range of forces of interest (see section 6.4.2), thus we decided to keep them in the design.

Also, the positioning described in section 5.2.2 has been kept.

7.3 Detailed schematics

The main technical issue for this electronic design was finding a transponder able to deliver enough energy to supply the whole system during data acquisition, storage and communication to the external reader. A research on new devices brought us to choose the M24LR64E-R from ST microelectronics (Figure 7.3), a dynamic RFID tag IC, containing a 64-Kbit EEPROM. It features an I2C interface for the communication with a connected microcontroller.

The M24LR64E-R can be accessed via the 13.56 MHz carrier electromagnetic wave. When connected to an antenna (through the pins AC0 and AC1), the operating power is derived from the RF field and no external power supply is required.

The M24LR64E-R provides also an energy harvesting analog output (Vout); when the energy harvesting mode is activated, the device can deliver the excess energy coming from the RF field to power supply the rest of the RFID Tag, namely, in the case of the autonomous sensor for knee prosthesis, the microcontroller, the sensors and the related analog front-end.
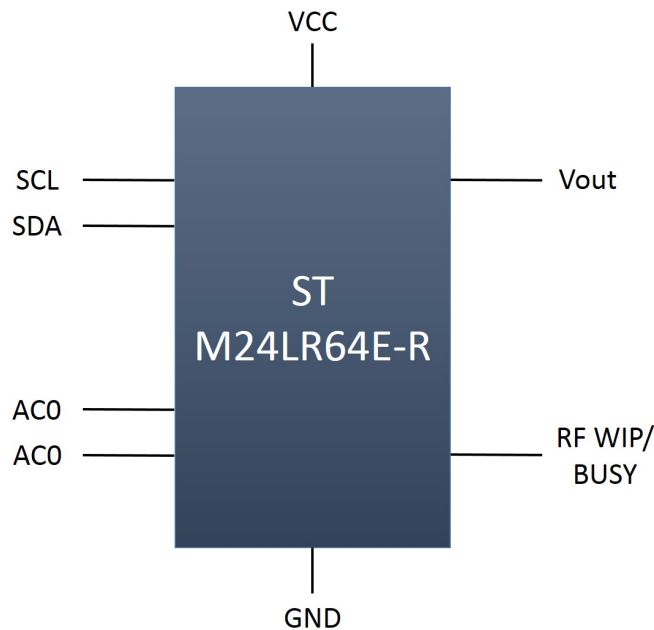
Figure 7.3: Logic diagram of the ST M24LR64E-R.

The user configurable digital output pin RF WIP/BUSY can be used to drive a microcontroller interrupt input pin.

The microcontroller used for this design is the MSP430F2274 by Texas Instruments. The microcontroller (master) and the M24LR64E-R (slave) are connected by the I2C bus, as shown in Figure 7.4.

Another technical issue was finding a small SMD antenna working at 13.56 KHz. The chosen coil was the SDTR1103-HF2-0002K by Premo, with an Inductance of 2 μH and a $Q \geq 20$. Its dimensions are shown in Figure 7.5.

The RFID Tag M24LR64E-R has an internal tuning capacitance of 27.5 pF, at a frequency of 13.56 MHz. An external capacitor is required in parallel to the internal one. Its value is calculated as follows:

$$f = \frac{1}{2\pi\sqrt{LC}}$$

C represents the equivalent capacitance of the internal tuning capacitance and the external one, to be put in parallel to it. L represents the inductance of the antenna, 2 μH for the Premo SDTR1103-HF2-0002K.
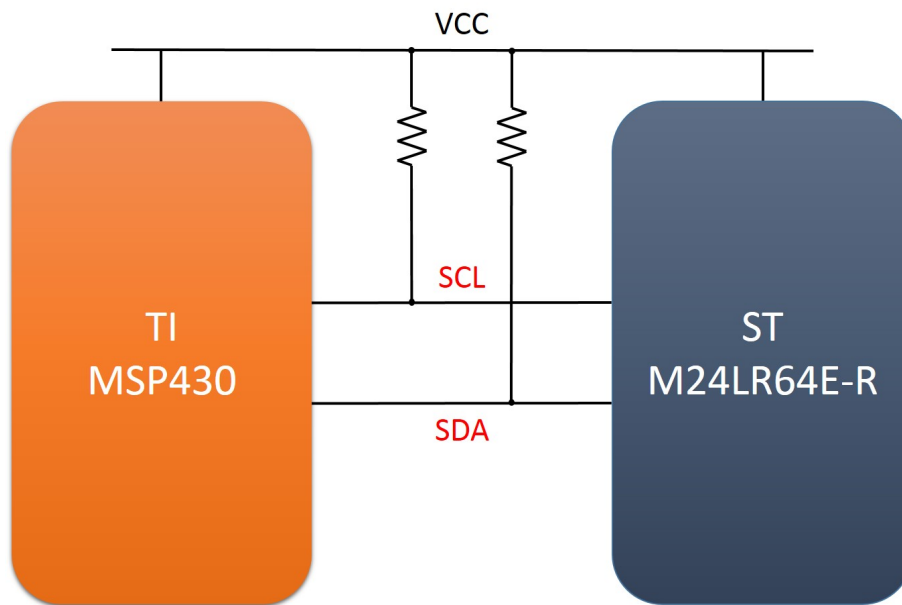
Figure 7.4: Microntroller and M24LR64E-R connected to the I2C bus.
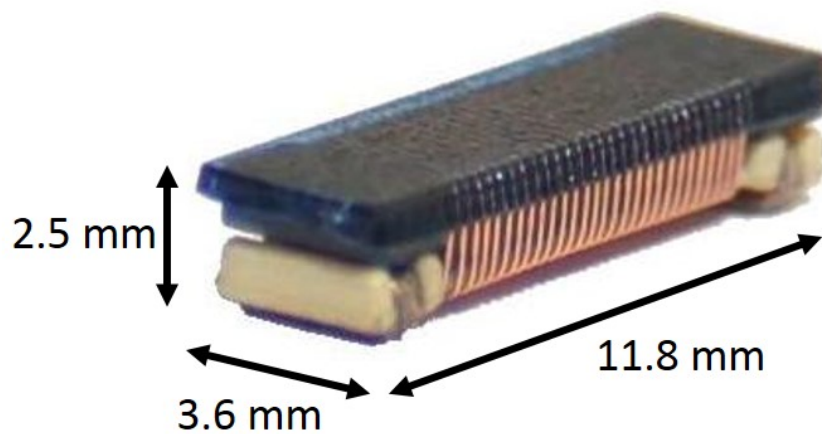
Figure 7.5: SDTR1103-HF2-0002K RFID antenna by Premo. Reprinted from [75].

$$f = \frac{1}{2\pi\sqrt{L(C_{tun} + C)}}$$

$$C = \frac{1}{4\pi^2 f^2 L} - C_{tun}$$

111

$$C \sim 41.4 pF$$

Thus, a 40 pF has been put in parallel to the AC0 and AC1 pins of the M24LR64E-R in the design.

The new PE insert, without the hole in the middle, presents a huge advantage for the positioning of the antenna: the PCB to be put inside it does not require a hole, too, and thus the antenna can be put in the front part of it, as shown in Figure 7.6. For coupling reasons with the external antenna, that can be placed on a protector knee belt, it should be oriented parallel to the sagittal (anterior to posterior) plane of the patient.
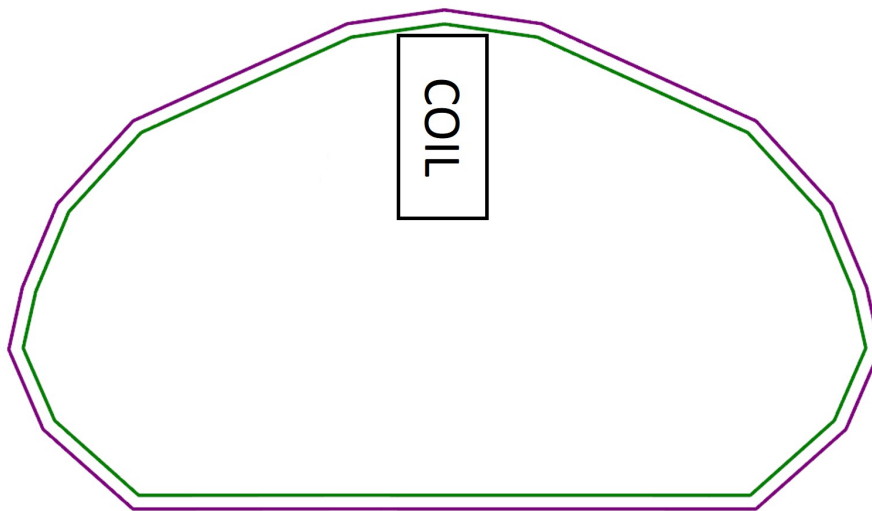
Figure 7.6: Positioning of the coil on the PCB.

The analog front-end used is based on commercial devices. In particular, we used two Texas Instruments LPV521 Operational Amplifiers for the sensors data (gain = 1000). This OpAmp was chosen fot its low power consumption: the typical supply current is 400 nA max in a voltage range of 1.6 to 5.5 V, making it a good choice for RFID readers and sensors applications. In addition, EMI protection was designed into the device to reduce sensitivity to unwanted RF signals from RFID readers. A dual-channel D/A converter, the Analog Devices AD5667R, was chosen for offset compensation. It has an I2C interface to communicate with the micontroller (master).

The schematics of the analog front-end is shown in Figure 7.7.

The sensors signals amplified are then converted by means of two ADC ports of the microcontroller and the digital data are stored in the EEPROM of the M24LR64E-R.

The low-dropout (LDO) voltage regulator TPS71433 by Texas Instruments was added to the
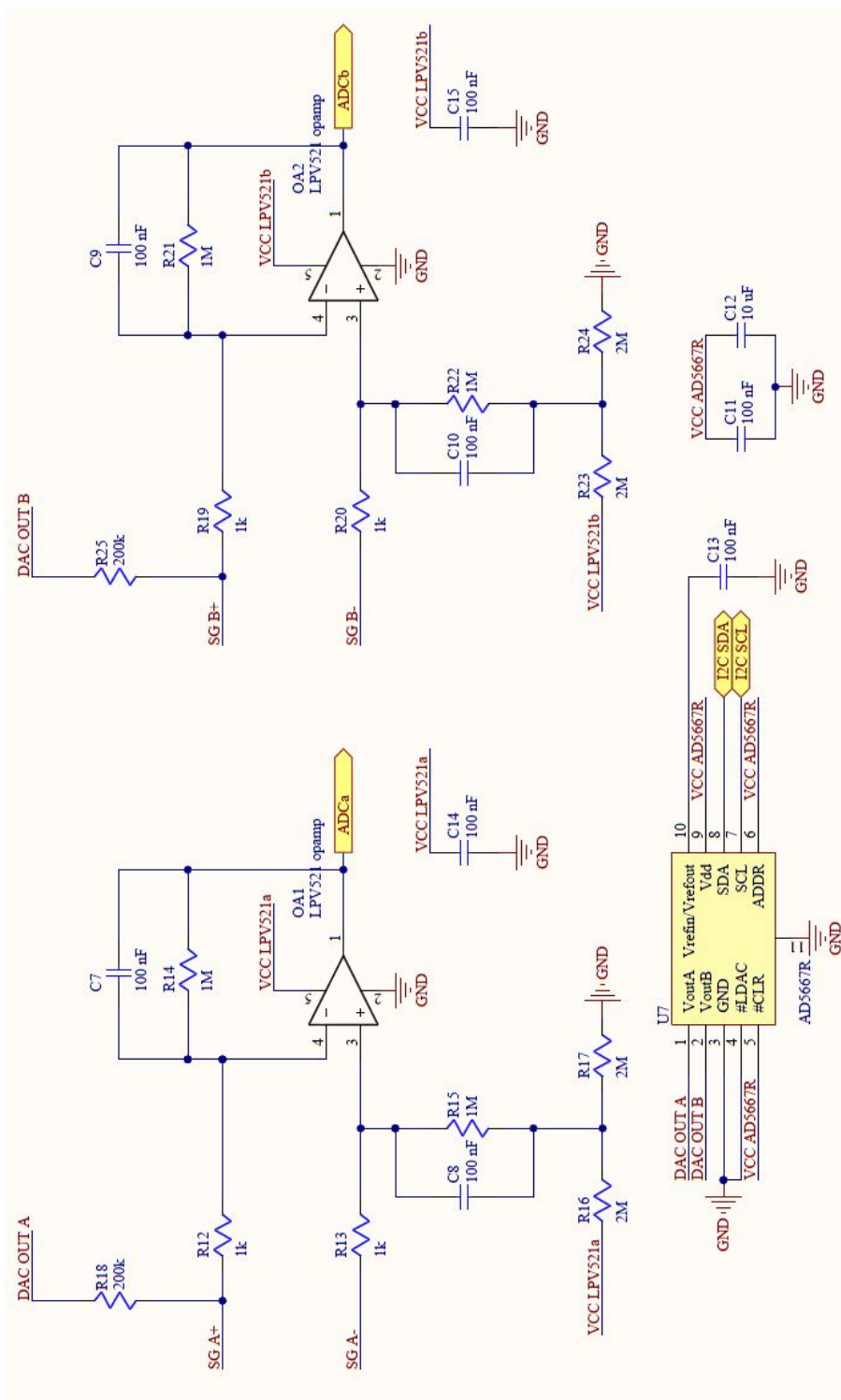
Figure 7.7: Analog front-end designed for the autonomous force sensor.

design, to regulate the power supply when the system is powered by the RF field of the external

reader.

Finally, a battery holder for 12 mm coin cells was added (see Figure 7.8), to test the system without the wireless powering. Since the system is not implantable, the battery could also be kept in the device, if necessary.
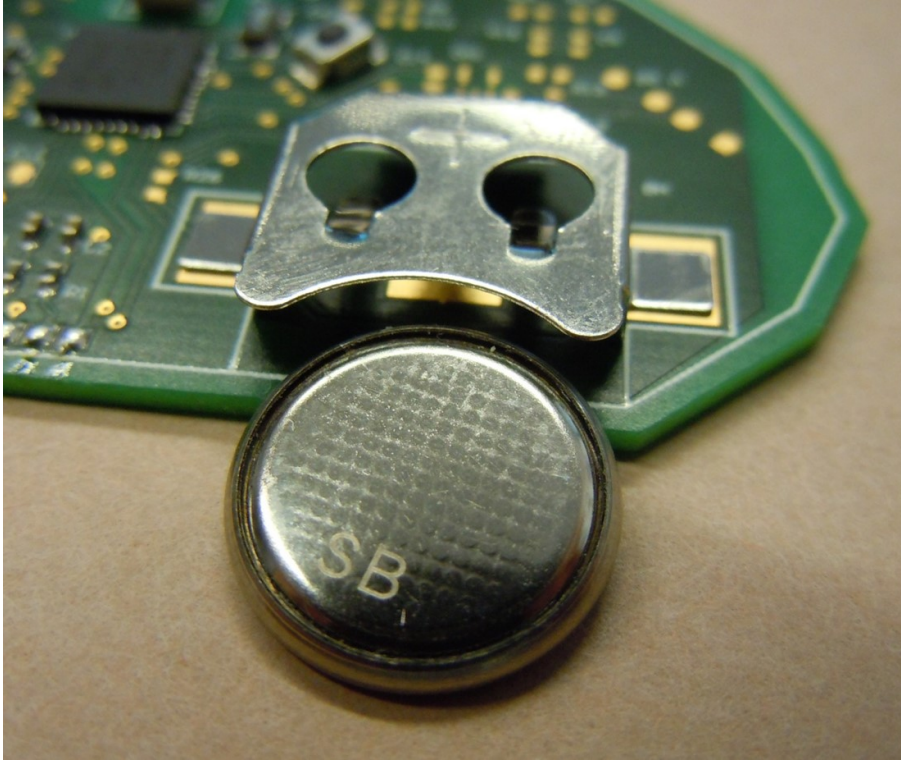
Figure 7.8: Battery holder for the 12 mm coin cell.

Figure 7.9 shows a simplified version of the full schematics of the autonomous force sensor.

The full schematics of the designed system is reported in Appendix A.

The designed PCB is shown in Figure 7.10.

7.4   Experimental setup and test

The electronic capsule containing the PCB described in the previous section can be embedded inside the PE insert conveniently modified. Figure 7.11 shows the bottom part of the PE insert with the PCB put in the cavity; the bottom (tibial) side is visible in the picture, the electronic components are located in the internal part.

In order to provide the autonomous sensor with the energy required for the measurements and to collect sensors data, an external reader is necessary. We used the CR95HF from ST microelectronics (see Figure 7.12), supporting an RF communication at 13.56 MHz. It can be

Figure 7.9: Simplified schematics of the autonomous force sensor for ligaments balance.

connected to a computer by an USB cable.

During the measurements, the external coil has to be placed in front of the prosthetic knee, as shown *in vitro* in Figure 7.13.

In order to save energy and to use the instrumented PE insert with a wireless power supply, the system architecture is organized in a way that the microcontroller is the only device directly powered by the M24LR64E-R energy harvesting pin.

All the other components are powered only when necessary for data acquisition, storage and transmission by general purpose pins of the microcontroller. The data acquisition flow is shown in figure 7.14 for a single acquisition from both the force sensors.

The first step is switching on the AD5667R D/A converter, that requires 3 ms for power supply stabilization. Then the EEPROM is switched on and the system configuration data stored in it

Figure 7.10: PCB designed for the autonomous force sensor for ligaments balance.
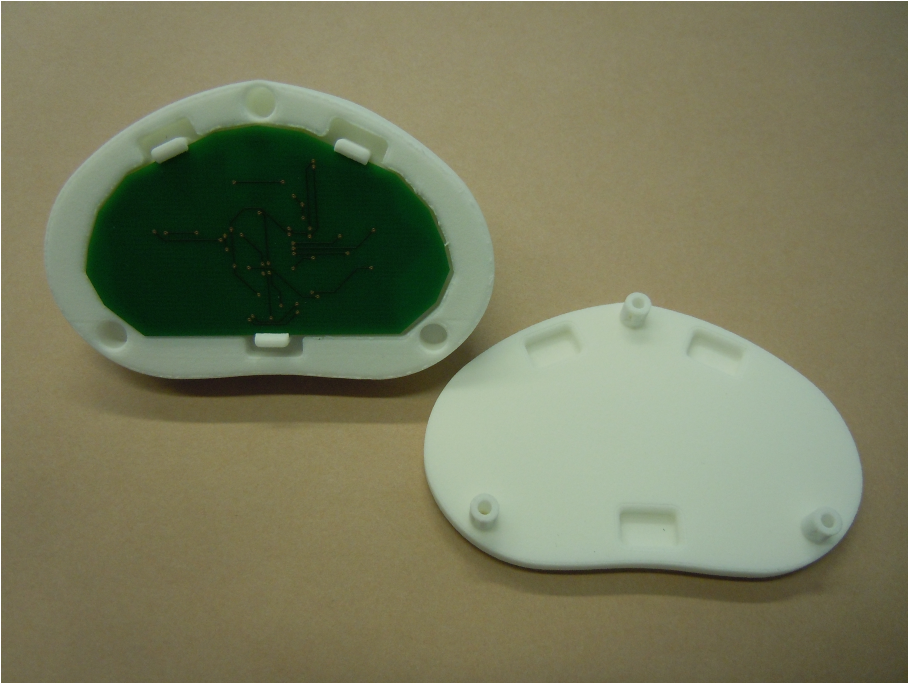
Figure 7.11: PCB embedded inside the PE insert used for the autonomous force sensor.

are read.

Then the acquisition phase from the first of the two strain gauges starts: first of all, the
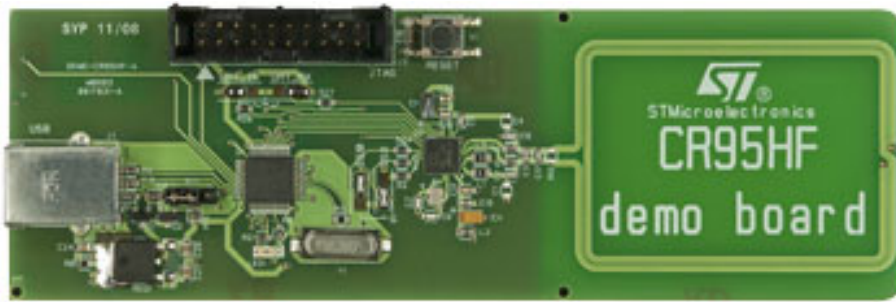
Figure 7.12: CR95HF reader from ST microelectronics. Reprinted from [76].
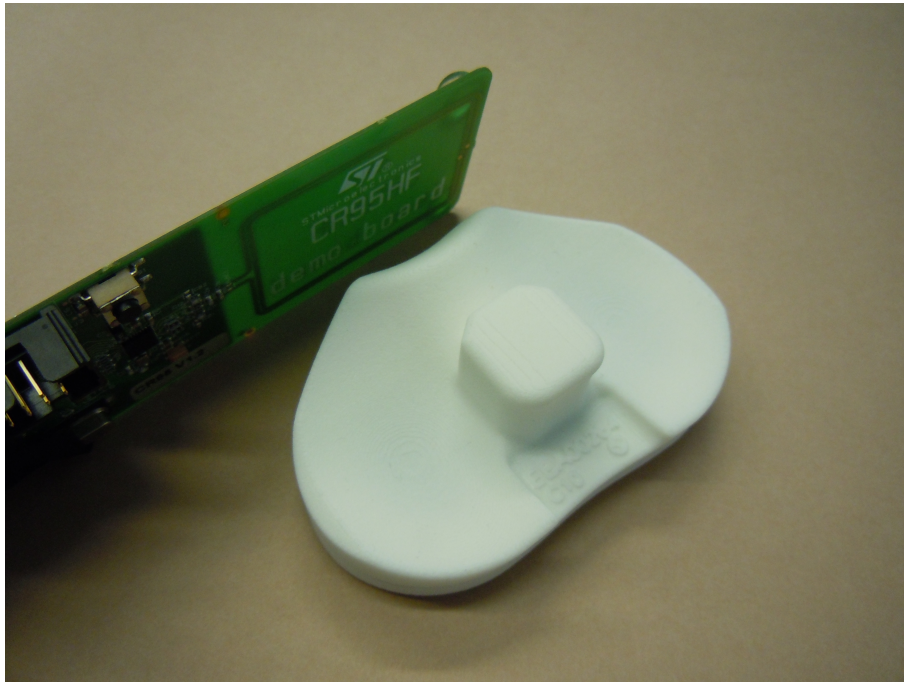
Figure 7.13: Placement of the external coil during measurements.

Wheatstone bridge is power supplied, then the amplifier is switched on; an ADC port of the microcontroller is used to convert the acquired data and store them in a temporary variable. After that, the operational amplifier and the power supply of the Wheatstone bridge are switched off.

The same operations are repeated for the second bridge, located on the other side of the instrumented prosthesis.

In the real measurements, these operations are repeated in a loop for the number of acquisitions required by the operator. In Figure 7.14, for simplification reasons, only a single acquisition from both the strain gauges bridges is presented.

At the end of the acquisition phase from the second Wheatstone Bridge, the algorithm contin-
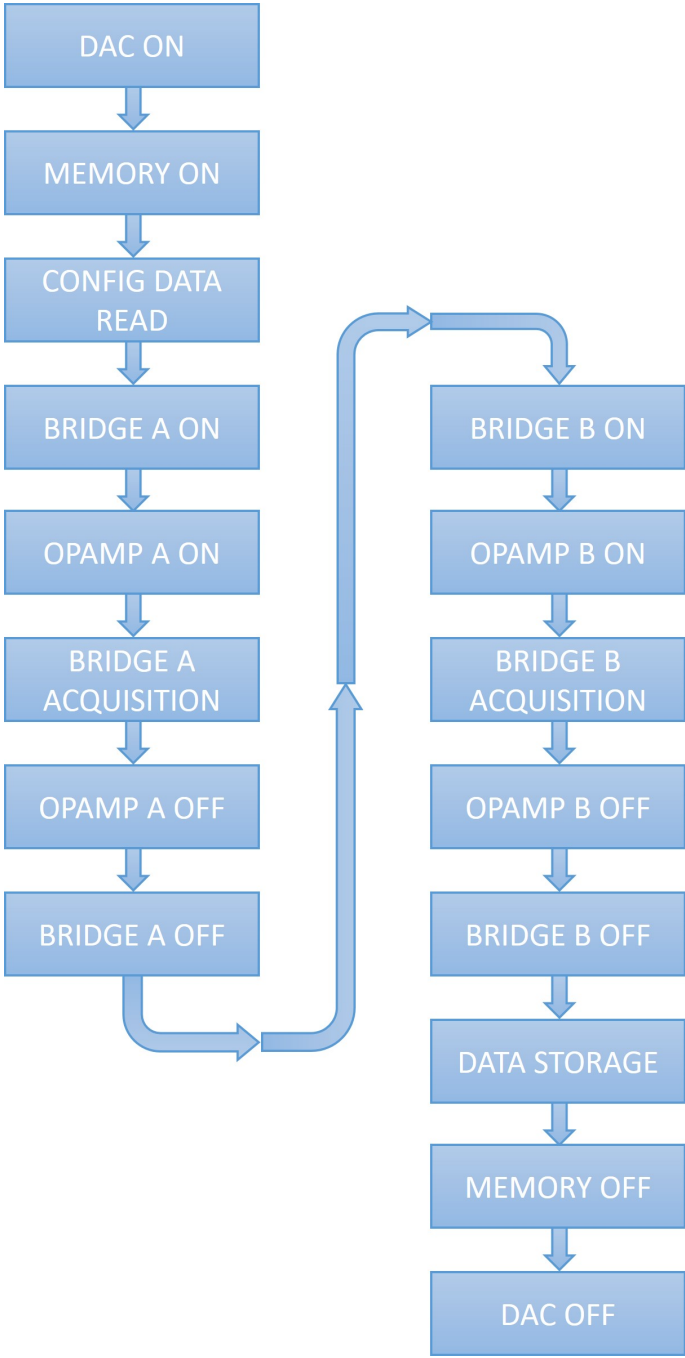
Figure 7.14: Data acquisition and storage flow.

ues by storing the data acquired in the memory. After that, the memory and the D/A converter are switched off.

Figure 7.15 shows the SCL and SDA signals of the I2C protocol during an acquisition phase from the analog sensors. In this example, only three measurements are performed. After the

start condition (1), the RFID Tag is put in Running mode and the D/A converter is initialized (2). After 3 ms required by the D/A converter power supply to stabilize, the configuration data stored in the memory are read (3) and the values required for the offset compensation of the two Wheatstone Bridges are written in the two channels of the D/A converters (4). After that, the three readings from the sensors are performed and the collected data is stored in the EEPROM (5). Finally, the RFID Tag is put in sleeping mode (6) and the STOP condition is sent (7).
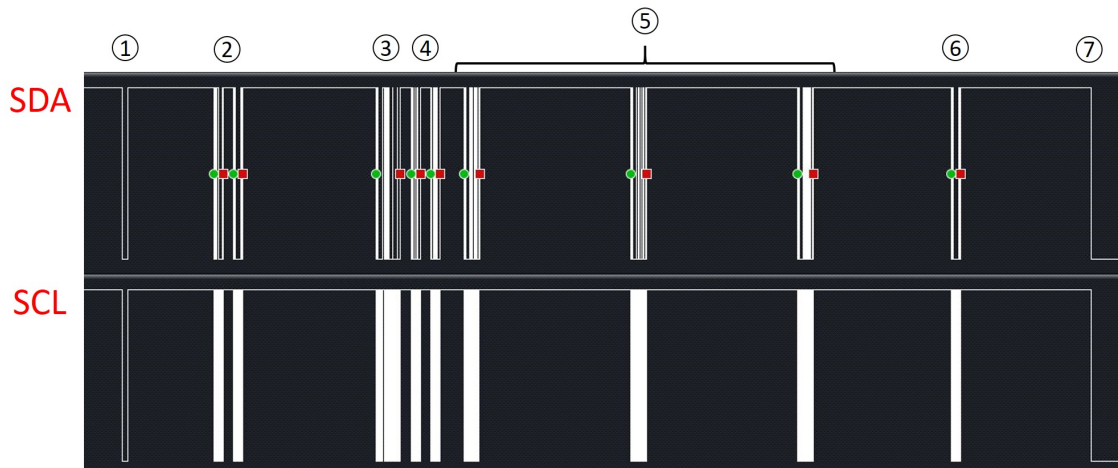
Figure 7.15: I2C signals during three sensor acquisitions. 1) START condition; 2) RFID Tag in running mode; 3) Configuration data are read; 4) D/A converters initialized; 5) Sensors data stored in the EEPROM; 6) RFID Tag in sleeping mode; 7) STOP condition.

The sensors data written in the memory will be read in a second phase, with the external reader that can access the memory without powering the whole system.

7.5 Conclusion

In this chapter, we described an autonomous sensors for force measurement inside a total knee prosthesis. This device can provide the force balance between the two prosthetic condyles during the replacement surgery, thus it could be a very important help for the orthopedic surgeons to balance the tension of the external ligaments and, as a consequence, to improve the implant precision and to reduce the risk of an early revision surgery.

An important advantage of this device is the fact that it is not implantable: it is used during the surgery and taken out of the knee when the ligament tension balance is performed. The documentation set required to get an approval from a medical advisory board for human implantation is consequently easier to provide.

The PE insert used for this final device was significantly different from the one previously used: it is fabricated by 3D printing, simplifying the realization of the cavity inside it to host the electronics than the PE insert molded. Moreover, It does not require the middle hole, leaving

much more space for the components on the PCB.

The concept of the electronic capsule already used for the instrumented prostheses can be kept with this new system.

The system architecture has been changed: in particular, we used a new RFID transponder working at 13.56 MHz, to provide wirelessy the energy required to the system. Moreover, to reduce the amount of energy required, we used the microcontroller as an electronic switch, by powering the different components of the system only during the minimum required time and switching them off immediately after.

This system has been designed with the purpose of acquiring data from the strain gauges designed by LMIS4, but, with minor modifications, could be used with every kind of analog sensor connected in a Wheatstone bridge configuration. For instance, it could be used with the magnetic sensors described in section 6 for kinematics measurements. The reason why we chose the force sensors, is the fact that the prosthesis manufacturer explained that such a system would have been much more interesting for them.

The next step in the test of this new device is the test *in vitro* with the automatic mechanical simulator of the knee joint. The mechanical parts of the simulator to which the prosthesis is connected are specifically designed for the F.I.R.S.T. knee prosthesis, thus they have to be modified in order to perform the test. For this reason, they are not presented in this thesis.

Conclusion

In this thesis, we presented the design and integration of an instrumented knee prosthesis for force and kinematics monitoring. We focused on the F.I.R.S.T. total knee prosthesis by Symbios Orthopedie SA, that was modified to provide the orthopedic doctors with information on its biomechanics.

Some important achievements have been made during this work: the first one was the definition of an architecture to acquire sensors data and transmit them wirelessy to an external reader.

We designed an RFID Tag based on commercial devices, that we used to acquire the total force applied to the prosthesis by using a manual mechanical simulator.

In a second phase, we increased the number and the kind of sensors used: we modified one of the PE inserts of the F.I.R.S.T. prosthesis by putting inside it strain gauges for force measurement and a dual-channel anisotropic magnetic resistor for the detection of the rotation angles. The sensor system was validated with a manual mechanical simulator and their outputs were compared to the ones of reference sensors (a reference load cell connected to the mechanical simulator for the strain gauges and an infra-red cameras system for the magnetic sensors).

Some measurements were successfully performed during repeated flexion-extensions of the prosthetic knee connected to the mechanical simulator. As far as we know, the results obtained represent the first example in literature of an instrumented knee prosthesis designed for simultaneous force and kinematics measurements.

A miniaturized version of the electronics, with all the sensors and components integrated into a PCB fitting the dimensions of the PE insert, has been designed and tested. These tests demonstrated that it is possible to have an instrumented knee prosthesis with all the components inside the PE insert.

This is a huge advantage compared to the other instrumented prostheses described in literature, because it means that no external modifications of the prosthesis are required. In other words, the differences between the passive F.I.R.S.T. prosthesis already implanted in the hospitals and its instrumented version are not visible.

Conclusion

This feature results in a double advantage: on one side, getting an approval for human implantation by a hospital medical advisory board is much easier, on the other side, the orthopedic doctors that will implant the instrumented prosthesis in a patient do not have to change the surgery technique, except for the fact that they can use the sensors system embedded in it to improve the positioning precision.

Another achievement obtained during this thesis, probably the most important, was the design of an electronic capsule containing all the sensors and the electronics required for the force and kinematics measurements inside it. It is meant to be embedded inside the PE insert. It is waterproof, bio-compatible and it allows to protect the human body from a dangerous contact with the electronics in case of an extreme wearing of the PE insert, that can occur some years after the replacement surgery.

One of its most important characteristics is the fact that, with small modifications, it could be put into different PE inserts. This can be done not only with other models of total knee prostheses, but also with other kinds of prostheses that are composed of a middle PE insert located between two metallic parts, for instance an ankle prosthesis.

Moreover, even in case of a failure of the electronics embedded inside the prosthesis, the implant does not require to be replaced, but can still be used as a traditional passive artificial joint.

Another important achievement obtained during this thesis was the design of an autonomous force sensor that can be used during the replacement surgery in order to balance the forces applied to the PE insert by the medial and lateral femoral condyles. This is very important to reduce the risk of an unbalanced wearing of the PE insert, that could result in an early necessity of a revision surgery. The force on the two sides can be measured by our sensor and, in case of an unbalance, it can be adjusted by modifying the tension of the external ligaments.

Understandably, some more work should be done in the upcoming future in order to have a fully functional instrumented prosthesis.

First of all, the new version of the communication and powering system, designed by EPFL-RFiC, should be integrated in the design, in order to provide the implant with the energy required for all the force and kinematics sensors and their related electronics.

Another option could be to use the RFID Tag tested for the single-use force sensor for the whole instrumented prosthesis, but more tests should be done to verify if it can deliver all the required energy.

Another important modification that could be done in the next future is to adapt the design of the electronics to the new PE insert, that does not have the hole in the middle. This can increase the space available for the electronics.

By combining the increased space available in the electronic capsule and by using the inte-

grated circuits developed by our partners, when they will be properly working, all the sensors required for the kinematics measurements could be added to the design.

Such a new system, should then be tested with the robotic mechanical simulator used for the last tests during the thesis, in order to validate the system.

Moreover, some long term experiments should be performed *in vitro*, to verify the mechanical resistance of the PE insert when the electronic capsule is embedded in it. It is important to check that its mechanical properties have not been changed, resulting in a risk of an early failure of the prosthesis.

The MRI-compatibility is another important feature that could be validated with *in vitro* tests. Even if the components of the instrumented knee prosthesis in principle are all MRI-compatible, the risks connected to this very important imaging technique should be investigated.

When all these steps will be successfully performed, *in vivo* tests should be performed. The documentation to obtain an approval from a medical advisory board should be prepared in collaboration with Symbios Orthopedie SA.

The first tests could be performed with the autonomous force sensors for balancing the ligaments tension. Being non-implantable, the documentation set required by the medical advisory boards is much easier to prepare.

In a second phase, when a human implantation will be accepted for the instrumented prosthesis, a technical support will be necessary not only during the knee replacement surgery, but also during the rehabilitation and the following years, to monitor the functioning of the instrumented prosthesis in real conditions.

Finally, when the system will be completely validated, new designs could be developed, to adapt the shape of the electronic capsule to the PE insert of other kinds of prostheses based on the same principle, such as ankle prostheses.

A Full schematics of the autonomous sensor for ligament balance
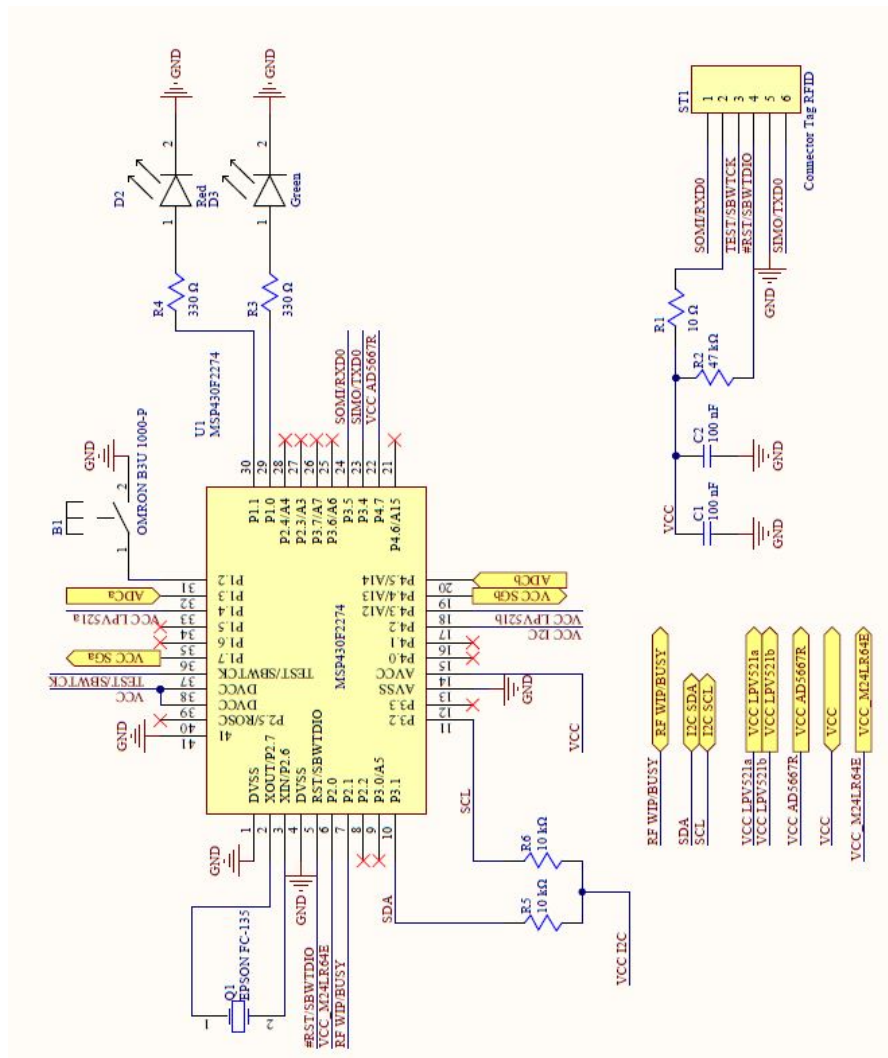
Figure A.1: Microcontroller subsystem of the autonomous sensor for ligament balance.

Figure A.2: Analog front-end of the autonomous sensor for ligament balance.
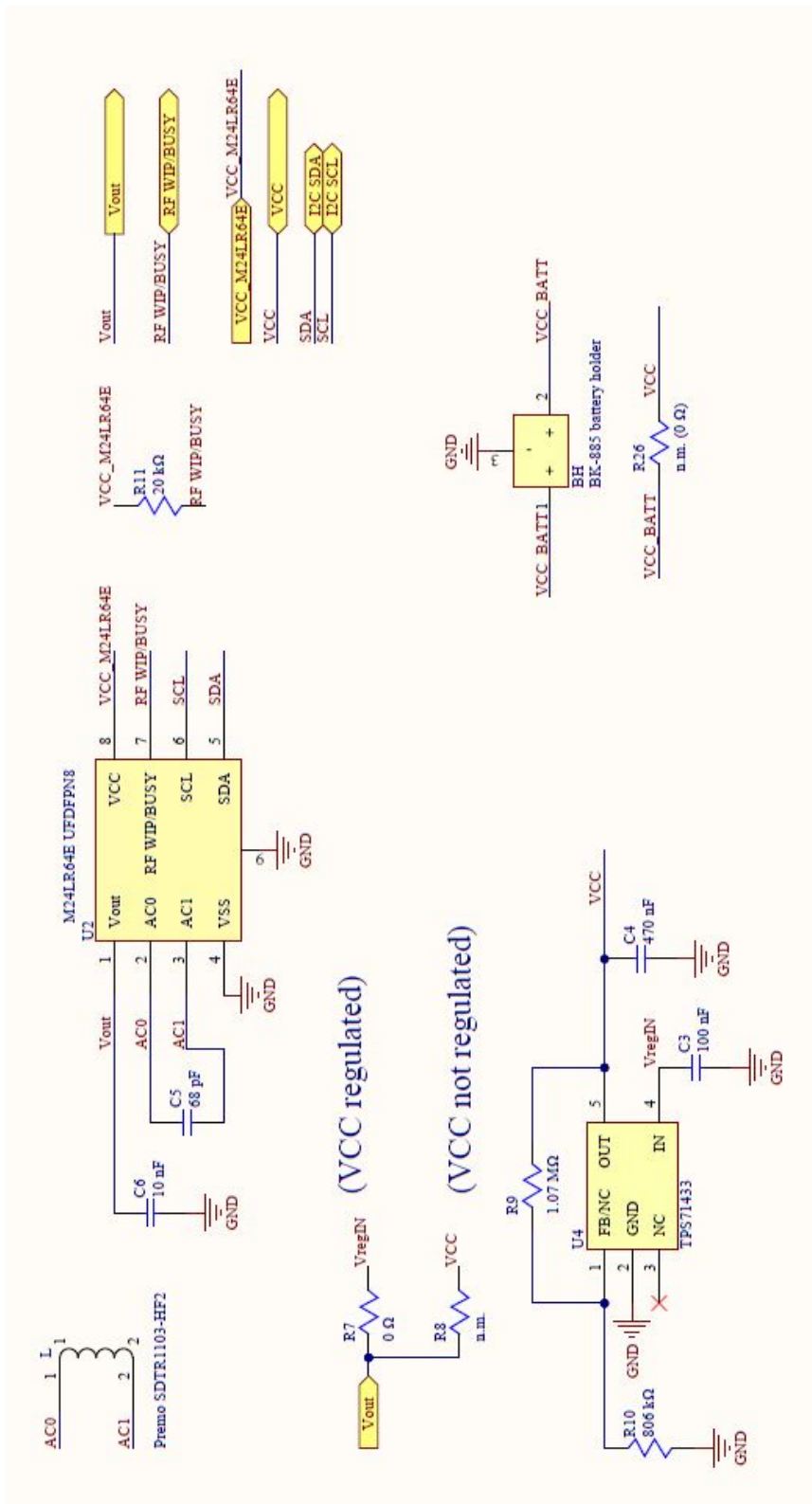
Figure A.3: Powering and communication subsystem of the autonomous sensor for ligament balance.

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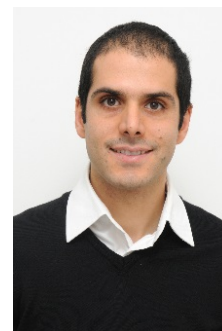
o Expertise on electronic design for medical devices
o Good knowledge of Low-Power RFID systems
o Strong background in biomedical engineering

Professional experience

2010–2014	**Doctoral Assistant**, EPFL (Switzerland).
	o Design and realization of an innovative instrumented knee prosthesis for force and kinematics measurements, to increase the precision of the implant during surgery and to monitor the joint during rehabilitation.
	o Responsible for the electronic system design and integration, according to the specifications of biocompatibility and MRI safety required for clinical trials.
	o Design of a Low-power RFID system for remote powering and data communication.
	o Contribute to write a proposal for a new project in collaboration with a company (Symbios SA, Switzerland).
	o Achievements: this instrumented prosthesis reduces the risk of an early revision surgery up to 10% and increases the lifetime of the prosthesis up to 15 years.
2009 (2 months)	**Research Assistant**, EPFL (Switzerland).
	o Compilation of surveys on Silicon Nano Wires (SiNWs) for biological entities detection and biosensors for action potential detection.
	o Contribute to write research projects proposals.
2008-2009 (6 months)	**Master Project**, University of Bologna (Italy)
	o Design and test of a Bone-conduction device used for rehabilitation of subjects with postural disease.
	o Achievements: compared to the standard technology that involves the use of earphones, the developed device lies on the temples and is less invasive for the patient.

Education

2010-2014	**PhD** in Manufacturing Systems and Robotics, EPFL (Switzerland).
2005-2009	**Master** in Electronic Engineering, University of Bologna (Italy). Specialization in Electronic Engineering for Biomedical Devices.

Technical skills

Technical Competences	Printed Circuit Boards design and test. RFID systems design. Low-power systems design. Microcontroller programming. Electronic Systems miniaturization and integration. Biocompatibility assessment for medical devices. Safety regulations for implantable devices.
Computer Competences	PCB design: Altium. Programming: C, Matlab, LabView. Editors: Microsoft Office. Database: Pubmed, IEEE Xplore.

Papers

Journal papers	A. Arami, M. Simoncini, et al., "**Instrumented Knee Prosthesis for Force and Kinematics Measurements**", IEEE transactions on automation science and engineering, vol. 10, no. 3, July 2013. D. Forchelet, M. Simoncini, et al., "**Enclosed electronic system for force measurements in knee implants**", Sensors 14, 2014.
Conference papers	A. Arami, M. Simoncini, et al., "**Instrumented Prosthesis for Knee Implants Monitoring**", IEEE Conference on Automation Science and Engineering (IEEE CASE), Trieste, Italy, 2011. C. Jacq, T. Maeder, S. Emery, M. Simoncini et al., "**Investigation of polymer thick-film piezoresistors for medical wrist rehabilitation and artificial knee load sensors**", Eurosensors 2014, Brescia, Italy, 2014

Languages

Italian	Mother tongue.
English	Fluent.
French	Fluent.

Other Competences

Organizational skills	Many years' experience as a team leader in summer volunteer camps for teenagers. Organization of computer courses addressed to beginners to obtain the European Computer Driving License (ECDL).
Social skills	Able to work well within a team and to adjust easily to different work environments. Remarkable experience in teaching to high school and university students. Worked in an international call center with people from different backgrounds and nationalities.
Hobbies	Marathon runner. Organization of trips worldwide for small groups.

Personal information

Year of birth	1981.
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