Effectiveness of Patient Specific Instrumentation for Total Joint Replacement and Implantable Sensing Technology in Orthopedics: A Review.

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Abstract - For many decades, research has been conducted for total ankle replacement to be established as the optimal surgical treatment for diseased or degenerative ankle joints. However, the development rate has been slow and acceptable mid and long term clinical results have only been published since the year 2000. On the other hand, computer assisted surgery and patient specific instrumentation design have improved the outcomes in total knee and hip replacements. These advances, as well as sensing technology for evaluating stress distribution, have enhanced mechanical design for knees and hips implants and provided valuable input and load condition knowledge that was not previously available. Moreover, while few reports exist regarding computer assisted surgery (CAS) and patient specific instrumentation for total ankle replacement (TAR), no studies regarding instrumented ankle prostheses capable of obtaining stress distribution data exist currently, or related works using sensing technology for improving patient specific instrumentation. Therefore, the aim of this paper is to outline the advantages of these two technological approaches, as they are intended to provide potential benefits for component alignment and therefore could be used to enhance TAR final outcomes.

Keywords — total joint replacement, implantable sensing technology, preoperative navigation system, ankle replacement.

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Abstract

For many decades, research has been conducted for total ankle replacement to be established as the optimal surgical treatment for diseased or degenerative ankle joints. However, the development rate has been slow and acceptable mid and long term clinical results have only been published since the year 2000. On the other hand, computer assisted surgery and patient specific instrumentation design have improved the outcomes in total knee and hip replacements. These advances, as well as sensing technology for evaluating stress distribution, have enhanced mechanical design for knees and hips implants and provided valuable input and load condition knowledge that was not previously available. Moreover, while few reports exist regarding computer assisted surgery (CAS) and patient specific instrumentation for total ankle replacement (TAR), no studies regarding instrumented ankle prostheses capable of obtaining stress distribution data exist currently, or related works using sensing technology for improving patient specific instrumentation. Therefore, the aim of this paper is to outline the advantages of these two technological approaches, as they are intended to provide potential benefits for component alignment and therefore could be used to enhance TAR final outcomes.

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I. INTRODUCTION

In 2012, musculoskeletal disorders represented approximately 2% of the world economic disease burden, as they decrease quality of life, social functioning and mental health [59]. The point prevalence of physical disability was estimated at 4-5 percent of the adult population of Canada, the United States of America and Western Europe, affecting mostly women [16]. As a result of this degenerative condition, arthroplasty has been widely investigated for different joints, providing fully successful and reliable clinical results for total replacements such as knee, hip and shoulder [4,36]. In addition, joint replacement has been considered for treatment of ankle joint diseases since the early 1970s [20, 86]. The results, however, were not acceptable, mainly because the designers and surgeons failed to reproduce the normal mechanics of the ankle joint, to provide implant stability (due to the inability to adequately restore ligament function) and to involve the subtalar joint in the coupled pattern of the ankle complex [20]. These disappointing results were not improved in the following decade, leading to ankle arthrodesis becoming the typical surgical treatment option for these patients [23]. The drawbacks of arthrodesis, such as nonunion, degenerative changes to surrounding joints, potential risk of infection and loss of mobility, helped create a renewed interest in the total ankle replacement option. Improvements in the bio-mechanical design of prostheses created a higher satisfaction level in the 1990s [37]. However, the results observed during this time were not as successful as those obtained for knees and hips, mostly because of the remaining poor understanding of ankle joint kinematics [86]. It was after the year 2000 that several reports started to demonstrate, through mid and long term studies, better results in total ankle replacement [52]. Among several studies, a systematic review reporting on 1105 TAR procedures was conducted to compare the outcomes of several implants technologies: 234 Agility^{tm}, 344 STAR®, 153 Buechel-Pappas^{TM}, 152 HINTEGRA®, 98 Salto^{TM}, 70 TNK® and 54 Mobility^{TM}. From this variety of different implants and designs, the average failure rate was approximately 10% at five years [35]. These results demonstrate the overall design improvements that ankle prostheses have achieved in the last few years, which hold a much better promise for total ankle replacement for the early future compared with that we had in the early 1970s.

Despite the improvements made to ankle prosthesis design over the last two decades, the ankle replacement success is also highly dependent on the alignment methods and surgical technique used [31, 33, 48, 66]. Moreover, one of the keys to success for TAR is component longevity, as the average of age for patients is estimated of 55 years old [87], compared to 68 years old for patients that undergo operative reconstruction of the knee [56]. This situation establishes an additional challenge for total ankle replacement to succeed; nonetheless, it has been demonstrated for knee reconstruction that the implant longevity is related to accurate component alignment [33]. Conversely to knee and hip joints, ankles have a smaller

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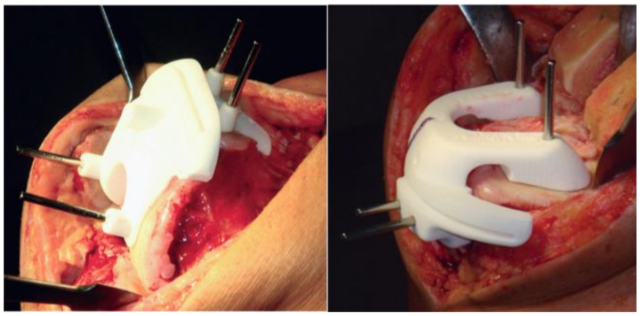


(A) (B)

Figure 1. Patient specific cutting guides for the VISIONARE™ navigation system. (A) Femoral block and (B) tibial block.

contact area and articulating surfaces: loads in the ankle can reach values as high as 500% the body weight (BW) during the stance face of walking [10]. Thus, it is vital to understand the challenges that ankle implants have to overcome in order to obtain the clinical acceptance that knees and hips implants have obtained, before investigating different technological approaches such as preoperative navigation systems and novel sensing methods as ways to improve the outcomes of total ankle arthroplasty.

II. PATIENT SPECIFIC INSTRUMENTATION FOR JOINT REPLACEMENT

The goal of patient specific technology is to customize disposable blocks or tools unique to each individual anatomy, intended to increase accuracy of bone preparation and decrease number of misaligned components [61].

The concept of these instruments was first introduced in total knee replacement systems [68]. Some of the potential benefits of these devices include reduced blood loss, no need to invade the intramedullary canal, reduced operation time and time under anesthesia, and very importantly, the ability for the surgeon to plan the best-fit alignment options for a patient prior to surgery day [64, 37]. When using patient specific instrumentation for ankle arthroplasty, there is an extra benefit not mentioned above: a reduction in reliance on intraoperative fluoroscopy, except as needed to verify the pre-operative plan is being followed appropriately [10]. It has been reported that the use of patient specific instrumentation in total knee arthroplasty (TKA) reduces the difficulty of cases in patients with severe osteopetrosis; it also minimizes the number of pins that need to be inserted, the holes from which create stress risers [64]. In addition, these MRI-based design instruments provided accurate bone resections, which is often difficult to achieve with conventional instrumentation [84]. Noble et al demonstrated, for a cohort of 29 patients who underwent total knee replacements, significant reduction in the number of instruments used during the procedure, duration of the hospital stay, and skin-to-skin time of operation. In addition, no adverse or complicated events were reported as instrument-related for several surgeries [62, 64, and 67].

Nonetheless, Chareancholvanich et al published no significant difference regarding blood loss, skin incision (length), bone cutting time, operative time, and length of stay in days [17]. These results were obtained from a randomized group of 80 patients for total knee reconstruction: 40 subjects underwent the procedure with the regular instrumentation, while the rest underwent with patient specific cutting guides (PSCG). In addition, the primary outcome of the study was to determine mechanical axis deviation in the coronal plane from both techniques. However, no statistically significance differences were observed after the implantation [17].

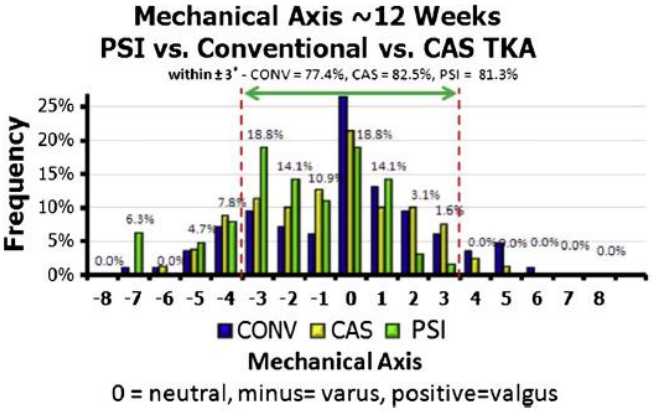


Figure 2. Histogram comparing the distribution of mechanical alignment (in the coronal plane) after total knee replacement by three different methods: computer assisted surgery (CAS), conventional instrumentation (CONV) and patient specific instrumentation (PSI). Figure adapted from study in reference [6].

Additional incongruences regarding the outcome provided by conventional instrumentation surgery compared to patient specific surgery instrumentation for knee replacements are shown in the literature [33, 39, 49, 55, 60, 77, 88 and 59]. For instance, there are clinical reports that indicate no significant differences between patients who went under total knee replacement using either conventional instrumentation (CON) or patient specific instrumentation (PSI) [33, 36, 39, 49 and 58]. Marimuthu et al conducted a retrospective analysis of 300 patients who underwent total knee replacement between February 2012 and June 2013 using the LEGION® total knee Prosthesis (Smith and Nephew, Memphis, Tennessee); 185 patients underwent with conventional instrumentation and 115 with patient specific guides or instruments from the VISIONARE™ (Figure 1) system (Smith and Nephew, Memphis, Tennessee). The results for the coronal alignment were based in the hip-knee angle (HKA), femoral coronal alignment and tibial coronal alignment [63]. The postoperative limb showed no statically significant difference between the two groups (CON and PSI) in terms of the proportion of outliers, which values were set at 2° and 3° as cut-off limits. 80.5% of the subjects who went with the conventional instrumentation procedure had a femoral coronal alignment within 2° of neutral (90°), while 81.6% had the same result for the PSI group. In terms of tibial coronal alignment, 89.7% of the patients for the CON group had the results within the 2° of neutral, compared with the 89.6% for the PSI group. For the sagittal alignment and the component rotation, no statically

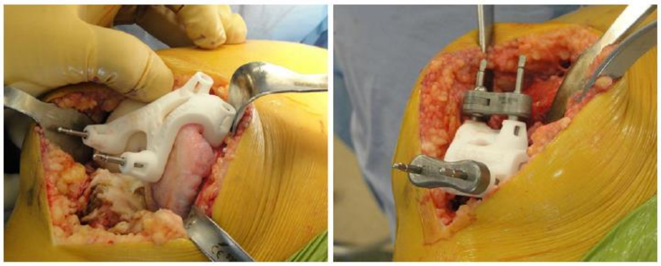

(A) (B)

Figure 3. Patient specific cutting guides for the SIGNATURE^{TM} Personalized Patient Care System. (A) Femoral block and, (B) tibial block. Adapted from [63].

significant difference was observed. Barret et al performed a study in which 66 TKAs with PSI were compared to 86 conventional TKAs and 81 based on computed assisted surgery (CAS) technology. The study was done between October 2009 and December 2010, using the TruMatch® Personalized Solutions (DePuy Synthes, Warsaw, Indiana) system with the P.F.C® Total Knee System (DePuy Synthes, Warsaw, Indiana). 81.3% of the PSI knees were reported within the 3° of the planned mechanical alignment (in the coronal plane), compared to 82.5% for CAS and 77.4% for conventional instrumentation [63]. When using 3° as the cut-off value, there was no statically difference between the three scenarios.

In 2012, Ng et al conducted a large retrospective analysis comparing the results from 569 TKAs using patient specific positioning guides (PSPG), with 155 surgeries performed with conventional methods. The navigation used was the SIGNATURE^{TM} Personalized Patient care system (Biomet Inc, Warsaw, Indiana), shown in figure 3. The results were based in different parameters [66]; they reported that the overall mechanical axis (OMA) passing through the central third of the knee was observed in 88 % of the patients who underwent with the PSPG group, while in 78% for patients with the conventional or manual instrumentation group; the hip-knee-ankle angle were similar in both technologies, however the number of outliers (outside ± 3°) were significantly fewer for the PSPG, 9% compared with 22% for the conventional procedure. In general, this work establishes considerably better outcomes when using patient specific guides, compared not only to manual instrumentation but to computer assisted navigation (CAN) as well. An interesting study compares the results achieved by customized patient instrumentation knee surgery, not only against conventional or manual methods, but against the preoperative plan created as part of the navigation system as well [14]. 50 patients; 25 consecutive patients underwent TKA with the preoperative TruMatch® navigation system (Depuy, Warsaw, Indiana), which included a preoperative plan to establish an ideal component alignment based on predefined surgeon preferences [14], while the other 25 went under the conventional technique. Figure 4 depicts a portion of a final preoperative navigation plan. As for the conventional group, the target ideal alignment was defined as 90° from both, the coronal and sagittal planes. In the customized instrumentation group (CIG), the absolute difference of the femoral alignment was 0.67° in the coronal plane and 1.2° in the sagittal plane, while the average magnitude of angular deviation of the tibial alignment was 0.9° in the coronal plane and 1.3° in the sagittal plane. The differences found for traditional instrumentation were 1.5° and 2.3° for the femoral coronal and sagittal alignment, respectively, and 1.8° for the tibial coronal alignment. The statistical differences were significant only for the femoral alignment; procedures performed within CIG demonstrated more accurate results than the traditional instrumentation group. An additional study of 32 TKAs using PSI® ZIMMER demonstrates good clinical results for all cases. Prior to knee reconstruction surgery, a preoperative plan is created and then approved by the surgeon before the unique patient guides are manufactured [37]. The reported results claim joint stability in all cases with a minimum range of motion (ROM) of 90° and correct mechanical alignment with the hip-knee-ankle line passing through the central third of the knee in all cases.

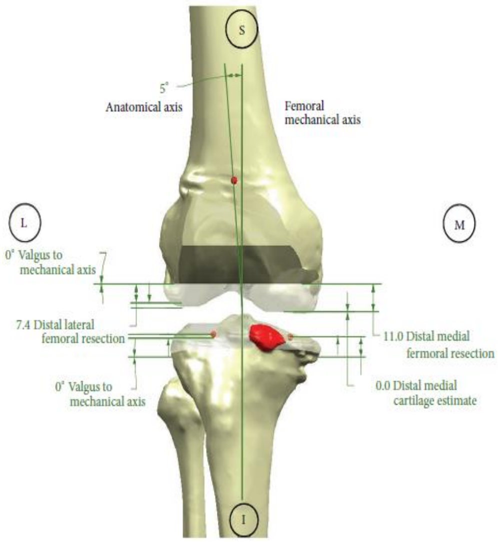


Figure 4. An extract of the preoperative navigation plan based on the CT scan images as part TruMatch® Personalized Solutions from DePuy Synthes (Warsaw, Indianda). [14]

Nuntley et al evaluated 150 patients who had a primary TKA, establishing three cohorts (50 subjects each) for further comparison [68]. In group 1 conventional or traditional instrumentation was used, in group 2 the SIGNATURE^{TM} system (Biomet, Inc, Warsaw, Indiana) was used for a mechanical restoration approach , while group 3 the patient-specific OtisMed^{TM} (OtisMed^{TM} Corp, Alameda, California) system was used for a kinematic approach [68]. The results of groups 1 and 2 are similar with more varus outliers than group 3, which had more valgus outliers than either group 1 or 2. Therefore, the authors claim that additional studies are needed to determine whether patient-specific instrumentation improves clinical functions and overall alignment outcomes [68, 77]. Stronach et al data for a consecutive series of 58 knee replacements assisted with PSI compared to a historical group

Table 1. Numbers in volume of total knee replacement assisted with Patient specific instrumentation. Cases from 2011 and 2012, adapted from [83]

Company name (alphabetical order)	*PSI TKA Global 2011*	*PSI TKA Global 2012*
Biomet	11 192	22 506
DePuy – Synthes	6 000	16 000
Medacta	4 600	6 200
Smith & Nephew	19 500	22 000
Wright Medical	1 600	2 000
Zimmer	9 800	13 850

of 62 consecutive primary TKAs performed with conventional instrumentation. The authors found no statistically significant difference in component alignment for femoral flexion, femoral and tibial varus/valgus angles, mechanical alignment or posterior tibia slope [77]. They concluded that TKA assisted by customized instrumentation did not improve the overall outcome of the procedure. In particular, they found that the average tourniquet time in the PSI group was 58.8 minutes, while the regular surgery group had an average tourniquet time of 57.0 minutes; the average volume of blood lost was also very similar: 114 ml in the regular group and 111 ml in the assisted by PSI group.

DeHaan et al reviewed 356 TKAs between July 2008 and April 2013; 306 of these surgeries were assisted by patient specific guides, while 50 patients received a traditional surgery [27]. The aim of the study was to evaluate whether or not customized instrumentation leads to decreased perioperative morbidity when compared to standard procedure; they also evaluated the technology cost and the sizing accuracy of the predicted pre-operative plans. The authors claim a reduction of 20.4 minutes when assisting the surgery with unique instruments; in addition, the predicted femoral sizes were correct in 74.3% of the cases, and 90.4% for the tibial component [27]. However, there is one important limitation to this study: the experiment is not randomized and the group of customized guides is nearly five times the number of patients in the traditional procedure group.

In contrast, a randomized study was conducted by Hamilton et al with 52 patients equally distributed between a conventional surgery group and a patient specific instrumented surgery group. In this case, the average total surgical time was not shortened by the use of unique patient instruments, with an average surgery completion time of 61.8 minutes, while the conventional method group completed the surgery in an average of 57.4 minutes. In addition, no significant differences with respect to mechanical alignment, measured radiographically, were also reported, but the patient specific technique did reduce the number of instruments used in surgery [38]. Conrad et al concluded that the outcomes of patient specific total knee replacements were generally improved (Figure 5) when compared to the results from a typical knee replacement surgery [46]. This study was conducted for a cohort of 100 patients who underwent TKA surgery with patient matched instrumentation (PMI), and compared with a group of 100 patients who had already received conventional surgery by the same orthopedic surgeon. Results demonstrated that the improvement obtained by the PMI group in the varus-valgus alignment for the femoral component was 1.5 times more likely to be within the ±3° of deviation from the neutral axis of the component; similar results for the mechanical axis alignment measurements indicate that PSI TKAs were 1.8 times more likely to be within the ±3° of the desired deviation from the neutral mechanical axis [38].

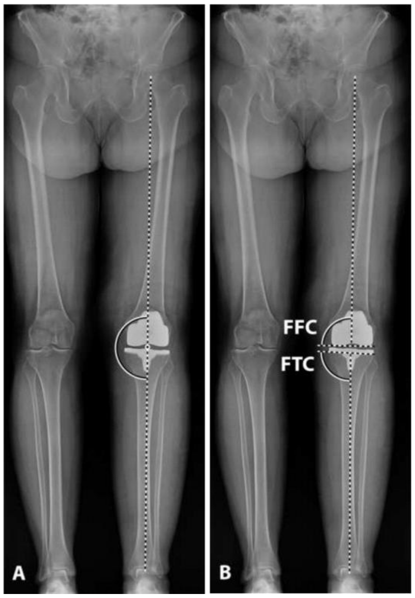


Figure 5. Standing coronal radiographs after total knee replacement was conducted assisted by patient specific instrumentation. (A) Measurement of the limb mechanical axis, (B) measurement of the femoral component (FFC) and the frontal tibial component (FTC) to determine varus/valgus alignment [42]

Although the results reported in several studies have been inconsistent, utilization of patient specific instrumentation is estimated to have become 1.5 times more common, as reported between 2011 and 2012. Approximately 82 556 total knee replacement surgeries were performed in 2012 using devices from seven orthopedic implant manufacturers and their patient specific instrumentation [84], however, no proven clinical benefit and minimal literature are yet available [38]. Table 1 shows a comparison between six manufacturers in 2011 and 2012.

Summarizing the incongruences mentioned above from different studies, it is generally accepted that the use of patient specific instrumentation can potentially improve total knee replacement outcomes in the future; not just in terms of component alignment but also from a cost savings and reduced surgery time standpoint, which eventually could represent savings to hospitals [84, 27] and therefore patients. Finally, it is important to compare conventional techniques with different computer assisted methods other than patient specific instrumentation and evaluate the results. Therefore, table 2 presents an overview of the results reported when conventional

Table 2. Coronal alignment outliers of partial reported outcomes in conventional and computer assisted total knee replacement surgeries. For further reference of the studies presented below, follow citation [66].

Year	*Number of studies*	*Number of navigated TKAs*	*Navigated outliers > ±3°*	*Percentage of navigated outliers*	*Number of standard TKAs*	*Standard outliers > ±3°*	*Percentage of standard outliers*
2000	1	15	0	0.0	15	5	33.3
2001	2	55	9	16.4	55	15	54.0
2003	2	132	0	0.0	133	21	15.8
2004	7	333	16	4.8	334	86	25.8
2005	10	743	81	11.0	865	313	36.2
2006	3	199	65	32.7	166	77	46.3
2007	8	682	74	10.8	580	142	24.5
2008	11	985	79	8.0	1022	240	23.5
2009	5	305	34	11.3	304	75	24.7
2010	2	100	7	7.0	96	37	38.5
2011	3	133	13	9.8	97	27	27.8

TKA and computer assisted surgeries were compared in several studies between 2000 and 2011 [66]. However, it must be noted that the purpose is not to compare the results from general computer assisted navigation (CAN) methods and patient specific instrumentation, as is considered out of the scope of the present work. Comprehensive studies related to different techniques in computer assisted orthopedic surgery can be found in the literature [50, 62]

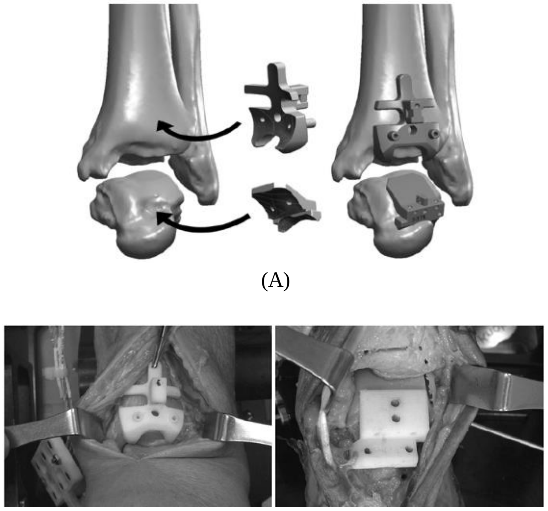
Conversely to total knee replacement, ankle arthroplasty has not been fully supported by computer assisted techniques such as pre-operative navigation systems and patient specific guides design. To date, only the work from Berlet et al reports a novel method to validate the use of a navigation system for total ankle replacement [10]. As shown in Figure 6, the aim is to evaluate repeatability of the tibia and talus alignment guide placement and deviation from the preoperative navigation plan. They reported mean variations less than 3° for each degree of freedom (DOF) for the tibia and talus alignment blocks. The largest variation reported in the tibia alignment guide was the internal/external rotation (transverse plane), which was still less than 1°; the medial/lateral translation (frontal plane) represented the largest error for the talus guide placement (less than 1 mm). The mean variation between the preoperative navigation report and the final position of the implants, INBONE® Total Ankle System (Wright Medical Technology, Arlington, Tennessee) was reported to be less than ±3° [64].

III. IMPLANTABLE SENSING TECHNOLOGY

In vivo data from orthopedic applications of sensor technology was first documented in the 1960s when forces, pressure and temperature were recorded for instrumented femoral head implants and for instrumental correction of scoliosis [71, 86]. These sensing systems have shown a remarkable evolution from the early days of strain gauges connected through percutaneous leads into today's wireless systems with telemetry and powered passively [59]. Figure 7 depicts the evolution of "smart" or instrumented implants. Although smart implants have been used exclusively as research tools [19, 59] they have provided critical data, improving implant design and characterizing *in vivo* physical environment. It is well known that stresses and strains are major factors influencing bone growth, remodeling and repair of the musculoskeletal tissues [19]. More importantly, sensing technology applied to biomechanics has been critical to gain insight into the complex structures of bones and joints; thus, it has made possible a better understanding of the mechanical interactions between bones, cartilage, ligaments, muscles and tendons [15, 18-25, 29, 51]. In more recent work, additional benefits for instrumented implants have been mentioned, such as identify implant misalignment, implant loosening, and component wear [51]. Moreover, the authors mention another potential use of the instrumented knee, which is soft tissue balancing assistance during implantation surgery. They claim that an instrumented tibial tray can provide direct feedback to the surgeon as to whether the knee is properly balanced or not [51]. In addition, Almouahed et al mentions the importance of collateral ligament balancing to ensure an even load distribution in the two compartments of the tibio-femoral joint [1].

Westerhoff et al developed an instrumented shoulder joint implant based on the Bio-Modular® Shoulder System (Biomet Inc. Warsaw, Indiana) [87]. The aim of the work was to measure contact forces and moments acting in the glenohumeral joint. They reported loads of approximately 40% BW in an abduction motion of 45°, one week after surgery. They also claimed that the results were similar to previous mathematical studies. Another study was conducted by Bergmann et al; the objective behind the work was to gain precise knowledge of *in vivo* loads in the shoulder joint. The instrumented shoulder prosthesis was equipped with 9-channel telemetry system, 6 strain gauges and an inductive power supply.

They reported the highest peak load in one patient positioned in forward flexion (>90°) and 2 kg extra weight, and it reached 238% BW. Figure 8 depicts the novel instrumented shoulder prosthesis implanted in 6 patients [36].


(A)

(B) (C)

Figure 6. PROPCHECY® INBONE® tibia and talus alignment guides onto the bone model surface (A) and cadaveric testing of each instrument placement, tibia (B) and talus (C). Adapted from [10]

The knee joint is one of the most important joints in the musculoskeletal system and is one of the most analyzed and studied mechanisms [30]. Several studies have been conducted to measure *in vivo* loads in the knee joint [2, 3, 20-23, 30, 32, 36, 80, 51]. Kutzner et al, reported average *in vivo* peak loads of 356% body weight (BW) during stair descent as the highest load condition for the knee joint. These results were obtained by using an instrumented knee implant on 5 subjects. The overall results for the resultant tibio-femoral contact force presented in this work are lower compared to those predicted by many mathematical models [85]. Erhart et al, used an instrumented knee implant to assess changes in the medial compartment of one single patient through *in vivo* measurements [30]. The subject was also equipped with a load modifying variable stiffness shoe. The authors determined that the special shoe helped reducing the medial peak load by 22%. Anderson et al [2] described a novel method for measuring knee forces *in vivo* for 11 patients. A thin (0.2 mm) flexible electronic pressure sensor was developed and inserted in the medial compartment. The results showed large variations in the force reading, but no “un-loaded" state could be detected. In addition, the work of Arami et al used smart implants to measure *in vivo* interaction forces in the knee joint [4]. The authors chose anisotropic magneto resistance (AMR) sensors to estimate joint orientation; the magnet was placed in the femoral component while the AMR sensors were inserted in the polyethylene. In order to measure contact forces on the joint, strain gauges were custom designed and fabricated to be inserted into the polyethylene insert. A revision knee implant was also instrumented for *in vivo* characterization of the replaced joint [21]. The authors reported average peak tibial forces of 2.2 % BW on day 6 after surgery; also, they reported an increment of 0.6 times the body weight in climbing stairs activity after 6 weeks of recovery. More recently, a novel sensing device has been developed by Homberg et al [51]; a tibia tray powered internally by an integrated piezoelectric energy harvesting system (figure 9). The most interesting feature about this device is the self-harvesting energy system, based in the piezoelectric effect. The system entirely powers all the sensor’s systems and the wireless circuits. The authors claimed that a subject of 55 kg can fully charge the storage capacitors in 11 steps; the total energy harvested per step is reported to be 1051 μJ, on average. *in vivo* results reported, from smart implants are realistic measurements of the interactions between the structural elements conforming the musculoskeletal [23, 32]. Similar results have been reported for the hip joint [3, 7, 9, 13, 24, 25, 29, 39, 88, 49, 41]. Table 4 summarizes a short sample of those results. However, considerable amount of literature exists concerning *in vivo* experiments for evaluating contact forces in the hip joint [25].

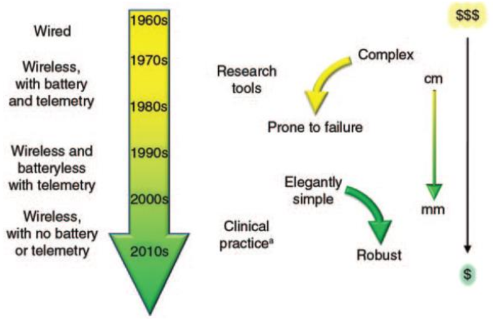


Figure 7. Smart implant evolution illustration. Adapted from [84]

Furthermore, vertebral body replacements and lumbar spine sensors have also been instrumented in several studies [65]. Telemeterized vertebral body replacements have been implanted in three patients by Rohlman et al; the results show interesting findings regarding the load conditions on spine during several exercises in the first month postoperatively. The authors report peak load forces of 450 N when standing and sitting; 420 N when upper body is flexed; and 700 N when additional weight in the hands is supported. Figure 8B shows a fabricated and instrumented vertebral body [36].

Graichen et al developed a miniaturized 9-channel telemetry transmitter, capable of measuring different and complex loading situations (shoulder, vertebral replacement and hip) during different activities [36]. The authors claim some advantages of this device over previous versions, a few of them are: less power consumption, hermetic sealing of all components inside the implants which therefore allows long term data transmission and electronic integration within a custom-made chip designed and built from semiconductor technology (bipolar complementary metal oxide semiconductor, BiCMOS). The limitations found are related to low efficiency of the inductive power supply at distances over several centimeters, as well as the RF transmission data is limited to less than 50 cm [36]. This device has been implemented on shoulder prosthesis from three different patients (figure 8A), however, the transmitter can be instrumented for proximal tibia trays and vertebral body replacement (Figure 8B).

Table 3. Summary of Experimental and modeled studies reporting maximum *in vivo* knee forces. For details about the study's authors, refer to the following citation [62].

Condition	*No. Of studies*	*No. of Subjects*	*Average Total force*
Overground	6	1	2.5
Overground	2	3	1.8 – 2.5
Overground	2	1	2.1 – 2.8
Overground	5	1	2.2 – 3.0
Treadmill	2	1	2.1
Treadmill	1	1	1.8 – 2.5
Model	2	12	2.1 – 3.9
Model	1	2	2.2
Model	2	4	2.7 – 3.8
Model	1	10	2.9 – 3.5
Model	12	1	3.9

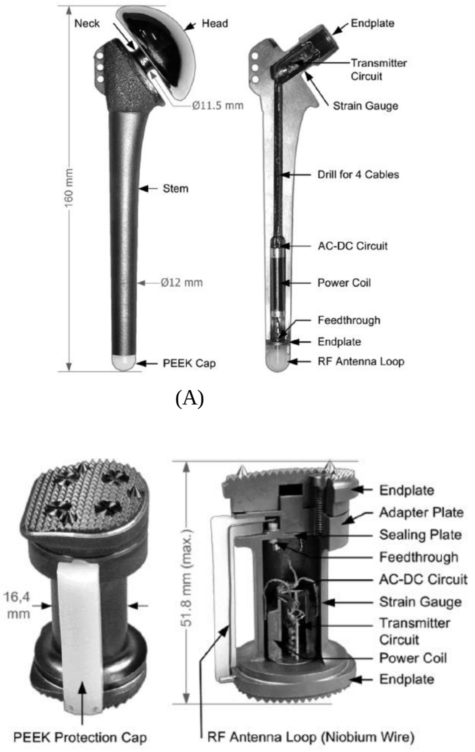
Table 4. Short summary of experimental studies conducted in *vivo* for evaluating resulting contact forces in the hip joint.

Study	*No. of subjects*	*highest peak loads (BW)*	*Activity*
Rydell [71]	-	3.5	dynamic walk
English et al [29]	1	3.59	One-legged stance 126 3.59 pelvis tilted up with hand support.
Davy et al [25]	1	2.8	Stair climbing
Bergmann et al [7]	1	8.7	Stumbling
Brand et al [13]	1	3.5	Freely walking at selected speed
Bergmann et al [9]	4	11 000 N	Stumbling

Despite the benefits and the relevance of *in vivo* measurements, predicted mathematical and computational models represent a potential tool to improve or create new implants designs [59]. However, for this to become reality, a study directly compared calculated hip joint forces with measured values form instrumented hip prostheses [76]. In this work, two subjects with instrumented implants were analyzed and the results were similar in pattern and magnitude, with average differences of 13.5% in the first subject and 18.1% in the second subject. Brand et al. [13] compared mathematical estimates calculated from laboratory observations with an instrumented hip prosthesis in one patient; the results were reported to be similar at peak loads. Heller et al. reported the first cycle-to-cycle validation of predicted musculoskeletal loading for climbing stairs and walking for four patients with instrumented hip implants [39]. The comparison of in vivo measurements and calculated (modeled) hip contact forces showed 13% of the relative deviation during walking, while 14% of the deviation occurred during stair climbing. Regarding the knee joint, several researchers have measured external force systems [61]. In 1970 Morrison et al reported, through a mathematical model, a variation from 206% BW to 400% BW in the maximum contact forces of the knee joint [61]. Taylor et al calculated peak force values as high as 620% of BW for one specific patient from their study, using a musculoskeletal lower limb model [41]. Costigan et al. conducted a study to estimate hip and knee joint kinetics of 35 young, healthy subjects when climbing stairs, using a subject-specific model for each joint; the result reported for the peak load in the knee joint was as high as 5 times (500%) the body weight [18]. Other studies based on mathematical models have shown variations from 310% up to 800% of body weight peak loads in the knee joint [51]. From a computational approach, different studies indicate of predicted models and in vivo measured systems for knee and shoulder joints [8, 32, and 59] (table 3). Conversely, computational models for the hip joint have shown better results between predicted models and experimental data [32, 13, and 76]. Though not yet perfected, smart components hold great promise for helping overcome the uncertainties of prediction models and to provide realistic data to improve implant designs and alignments [38, 46, 1-5, 7-9, 13].

IV. CONCLUSIONS

As companies continues to improve total ankle replacement designs and better clinical outcomes are reported, a potential possibility exists to provide the implant components with novel sensing technology. In fact, difficulties in understanding and predicting ankle joint kinematics could be overcome in the future through the design and use of instrumented implants that could lead to better failure rates of total ankle arthroplasty than have been seen in the last decades [1-18]. This argument is extrapolated from the success reported in sensing technology to several orthopedic areas, such as total joint replacements of the knee, hip and shoulder; also, the critical data generated by smart systems has made it possible to better understanding the biomechanics of the joints, from the standpoint of structural component interactions (ligaments, muscles, tendons and bones). Therefore, sensing technology may overcome some of the current limitations of reproducing natural ankle kinematics, which has been reported as part of the failure rate of ankle implant technology [82]. However, the reduced size of the ankle joint as compared to the hip or knee joints [11] is an important physical limitation to consider for possibly instrumented ankle prostheses. In addition, the small market for total ankle arthrodesis compared to knees and hips could also have limited the use or design of instrumented ankle components. From a technological perspective, as electronic-mechanical sensing continues its road toward miniaturization, component validation and extrapolation to different populations will become feasible. In addition, smaller devices



(A)

(B)

Figure 8. Instrumented shoulder endoprosthesis and section view to depict the sensing electronics (A) and Instrumented vertebral body and section model to depict eletro-mechanical measurement system (B). Adapted from [63]

can also provide potential benefits for patient specific instrumentation such as ensuring the correct placement of the blocks onto the bony surfaces and a better understanding of the guide-bone surface interaction when forces are applied to lock the instruments in position.

Despite the different findings on whether patient specific instrumentation provides better outcomes in clinical studies or not, evaluating guide positioning trough sensing devices may overcome the difficulties experienced when cartilage layers are present in between the guide and bone interface. In fact, it is known that the correct fit of the alignment block or guide is a big concern and sometimes a drawback of this technology, mainly because of the dependence on the quality of the CT scan or MRI and the ability to reproduce, accurately, the bone matching surface.

Lastly, reproducibility for navigation systems for total ankle replacement holds a better promise when compared to the total knees [14], mostly because of cartilage absence or thinner layers present in the ankle joint when TAR is needed. Therefore, design and fabrication of miniaturized devices for sensing forces and strains can also represent a potential benefit for navigation systems used in total ankle arthroplasty

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(B) (C)

Figure 9. Images depicting the instrumented tibia with self-harvesting energy system as an assembly (A) and with the sensors grid and circuit board (B). Adapted from [85]

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