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REVIEW ARTICLE

Patient-Specific Design of Knee and Ankle Implant: A Short Review on the Design Process, Analysis, Manufacturing, and Clinical Outcomes

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ABSTRACT

The knee and ankle are complex structures, with each segment interdependently interacting with the others. Clinical interventions may thus cause functional changes such as joint motion and tissue deformation not only at the modified site but also in the surrounding areas and even throughout the foot. Iatrogenic complications such as joint arthritis, secondary fractures, and foot pain are caused by these abnormal biomechanical changes. Due to increasing osteoarthritis, it has become increasingly important to find solutions to ankle and knee arthroplasty that ensures a more pain free and natural feeling implant. A prosthesis that is precise and component-fitting produces considerable post-operative improvements and shows a high degree of patient satisfaction in the short to medium term. In this paper, we discuss in depth about the design process of the three-dimensional customized implants and the manufacturing process. The clinical outcomes of usage of Patient Specific Implants are also reviewed in short.
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Keywords: Patient Specific Implant (PSI), Customized Implant (CIM), Knee Arthroplasty, Ankle Arthroplasty, Total Knee Arthroplasty (TKA), Unicompartmental Knee Arthroplasty (UKA)

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INTRODUCTION

With the increasing prevalence of osteoarthritis and the rising life expectancy of individuals, arthroplasty procedures are becoming more commonplace. Depending on the severity of the joint disease, surgeons may opt for total arthroplasty (TA) or uni-compartmental arthroplasty (UA). However, the conventional approach of using standardized implants may lead to issues such as incorrect placement, patient dissatisfaction, and premature implant failure (1, 2, 8). Recognizing the limitations of the "one-size-fits-all" approach, there is a growing need for more personalized and precise methods of performing knee arthroplasty in the twenty-first century, particularly as younger and more active patients seek long-term solutions. Embracing modern technology, advancements are paving the way for individualized, accurate, repeatable, and anatomically tailored approaches to knee and ankle arthroplasty. One such approach gaining prominence is the utilization of Patient-Specific Implants (PSIs). PSIs offer a more customized solution by considering the unique anatomy of each patient's internal organs and joint structures. Zadpoor et al. (2017) highlight the importance of a personalized approach in the creation of various medical devices, including implants. This involves leveraging medical imaging technologies such as computed tomography (CT) or magnetic resonance imaging (MRI) to obtain detailed and precise information about a patient's internal anatomy (1).

Total Knee Arthroplasty (TKA) demands careful consideration regarding component design in order to achieve optimal outcomes, particularly among Asian populations that may exhibit variations in anatomy. To guide these decisions, research has identified recommendations that take into account patient-specific attributes as well as gender differences (2). As described by Pastides et al. (2016), "a group of 100 TKA patients who received total knees showed improved reproducibility of ideal mechanical axes using specialized implants compared with traditional ones" (3). According to Fitz et al. (2009), "in addressing limitations associated with commercial off the shelf implants such as inadequate cortical bone support at the tibia and limited options for femur sparing strategies. Patient-specific resurfacing designs represent a promising alternative" (4).

Zhang et al. (2019) called the ankle joint - "one of most significant weight-bearing joints in the entire human body" (5). In case of ankle implants, Wang et al. (2016) found that, "for foot illnesses with distinct structural abnormalities, such as hallux valgus, patient-specific models are recommended since using a modified normal foot as a representation may result in part of the ''abnormality" being lost" (6). The utilization of three-dimensional (3D) printing technology in foot and ankle surgery dates back to 1997, when it was initially employed for the assessment of intra-articular calcaneal fractures (7). Since then, 3D printing has made significant contributions to the field by providing innovative solutions for surgical planning, preoperative evaluation, and the creation of patient-specific implants and guides. Its introduction has revolutionized the way foot and ankle surgeons approach complex fractures, enabling more precise and tailored interventions to improve patient outcomes. In recent years, three-dimensional (3D) printing has emerged as a valuable tool for surgeons, offering them unprecedented capabilities to address complex clinical cases, particularly within the realm of foot and ankle surgery (8). This advanced technology provides surgeons with a novel and highly promising approach to effectively manage lower extremity pain and deformity, a task that may not always be feasible with conventional treatment options (9). By harnessing the power of 3D printing, surgeons can now precisely design and create patient-specific implants, prosthetics, and surgical guides, enabling tailored interventions that cater to the unique anatomical requirements of each individual. This innovative approach has the potential to revolutionize the field, offering new possibilities for improved outcomes, enhanced functionality, and overall patient satisfaction.

Many sciences have happened in the current age to help working results following patella and bone arthroplasty. With new science, it is immediately attainable to devise tailor-made implants for each patient. Patient specific approach to arthroplasty has the ability to take into account the effects of underhangs hangs/overhangs to complete the inclusion of the respected cartilage (10). The important questions are by what methodologies and what exactly may be revised through customization of implants? This review paper is destined to review existing patient-specific patella and bone designs, their design processes, the production of these implants, and the effects of utilizing patella and bone PSIs. And it is counted on that this study will be able to present new intuitiveness to scientists for cultivating patient particular body parts and bone implants.

METHOD

Strategy of literature search

The Google Scholar, MEDLINE, CORE, and Scopus databases were searched for related studies published prior to 2021 for this literature review. The following keywords were used in the research: "Customized knee prosthesis" and "patient-specific knee prosthesis" are terms used interchangeably.

Criteria for inclusion and exclusion

For the inclusion criteria – (1) Papers published in English only were included. (2) Paper is intended to include papers from 2009 to 2020 (3) Only Total Arthroplasty was considered for review (4) Studies should include biomechanical aspects (5) Studies should be original and duplicates of previous literature.

For the exclusion criteria the following were taken into consideration – (1) Studies containing Uni-compartmental or bi-compartmental Arthroplasty were not included (2) Studies comparing different geographies should not be included. (3) Arthroplasty on animals is not considered (4) Implants designed for animals are not included.

RESULTS AND DISCUSSION

Patient Specific Knee Implant

The knee joint is highly susceptible to injuries and the degenerative condition known as osteoarthritis. When patients experience significant knee joint damage accompanied by escalating pain and diminished functionality, healthcare professionals often recommend undergoing a total knee replacement (TKR) procedure. In order to improve patient satisfaction, numerous implant designs have been developed with the goal of replicating the natural kinematics of the knee joint. These innovative designs aim to restore optimal joint function, alleviate pain, and enhance overall patient outcomes. By mimicking the biomechanics and movement patterns of a healthy knee, these implants provide patients with the potential for improved mobility, increased comfort, and a better quality of life. Achieving precise positioning of components in total knee arthroplasty (TKA) is crucial for promoting balanced stress distribution across the bearing surface of the implant. The ultimate objective following the surgical procedure is to establish a neutral mechanical axis, ensuring that weight-bearing forces travel seamlessly from the center of the femoral head to the center of the knee joint and further to the center of the ankle joint. By striving for this alignment, optimal joint function can be restored, minimizing the risk of uneven stress distribution and subsequent implant failure. In recent years, the utilization of patient-specific implants in TKA has emerged as a groundbreaking advancement in the field. This innovative approach has demonstrated significant advantages over standard procedures, particularly in terms of preserving bone integrity. By tailoring the implant design to the patient's unique anatomy, bone loss can be substantially reduced, promoting a more conservative surgical approach and potentially facilitating easier revision surgeries in the future, if necessary (23). This personalized approach not only helps in maintaining the structural integrity of the joint but also holds great potential for improving long-term outcomes and patient satisfaction. Additionally, the implementation of patient-specific implants in TKA offers the opportunity for precise anatomical matching, which may result in improved joint stability and kinematics. The custom-designed implants are meticulously crafted to fit the patient's individual joint contours, enhancing the potential for a more natural and harmonious range of motion. This can lead to enhanced functional outcomes, increased joint stability, and reduced postoperative complications. By prioritizing accurate component positioning and leveraging patient-specific implants in total knee arthroplasty, surgeons can optimize stress distribution, preserve bone integrity, and potentially improve long-term patient outcomes. These advancements hold great promise in revolutionizing the field of knee surgery, paving the way for more successful and tailored interventions that address the specific needs of each patient.

3D Modelling of Knee Bone

In recent years, there has been a notable and consistent increase in the application of 3D printing technology for patient-specific treatments. This versatile technique is widely utilized to produce a range of customized medical solutions, including anatomical models, personalized molds, surgical guides, and implants. Both magnetic resonance imaging (MRI) and computed tomography (CT) imaging have played pivotal roles in the creation of these patient-specific instruments. The utilization of MRI imaging brings unique advantages to the process. It allows for the accurate representation of the remaining articular cartilage in the affected area, which is crucial for achieving optimal surgical outcomes. By incorporating the information about the residual cartilage, the cutting guide can be designed to cover a larger contact area, ensuring a precise fit and enhancing stability. Furthermore, the MRI data enables the cutting guide to be directly placed on both the bone and the remaining cartilage within the knee joint, promoting better alignment and more comprehensive surgical planning. On the other hand, CT imaging presents certain limitations in the context of considering the presence of remaining cartilage. Unlike MRI, CT scans do not provide explicit information about the cartilage, making it challenging to account for its presence during the planning phase. As a result, the cutting guidance in CT-based imaging must rely on multiple bone locations to guide the surgical procedure. While this approach can still be effective, it does not offer the same level of accuracy and specificity as MRI-based techniques (11).

According to a study conducted by Koch et al. (2013), which analyzed 301 total knee replacements (TKRs) utilizing CT-based patient-specific instrumentation (PSI), it was found that only a minimal 10.8 percent variation in preplanned size occurred among a total of 602 components (12). Similarly, Stronach et al. (2014) reported that the accuracy of MRI-based component sizing was observed in 47 percent of tibia cases and 23 percent of femur cases (13). In another investigation by Lustig et al. (2013), who utilized MRI-based PSI, it was found that femoral component matching was achieved in 52 percent of cases, while tibial component matching was observed in 50 percent of cases. The study also noted that the relative probability of an outlier, or a discrepancy from the intended alignment, was 5.28 times higher when employing a CT-based guide compared to an MRI-based guide (14). These findings suggest that using MRI instead of CT imaging yielded better overall alignment and reduced the occurrence of outliers.

Considering the implications of these studies, it becomes apparent that for surgeons seeking to utilize patient-specific guidelines for total knee arthroplasty (TKA), MRI is the preferred imaging modality (15). The research findings highlight the advantages of MRI-based PSI, including improved accuracy in component sizing, better alignment outcomes, and a lower risk of outliers. By utilizing MRI, surgeons can enhance the precision and effectiveness of TKA procedures, ultimately leading to improved patient outcomes and overall surgical success (12, 13, 14, 15).

3D Modelling of Knee PSI

Traditional total knee replacements (TKRs) typically consist of three components: a femoral component, a tibial component, and a patellar implant. The literature reveals a wide array of knee implants available in the market, with over 150 different types identified (16). These implants offer flexibility and adjustability for use in various sections of the knee, such as the insulated option for either tibiofemoral joint (iUni), the comprehensive coverage across all three knee sections (iTotal), or the targeted confinement to a single tibiofemoral joint adjacent to the patello-femoral joints (iDuo) (27). In an effort to design total knees that more accurately restore normal knee mechanics, Walker et al. (2014) developed concepts that hold potential for advancement in this area (17). Their focus centered around the primary objective of restoring anatomic function by devising a strategy to create complete knees that can both guide and accommodate femoral-tibial kinematics. This approach aimed to direct intercondylar motion while considering guidance from condylar surfaces. Furthermore, Patil et al. (2015) presented a specialized TKR design, as depicted in Figure 1 (18). Their work focused on tailoring the TKR design to better align with individual patient needs and anatomical variations. By taking into account specific patient characteristics and employing a personalized approach, the authors aimed to optimize the fit and function of the TKR implant.

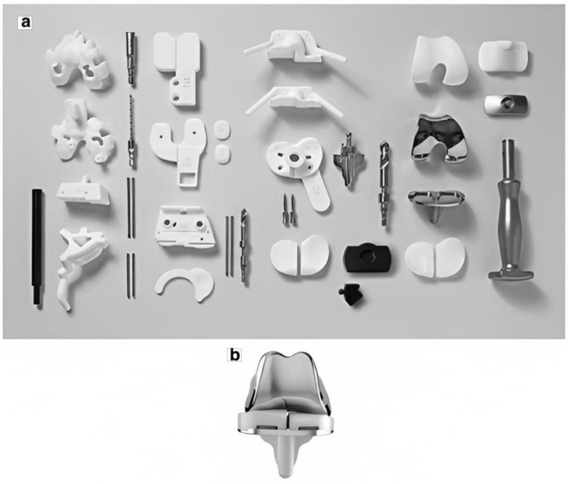

Figure 1: a) Photograph of patient-specific cutting guides. b) Photograph of patient-specific implant.

In a study conducted by Schroeder et al. in 2019, a CT-based knee imaging technique was employed to generate a three-dimensional computer-aided design (CAD) model (19). This model was utilized to create patient-specific geometry for the computer-integrated manufacturing (CIM) process, with the ultimate goal of simulating a significant surgical procedure. In particular, the focus was on the precise positioning of tibial trays in off-the-shelf (OTS) implants, aiming to achieve optimal bone coverage while minimizing rotational errors. To ensure the best possible bone coverage without excessive overhang, the researchers carefully selected the most suitable tibial trial based on the generated models. Once the ideal size was determined, the alignment of the implant was assessed to evaluate rotational deviation using two distinct methods. The first method, as described by Cobb et al. (2008), involved aligning the implant to an axis formed by connecting the centers of the medial and lateral tibial plateaus. The second method aligned the implant to an axis formed by connecting the center of the tibial plateau and the medial one-third of the tibial tubercle (20). The deviations from these alignment lines were then calculated and presented in Figure 2. To analyze the results, statistical analysis was conducted using either pre-existing or customized tools, ensuring accuracy and reliability. The CIM approach employed in this study demonstrated a significant reduction of over 3 mm in under-hanging compared to alternative methods, suggesting improved implant positioning and bone coverage (19).

These findings highlight the potential of utilizing CT-based knee imaging combined with CAD modeling and CIM techniques to enhance surgical outcomes in knee implant procedures. By customizing the implant geometry and optimizing alignment based on patient-specific factors, surgeons can strive for improved bone coverage and reduced rotational errors. The study's results provide valuable insights into the benefits of this approach, offering a promising avenue for further advancements in the field of knee surgery.

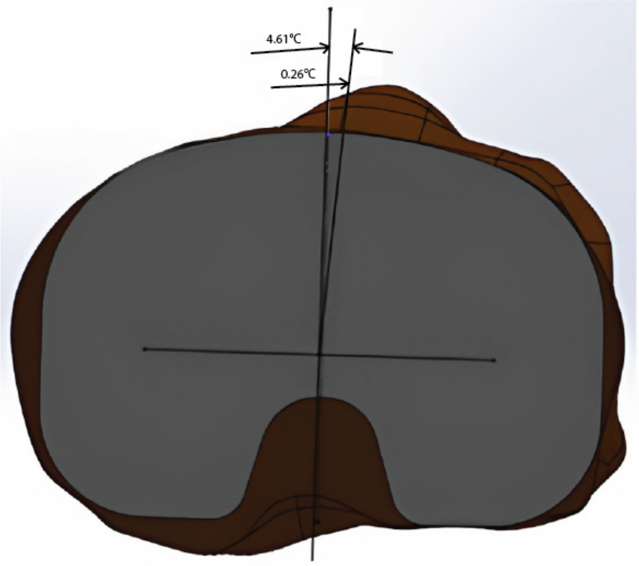

Figure 2: Representation of the CAD analysis depicting the difference in tibial rotation between the tibial 3rd and Cobb landmarks (19).

Finite Element Analysis of Knee PSI

Utilizing finite element (FE) analysis, the implementation of a customized implant with a free-form bone interface has shown potential in providing a more balanced distribution of stress on the bone interface compared to standard femoral components. In a study conducted by Koh et al. (2018), the loads used for model validation and predictions under deep-knee-bend loading conditions were classified into four distinct categories, providing comprehensive insights into the loading patterns experienced by the knee joint (43). The developed model encompasses the various soft-tissue components within the patellofemoral (PF) and tibiofemoral (TF) sections of the knee joint, as well as the bony structures of the lower limb. This includes the incorporation of major ligaments, articular cartilage, and menisci, which play crucial roles in joint stability and functionality. In a study conducted by Most et al. (2003), rigid bodies were employed to simulate the bone structures, ensuring accurate representation and interaction within the model (44). To accurately represent the mechanical properties of the cartilage and menisci, Kang et al. (2017) described the cartilage as a linear elastic isotropic material, while the menisci were modeled as transversely isotropic linear elastic materials, considering their different mechanical properties in the circumferential, axial, and radial directions (45). The ligament bundles were simulated using nonlinear springs, with the material characteristics based on relevant published research (46, 47, 48). These comprehensive representations within the model contribute to a more realistic and accurate simulation of the knee joint biomechanics.

By utilizing FE analysis and incorporating these various elements, researchers aim to better understand the complex mechanics of the knee joint and evaluate the performance of customized implants with improved stress distribution on the bone interface. These advancements in modeling techniques provide valuable insights into optimizing implant design and enhancing surgical outcomes in knee joint replacements.

Wang et al. (2019) introduced a novel dynamic finite element model that aimed to simulate a squatting action using the Oxford knee rig, enabling a comprehensive evaluation of the biomechanical performance of the knee joint. What sets this dynamic model apart from previous studies is its incorporation of patient-specific muscle and joint loads derived from an OpenSim musculoskeletal model, providing a more accurate representation of the physiological conditions. This advanced model considered various scenarios, including cases where both cruciate ligaments were preserved, only the anterior cruciate ligament was excised, and situations where both cruciate ligaments were excised. Additionally, a commercially available symmetric full knee implant with intact cruciate ligaments was simulated to facilitate comparative analysis and assess its performance (42). By implementing this dynamic finite element model and incorporating patient-specific muscle and joint loads, the researchers aimed to gain deeper insights into the biomechanics of the knee joint during a squatting motion. This approach allows for a more realistic evaluation of different scenarios, including variations in cruciate ligament preservation and the use of different implant configurations. The findings from this study can potentially contribute to the optimization of knee implant designs and surgical techniques, leading to improved functional outcomes and patient satisfaction.

Manufacturing of Implants

To ensure timely production of knee implants and accommodate the increasing demand for personalized implants, it is important to employ a scalable manufacturing technique. Typically, the implant's final geometry is transmitted to a CAD/CAM program, which refines the design and generates computer numerical control (CNC) toolpaths for milling the implant using CNC milling machine equipment. Alternatively, rapid prototyping can be used to verify the accuracy of implant components and aid in surgical assessment. As technology advances and becomes more accessible and cost-effective, there is potential for direct manufacturing of final implants. Currently, wax replication and cobalt-chrome castings are used to create physical copies of the knee and implant components (21, 22). The femoral component, commonly made of a cobalt-chrome alloy, features symmetrically arc-shaped condylar surfaces. A groove runs through the center anterior of these condylar entities, allowing the patella to move smoothly during knee flexion and extension. On the other hand, the tibial component consists of two parts: an ultra-high molecular weight polyethylene (UHMWPE) tibial insert or spacer and a tibial tray made of titanium alloy (24).

Clinical Outcome of Patient Specific Knee Arthroplasty

A consecutive study by Ran Schwarzkopf et al. (2015) investigated 621 patients who underwent total knee arthroplasty (TKA). Out of these patients, 307 received patient-specific instrumentation (PSI) implants, while 314 received conventional implants. The study aimed to assess differences in expected blood loss, hospital stay, range of motion, and surgical time among the groups. The findings revealed significant benefits associated with PSI implants, including reduced blood loss, shorter hospital stay, and decreased postoperative range of motion (25). Comparing a fixed-bearing design, it was found that the CIM implant exhibited lower contact stresses at the tibiofemoral joint and more uniform stress distribution at the bone-implant interface (26). Patients with isolated bicompartmental arthritis achieved satisfactory outcomes with the patient-specific iDuo G2 knee prosthesis (28). In contrast to standard posterior cross-maintaining (PCR) design, the CIM TKA group demonstrated improved patella flexion and posterior femoral frugality during flexion (29). Reimann et al. (2019) found that the PSI group showed significantly better Knee Society Scores (KSS) and function scores, indicating improved basic daily function and higher patient satisfaction levels (30). Multiple poly articular insert thicknesses in trial implants helped streamline the turnover process (31). Buch et al. (2019) emphasized the positive impact of personalized implants on patient outcomes, particularly in a "Fast Track" setting, suggesting implant selection as a crucial factor in TKA surgery success (32). Furthermore, O'Connor et al. (2019) highlighted cost savings associated with tailored implants, resulting from reduced treatment expenses and lower postoperative facility spending (33). Studies indicate that TKA tailored to the patient's kinematics can improve joint function (34, 36). Patient-specific knees accurately restored anatomical joint lines and posterior condylar offset (35). Kay et al. (2018) reported positive patient-reported outcomes, including pain relief, improved function, and satisfaction, alongside a decreased rate of manipulation (37). However, patient-specific posterior stabilized implants may lead to a new complication of patellar crepitation, requiring additional surgeries (38). Patient-specific design (PSD) TKA reduces the need for extensive bone cuts, eliminates intramedullary rod requirements for alignment, and offers complete metal coverage for damaged bony surfaces, potentially reducing blood loss (39, 40). Modifications to the locking mechanism and tibial insert design were made in response to observed early failures in a patient-specific prosthesis study by Meheux et al. (2019). The modified PSD-2 group exhibited improved function scores, shorter hospital stays, better radiographic alignment, and no failures compared to the PSD-1 group and standard TKA (41).

In summary, patient-specific implants in TKA have shown benefits such as reduced blood loss, shorter hospital stays, improved joint function, and higher patient satisfaction levels. However, complications, including patellar crepitation, need to be considered. Personalized implants have the potential to enhance surgical outcomes and reduce costs, but ongoing research and modifications are crucial for optimizing their effectiveness and safety.

Patient Specific Ankle Implant

In the treatment of primary and secondary end-stage AO, total ankle replacement (Figure 3) has emerged as a viable option to ankle fusion. Younger and more active individuals with severe ankle abnormalities are now candidates for joint replacement (49). Current surgical therapy options, on the other hand, are either linked with a high number of problems (TAA) or significantly limit ankle range of motion (ankle arthrodesis), both of which are unacceptable in this youthful and active patient group (50). As a result, the quest for effective TAA continues, resulting in the creation of novel implants and instruments (51). In this part of the paper, we will discuss in depth about the Patient-specific ankle implant, it's modeling and clinical outcomes.

3D Modelling of Ankle Bones

To create 3D models of ankle bones, the ankle specimen is subjected to Computer Tomography (CT) scanning with precise resolution and slice distance. Through semi-automatic segmentation of cortical outlines observed in the DICOM images, the CT scans are further processed to generate separate 3D models for the tibia, fibula, talus, and calcaneus bones. Design parameters are then extracted from each of these CT scan-based bone models to develop customized artificial joint surfaces that closely approximate the anatomy of the individual specimen (52). Solid portions are created between the neighboring surfaces of every joint bone to create the cartilages. To create the encapsulated soft tissue, bones, cartilages, and prosthetic components are removed from the specified complete soft tissue. Solid models are created when appropriate surfaces are secured. To replicate the ground support, a horizontal plate tangent to the flat surface of the soft tissue can also be created (53). Gharini et al. (2020) conducted a study where they acquired CT scan data of a patient's ankle who underwent total ankle replacement. The acquired data was processed using ImageSim software, which utilized advanced image processing techniques to segment and identify the specific area/volume of interest (54). The segmentation process was employed to detect the bones and hard tissue boundaries, enabling the creation of a three-dimensional model based on the image data. Subsequently, the implant was designed and fabricated using this three-dimensional model as a reference. According to Zhang et al. (2019), 3D printing technology was found to offer improved safety and effectiveness compared to routine treatment for log-splitter injuries. It resulted in shorter operation times, reduced intraoperative blood loss, fewer fluoroscopies, and higher rates of favorable functional outcomes (55). Similarly, Yao et al. (2019) conducted a study showing that using pre-shaped minimally invasive steel plates based on personalized 3D-printed models can enhance the rate of calcaneal fracture reduction (56). Additionally, patient-specific surgical plans and guidelines created from CT scans can assist in achieving accurate and consistent radiographic alignments for total ankle arthroplasty (57).

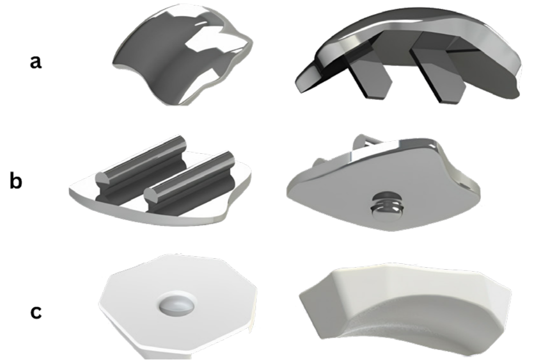

Figure 3: Representations of some common weather symbols. (a) Talus implant. (b) Tibia implant (c) Polyethylene middle part (54)

3D Modelling of Ankle PSI

Customizable implants offer a versatile and user-friendly solution that caters to the unique requirements of individual patients and enables precise preoperative planning. The utilization of patient-specific 3D-printed titanium implants has emerged as an innovative approach for effectively treating complex bone abnormalities and lower limb deformities, surpassing the complications associated with traditional autografts, allografts, and bone transfer methods, as highlighted by Dekker et al. (2018) (58). In the realm of foot and ankle surgeries, So et al. (2018) conducted a study exploring the application of bespoke 3D titanium implants for addressing bone loss resulting from unsuccessful procedures. Their findings demonstrated successful recovery without complications at one-year post-operation when a titanium cage was employed to address failed ankle arthroplasty, nonunion of calcaneal osteotomy, and first tarsometatarsal joint arthrodesis (59). Remarkably, the use of a customized 3D printed titanium truss structure facilitated limb salvage in the face of significant distal tibial bone loss, an irreparable talus fracture, and multiple foot fractures, highlighting the transformative potential of 3D printed implants in foot and ankle surgery, effectively surmounting the limitations and challenges associated with autografts and allografts (60). The process of incorporating 3D printed implants in foot and ankle surgeries typically entails a preoperative CT scan to capture accurate anatomical details, followed by implant trial, computer model design, meticulous editing, and ultimately, the precise manufacturing of the final implant size through 3D printing techniques

(61). These steps ensure the optimal fit and functionality of the implant, tailored to the patient's specific needs. Moreover, Mulhern et al. (2016) observed favorable outcomes in a patient who received a 3D printed titanium truss implant. The patient achieved weight-bearing stability, freedom from pain, appropriate implant alignment, and notable evidence of bone formation throughout the titanium truss, as confirmed by radiographic examination (62). Collectively, these studies underscore the significant potential of customizable 3D printed titanium implants in revolutionizing foot and ankle surgeries. By offering tailored solutions, these implants contribute to enhanced surgical outcomes, improved patient recovery, and ultimately pave the way for more successful and innovative approaches in the field of orthopedic interventions.

STL models of both ankles are imported into Solidworks, and a replacement tibia is put in place of the damaged tibia using the mirroring tool. This model is later used to design implants and bone resections. This procedure facilitated the introduction of unique implants that accurately mirrored the form of the bone for a good fit. In Solidworks, bone resection on the tibia and talus can be executed, and the suitable shape and articulating surfaces can be captured and used as guiding surfaces to construct a new tibia, talus, and polymer insert from the respected geometry (54).

Finite Element Analysis of Ankle PSI

Multiple studies have demonstrated the growing significance of computational methods, particularly finite element analysis, in deepening our understanding of the biomechanics of human musculoskeletal components. Through remarkable advancements in computational and modeling techniques, it is now possible to construct intricate 3D finite element (FE) models of the foot and ankle, incorporating precise anatomical features and capturing the complexities of their interaction behaviors. These advanced models, developed based on computed tomography or magnetic resonance imaging data, successfully replicate the anatomical characteristics of foot segments, enabling a more accurate and comprehensive evaluation of foot biomechanics (63, 64, 65, 66, 67). By employing computational methods such as finite element analysis, researchers have gained invaluable insights into the intricate mechanisms underlying foot and ankle function. The ability to generate highly detailed 3D FE models based on imaging modalities like computed tomography or magnetic resonance imaging has revolutionized the study of foot biomechanics. These models provide a virtual representation of the foot's complex anatomy, enabling researchers to analyze the stress distribution, load transfer, and deformation patterns within the foot and ankle structures.

In a comprehensive study conducted by Bouguecha et al. (2011), a qualitative comparison between estimated bone remodeling in the distal tibia and documented radiographic abnormalities in the literature revealed a notable agreement between the simulation results and clinical data (68). It is worth noting that, similar to other researchers, the model employed in this study did not include the fibula bone, which is an aspect that warrants further investigation (69, 70). Elliot et al. (2014) conducted a study focused on wear rates, revealing that the highest wear rate values observed were 25.598MPa with a rate of 3.74mm^3/year. Additionally, the maximum surface Mises' stress achieved using a new optimization model was 11.52MPa (71). These findings align with a similar investigation carried out by Fryman et al. (2010) (72). Examining the stresses in the prosthetic foot-back ankle complex, Ozen et al. (2013) found that these stresses increased compared to a natural foot-ankle, while the stresses in the forefoot were reduced (64). This highlights the importance of considering stress distributions in various regions of the foot-ankle complex when assessing the performance of prosthetic designs. To delve into the clinical aspects surrounding total ankle replacement (TAR), Terrier et al. (2014) proposed a numerical model that explored critical factors such as patient selection, surgical procedures, implant design and site, as well as the choice between fixed-bearing and mobile-bearing prostheses. This comprehensive model aims to provide insights into the multifaceted considerations involved in TAR procedures, guiding decision-making processes for improved patient outcomes (73). The collective findings from these studies contribute to our understanding of bone remodeling, wear rates, stress distributions, and various clinical aspects related to foot and ankle biomechanics. By utilizing advanced numerical models and simulations, researchers continue to advance our knowledge in these areas, laying the groundwork for enhanced treatment strategies, improved implant designs, and more personalized interventions in the field of foot and ankle orthopedics.

In a previous study by Tao et al. (2010), researchers investigated a simplified finite element (FE) model of the foot and emphasized the importance of considering external muscle forces and the dynamic mechanical characteristics of tissues in simulation analyses (74). Building upon this work, Chen et al. (2015) developed a model of the heel pad using magnetic resonance (MR) scans to accurately identify and incorporate the skin and fatty tissue components. To capture the nonlinear and time-dependent properties of soft tissues, the tissue components of the heel pad were modeled as nonlinear elastic and viscoelastic materials (75). Notably, this study demonstrated the superiority of dynamic loading conditions over static models employed in previous investigations, highlighting the significance of incorporating realistic and dynamic biomechanical factors (76). Subsequent studies further advanced the field by adopting dynamic modeling approaches. In these models, the bone components were represented as linear elastic materials, while the other components, such as ligaments and tendons, were modeled as viscoelastic materials to capture their time-dependent behavior (77, 78). Wang et al. (2014) contributed to this line of research by presenting an FE model of flatfoot based on computed tomography (CT) data. The model encompassed 17 bone segments, 62 ligaments, 9 tendons, the plantar fascia, and various soft tissues with varying material properties. While the bones and soft tissues were directly measured using CT scans, the ligaments, tendons, and plantar fascia were manually generated based on anatomical references from specialized sources (77). Remarkably, this model demonstrated good agreement among the contact zones, stress distributions, and peak stresses, further validating its accuracy and effectiveness (77). The integration of dynamic loading conditions, realistic tissue properties (Table I), and sophisticated imaging techniques has greatly enhanced the understanding of foot biomechanics. By utilizing advanced FE modeling approaches and incorporating detailed anatomical structures, researchers have achieved more accurate and reliable predictions of stress distribution and contact behavior within the foot. These advancements pave the way for improved diagnosis, treatment planning, and the development of personalized interventions for foot-related conditions

Table I: Material Properties Used in Finite Element Models

Part	Density [Kg/]	Young's Modulus [MPa]	Viscous Modulus [Pa.s]	Poisson's ratio
Bone	449 (80)	7300 (79,53)	0	0.3 (53)
Ligament	1000 (77)	260 (79,53)	100 (77)	0.4 (79,53)
Tendon	1000 (77)	1500 (1)	100 (77)	0.4 (77)
Soft Tissue	1000 [80)	2.49 (80)	100 (77)	0.49 (80]

CONCLUSION

Customized implants with a bone interface that follows the natural contours can distribute loads more evenly compared to standard femoral components. Based on the review, the Patient-specific design (PSD) total knee arthroplasty (TKA) has been shown to offer numerous advantages, including reductions in blood loss, length of hospital stay, postoperative range of motion, and surgical/tourniquet time. However, it is important to note that the initial implementation of PSD-1 encountered certain failures related to tibial sinking and issues with the polyethylene locking mechanism. Despite these challenges, the subsequent iteration, PSD-2, exhibited notable improvements and yielded superior outcomes.

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