Design of an Assistive Technology for Post-Implant Knee Surgeries: A Systems Thinking Approach

By

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Dedication

To the indomitable spirits of **Gaza's** children, the unwavering strength of their parents, the tireless dedication of their teachers, and the relentless pursuit of knowledge by researchers, this work stands as a tribute. Amidst the shadows of adversity and the echoes of tragedy, may it Honor the memory of those lost and inspire a future where peace prevails over oppression.

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Abstract

This study investigates the high failure rates of knee implant surgeries at Shifa International Hospital, Islamabad by analyzing the complexities of factors influencing surgical outcomes. The research aims to improve patient recovery and surgical success. This multifaceted approach combines systems thinking, the development of a patient-centered Model of Care (MoC), and the design of an assistive technology for post-operative rehabilitation. The research introduces an innovative model that addresses inconsistencies in previous studies and emphasizes the importance of context-specific determinants.

Building upon this analysis, a tailored MoC is presented, adapting an established framework to the Pakistani healthcare context. This patient-centric MoC promotes standardized care across diverse settings, focusing on patient education, surgical expertise, and adherence to post-surgical rehabilitation protocols. Furthermore, the research presents the design of a novel assistive device equipped with an ESP32 microcontroller to enhance post-operative rehabilitation. This device stands out for its affordability, being 7.5 times cheaper than the cheapest wearable sensor technology currently available. Additionally, it boasts high technological feasibility as all its components are readily available in Pakistan. The device offers functionalities comparable to expensive and complex rehabilitation technologies. It monitors ROM (range of motion), provides feedback during exercise routines, and integrates with ThingsBoard.io for data visualization. The design holds promise for future integration of machine learning algorithms, potentially improving post-operative care through predictive analytics.

In conclusion, this research offers a unique and comprehensive strategy to address the critical issue of high failure rates in knee implant surgeries. By combining systems thinking, a patient-centered MoC, and the design of a highly affordable and technologically feasible assistive technology, the research has the potential to reduce the burden on healthcare systems, enhance patient well-being, and serve as a foundation for a nationwide orthopedic rehabilitation solution that is cost-effective and widely accessible in Pakistan.

Contents

List of Tables

List of Figures

List of Abbreviations and Symbols

Abbreviations

- Rehab Rehabilitation
- QoL Quality of Life
- MRI Magnetic resonance Imaging
- CT scan Computerised Tomography scan
- ADAM Arthroplasty Demand and Allocation Management
- TRL Technology Readiness Level
- TKA Total Knee Arthoplasty
- OA Osteoarthritis
- MoC Model of Care
- UKA Unicompartmental Knee Arthroplasty
- IMU Inertial Measurement Unit
- CLD Causal Loop Diagram
- DrEaMing Drinking, Eating, and Mobilising
- LED Light Emitting Diode
- GPIO General Purpose Input Output
- ISR Interrupt Service Routine

- MQTT Message Queuing Telemetry Transport
- TKR Total Knee Replacement
- ROM Range of Motion
- OFS Optical Fiber Sensor
- KAI-R Knee Assistive Instruments for Rehabilitation
- ST Systems Thinking
- mGES Modified Gait Efficiency Scale
- THA Total Hip Arthoplasty
- BMI Body Mass Index
- IoT Internet of Things
- ML Machine Learning

CHAPTER 1

Introduction

In the arena of orthopedic surgery, the success of knee post-implant procedures is a paramount concern, affecting the quality of life for countless individuals. The burgeoning field of medical research continually seeks to enhance surgical techniques and postoperative outcomes, yet certain institutions face daunting challenges that impede progress. The case of Shifa International Hospital in Islamabad is illustrative, where knee post-implant surgeries exhibit a disconcerting failure rate. Such a scenario mandates a thorough examination of the multifarious factors that contribute to these outcomes and a strategic approach to mitigate them.

The field of implant surgery has made significant advances in medical practice, encompassing a wide range of procedures that involve the insertion of artificial devices or materials into the human body. These interventions have been applied in a variety of medical specialties, from orthopedics to cardiology and dentistry. Among the many aspects of implant surgery, knee implants stand out as an important one, offering solutions to a myriad of knee-related problems such as osteoarthritis, injuries and degenerative conditions. The overarching goal of knee implants is to not only restore mobility but also reduce debilitating pain and improve overall quality of life for people experiencing knee problems. Approximately 20% of people who have undergone total knee arthroplasty (TKA) report unfavorable postoperative outcomes, often with chronic pain after surgery [1][2]. This chronic pain can have profound consequences for patients, including decreased function, worsened general health, increased anxiety levels, depression, sleep disturbances, and chronic opioid use [3][4]. Unfortunately, identifying the root cause of chronic pain after TKA can be a significant challenge, leaving a significant number of patients with persistent pain without a clear explanation [5].

Identifying risk factors associated with poor postoperative outcomes after TKA is essential. This will allow more accurate patient selection and help set realistic expectations [6]. Previous systematic reviews have identified patient-related modifiable and non-modifiable preoperative risk factors. These factors include things like gender (female bias), younger age, lower socioeconomic status, increased preoperative pain, presence of comorbidities, low back pain, poor functional status and psychological disorder factors such as depression and anxiety [7]. In addition to these identified risk factors, there is growing interest in understanding the influence of metabolic factors and inflammatory markers on postoperative TKA outcomes. Metabolic conditions such as obesity and diabetes, as well as the broader metabolic syndrome (which includes obesity, hypertension, dyslipidemia and insulin resistance), are risk factors for the development of the disease and initiation of knee osteoarthritis (OA) [8, 9, 10]. However, their relationship with the development of chronic pain after surgery remains unclear. Recent research highlights that osteoarthritis is more than just a condition of wear and tear. Metabolic factors and inflammatory markers, including C-reactive protein and inflammatory cytokines and chemokines (which also play important roles in diabetes, obesity, and metabolic syndrome), are increasingly recognized as has an influence on both the development of osteoarthritis and pain regulation [11]. Studies indicate that increased systemic inflammation is associated with higher preoperative pain scores in patients with knee osteoarthritis [12]. Systemic inflammation is characterized by elevated concentrations of circulating proinflammatory cytokines, including interleukin-6 (IL-6) and tumor necrosis factor α (TNFα), which can sensitize the nervous system as well. peripheral and central [13][14]. Alterations in the processing of pain signals in the central nervous system may play a central role in the occurrence of chronic pain. Furthermore, in addition to its prevalence in osteoarthritis patients [15][16], initial studies suggest that alterations in central pain processing may even determine long-term benefits obtained from joint replacement surgery. Therefore, metabolic factors and inflammatory markers may directly influence postoperative outcomes.

This research stands at the confluence of innovation and scientific inquiry, embarking on a multifaceted exploration to discern the underpinnings of successful implant surgeries. This journey is not one of isolation but a synthesis of various academic disciplines and methodologies. Systems thinking, with its holistic approach to complex problems, provides the foundational framework for this study. It enables us to capture the essence of the intricate web of factors influencing surgical outcomes, transcending the limitations of traditional linear analysis. Through this lens, this research views each surgical case as a unique amalgam of variables, each exerting its influence on the patient's recovery trajectory.

As research navigates the complexities of this issue, research acknowledges that the breadth of factors extends beyond the operating room. Geographic location, cultural dynamics, and individual patient characteristics constitute a triad of influences that shape the prognosis of surgical interventions. The recognition of these elements is critical in constructing a responsive and robust healthcare model that addresses the specific needs of the patient population.

In response to the exigencies presented by the high failure rates, this research introduces a tripartite research initiative. It is a confluence of a systematic review, an innovative Model of Care [MoC], and the development of an advanced assistive device, each chapter of research building upon the insights gleaned from its predecessors. This structured approach ensures that each facet of the problem is addressed with precision and clarity, contributing to a comprehensive understanding of the determinants of surgical success.

This initiative is not only a response to a localized issue but resonates with the global pursuit of medical excellence. By dissecting the complexities of knee post-implant surgery outcomes at Shifa International Hospital, This research aims to establish protocols and methodologies that can be applied universally. It is a step towards a future where the success of such procedures is not left to chance but assured through meticulous planning and execution grounded in rigorous scientific research.

1.1 Problem Statement

Despite the expectation of pain relief and improved functionality in post knee-implant surgeries, complications and high failure rates persist. At Shifa International Hospital, these failure rates surpass global averages

1.2 Research Gap

This study addresses the urgent need to uncover the root causes of suboptimal outcomes in post knee-implant surgeries. It aims to explore overlooked or inadequately managed factors, essential for improving surgical success.

1.3 Aims and Objectives

1. Systems Thinking Analysis: Apply systems thinking to comprehensively identify contributing factors in post-implant knee surgeries. This involves analyzing patient-specific variables, surgical techniques, and postoperative care protocols through a holistic perspective.

2. Development of a Model of Care (MOC): Utilize design thinking methodologies to create a robust Model of Care (MOC) that incorporates the identified factors influencing patient recovery after post-implant knee surgeries. This step involves synthesizing insights to develop an effective and patient-centric care framework.

3. Prototyping Assistive Technology: Employ product design principles to design and develop a prototype for an innovative assistive technology. This technology will specifically target the factors contributing to complications in post-implant knee surgeries, integrating insights from systems thinking and the developed Model of Care.

CHAPTER 2

Literature Review

The structure of this thesis is designed to reflect the progressive stages of this research, aligning with the objectives that guide the exploration into improving post-implant surgery outcomes. Initially, this research focuses on systems thinking to identify and analyze the complex factors involved. This foundational analysis is crucial for understanding the broader implications of the subsequent interventions. Moving forward, research dives into the model of care (MoC) phase, where this work synthesizes the insights gained from leading healthcare systems to tailor a MoC suitable for the local Pakistani context. This phase is pivotal for conceptualizing a care framework that addresses identified systemic challenges. Further, focusing on the assistive device, where the study channels the findings into the practical design and development of a device aimed at aiding patient recovery. Each of these sections is self-contained, with a literature review, methodology, and results, allowing a deeper understanding of the specific contributions to the overarching goal of enhancing surgical outcomes.

2.1 Identification and Analysis of Factors

Total knee arthroplasty (TKA) is known to reduce pain and improve function in most people with severe knee osteoarthritis (OA) [17]. Postoperative physical therapy (PT) aims to improve physical function, daily activities, overall quality of life (QOL) [18] [19] [20] [21] and prolong healthy lifespan. Therefore, it is essential to evaluate quality of life as an outcome measure for TKA patients. In recent years, there has been increasing emphasis on understanding patient perspectives and satisfaction in assessing quality of life after TKA [22]. Self-report questionnaires serve as a tool to assess whether patient expectations are met after TKA [23]. The Knee Injury and Osteoarthri tis Outcome Score (KOOS) is a well-established method for assessing quality of life after TKA [24]. In addition to assessing pain, symptoms, and quality of life, KOOS can provide information on a variety of functional abilities relevant to the patient through subcategories, including recreational as well as industrial activities. daily work. TKA has been shown to improve the quality of life of patients with knee osteoarthritis [21], [25], especially in terms of physical function [26], [27] and pain relief [28]. These improvements were especially significant 8 to 12 weeks after TKA compared with before TKA, with stable results maintained after 12 months [29], [30]. Although assessment of physical function and pain is often performed, several clinical and sociodemographic variables, including preintervention quality of life, psychological factors, obesity, and support society, may also have an impact on outcomes after TKA [20],[21],[25],[31]. Psychological factors have recently attracted attention as predictors of satisfaction, pain, and physical function [32] and they are strongly related to quality of life after TKA [33]. One such psychological factor is self-efficacy, which refers to an individual's confidence in their ability to achieve desired outcomes through their actions [34]. Self-efficacy, which can be measured with the modified gait efficiency scale (mGES), may influence quality of life after surgery, although research on this topic is limited . mGES assesses an individual's confidence in walking safely in difficult conditions and is scored using a Likert scale. Preoperative mGES scores were associated with the patient's physical activity level after TKA [35]. Although rehabilitation after conventional TKA primarily assesses physical aspects, it is important to include assessment of psychological factors. Preoperative mGES scores also correlated with the time required to regain the ability to walk independently after TKA [36]. Therefore, mGES scores may serve as an important predictor of improvement in quality of life after TKA.

Osteoarthritis (OA) is the most common joint disease and a leading cause of discomfort, reduced function, and disability in older adults [37]. It ranks as the second most common diagnosis in older adults seeking medical care and is the leading cause of disability in this age group [38], [39]. In severe osteoarthritis, total joint replacement (TJR) is the preferred treatment option, providing significant improvements in function and pain relief [40]. Many factors have been identified as contributing to the adverse outcomes of such cases. These include unrealistic expectations, contralateral knee pain, increased psychological distress, high body mass index, dependence on walking aids, older age, female gender, and presence of thyroid disease. All showed a significant association with worsening physical function after total knee arthroplasty (TKA) [41]. However, it should be noted that these findings often lack consistency across different studies, and the precision of this association with outcomes after TKA remains somewhat elusive [42]. Osteoarthritis is a common joint condition that also causes persistent musculoskeletal discomfort [43]. Approximately 80–90% of cases originate in the middle compartment and are usually limited to a single compartment [44]. In cases where unicompartmental osteoarthritis is resistant to conservative treatment methods, surgical methods such as total knee arthroplasty (TKA), high tibial osteotomy, and arthroplasty can be chosen. unicompartmental knee joint (UKA). UKA Oxford Stage 3, introduced by Murray and Goodfellow et al in 1998, is one such option [45]. UKA offers many benefits, including minimal incisions, preservation of vital ligaments, minimized bone removal, reduced blood loss and pain, improved function, shorter hospital stays, savings costs and faster recovery [46], [47]. However, it should be noted that UKA also has disadvantages, including surgical complexity and higher revision rates compared to total knee arthroplasty (TKA) [48], possibly due to the issues of patient selection and implant placement [47],[49],[50]. Over the past two decades, advances in implant technology, materials, surgical techniques, and patient selection criteria have led to improved UKA outcomes [51],[52],[53]. Surgeons should carefully evaluate potential pitfalls as well as clinical and radiological factors that contribute to early failure of UKA. As the surgeon gains experience, implant placement becomes more precise. TKA is a long-standing solution for advanced knee osteoarthritis unresponsive to medical therapy [54],[55]. It results in significant and lasting improvements in general and disease-specific quality of life, especially pain relief and improved function, leading to high patient satisfaction [56]. Several factors influence knee range of motion after TKA. An important factor is the posterior movement of the femur [57], [58], [59], [60], [61], [62], [63], [64], [65]. Other factors include preoperative range of motion, soft tissue condition, knee stability, adjacent anatomical structures, implant design, and more. Traditional implant designs have yielded excellent results over time, achieving up to 120 degrees of knee flexion [66]. However, modern surgical designs and techniques aim to tailor the implant to the individual's anatomy to provide greater patient satisfaction. Different prosthetic designs are available for TKA, including cross-retention (CR), cross-sacrifice, and posterior stabilization (PS) designs [67], [68], [69]. The custom implant fits a variety of anatomical variations with left and right femur shapes and different sizes. Customization ensures optimal soft tissue balance. Total knee arthroplasty (TKA) and total hip arthroplasty (THA) are increasingly popular procedures [70], [71], [72]. Rates of revision TKA (rTKA) and THA (rTHA) are also increasing, especially in joint revision [73]. Preoperative depression is well studied in primary THA and TKA [74], [75], [76], [77]. However, its impact on total joint replacement remains unexplored. This is an important area for research because psychiatric disorders such as depression are more common in joint replacement patients than in the general population [74], [78], [79], [80], [81]. Depression may decrease after joint replacement, depending on the degree of pain relief [76], [77], [79], [82]. The incidence of depression in primary failed total joint replacements and its consequences after rTKA or rTHA remain unclear. In this complex landscape of knee implant surgeries, it becomes evident that multiple factors interact to influence the ultimate outcome of these procedures. The intricacies of these surgeries extend far beyond what can be captured in a single glance. To shed light on this multifaceted nature. Furthermore, these studies provide a comprehensive overview of various determinants, encompassing the experience of the surgeon, pre- and post-operative care, and patient-specific conditions. This comprehensive perspective acknowledges the multifaceted nature of knee implant surgeries, where no single factor can be isolated from the rest. It's a dynamic interplay of elements that ultimately shapes the patient's experience and outcome. ***Contradicting factors in this regard of knee implant surgeries are particularly intriguing. These are variables or conditions that, based on different studies, have shown varying or even opposing effects on surgical outcomes. Such contradictions can arise from differences in study designs, patient populations, surgical techniques, or other variables.*** Take, for example, the experience of the surgeon, a crucial factor in surgical success: On one hand, Kazarian et al. (2019) [83] found that high-volume surgeons and non-trainee surgeons had lower proportions of implant malalignment, highlighting the importance of experience . On the other hand, Ragucci et al. (2020) [84] reported a high success rate for implants placed and rehabilitated by inexperienced post-graduate students, suggesting that perhaps other factors play a role . Radiotherapy in spinal implant surgery offers another fascinating contradiction. While Wong et al. (2020) [85] found that patients who received radiotherapy before or after spinal implant surgery for metastasis were less likely to experience implant failure, concerns about the broader effects of radiotherapy on bone health persist. Even a seemingly straightforward factor like a patient's health conditions presents its own paradox. Hoell et al. (2016) [86] identified body mass index (BMI) and smoking as significant risk factors for knee implant surgery failure, emphasizing the role of these variables. In contrast, Ragucci et al. (2020) [84] found that none of the investigated health-related variables significantly affected implant survival rates, suggesting a more complex interplay of factors. ***These contradictions underscore the complexity of determining the exact factors that contribute to the success or failure of knee implant surgeries. They remind us that these surgeries exist within a dynamic, multifaceted ecosystem, where countless variables converge and diverge.*** As the research journey progress, This research aims to untangle these complexities and develop a more comprehensive understanding of the factors that truly matter in optimizing knee implant surgery outcomes. However, the journey from implant to post-operative outcome is not simple, marked by complex nuances and notable differences in outcomes between patients. The diversity of this outcome has been the subject of extensive research, revealing a multitude of contributing factors. These studies have indeed resulted in significant advances in understanding the outcomes of implant surgery. However, despite considerable individual research efforts, ***a fundamental question persists: the absence of a unified and general approach to deciphering the complexity of these results. Research findings, although robust, are often context dependent, reflecting specific time frames, locations, and patient populations. This dichotomy poses a challenge: Even if some factors appear essential in one study, they may not be important in another. This disparity highlights gaps in understanding and interpreting research results***. Therefore, there is a need for a comprehensive approach capable of exploring the multifaceted nature of implant surgery outcomes, providing a general framework that transcends the specifics, and thereby providing a unified roadmap. to understand and optimize these results. This study uses a unique and comprehensive approach to address the complexity inherent in implant surgery outcomes. He recognizes that although current research has produced valuable insights, the crux of the matter lies in the perception and applicability of these findings. It seeks to bridge the gap between different research findings, recognizing that each study is a piece of the puzzle rather than a definitive answer. This study aims to introduce a general approach that transcends time, place, and specific patient groups, providing a unified perspective on implant surgery outcomes. The importance of this research goes beyond theoretical exploration. It illustrates a dynamic approach rooted in systems thinking, recognizing the flexible and multifaceted nature of medical models. To illustrate this approach, the research presents a case study focusing on Shifa International Hospital in Pakistan. This unique case study delves into the high rate of implant failure observed in the Pakistani context, highlighting the complexity of implant surgical outcomes in a region where such research is rare. . In doing so, it provides a comprehensive understanding of the problem, including its indirect connections and depth. Ultimately, this study paves the way for a more comprehensive and widely applicable understanding of transplant surgery outcomes, serving as a model to address similar challenges in other settings all over the world.

2.2 Model of Care

Total knee replacement (TKR) surgery is a common and effective treatment for end-stage knee osteoarthritis, which causes severe pain and disability [87]. However, the success of TKR surgery depends not only on the surgical procedure, but also on the post-operative rehabilitation, which aims to restore the function, strength, and mobility of the knee joint [88]. Post-operative rehabilitation is a complex and multidimensional process that involves various healthcare professionals, settings, and interventions (link to pdf). Therefore, it requires a well-designed and coordinated model of care (MoC) to ensure optimal outcomes and patient satisfaction [89].

A MoC is a comprehensive framework that defines the best practice of care delivery for a specific patient population or health condition (link to pdf). It describes the "who, what, when, where, how, and why" of care provision, based on the best available evidence, clinical expertise, and patient preferences [88]. A MoC also considers the context and resources of the healthcare system, and evaluates the effectiveness, efficiency, and sustainability of the care delivery . Developing and implementing a MoC can improve the quality, safety, and value of healthcare services, as well as the collaboration and communication among healthcare providers and patients . In Pakistan, there is a lack of standardized and evidence-based MoCs for post-operative rehabilitation after TKR surgery. This may result in suboptimal care quality, high variability, and poor outcomes for patients who undergo this surgery . Moreover, Pakistan faces several challenges in providing adequate and accessible healthcare services for its population, such as resource constraints, workforce shortages, infrastructure limitations, and geographical disparities . These challenges may further compromise the delivery and continuity of post-operative rehabilitation for TKR patients, especially in rural and remote areas . Therefore, there is an urgent need to develop and implement a patient-centered and context-specific MoC for post-operative rehabilitation after TKR surgery in Pakistan.

This research aims to propose a MoC for post-operative rehabilitation after TKR surgery in Pakistan, based on the best available evidence and the local healthcare context. First this study will review the current literature on MoCs for post-operative rehabilitation after TKR surgery in different countries and settings, and identify the key components and principles of effective and efficient care delivery (Orthopedic MoC NHS-UK, Orthopedic MoC Australia). Then this work will describe the proposed MoC for Pakistan, and explain how it addresses the specific needs and challenges of the Pakistani healthcare system and population. This research also discusses the potential benefits, limitations, and implications of the proposed MoC, and provides recommendations for its implementation and evaluation.

2.3 Device Prototype and Research Infrastructure

Total Knee Arthroplasty (TKA), commonly known as total knee replacement, is a surgical procedure aimed at relieving pain and restoring function in individuals with severely damaged knee joints, often due to conditions like osteoarthritis or rheumatoid arthritis. During TKA, the damaged portions of the knee joint are surgically removed and replaced with artificial components, typically made of metal and plastic. This procedure has proven highly effective in improving mobility and quality of life for patients with debilitating knee pain. However, the success of TKA extends beyond the operating room, into the crucial phase of post-surgery rehabilitation. Rehabilitation after TKA plays a pivotal role in helping patients regain strength, flexibility, and range of motion in their new knee joint. It involves a structured program of exercises, physical therapy, and lifestyle adjustments tailored to the individual patient's needs. The primary objectives are to reduce pain, minimize swelling, and enhance the functionality of the replaced knee. Rehabilitation following TKA is a gradual process, often lasting several weeks to months. It requires dedication and collaboration between patients, physical therapists, and healthcare providers. The exercises prescribed are designed to progressively challenge the knee joint while ensuring its safety and stability. Patients are encouraged to regain their independence in activities of daily living and gradually return to their normal routines.

This work addresses the development an assistive technology for rehabilitation after total knee arthroplasty. Early Developments in Joint Monitoring began with a primary focus on various sensing technologies aimed at detecting joint parameters and movements. These initial systems were often cumbersome, complex, and necessitated skilled operation. However, as sensor technology advanced, joint monitoring became more accessible, convenient, and cost-effective. Wearable sensors underwent significant improvements in terms of reliability and widespread usage across domains like healthcare, entertainment, and security [90]. This evolution of sensing technologies and algorithms over time marked a crucial transition. The emphasis shifted towards creating simpler, user-friendly, cost-effective, non-invasive, and wearable systems with wireless communication capabilities. This shift allowed for real-time monitoring and analysis of continuously collected data, customized to meet the specific needs of the individual under observation [90]. Furthermore, key parameters for joint monitoring, especially in physiologic joint movement analysis, became pivotal in various mobility-related activities such as rehabilitation, sports medicine, human activity assessment, and virtual guided training. The measurement of the range of motion (ROM) of joints played a critical role in determining the maximum force that could be exerted and the optimal joint angle range for specific activities or motions [90]. The subsequent introduction of Optical Sensor-Based Systems brought about significant enhancements in precision and unobtrusiveness. These systems utilized either intensity modulation or optical navigation methods, with optical fiber sensors (OFS) being employed for intensity modulation. This innovation greatly improved the accuracy and subtlety of joint monitoring systems [90]. Moving forward, the evolution of goniometers in clinical monitoring was noteworthy. These devices, used to determine the range of angular motion of human body joints, transitioned from traditional mechanical or electromechanical systems based on resistive potentiometers or strain gauges to more precise and flexible optical-based systems. This transformation addressed the limitations of traditional goniometers, such as their size, imprecision, and fixed configurations, which did not align with natural joint movements [90].

Smart Sensor Implant Technology in Total Knee Arthroplasty (TKA) introduced further innovation. Advances in computer technology and implant design led to the development of smart sensor implant technology within TKA. These intelligent implants not only provided diagnostic capabilities but also therapeutic benefits. They facilitated real-time monitoring of embedded sensors, offering early management solutions, improving patient satisfaction rates, and enhancing functional outcomes [91]. The incorporation of smart sensor (SS) devices into polyethylene spacers for intra-operative monitoring or integration into tibial baseplate components for patient monitoring marked a significant stride in the evolution of SS technology. The transition from percutaneous lead wires to miniaturized, wireless SS devices further enhanced their practical application in patients [91]. Smart Sensor Technology found multifaceted applications in TKA, ranging from intra-operative assessments to long-term monitoring of TKA implants and patient rehabilitation. It facilitated objective assessments of ligament and soft tissue balancing, load-bearing analysis, joint stability, and early detection of infection or implant wear. Additionally, this technology enabled remote monitoring of rehabilitation progress and the modification of physiotherapy regimes based on performance data [91]. Looking towards the future, the prospects of smart sensor technology in diagnostics suggested long-term surveillance of TKA, where diagnostic chips remain dormant until detecting an abnormality. Advancements might also include 'Self-Treatment' options using nanotechnology and drug delivery systems for local release of antibiotics. However, the adoption of SS-based TKA technology faces challenges such as cost, safety data, and data security, which must be addressed for its widespread acceptance and implementation [91]. In the perspective of IoT-Based Solutions and Knee-Rehab System, recent years have witnessed the emergence of lighter, portable, and adjustable Continuous Passive Motion (CPM) machines with user-friendly interfaces and Android-based applications. These developments not only simplified systems but also made them cost-effective, non-invasive, and wearable. These systems enhanced their real-time monitoring capabilities, making them more accessible and beneficial [92]. Advancements in wearable technology led to the creation of wearable gesture sensing devices, which employed textile strain sensors for monitoring the flexion angle of elbow and knee movements. These devices offered a more comfortable and practical alternative to traditional motion capture systems, which were often rigid and cumbersome [93]. Further progress was observed with the development of the Knee Assistive Instruments for Rehabilitation (KAI-R). This wearable device aimed at supporting post-TKA rehabilitation and consisted of mechanisms for knee and hip joint support, along with a foot pressure sensor system. The KAI-R system focused on replicating the complex motion of the knee joint and increasing the flexion angle, contributing significantly to the rehabilitation process [94]. A significant advancement in the KAI-R system was the integration of a foot sensor system. This system used conductive rubber to detect the state of heel contacts, translating pressure into voltage. The detected voltage levels helped in confirming the lifting of the foot from the ground, which was essential in the control system of KAI-R. This development represented a significant step towards more accurate and responsive rehabilitation systems [94]. To validate the effectiveness of KAI-R, experiments were conducted. The system was tested and compared with non-assistive walks, and the results indicated that KAI-R could increase the flexion angle of the knee and the height of the foot during the swing phase, critical factors in preventing falls in elderly patients. These findings suggested that KAI-R could be a valuable tool in post-TKA rehabilitation, and future work includes more extensive testing and clinical trials [94]. Recent advancements in sensor-based systems have led to the development of a sensor-based system for effectively monitoring the rehabilitation progress of Total Knee Replacement (TKR) patients. This system incorporates a hardware module with a triaxial accelerometer and gyroscope, a microcontroller, a Bluetooth module, and a software app. The system focuses on measuring three key indices: the number of swings, the maximum knee flexion angle, and the duration of each practice session. This proposed device offers benefits like ease of use, no spatiotemporal constraints, and accurate monitoring of rehabilitation progress. Comparative studies with professional equipment like the Cybex isokinetic dynamometer have shown that the system's performance is comparable, with minimal errors in angle measurements [95].

With the increasing prevalence of degenerative arthritis and rheumatoid arthritis, especially among the elderly, TKR surgeries have become more common. The success of these surgeries heavily depends on effective post-surgery rehabilitation. The importance of regular rehabilitation exercises is emphasized to enable patients to adapt to the artificial joint and regain mobility. A lack of proper rehabilitation can lead to issues like swollen or deteriorated knee conditions post-surgery. Therefore, the need for an effective method to monitor the rehabilitation progress using sensor devices and smartphones has become more critical [95]. The study utilized a six-axis Inertial Measurement Unit (IMU), comprising a triaxial accelerometer and gyroscope, to calculate the knee angle. This system offers high accuracy in the short term and is sensitive to motion. However, it can accumulate errors over long periods. By applying Kalman filtering to the rotation angles calculated from the accelerometer and integrated from the gyroscope's angular velocity, the real roll and pitch angles are determined. This method addresses the issues of long-term measurement accuracy [95]. To monitor rehabilitation progress, users' knee motion angles were tracked, varying from 60° to 180°. The system faced challenges in quantitatively measuring the effect of each rehabilitation course. To address this, Fuzzy c-means (FCM) was applied to identify the centroid of acceleration signals, allowing for the calculation of an equivalent Range of Motion (ROM) to represent the effect of a rehabilitation course [95]. The use of an Android smartphone to receive and record signals from the sensor devices marked a significant step in rehab monitoring. The system required users to input basic information and preferred animation types to personalize the experience. The smartphone, paired with the sensor devices, enabled orthopedists to track and monitor patients' rehabilitation status actively. Features like a swing counter and a color bar displaying the percentage completion of the designated course were incorporated to encourage continuous exercise and monitor progress [95]. The system was experimentally validated from June 2015 to May 2016 with 35 subjects at Chang Gung Memorial Hospital. The study adhered to ethical standards and obtained informed consent from all subjects. The experiments were designed to validate the accuracy and effectiveness of the developed sensor system in rehabilitation monitoring [95]. This all leaves a gap in-between a low-cost, open-source solution with novelty in development process using design thinking which also incorporates collection of data for enabling future research. Summary of key findings are shown in table 2.1

Year	Publishing Platform	Key Findings	Technology Focus
2012	J-Stage, Journal of Advanced Mechanical Design, Systems, and Manufacturing	KAIR, a wearable device for postTKA rehabilitation, supports knee/hip joints and utilizes a foot pressure sensor system. KAIR increases flexion angle and contributes to rehabilitation. Foot pressure sensor confirms heel contact for control system.	Knee Assistive Instruments for Rehabilitation (KAIR)
2012	Same as above	Experiments showed KAIR increased knee flexion and foot height during swing phase, potentially preventing falls.	KAIR Effectiveness Evaluation
2019	Sensors	Sensor technology advancements led to simpler, userfriendly, costeffective, noninvasive wearable systems with wireless communication. Emphasis shifted to realtime monitoring and analysis for customized rehabilitation. Importance of Range of Motion (ROM) measurement for joint monitoring. Optical SensorBased Systems improved precision and unobtrusiveness.	Sensor Technology Advancements
2019	Same as above	Goniometers transitioned from mechanical to opticalbased for improved precision and flexibility.	Goniometer Evolution
2020	IAES, Bulletin of Electrical Engineering and Informatics	Lighter, portable, and adjustable Continuous Passive Motion (CPM) machines with userfriendly interfaces are emerging. Advancements in wearable technology led to creation of gesture sensing devices using textile strain sensors.	Advancements in Wearable Technology & CPM Machines
2020	Sensors	Sensor based system with accelerometer, gyroscope, microcontroller, Bluetooth, and smartphone app. Measures number of swings, maximum knee flexion angle, and duration of sessions. Offers ease of use, no spatial constraints, and accurate monitoring.	Sensorbased Rehabilitation Monitoring System
2020	Same as above	Kalman filtering addresses longterm accuracy issues with gyroscope and accelerometer data. Fuzzy cmeans (FCM) method calculates equivalent Range of Motion (ROM) for each rehabilitation course. Android smartphone app receives and records sensor data, personalizes user experience, and allows monitoring by orthopedists.	System Functionality & Data Processing Techniques
2020	Same as above	System validated with 35 subjects at Chang Gung Memorial Hospital	System Validation
2021	Elsevier, Journal of Clinical Orthopaedics and Trauma	Smart sensor implants in TKA offer diagnostic and therapeutic benefits. Realtime monitoring facilitates early intervention and improves patient outcomes. Applications include ligament/soft tissue balancing, loadbearing analysis, joint stability, and infection/wear detection. Enables remote monitoring and physiotherapy regime adjustments.	Smart Sensor Implant Technology
2021	Same as above	Future prospects include longterm surveillance and "SelfTreatment" options using nanotechnology. Challenges include cost, safety data, and data security.	Smart Sensor Implant Technology

Table 2.1: Summary key findings for assistive technology

CHAPTER 3

Methodology

3.1 Systems Thinking

Systems Thinking is a holistic approach to understanding complex systems. In this context, a system refers to a set of interconnected elements or components that work together to achieve a common purpose. Systems Thinking recognizes that real-world systems, including healthcare systems, are characterized by intricate interdependencies, feedback loops, and non-linear relationships. In healthcare, this means recognizing that healthcare systems are not just isolated hospitals, clinics, or individual patient experiences. Instead, they are vast and interconnected networks involving various elements such as patients, healthcare providers, institutions, technologies, policies, and treatments. Systems Thinking acknowledges that changes in one part of the healthcare system can have ripple effects throughout the entire system. For example, a change in healthcare policy can affect patient outcomes, healthcare costs, and the behavior of healthcare providers.

3.1.1 System Dynamics

System Dynamics is a methodology for modeling and analyzing complex systems over time. It involves creating models that represent the feedback loops and causal relationships within a system. These models can be used to simulate how the system responds to various interventions and changes. In healthcare, this means creating dynamic models that capture the evolving nature of healthcare systems. These models can simulate the impact of changes in healthcare policies, resource allocation, patient behavior, and more over time.

3.1.2 Causal Loop Diagrams (CLDs)

Causal Loop Diagrams are visual representations of feedback loops within a system. In healthcare, these diagrams help illustrate how changes in one variable affect other variables, either positively (reinforcing loops) or negatively (balancing loops).

3.1.3 Stock and Flow Diagrams

Stock and Flow Diagrams are used to depict the accumulation and flow of resources or variables within a system. In healthcare, these diagrams help visualize how resources, such as patients, medications, or healthcare providers, accumulate and flow through the system.

3.1.4 Benefits in Healthcare

Systems Thinking and System Dynamics, including tools like Causal Loop Diagrams (CLDs) and Stock and Flow Diagrams, offer substantial benefits in healthcare. They provide a holistic view of healthcare systems, highlighting interconnectedness and complexity. These methodologies assist in understanding cause-and-effect relationships and enable risk-free analysis through simulations. CLDs offer visual representation of complex feedback mechanisms, aiding in effective policy planning and identifying potential unintended consequences. Stock and Flow Diagrams are instrumental in resource management, scenario testing, and evaluating the impact of healthcare policies. Overall, these approaches enhance healthcare system management and policymaking by offering deeper insights into the dynamics of healthcare delivery and outcomes.

3.1.5 Tool

In the research, this research harness the capabilities of SageModeler, a cutting-edge online tool for Systems Thinking and System Dynamics. SageModeler is a user-friendly platform that empowers researchers, particularly in the field of healthcare, to create, visualize, and simulate dynamic models of complex systems. This versatile tool allows us to construct Causal Loop Diagrams and Stock and Flow Diagrams, two pivotal components of System Dynamics, with ease. SageModeler offers a collaborative environment where the research team can work seamlessly to map out the intricate interdependencies and feedback loops within healthcare systems. By using SageModeler, this research can simulate the impact of various interventions, scenarios, and policies, enabling us to explore how changes in one aspect of the healthcare system propagate throughout the entire network. SageModeler is an invaluable asset in the research, providing the means to gain a comprehensive understanding of healthcare systems and their dynamics, ultimately aiding in the formulation of innovative, holistic solutions to complex challenges within the healthcare domain.

3.1.6 Drawbacks

Systems thinking have limitations in their application within complex systems. They may not fully capture the context due to their inability to generalize across different scenarios. The creation of system webs can be hindered by varying stakeholder perspectives and the complexity of power relations. Moreover, ST require extensive narrative support to clarify ambiguous relationships and assumptions, and they can be challenging to validate due to potential data gaps and the intricate nature of their design.

One recognized **limitation** of applying systems thinking with Causal Loop Diagrams (CLDs) is the potential for complexity, resembling "spaghetti." To address this, this research present research findings in a structured format, focusing on the key factors influencing the 0th degree variable (surgery outcome). this research categorize these factors based on their degree of connection:

- 1st Degree Connections: Represented visually in diagrams, showcasing directly impactful variables and their relationships.
- 2nd & 3rd Degree Connections: Listed in tables, providing a comprehensive overview of less immediate, yet relevant, factors.

While this research acknowledge the value of systems dynamics modeling for understanding intricate interactions, the **focus is on identifying the core factors influencing surgery outcome**. This approach balances comprehensiveness with clarity, facilitating the interpretation of the findings.

3.2 Model of Care

This research seeks to design a Model of Care (MoC) for orthopedic issues within the healthcare system of Pakistan, focusing on enhancing post-implant surgery outcomes. The MoC is a structured framework that defines the optimal provision of care and services for individuals navigating through health-related conditions or events. It ensures that care is timely, appropriate, and delivered by the correct team in the most suitable setting. The methodology for creating an MoC is inherently a task of change management, aiming to improve service delivery. This process includes several critical stages, starting with the planning phase, where objectives and resources are identified. This is followed by the development phase, which outlines the structure and components of the MoC. Implementation involves the practical application of the MoC within the healthcare setting, while the evaluation phase assesses the effectiveness and impact of the MoC. Finally, the sustainability assessment ensures that the MoC can be maintained over time with ongoing resources and support. the MoC will be patient-centric, allowing for local adaptability and promoting coordinated care that encourages resource efficiency and prioritizes safe, high-quality patient care. It incorporates a solid, standardized framework for outcome measurement and process evaluation, fostering innovation in the organization and delivery of care, and projecting a forward-looking perspective for future services. The MoC will be grounded in the strongest available evidence, align with strategic objectives and programs, and be developed collaboratively with stakeholders including clinical staff, healthcare associates, the community, and patients and their representatives. this research aim to draw from established MoCs, such as those from the NHS and South Australian health agencies, to inform the development of an MoC for Pakistan. The 'Enhancing Recovery' approach, a successful MoC variant, is also a key reference for the methodology. This approach expedites patient recovery post-surgery and incorporates principles such as early preoperative evaluation, planning, preparation, stress minimization during the operation, systematic postoperative and perioperative care, and prompt post-surgery mobilization. To manage the 'Enhancing Recovery' approach effectively, the MoC will include elements such as staff education and training, process enhancement, booking layout, procedure-specific care plans, and patient education to elevate compliance to health professional instructions. Patients will have individualized care plans to ensure daily milestones are met, contributing to their recovery progress. The 'Enhancing Recovery' figure 3.1 approach will be exemplified by case studies from Torbay Hospital and Hvidovre Hospital in Denmark, where a strong project management framework, clinician engagement, evidence-based practices, and infrastructural support have contributed to its successful implementation. the MoC will adapt these principles, tailoring them to the socio-economic and cultural context of Pakistan to address the current challenges faced in post-implant surgery outcomes.

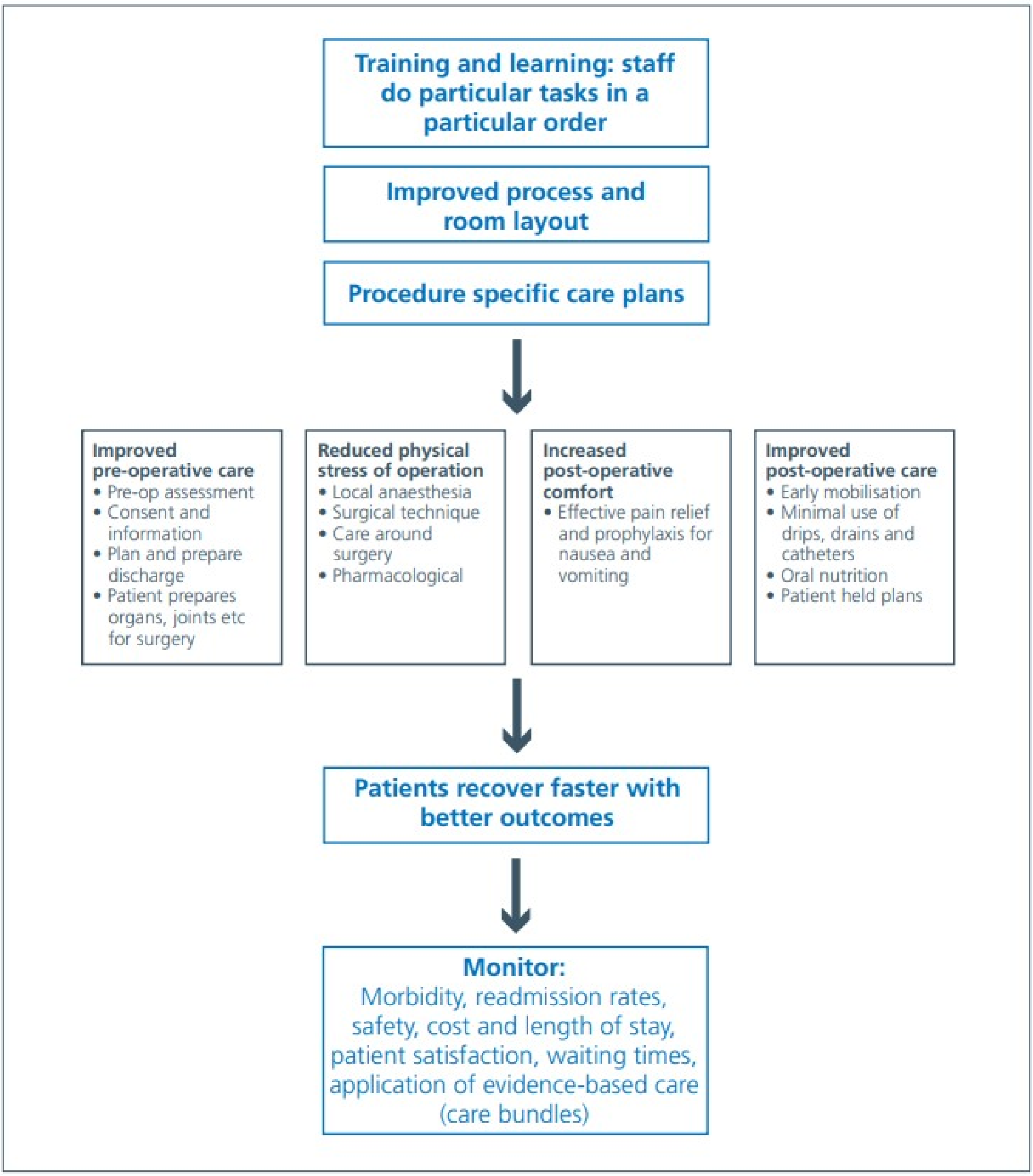


Figure 3.1: The figure visualizes a systematic recovery enhancement model for post-implant surgery patients, integrating staff training, optimized processes, and patient-focused care plans.

3.3 Design Thinking and Product Design

The methodology employed for the development of the knee transplant recovery device integrates design thinking principles with a structured product design and development approach. This comprehensive methodology ensures a humancentric focus, iterative ideation, and systematic implementation, ultimately resulting in technologically advanced and userfriendly products.

3.3.1 Design Thinking Framework

- Empathize: The first step in design thinking involves understanding endusers and their needs. This empathetic approach entails interviews, interactions, and observations to gain insights into user challenges and pain points.

- Define: With user needs identified, the next step is to define a clear problem statement. This phase distills gathered information into actionable problem statements that guide the design process.

- Ideate: Ideation is a creative phase involving the generation of multiple solutions. Brainstorming sessions, workshops, and discussions lead to the exploration of various concepts and ideas.

- Prototype: Prototyping transforms selected concepts into tangible representations. Physical prototypes allow for handson exploration and refinement, aiding in the development process.

- Test: Prototypes are tested to gather user feedback and assess proposed solutions' feasibility. Iterative testing and refinement ensure that the final product meets user expectations. This whole process can be visualized as under in figure 3.2.

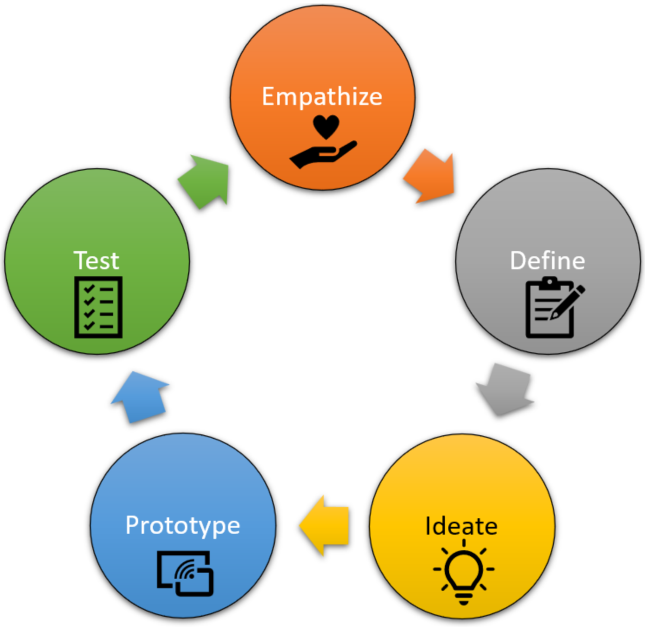


Figure 3.2: The diagram encapsulates the Design Thinking framework, highlighting the iterative process of empathizing with users, defining the problem, ideating solutions, prototyping, and testing to develop effective and user-centric designs.

3.3.2 Product Design and Development

- Conceptualization: the prototype reimagines knee implant post-operative care, focusing on patient-centricity and remote monitoring.
- Requirements Analysis: this research analyzed technical needs to develop an embedded assistive device. This device utilizes an ESP32 microcontroller and advanced sensor technology to monitor joint angles and movement, providing crucial real-time feedback for exercises.
- System Architecture: The device seamlessly communicates with ThingsBoard.io for data visualization, enabling connected and remote healthcare environments.
- Prototyping and Development: this research developed the device using the specified architecture, programming components and integrating the sensor technology.
- Testing and Validation: Rigorous testing ensured the device's reliability and accuracy in various scenarios, including real-world clinical settings at Shifa International Hospital, Islamabad.

In addressing the research problem concerning the advancement of healthcare wearable technology, a novel methodology was developed by merging principles from design thinking and product design & development. The integrated methodology, as depicted in the provided figure 3.3, combines elements from both approaches to enhance problem-solving and innovation for TKA procedures. This integrated methodology allows for a dynamic exploration of diverse techniques and strategies inherent to both design thinking and product design & development. By leveraging the strengths of each approach, it aims to broaden the solution space and facilitate a structured yet creative research process. Specifically, the methodology encourages iterative problem identification, solution generation, prototyping, and validation, emphasizing user-centric design principles and feasibility considerations. Through this approach, the research seeks to contribute to the advancement of healthcare wearable technology by addressing identified challenges effectively.

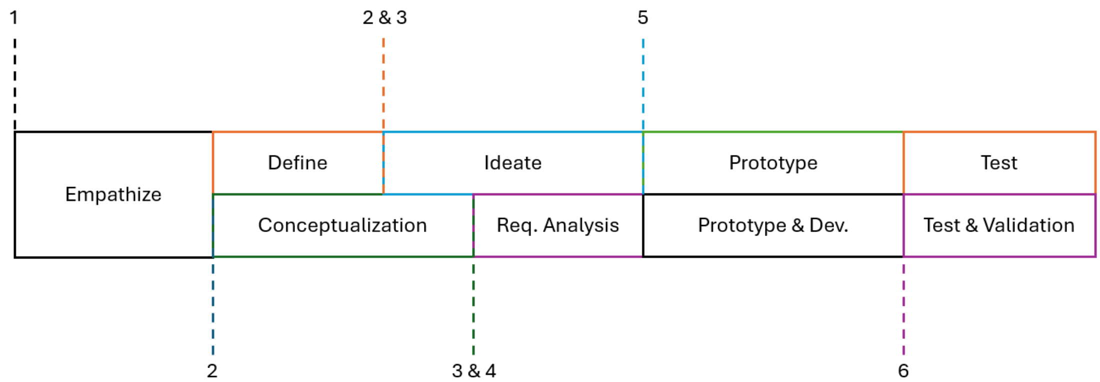


Figure 3.3: The diagram encapsulates the original methodology drafted to incorporate both design thinking and product design and development

CHAPTER 4

Results and Discussion

4.1 Identification and Analysis of Factors: Systems Thinking

Following the application of systems thinking, the essential factors responsible for patient satisfaction were identified. These factors encompass a range of influences that extend up to the 3rd degree connection of factors, as presented in the tables below. It's important to note that these factors are interconnected, and while there are more nuanced aspects to each, these major factors capture the most critical information. Furthermore, they are subject to causal relationships and feedback loops, which are not explicitly represented for the sake of simplicity. The primary connections are illustrated in the network diagrams, figures 4.1 and 4.2. Sub-factors are described tables below (tables 4.1, 4.2, 4.3, 4.4, 4.5, 4.6)

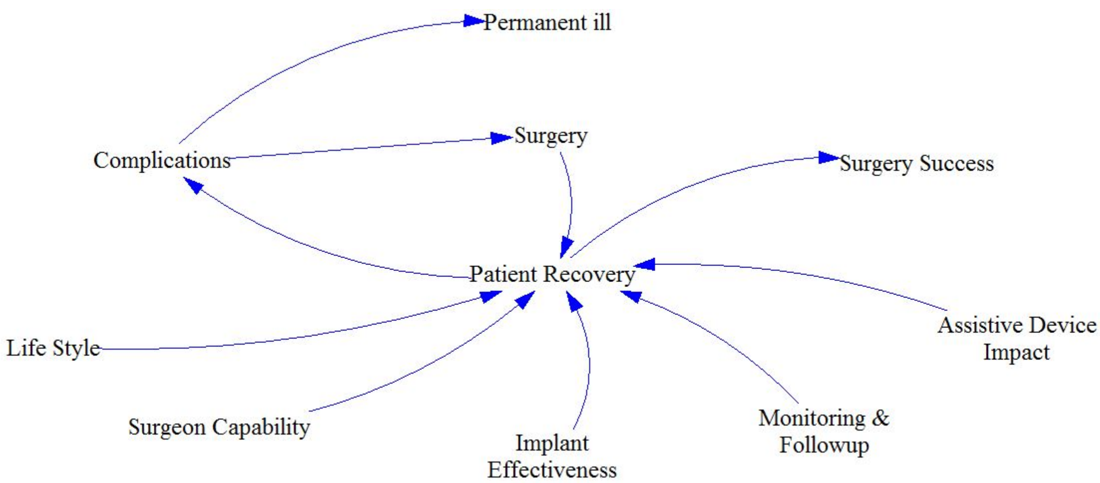


Figure 4.1: This diagram visualizes 1st degree key factors influencing the success of knee post-implant surgeries.

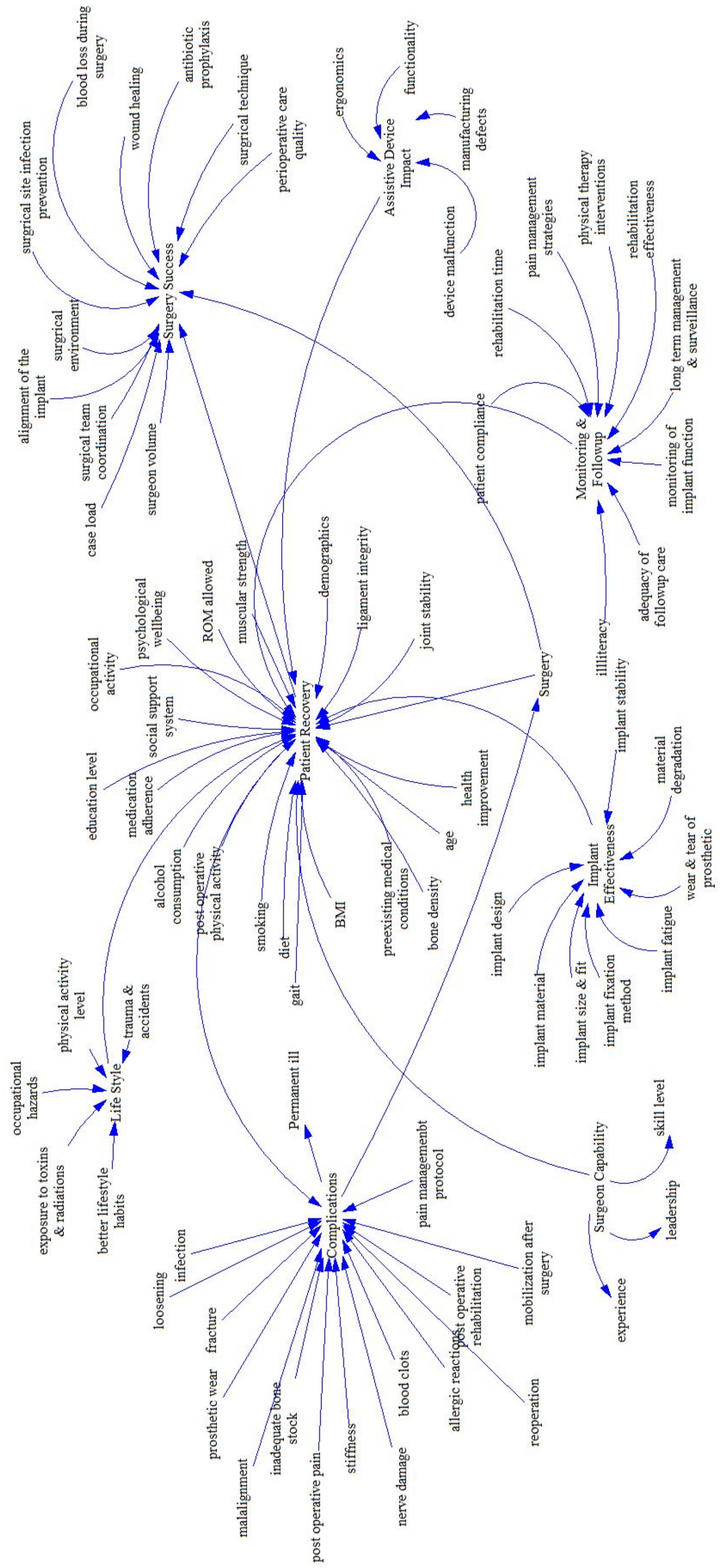


Figure 4.2: This diagram illustrates the original complex network of second-degree variables that influence the results of post-knee-implant surgeries.

Sr. no.	Patient-Related Factors	
1	Patient diet	Nutritional status
		Nutrient intake (e.g., vitamins, minerals)
		Dietary habits and choices
2	Patient gait	Musculoskeletal system (muscle strength, joint integrity)
		Balance and coordination
		Sensory input (vision, proprioception)
		Neurological control
		Posture
		Range of motion
3	Patient age	Musculoskeletal changes with age
		Sensory changes with age
		Cognitive changes with age
		Metabolic changes with age
4	Patient health status	Presence of medical conditions or illnesses
		Severity and management of medical conditions
		Impact of chronic diseases on overall health
5	Body mass index (BMI)	Weight and height
		Body fat distribution
		Impact on musculoskeletal system and joints
6	Pre-existing medical conditions	Nature and severity of the medical condition
		Treatment and management of the condition
7	Diabetes control	Blood glucose levels and management
		Effect on nerves and blood vessels
8	Cardiovascular health	Heart function and blood circulation
		Endurance and fitness level
9	Respiratory health	Lung capacity and function
		Respiratory conditions or diseases
10	Bone density	Bone health and strength
		Risk of fractures and osteoporosis
11	Joint stability	Ligament and joint health
		Presence of joint-related conditions
12	Ligament integrity	Strength and health of ligaments
		Impact on joint stability
13	Muscular strength	Muscle mass and strength
		Impact on mobility and stability
14	Range of motion	Joint flexibility and mobility
		Impact on movement patterns
15	Nutritional status	Adequacy of nutrient intake
		Impact on overall health and recovery
16	Psychological well-being	Emotional and mental health
		Impact on motivation and coping mechanisms
17	Smoking status	Tobacco use and its impact on circulation and lung function
18	Alcohol consumption	Effect on balance and coordination
19	Medication adherence	Compliance with prescribed medications
		Effect on disease management
20	Education level	Impact on health literacy and understanding of medical information
21	Occupational factors	Nature of work and its impact on physical demands
22	Postoperative physical activity level	Level of activity and exercise after surgery
23	Social support system	Presence of a supportive network of family and friends
		Impact on mental health and recovery

Table 4.1: Pateint related factors

Sr. no.	Surgeon, Surgical, and Implant Related Factors	
1	Surgeon experience and skill level	Years of experience in performing surgeries
		Number of surgeries performed
		Training and specialization in the specific procedure
		Continuous professional development and learning
2	Surgeon volume and case load	Number of surgeries performed within a specific time frame
		Variety of cases encountered
		Impact on familiarity and proficiency with the procedure
3	Surgical team coordination	Communication and teamwork among surgical team members
		Ability to work together efficiently during the procedure
4	Implant design	Engineering and design of the implant
		Features and specifications of the implant
5	Implant material	Type of material used for the implant (e.g., metal, ceramic, polymer)
		Biocompatibility and suitability for the patient
6	Implant size and fit	Customization of the implant to match the patient's anatomy
		Proper fit within the joint or bone structure
7	Implant fixation method	Technique used to secure the implant in place (e.g., cemented, press fit, hybrid)
8	Surgical technique	Approach and method used during the surgery
		Precision and accuracy of the surgical steps
9	Perioperative care quality	Quality of care provided before, during, and after the surgery
		Impact on patient outcomes and recovery
10	Antibiotic prophylaxis	Use of antibiotics to prevent infection during surgery
		Effectiveness in reducing the risk of infection
11	Wound healing	Ability of the patient's body to heal the surgical incision or wound
		Impact on recovery and complication rates
12	Blood loss during surgery	Amount of blood loss during the procedure
		Effect on patient's hemodynamic stability and recovery
13	Surgical site infection prevention measures	Precautions taken to minimize the risk of infections at the surgical site
		Impact on postoperative infection rates
14	Proper alignment of the implant	Precision in aligning the implant within the joint or bone structure
		Effect on joint function and implant longevity
15	Implant stability	Ability of the implant to remain securely in place over time
		Impact on long term outcomes and implant survival.

Table 4.2: Surgeon, Surgical, and Implant-Related Factors

Sr. no.	**Complications and Post Surgery Factors**	
1	Infection	Surgical site cleanliness and hygiene
		Proper wound care and infection prevention measures
		Effectiveness of antibiotic prophylaxis
		Patient's immune system and ability to fight infections
2	Loosening	Proper implant fixation method and stability
		Surgical technique and precision in implant placement
		Quality of bone implant interface
3	Fracture	Adequate bone density and strength
		Appropriate implant size and fit
		Surgical technique and precision
		Proper alignment of the implant
4	Prosthetic wear	Type and quality of implant material
		Joint mechanics and patient activity level
		Alignment and fit of the implant
5	Malalignment	Surgical technique and precision in implant placement
		Proper alignment and fit of the implant
6	Inadequate bone stock	Preoperative bone health and density
		Previous bone loss due to injury or medical conditions
7	Postoperative pain	Surgical technique and trauma to surrounding tissues
		Effectiveness of pain management protocols
		Individual pain tolerance and sensitivity
8	Stiffness	Extent of soft tissue damage during surgery
		Postoperative rehabilitation and range of motion exercises
9	Nerve damage	Surgical technique and proximity to nerves
		Individual patient anatomy and nerve sensitivity
10	Blood clots	Postoperative immobility and reduced blood flow
		Effectiveness of blood clot prevention measures
11	Allergic reactions	Patient's immune response to implant materials or medications
12	Reoperation	Failure of the initial surgery to address the problem
		Complications or unsatisfactory outcomes
13	Poor postoperative rehabilitation	Quality and consistency of rehabilitation programs
		Patient compliance with rehabilitation protocols
14	Delayed mobilization after surgery	Patient's overall health and healing ability
		Postoperative pain management and comfort level
15	Pain management protocol	Type and administration of pain medications
		Patient's response to pain management strategies.

Table 4.3: Complications and Post-Surgery Factors

Sr. no.	**Product and Device Related Factors**	
1	Manufacturing defects	Quality control during the manufacturing process
		Materials used in manufacturing
		Compliance with industry standards and regulations
2	Material degradation	Choice of materials for the implant
		Exposure to environmental factors (e.g., temperature, moisture)
3	Device malfunction	Engineering and design of the implant
		Materials used in the device
		Wear and tear over time
4	Wear and tear of prosthetics	Patient activity level and usage of the prosthetic
		Type and quality of materials used in the prosthetic
5	Implant fatigue	Cyclic loading and stress on the implant
		Material properties and durability of the implant
6	Poor fit or sizing of the implant	Proper preoperative planning and measurements
		Surgical technique and precision in implant placement.

Table 4.4: Product and Device-Related Factors

Sr. no.	**Environmental and Lifestyle Factors**	
1	Trauma or accidents	Type and severity of the trauma or accident
		Force and impact involved in the injury
		Individual healing ability and overall health status
2	Physical activity level	Type, duration, and intensity of physical activities
		Impact on musculoskeletal health and joint function
		Presence of proper warm up and cool down routines
3	Occupational hazards	Nature of occupational tasks and demands
		Exposure to repetitive movements or heavy lifting
		Use of proper protective equipment
4	Exposure to toxins or radiation	Type and duration of exposure to harmful substances
		Impact on bone health, tissues, and overall health
5	Changes in lifestyle habits	Diet and nutritional choices
		Smoking and alcohol consumption
		Physical activity and exercise routines.

Table 4.5: Environmental and Lifestyle Factors

Sr. no.	**Follow Up and Monitoring Factors**	
1	Adequacy of follow up care	Patient compliance with follow up appointments
		Quality of healthcare facilities and resources
		Monitoring of postoperative progress and potential complications
2	Monitoring of implant stability and function	Regular radiographic evaluations
		Clinical assessments by healthcare professionals
		Patient reported symptoms and experiences
3	Long term management and surveillance	Ongoing healthcare provider involvement
		Continuation of appropriate postoperative care and protocols
		Monitoring for potential long term complications or wear related issues
4	Rehabilitation program effectiveness	Tailoring of rehabilitation programs to individual patient needs
		Compliance with rehabilitation protocols
		Regular assessments of patient progress and outcomes
5	Physical therapy interventions	Appropriateness and frequency of physical therapy sessions
		Type and level of exercises prescribed
		Collaboration between the physical therapist and the patient
6	Pain management strategies	Individual patient pain tolerance and preferences
		Efficacy of pain medications and therapies
		Adjustment of the pain management plan based on the patient's response
7	Postoperative rehabilitation timeline	Duration and intensity of the rehabilitation program
		Early mobilization and activity progression
		Factors affecting the patient's readiness for different stages of rehabilitation.

Table 4.6: Follow-Up and Monitoring Factors

These factors collectively form the system under consideration in this case study of implant surgery outcomes in Pakistan. They provide the basis for a comprehensive analysis of the intricate web of influences affecting these outcomes. The interrelationships among these factors are central to understanding the complexity of this healthcare context and devising strategies for improvement. In the context of this research on post-implant surgery outcomes in Pakistan's healthcare system, several critical factors have been identified. These factors represent the complex interplay of variables that influence the success of implant surgeries and patient recovery. Here is a summary of the key factors that have been extracted from the scenario (factors are assigned characteristics for making elaborative link between other factors in network diagram. The main stock has also been reinstated for more meaningful network diagram) as shown in figure 4.3. Moreover, these factors are also stated in below table (4.7).

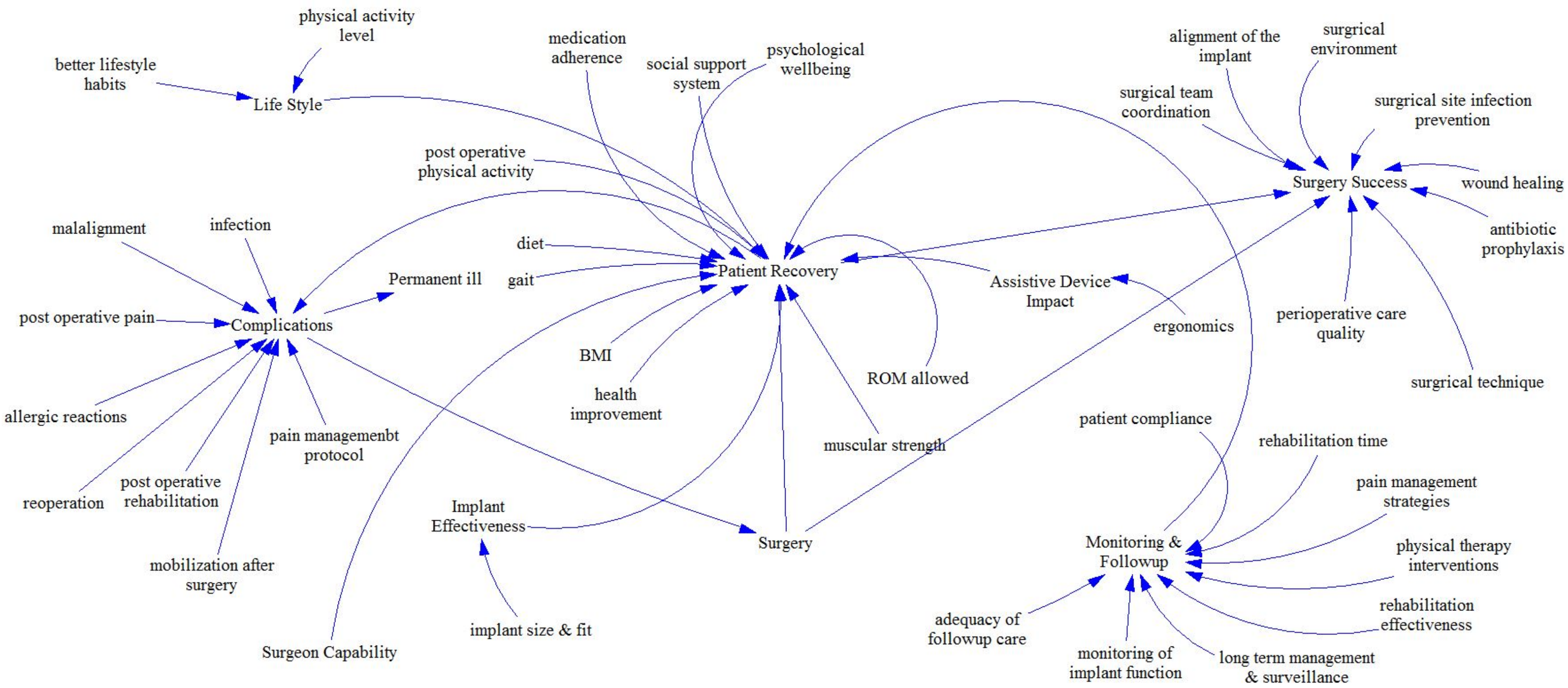


Figure 4.3: This diagram illustrates the scenario specific complex network of second-degree variables that influence the results of post-knee-implant surgeries.

Sr no.	Factors	
1	**Patient Recovery**	Patient's Good Gait
		Patient's Health Improvement
		Body Mass Index (BMI)
		Muscular Strength
		Range of Motion Allowed
		Psychological Well being
		Medication Adherence
		Postoperative Physical Activity
		Social Support System
		Good Lifestyle
		Surgery
		Device Impact
		Surgeon Credibility
		Surgery Success
		Good Monitoring and Follow up
2	**Surgery Success**	Surgical Team Coordination
		Implant Fixation Method
		Good Surgical Technique
		Perioperative Care Quality
		Antibiotic Prophylaxis
		Wound Healing
		Good Surgical Environment
		Proper Alignment of the Implant
		Surgery
3	**Complications**	Infection
		Malalignment
		Postoperative Pain
		Allergic Reactions
		Reoperation
		Poor Postoperative Rehabilitation
		Delayed Mobilization After Surgery
		Good Pain Management Protocol
		Permanent Ill
4	**Good Monitoring and Follow Up**	Adequacy of Follow Up Care
		Monitoring of Implant Stability and Function
		Long Term Management and Surveillance
		Rehabilitation Program Effectiveness
		Physical Therapy Interventions
		Pain Management Strategies
		Postoperative Rehabilitation Timeline
		Patient Compliance
5	**Product and Device Related Factors**	Poor Fit or Sizing of the Implant
6	**Device Impact**	Device Ergonomics
7	**Good Lifestyle**	Physical Activity Level
		Positive Changes in Lifestyle Habits
8	**Implant Effectiveness**	Implant Size and Fit

Table 4.7: Factors based on the scenario of Shifa Hospital Islamabad

This research employs a systems thinking approach to identify and analyze the contextual factors influencing post-operative outcomes following knee implant surgery. this research acknowledge the validity of existing research, but argue that neglecting the specific **context** in which findings are applied can limit their translatability and effectiveness. This research approach emphasizes the critical role of **context-specific analysis** in achieving optimal patient outcomes.

4.2 MoC for Hospitals

The research into developing a Model of Care (MoC) for orthopedic issues in Pakistan yielded significant insights into the best practices and requirements for a continuum of orthopedic rehabilitation services. The MoC emphasizes service delivery through multidisciplinary teams across various settings, including acute, post-acute inpatient, ambulatory, and community environments. A key finding was the importance of providing multiple and responsive access points to rehabilitation, especially community-based programs, which should be tailored to individual needs and clearly aligned with the Rehabilitation Service Plan. The evaluation from this study revealed the necessity of partnerships in patient-centered care, where family, carers, health professionals, and community services collaborate to provide integrated care. The involvement of general practitioners as a crucial component in the delivery of orthopedic rehabilitation services was also highlighted. For specific populations, such as those in rural regions and individuals from diverse cultural backgrounds, services need to adhere to the key requirements of the established models, ensuring cultural appropriateness and accessibility. The importance of ***establishing formal links*** between rural and metropolitan rehabilitation sites was identified as a crucial factor in facilitating service provision. The workforce strategy requires a focus on meeting benchmark ***requirements for training and professional development*** to ensure adequate staffing resources. The availability of multi-disciplinary teams, including allied health staff seven days a week, emerged as a vital element in commencing and maintaining timely rehabilitation, reflecting projected demand. Training and professional development for staff should be ongoing and adaptable, with strategies tailored to the specific needs of metropolitan or rural regions. In terms of infrastructure, the research underlined the need for physical infrastructure that supports evidence-based orthopedic rehabilitation care. Moreover, the use of information technology systems is crucial in enhancing service delivery and facilitating innovative models like e-rehabilitation. Quality and research components necessitate that all inpatient and ambulatory orthopedic rehabilitation sites report to national benchmarking centers, such as the Australasian Rehabilitation Outcomes Centre. The establishment of statewide databases for orthopedics, with minimum data sets for reporting, and the implementation of statewide quality initiatives, were identified as measures that promote consistency and minimize duplication.

The model evaluation process highlighted the importance of assessing the implementation of orthopedic rehabilitation models to facilitate continuous improvement, with a focus on process, impact, outcome, and structure. The evaluation of the arthroplasty rehabilitation model provided a template that includes process adherence, patient and general practitioner satisfaction, quality of life outcomes, and cost-effectiveness as key indicators.

Now, diving into specific orthopedic domains, the subsequent sections delineate tailored approaches for Fragility Fractures, General Orthopaedic Trauma, and Arthroplasty Rehabilitation. Each section presents nuanced strategies, highlighting the importance of community management, accessibility, and integration with projects like ADAM for arthroplasty rehabilitation from best health practices in Australia. These insights collectively contribute to the overarching goal of enhancing orthopedic rehabilitation services in Pakistan, ensuring quality, accessibility, and continuous improvement.

4.2.1 Fragility Fractures

For fragility fractures, acute management should prioritize community management wherever possible, reserving hospitalization for those needing acute or orthogeriatric care. The role of hospital-based fragility fracture coordinators in developing patient care plans emerged as crucial for ensuring appropriate support and commencement of secondary prevention post-discharge, As shown in figure(6).

4.2.2 General Orthopaedic Trauma

In terms of general orthopaedic trauma, the research stressed the importance of service accessibility and equity across the continuum. Acute initial management should be based on the severity and nature of the trauma, with timely surgical intervention and commencement of rehabilitation being key determinants of successful acute inpatient care, As shown in figure 4.4.

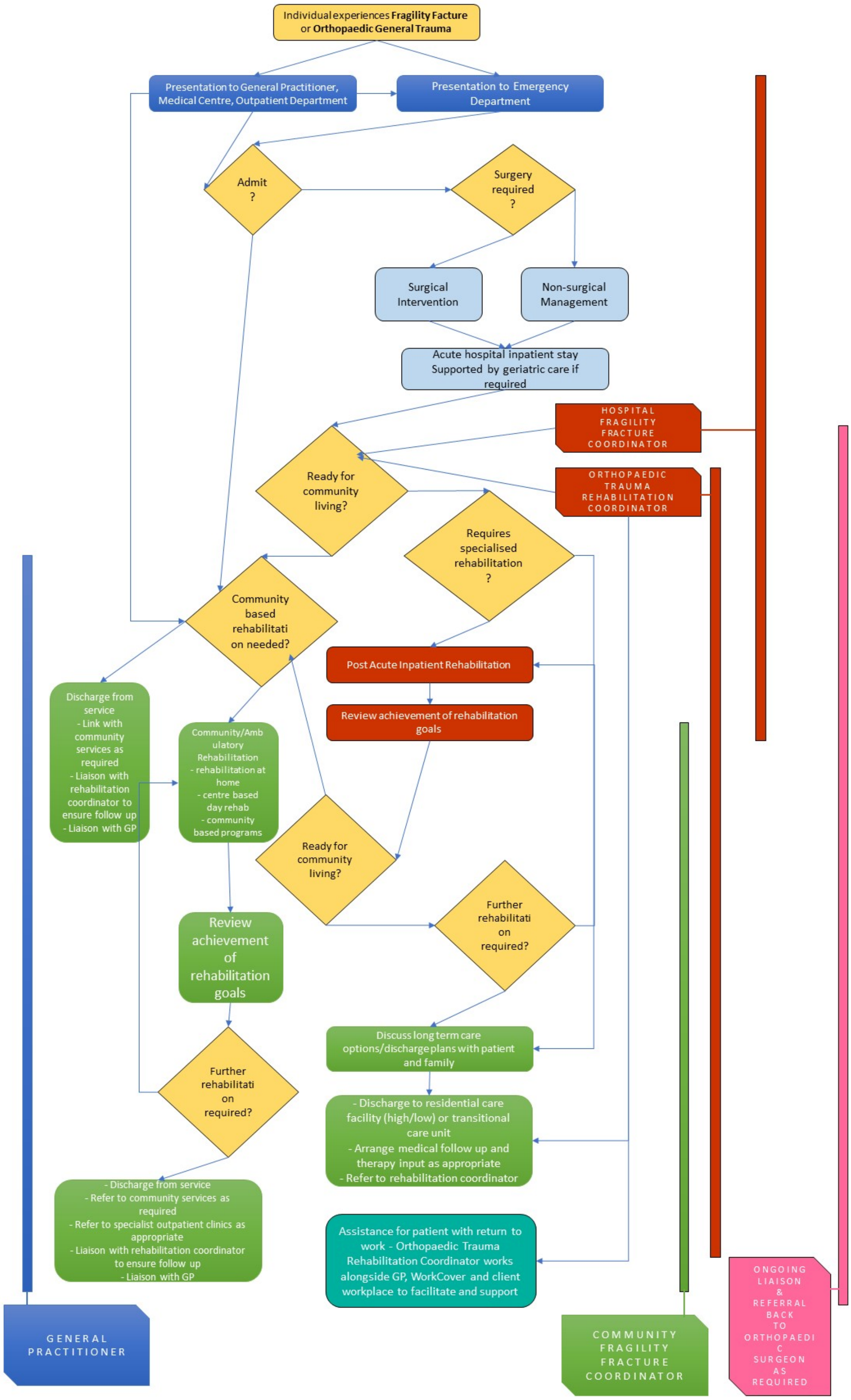


Figure 4.4: Orthopedic care journey: Consultation to community rehab, highlighting fragility fractures and trauma management.

4.2.3 Arthroplasty Rehabilitation

For arthroplasty rehabilitation, the integration of service continuum with projects like ADAM is essential to ensure seamless care throughout the patient's journey. The findings also emphasize the importance of ongoing maintenance and function after arthroplasty surgery, with access to community support services and long-term follow-up being paramount for patient recovery and quality of life, As shown in figure 4.5.

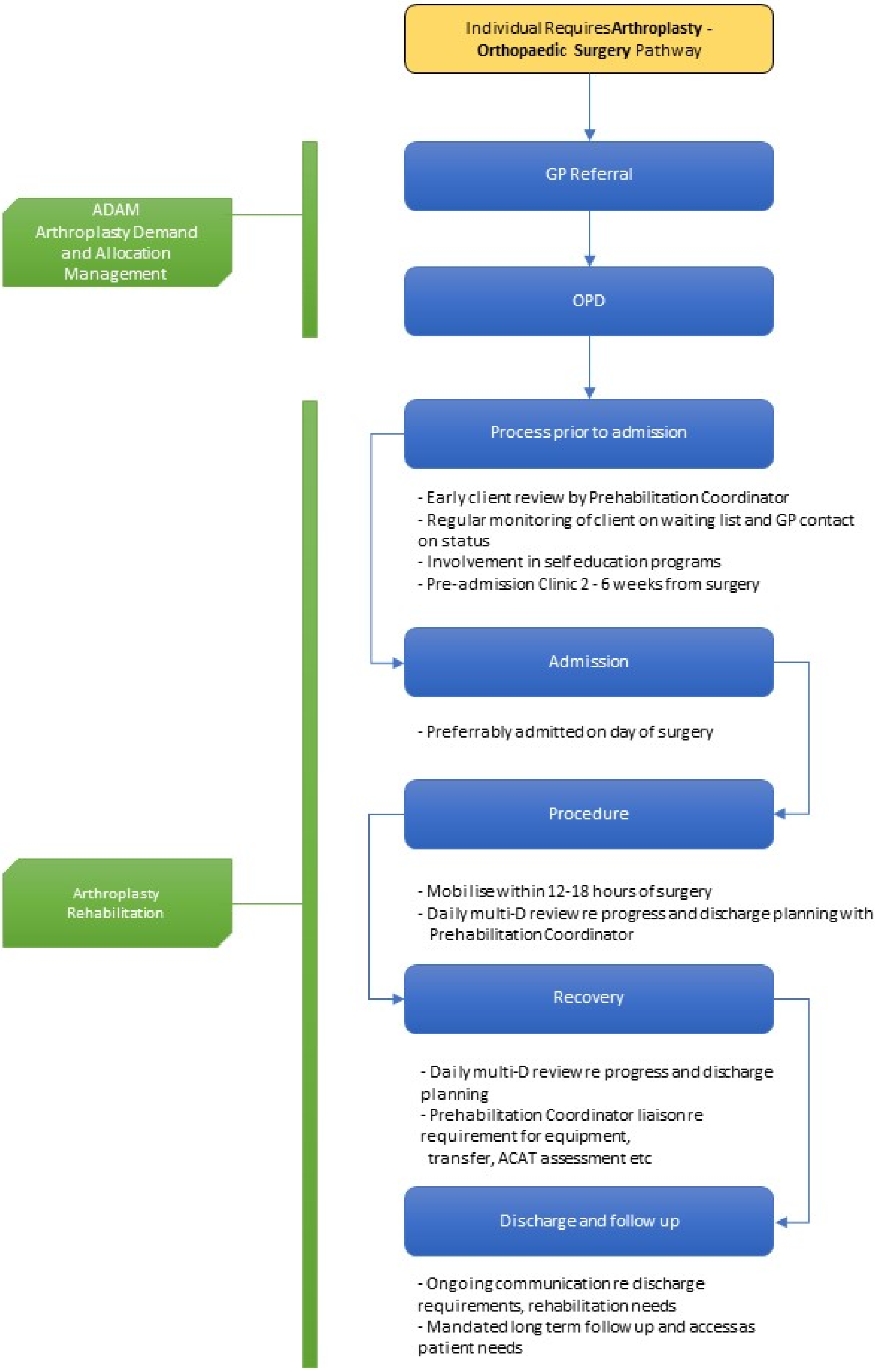


Figure 4.5: Patient guide to arthroplasty rehab: Clear path to recovery with prehab and community support.

4.3 MoC for Hospitals & Patients - Booking Mechanism

The given below flowchart shows smooth booking mechanism for both patients and doctors 4.6.

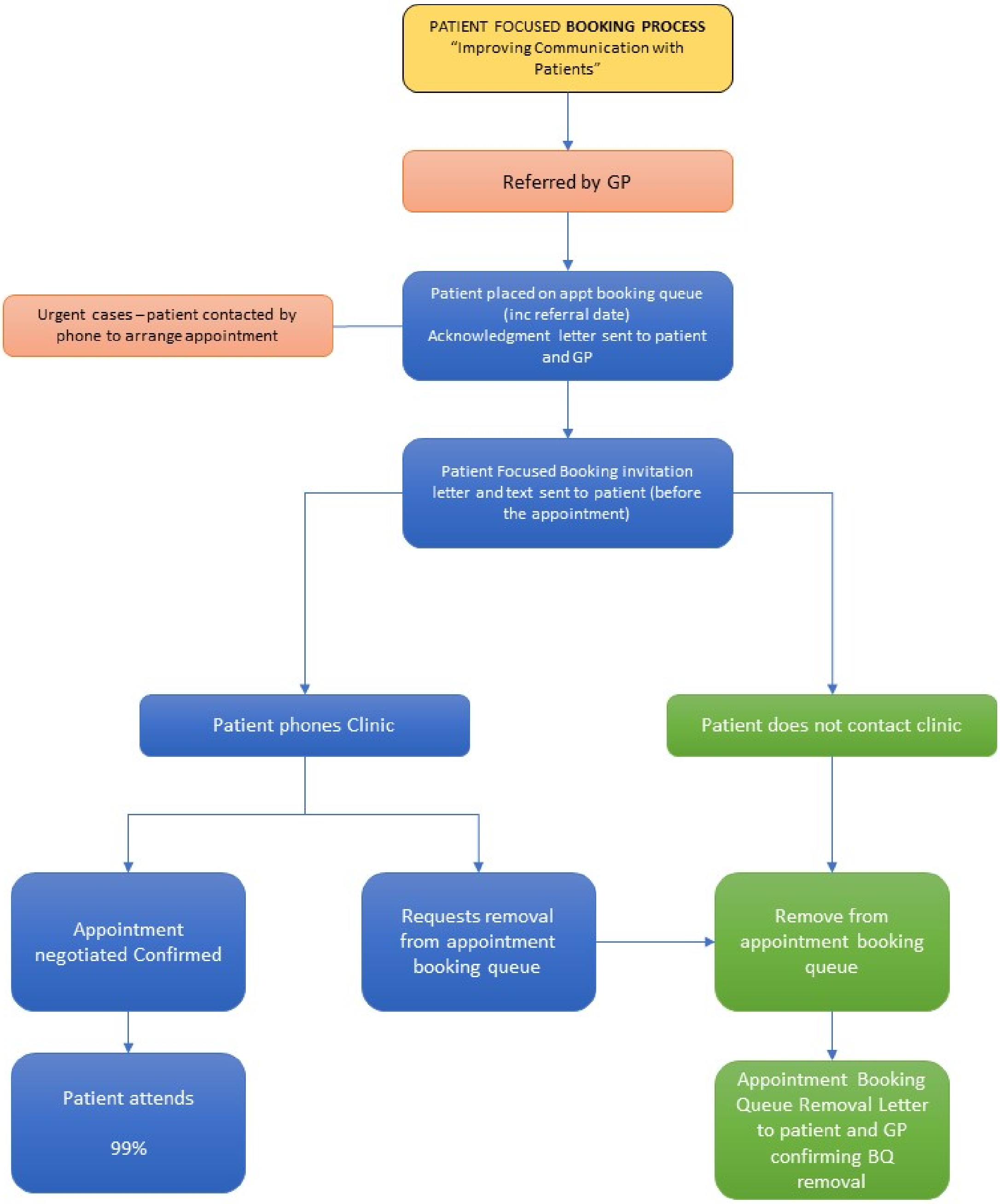


Figure 4.6: This flowchart presents the patient-focused booking mechanism designed to improve communication and efficiency in scheduling orthopedic procedures, emphasizing the integration of patient and practitioner involvement from referral to appointment attendance.

4.4 MoC for Patient - Perioperative Guide Glimpse

Perioperative guide are presented in leaflets given in appendices, here is a short 4.8 overview of that.

Title	Summary
Perioperative Team and Patient Empowerment	A multidisciplinary team approach is the foundation of effective perioperative care. The patient's active participation in their care is central to this model.
Preoperative Preparation	The MoC emphasizes preoperative preparation, advocating for patients to improve their physical condition prior to surgery.
Managing Medical Conditions	Optimal control of pre-existing medical conditions is crucial for a smooth recovery. The MoC encourages regular health checks and management of these conditions.
Mental Health and Dental Health	The MoC provides for the assessment and support of patients' mental health needs, including the management of preoperative anxiety. Dental health is also addressed.
Surgery Readiness & Postoperative Care	Patients are guided on how to ready themselves for surgery and are encouraged to engage in 'DrEaMing'—Drinking, Eating, and Mobilising—as soon as medically feasible.
Enhanced Recovery Programs	The MoC draws from the principles of enhanced recovery programs, which are designed to return patients to their preoperative health status as quickly as possible.

Table 4.8: Perioperative guide glimpse.

4.5 MoC for Patient Before General Physician Visit

The leaflet contains the guide for decision making and queries for a patient to ask when visiting his/her physician before surgery is given in supplementary material. This leaflet is a guide for patients to make the most of their medical appointments. It stresses the importance of understanding the potential paths of action regarding treatment, including the option to delay treatment if the patient wishes. It prompts patients to consider discussions with healthcare professionals about the benefits, risks, alternatives, and outcomes of not pursuing treatment. The guide suggests patients should deliberate these options with their support system and come prepared with questions to their medical appointment to ensure they have all the necessary information to make informed decisions about their health.

4.6 State-of-the-Art Rehabilitation Devices

Successful rehabilitation is critical for patients recovering from total knee arthroplasty (TKA), also known as knee replacement surgery. Advancements in technology are creating a new generation of assistive devices to aid in post-TKA rehabilitation. This report explores the state-of-the-art in rehabilitation devices, analyzing the different technologies used and the benefits they offer to the patients. this research then examine current market trends, including a survey of user reviews for various rehabilitation device manufacturers. Finally, the report identifies a gap in the application of these existing technologies and proposes the development of a culturally-appropriate and cost-effective solution specifically designed for TKA patients in Pakistan.

4.6.1 Key Areas for Rehab Devices

Successful rehabilitation is crucial for maximizing long-term outcomes and optimizing quality of life. Advancements in assistive technology are revolutionizing post-TKA rehabilitation, offering patients a wider range of tools to support their recovery journey. Here's a table 4.9 summarizing key areas in state-of-the-art rehabilitation devices for TKA patients.

Category	Technology	Description	Benefits
Sensor-based Technologies	Wearable Sensors (accelerometers, gyroscopes, magnetometers)	Track joint motion, ROM, gait patterns	Real-time data collection, personalized feedback, progress monitoring
	Smart Implants	Sensors integrated into prosthetic implants	Monitor joint stress, stability
Assistive Devices	Continuous Passive Motion (CPM) Machines (lighter, portable, user-friendly)	Provide passive joint movement	Improve ROM, reduce stiffness
	Robotic Exoskeletons	Wearable devices with controlled mechanical assistance	Facilitate proper gait mechanics, promote weight-bearing exercises
Advanced Monitoring Systems	Smartphone-based Systems (paired with wearable sensors)	Monitor rehabilitation exercises through apps	Real-time visual feedback, adherence encouragement
	Telehealth Platforms	Remote monitoring platforms for therapists and patients	Track progress remotely, personalize exercise plans, offer virtual consultations.

Table 4.9: Key areas of TKA rehab devices.

The average cost of devices (typically in under-developed countries) are as under:

- **Wearable Sensors:** \$100 - \$500+ (depending on complexity and features)
- **Continuous Passive Motion (CPM) Machines:** \$1,000 - \$10,000+ (usually rented for recovery period)
- **Robotic Exoskeletons:** \$10,000 - \$100,000+ (generally used in clinical settings)

4.6.2 A Market Survey

This section analyzes existing market trends in assistive rehabilitation devices for post-TKA recovery. A selection of companies whose data was available within the identified key areas were evaluated based on user reviews and ratings as shown in table 4.10.

Company	5-Star (%)	4-Star (%)	3-Star (%)	2-Star (%)	1-Star (%)	Total	Rating
DonJoy	57%	13%	10%	5%	16%	139.00%	5.0232
Bauerfeind	73%	14%	5%	3%	5%	226.00%	5.0377
Breg	17%	22%	0%	17%	44%	-71.00%	4.9882
ProCare	53%	15%	14%	7%	10%	145.00%	5.0242
BioSkin	48%	22%	12%	8%	10%	142.00%	5.0237
VQ OrthoCare	40%	0%	0%	0%	60%	-60.00%	4.99
McDavid	61%	17%	12%	3%	7%	190.00%	5.0317
Shock Doctor	22%	20%	19%	19%	20%	8.00%	5.0013
Össur (Not Listed)	12%	25%	21%	14%	27%	-23.00%	4.9962
Medi	24%	16%	9%	20%	31%	-29.00%	4.9952

Table 4.10: Market survey and corresponding ratings(-300 to 300 % using the formula 2x5star+4star-2star-2x1star) assigned.

Data Acquisition and Analysis:

- Ten companies were chosen for review analysis: ***DonJoy*** (Mueller Sports Med), ***Bauerfeind, ProCare, BioSkin, VQ OrthoCare, McDavid, Shock Doctor, Össur,*** and ***Medi***. Data for ***Breg, Sensoria,*** and ***Kimia*** was unavailable.
- A rating breakdown was compiled, categorizing reviews into 5-star (highly satisfied), 4-star (satisfied), 3-star (neutral), 2-star (dissatisfied), and 1-star (very dissatisfied) ratings.

Findings:

- Bauerfeind and McDavid exhibited the highest overall customer satisfaction within the sample. Both companies received a significant percentage (over 57%) of 5-star ratings and minimal negative feedback (under 8% of reviews fell into the 1-star category).
- Other companies within the sample demonstrated a wider range of user satisfaction ratings. While some, like ProCare and BioSkin, maintained a majority of positive reviews

(over 50% of reviews were 4-star or 5-star), others like Breg and Shock Doctor received a more balanced distribution of ratings across the spectrum.

- Limited data was available for Össur. Further investigation into the company's product offerings and user reviews may be necessary, but for the sake of progress, the analysis proceeds.

This analysis is based on a limited sample of companies and online review platforms. A more comprehensive understanding of the market landscape may require including additional brands and broader data sources. User reviews can be subjective and may not reflect the effectiveness of a device for all users. It is important to consider individual needs and consult with a healthcare professional when selecting a rehabilitation device. This initial market survey suggests that ***Bauerfeind and McDavid are leaders in customer satisfaction*** within the analyzed sample of companies offering assistive rehabilitation devices for post-TKA recovery. However, further research is recommended to gain a more holistic view of the market landscape and identify the most suitable options for individual patient needs.

4.6.3 Tailored Solution

While existing market research provides valuable insights into commercially available knee braces and rehabilitation devices, a critical gap exists in their applicability to the Pakistani context. This research proposes the development of a culturally-appropriate and cost-effective solution specifically designed to address the unique challenges faced by post-TKA patients in Pakistan. This tailored approach holds immense potential for significantly improving post-surgical outcomes. Here's where the gap becomes evident:

1. **Cost-Effectiveness:** The brace design should prioritize affordability to ensure accessibility for a wider patient population.
2. **Patient Education:** Educational materials and support programs are crucial to empower patients with knowledge about proper brace usage and post-surgical rehabilitation.
3. **Distribution and Access:** A robust distribution plan is necessary to ensure the brace reaches patients in underserved and remote areas.
4. **Local Adaptation:** Collaboration with local medical professionals can help tailor the brace design to the specific physiological needs of the Pakistani population.

5. **Monitoring and Follow-Up:** Implementing a system for remote monitoring and follow-up care, especially in resource-limited areas, is essential for timely problem identification and improved overall outcomes.

6. **Continuous Improvement:** Ongoing research and development efforts should address emerging challenges and incorporate feedback from patients and healthcare providers to continuously refine the brace's effectiveness.

By addressing these considerations, this research proposes a targeted approach to bridge the gap between existing rehabilitation technologies and the specific needs of the Pakistani healthcare system. This custom-designed knee rehabilitation device, coupled with educational initiatives and accessible follow-up care, has the potential to significantly improve post-TKA outcomes for patients in Pakistan.

4.7 Designing of Prototype

4.7.1 Device Features

This table 4.11 outlines the specifications of the proposed post-TKA rehabilitation device and how each feature addresses the key considerations for a culturally-appropriate and cost-effective solution in Pakistan.

4.7.2 Components

i. Esp32 Wroom 32 Microcontroller (a)

ii. Touch Sensor TTP 223 (b)

iii. Piezo Active Buzzer (c)

iv. LED (d)

v. Jumper Wires (e)

vi. OLED Display SSD 1306 (f)

vii. GY521 MPU6050 Gyroscope Accelerometer Sensor Module (g)

viii. TP4056 Li-Ion Protection and Charger module

Feature	Specification	Addresses Key Consideration
Cost	Low-cost materials and manufacturing processes	Low Cost: Ensures affordability and accessibility for a wider patient population in Pakistan.
Technology Readiness Level (TRL)	Viable (TRL 4-6)	TRL Viable: Utilizes proven technologies and focuses on prototype development and testing in a relevant environment (Pakistan).
Feasibility in Pakistan Context	Adaptable design and low power consumption	Feasible in Context: Accounts for resource limitations and potential lack of consistent power access.
Open-source Technology (OTA) Platform (Thingsboard)	Cloud-based platform for remote monitoring and data management	Cost-Effective & Distribution: Leverages existing open-source platform to minimize development costs and facilitate potential integration with existing healthcare infrastructure.
Angle Setting	Adjustable range of motion based on rehabilitation protocols	Patient Education & Local Adaptation: Allows customization based on individual needs and potential for adaptation to local physiotherapy practices.
Device On/Off Switch	User control over device operation	Patient Education & Usability: Empowers patients and promotes user-friendliness.
Alerts at Edge (Device-level)	Audible or visual notifications for incorrect movement patterns	Patient Education & Compliance: Provides immediate feedback to patients, promoting adherence to rehabilitation protocols.
Alerts at Cloud	Alerts sent to healthcare providers or caregivers via the cloud platform	Monitoring & Follow-up: Enables remote monitoring of patient progress and allows for timely intervention by healthcare providers.
Dashboard for Visualizations	Web-based dashboard for visualizing patient data (optional)	Monitoring & Follow-up: Provides healthcare providers with a comprehensive view of patient progress for informed decision-making.
Data Transmission to Cloud	Secure data transmission protocols	Data Security: Ensures patient data privacy and security.
Database (DB)	Secure cloud-based database for storing patient data	Data Security & Monitoring: Provides a central repository for patient data, facilitating monitoring and analysis.
Device Identification (Thingsboard Token)	Unique identifier linking device to patient	Patient Identification & Monitoring: Enables accurate data association and personalized feedback.
Movement Alerts (Optional)	Customizable alerts for exceeding or falling below pre-defined movement thresholds	Patient Education & Compliance: Provides additional feedback options for tailored rehabilitation protocols.
Calibration (Automatic)	Pre-programmed automatic calibration	Usability & Efficiency: Eliminates the need for manual calibration, simplifying device operation for patients and healthcare providers.

Table 4.11: Features mapping to key considerations

ix. 3.7v 600mah Lipo Battery

4.7.3 State Diagram

The figure 4.7 shows the device state diagram which represents its working states.

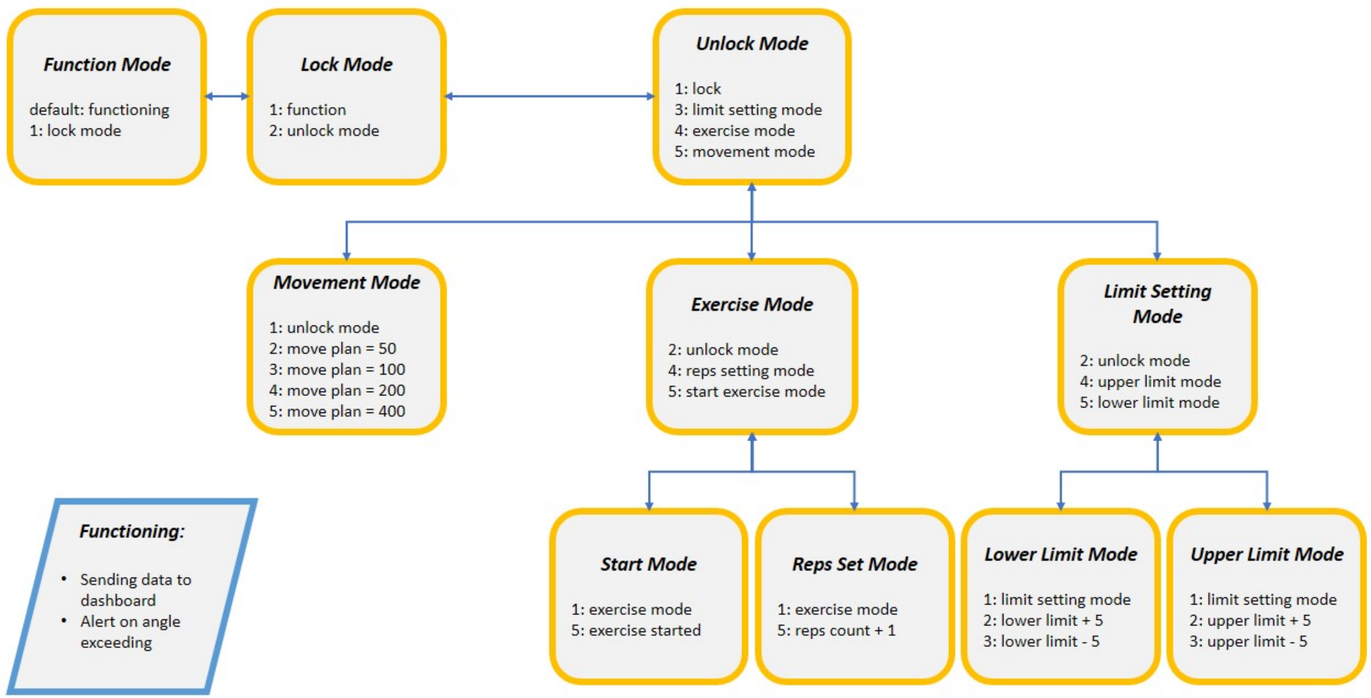


Figure 4.7: Device Operational State Diagram. This schematic depicts the device's operational modes and transitions, from the 'Function Mode' to specific 'Lock' and 'Unlock Modes'. Sub-modes include 'Movement', 'Exercise', and 'Limit Setting', with functionalities such as data transmission, angle monitoring, and parameter adjustment. This diagram is key to comprehending the device's operational dynamics.

4.7.4 Circuit Diagram

The figure 4.8 shows the circuit diagram of the device.

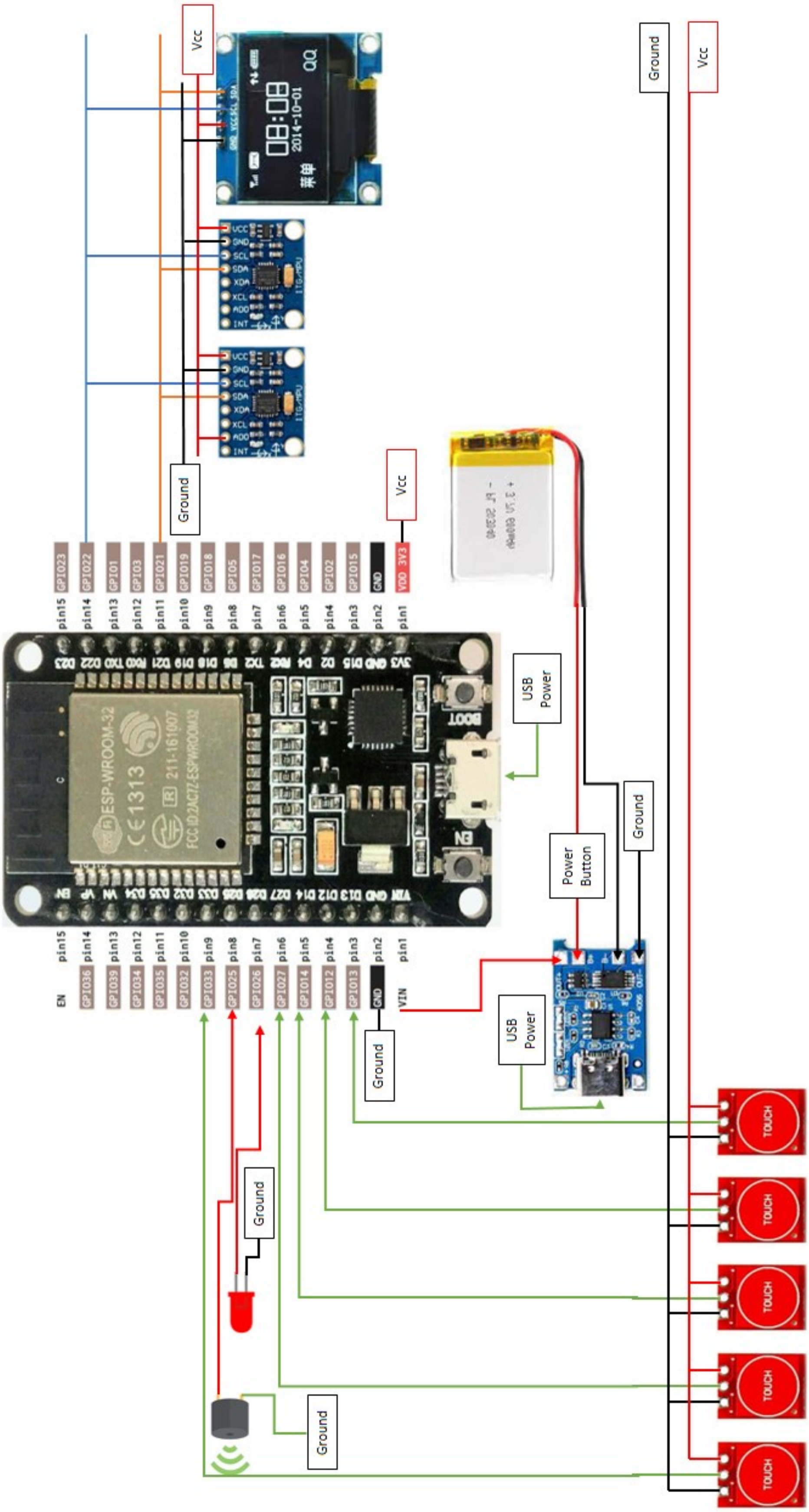


Figure 4.8: Schematic details: Connections for all components, power, & outputs.

4.7.5 Prototyping Details

Thsi Research have developed assistive technology designed to aid patients during knee transplant recovery. This technology focuses on embedded device development rather than the material perspective. Research goal is to provide guidance to patients through their recovery journey, translating to features such as maintaining the patient in a prescribed position (angle of the knee joint) and guiding movement exercises. The device incorporates edge computing capabilities to ensure patient privacy and usability in underdeveloped areas. Additionally, the device collects raw data on the patient's joint angle, pitch, roll, and yaw acceleration for future research. This data can be used to apply machine/deep learning, developing models that predict recovery time and identify potential injury risks due to inefficient or extensive movements. The device operates both with and without internet connectivity, featuring a battery backup and charging capability for wireless use. The embedded device is programmable, allowing qualified assistive technology developers to update the core code. Furthermore, This research intends to make the technology open source to foster research and development. The device configuration follows the circuit diagram, incorporating touch sensors for navigation, a buzzer, and LED for patient alerts when the angle exceeds the prescribed limit. Power can be supplied either through a battery or the main supply. An OLED display provides information about the current state and angle.

To understand how the angle is obtained, it is essential to delve into the detailed working of the MPU6050. It is a versatile 6-axis MotionTracking device designed to provide accurate and precise motion information. It integrates a 3-axis gyroscope, a 3-axis accelerometer, and a Digital Motion Processor (DMP) into a small package. Let's break down the information and elaborate on the workings of the MPU6050:

Working of the Accelerometer

1. Weightless State Illustration: In a weightless state (e.g., in outer space), imagine a ball inside a 3D cube. If the cube moves suddenly to the left with acceleration 1g, the ball will hit the wall X. This impact provides an output value of 1g along the X-axis.

2. Gravitation Force: On Earth, even if the cube is not moving, the ball still exerts a force of 1g on the Z-axis due to gravity. Accelerometers, in reality, use Micro-Electro-Mechanical Systems (MEMS) fabrication technology.

3. MEMS Accelerometer: A MEMS accelerometer is a micro-machined structure suspended by polysilicon springs. When accelerated along the X, Y, or Z axes, the structure deflects, changing the capacitance between fixed and suspended plates. This change is proportional to the acceleration along that axis.

Working of the Gyroscope

1. Coriolis Effect: Gyroscopes measure angular rotation using the Coriolis Effect. When a mass moves with velocity, and an external angular rate is applied, the Coriolis Effect generates a force perpendicular to the direction of movement.

2. MEMS Gyroscope: The MEMS gyroscope has a proof mass that oscillates continuously, responding to the Coriolis effect when the structure is rotated. The sensor detects this change in capacitance (Δ C) caused by the Coriolis effect and converts it into a voltage signal.

3. Modes of Operation:
   - Roll Mode: Angular rate along the X-axis.
   - Pitch Mode: Angular rate along the Y-axis.
   - Yaw Mode: Angular rate along the Z-axis.

4. Measuring Acceleration:
   - The MPU6050's accelerometer has programmable full scale ranges of ±2g, ±4g, ±8g, and ±16g.
   - The MPU6050's accelerometer has programmable full scale ranges of ±2g, ±4g, ±8g, and ±16g.
   - It uses three 16-bit analog-to-digital converters to simultaneously sample the three axes of movement.

5. Measuring Rotation:
   - The gyroscope measures angular rotation over programmable full scale ranges of ±250°/s, ±500°/s, ±1000°/s, and ±2000°/s.
   - Three more 16-bit analog-to-digital converters sample the three axes of rotation.

6. Measuring Temperature:

- The MPU6050 includes a temperature sensor with a range of -40 to +85°C and a ±1°C accuracy.

7. I2C Interface:

   - The module communicates with Arduino via the I2C interface, supporting addresses 0x68HEX and 0x69HEX.

8. Adding External Sensors:

   - External sensors can enhance accuracy by connecting them to the MPU6050 via a separate I2C bus.

9. Technical Specifications:

   - Operating Voltage: 5V (typical)
   - Accelerometer Range: ±2g, ±4g, ±8g, ±16g
   - Gyroscope Range: ±250°/s, ±500°/s, ±1000°/s, ±2000°/s
   - Temperature Range: -40 to +85°C
   - Asolute Maximum Acceleration: Up to 10,000g

The next stage is to calculate angle of flexion and extension while not exceeding the range of motion (ROM) – Simple mathematical approach is used for this purpose

Angle Measurement

angle = atan2(a1.acceleration.x, sqrt(a1.acceleration.y a1.acceleration.y + a1.acceleration.z a1.acceleration.z)) 180 / PI;

1. atan2 Function:

   - atan2 is a trigonometric function that returns the arctangent of the quotient of its arguments. It is used to calculate the angle whose tangent is the quotient of the specified numbers.

2. Accelerometer Values:

   - a1.acceleration.x: This represents the acceleration along the x-axis.
   - a1.acceleration.y: This represents the acceleration along the y-axis.

- a1.acceleration.z: This represents the acceleration along the z-axis.

3. Squaring and Summing Y and Z Acceleration:

    - a1.acceleration.y a1.acceleration.y + a1.acceleration.z a1.acceleration.z: This part of the formula calculates the sum of the squares of the y-axis and z-axis accelerations.

4. Square Root:

    - sqrt(a1.acceleration.y a1.acceleration.y + a1.acceleration.z a1.acceleration.z): This calculates the square root of the sum of the squares obtained in the previous step.

5. atan2 Arguments:

    - The first argument of atan2 is a1.acceleration.x, representing the acceleration along the x-axis.
    - The second argument is the result of the square root calculation, representing the magnitude of the acceleration in the y-z plane.

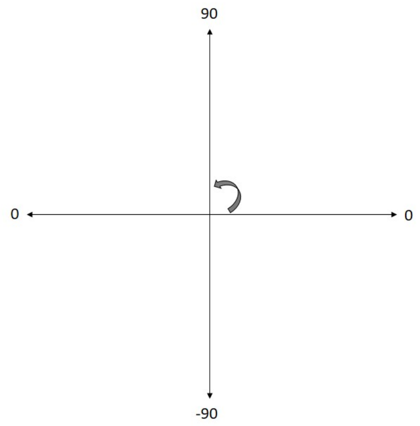
6. Converting Radians to Degrees:

    - The entire expression is multiplied by 180 / PI to convert the angle from radians to degrees.

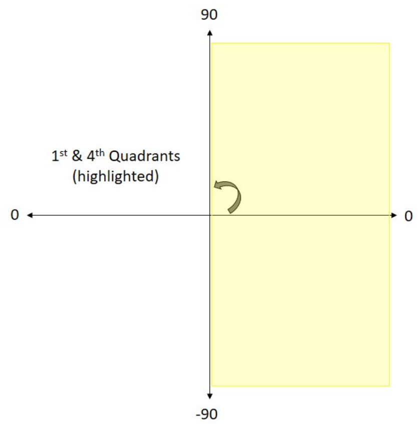
On Device MPU Placement

When considering the placement of Motion Processing Units (MPUs) for monitoring joint movements, This research encounter a challenge related to the range of motion that needed to be captured. Typically, an MPU covers a range from 0 to 90 degrees, extending further if rotating it more in the same direction. Then, it covers from 0 to -90 degrees and back to 0, completing a full circle as shown in Figure 4.9 (a). The problem with this setup is that it often requires a rotation freedom of around 180 degrees. To address this, the study adopts a different approach by using the angle range from -90 to +90, which gives us a continuous 180-degree span without any gaps or repeating values, as illustrated in figure 4.9 (b). fig 17... d1 to 1d4 here

Now, to simplify calculations, this study need to work with positive values. The research can't simply use the absolute function, as it would result in repetitive values. So, to transform range from (-90 to 90) degrees to (0 to 180) degrees, now adding +90 to the values obtained. The key



(a)



(b)

Figure 4.9: **(a)** Range of Motion Interpretation for Motion Processing Units (MPUs). This diagram illustrates the angular measurement capabilities of an MPU when tracking joint movement. It denotes the standard measurable range from 0 to 90 degrees and from 0 to -90 degrees, indicating the MPU's ability to record a full 180-degree span. This representation is critical for understanding how the MPU registers rotational motion around a single axis, which is essential for accurate joint movement monitoring in biomechanical applications. **(b)** Extended Range of Motion Coverage Using MPUs. This diagram emphasizes the enhanced measurement strategy for joint rotation, highlighting the first and fourth quadrants to illustrate the continuous 180-degree range of motion capture from -90 to +90 degrees. This approach mitigates the limitation of a 0 to 90-degree range by providing a full semi-circular span without overlap, which is essential for applications requiring comprehensive rotational analysis across a single pivot point.

question then becomes how to position MPU 1 and MPU 2 on the thigh and shin in such a way that they effectively cover the 0 to 180-degree range for both MPUs. To determine the angle between the thigh and shin, further work devised a formula:

$$CurrentAngle = (ThighAngle) - (ShinAngle) + 135$$

The thigh and shin angles are calculated separately using the equation given below:

$$hypo = sqrt(a1.acceleration.ya1.acceleration.y + a1.acceleration.za1.acceleration.z)$$

$$angle = atan2(a1.acceleration.x, hypo) * 180/PI;$$

This formula is based on the logic that this research is primarily interested in capturing the movement depicted in a specific figure 4.10. Therefore, the placement of the MPUs aligns with

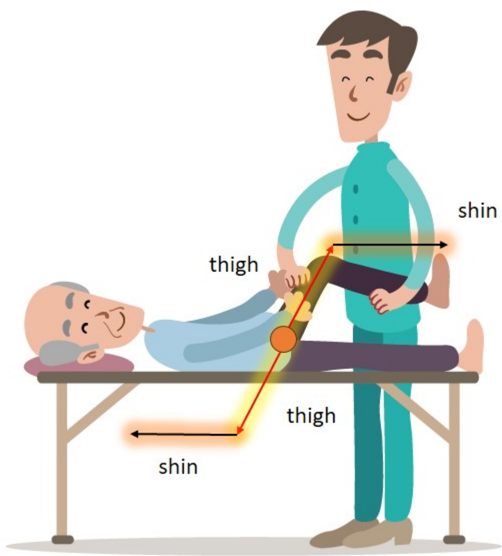


Figure 4.10: Illustration of MPU Placement for Knee Joint Angle Measurement. This image depicts the optimal positioning of two Motion Processing Units (MPU 1 and MPU 2) on the thigh and shin to measure the flexion angle of the knee joint.

the figure, ensuring accurate monitoring of the angle between the thigh and shin as specified in figure 4.11.

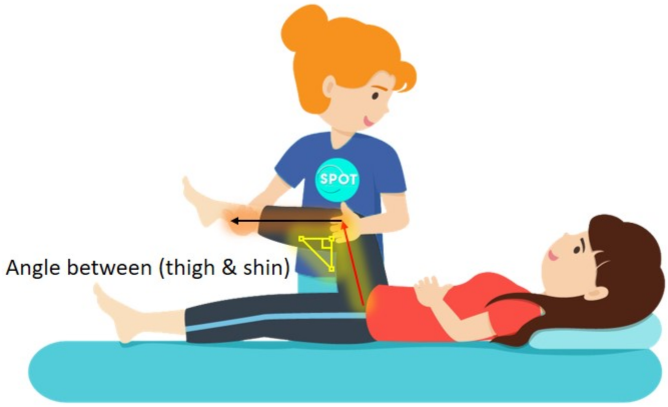


Figure 4.11: Demonstration of Knee Flexion Angle Measurement. The diagram illustrates the practical application of angle measurement between the thigh and shin. It provides a visual guide for the positioning of the device to measure the current angle.

Device Operation States

The device operates through three primary states: function mode, lock mode, and unlock mode, each with distinctive functionalities, as shown in tabular form in table 4.12

Sr No.	Mode	Description	Button Actions
1	Function Mode	Default mode, sends data, triggers alerts for exceeding limit.	Button 1: Lock Mode
2	Lock Mode	Restricts functionality.	Button 1: Function Mode, Button 2: Unlock Mode
3	Unlock Mode	Accesses additional modes.	Button 1: Lock Mode, Button 3: Limit Setting, Button 4: Exercise Mode, Button 5: Movement Mode
4	Movement Mode	Sets target movement value.	Button 1: Unlock Mode, Button 2: 50, Button 3: 100, Button 4: 200, Button 5: 400
5	Exercise Mode	Sets exercise parameters.	Button 1: Unlock Mode, Button 2: Reps Setting, Button 4: Start Exercise, Button 5: Enter Reps Setting
6	Reps Setting Mode	Sets number of repetitions.	Button 1: Exercise Mode, Button 5: Increment Reps (+1)
7	Limit Setting Mode	Sets knee movement limits.	Button 1: Unlock Mode, Button 4: Upper Limit, Button 5: Lower Limit
8	Lower Limit Mode	Sets minimum knee flexion angle.	Button 1: Limit Setting, Button 2: Increase (+5°), Button 3: Decrease (-5°)
9	Upper Limit Mode	Sets maximum knee flexion angle.	Button 1: Limit Setting, Button 2: Increase (+5°), Button 3: Decrease (-5°)
10	Start Exercise Mode	Initiates exercise routine.	Button 1: Exercise Mode, Button 5: Starts exercise (until rep count reached)

Table 4.12: Tabular form of device operational states

For visualization and enabling future research

ThingsBoard.io is an open-source IoT platform designed to facilitate the seamless integration and management of connected devices. With a focus on scalability, flexibility, and ease of use, ThingsBoard empowers businesses, developers, and enthusiasts to harness the potential of IoT applications.

Key Features are:

1. Device Management: ThingsBoard simplifies the onboarding of devices through its intuitive device management interface. Users can effortlessly register and monitor their devices, streamlining the process of adding new assets to the IoT ecosystem.

2. Data Collection and Processing: One of the core strengths of ThingsBoard lies in its

ability to efficiently collect, process, and store data from diverse IoT devices. It supports multiple data sources, making it a versatile solution for applications ranging from smart homes to industrial IoT.

3. Real-time Visualization: Real-time data visualization is a hallmark feature of ThingsBoard. Through customizable dashboards, users can monitor and analyze data streams from connected devices. The platform offers a variety of widgets and visualization tools to cater to different industry needs.

4. Rule Engine: Automating decision-making processes is made possible through ThingsBoard's Rule Engine. Users can define rules and actions based on incoming data, enabling automated responses to specific conditions or events.

5. Integration with External Systems: ThingsBoard is designed to seamlessly integrate with external systems and platforms. Whether it's third-party applications, databases, or analytics tools, the platform offers APIs and connectors for smooth interoperability.

How ThingsBoard Works

1. Device Integration: Devices, such as the ESP32 mentioned earlier, are integrated into ThingsBoard through MQTT or HTTP protocols. This integration allows devices to send telemetry data, attributes, and other relevant information to the ThingsBoard platform.

2. Telemetry and Attributes: Telemetry data represents the time-series information generated by devices. This could include sensor readings, GPS coordinates, or any other data that changes over time. Attributes, on the other hand, are static properties associated with devices.

3. MQTT and HTTP Protocols: ThingsBoard supports both the MQTT and HTTP protocols for data communication. MQTT (Message Queuing Telemetry Transport) is a lightweight, efficient protocol for devices with limited resources, while HTTP provides a more straightforward approach.

4. Device Tokens and Security: Token IDs play a crucial role in securing the communication between devices and ThingsBoard. These tokens serve as authentication keys, ensuring that only authorized devices can send data to the platform. This layer of security is vital for protecting sensitive IoT data.

5. Dashboard Creation: Users can create customizable dashboards using the ThingsBoard interface. Dashboards allow for the visualization of real-time data, historical trends, and key performance indicators. Widgets such as gauges, charts, and maps enhance the user experience.

6. Rule Engine Execution: The Rule Engine is a powerful tool within ThingsBoard that enables users to define conditions and actions based on incoming data. For instance, if a sensor reading exceeds a predefined threshold, the Rule Engine can trigger an alert or initiate a specific action.

7. External Integrations: ThingsBoard supports integrations with external systems, databases, and analytics tools. This ensures that the data collected by IoT devices can be seamlessly utilized in broader business intelligence processes.

Token IDs in ThingsBoard

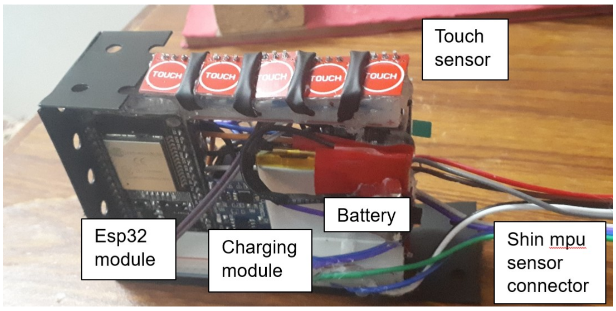
Token IDs play a crucial role in securing communication between IoT devices and the ThingsBoard platform. Each device is assigned a unique token ID, which serves as a form of authentication. When a device attempts to send telemetry data or other information to ThingsBoard, it includes its token ID in the request. ThingsBoard verifies this token ID to ensure that the device is authorized to send data. This mechanism adds a layer of security, preventing unauthorized devices from compromising the integrity of the IoT data ecosystem.

4.8 Device Conceptual Model and Testing

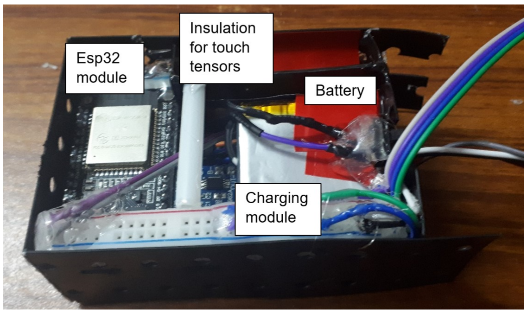
The conceptual model encompasses all the functionalities outlined in figure 4.7, and the wiring configuration faithfully follows the circuit diagram as detailed in figure 4.8. To demonstrate its practicality, the embedded device is meticulously assembled into a compact form, visually depicted in figure 4.12. Subsequently, rigorous testing ensues to validate its operational capabilities. This comprehensive assessment encompasses tasks such as establishing seamless Wi-Fi connectivity, transmitting real-time data to the thingboard.io platform as shown in figure 4.13, utilizing the exercise mode for physical rehabilitation, and assessing the efficiency of the alarm system by surpassing predefined angle limits. Remarkably, the device passes these tests with flying colors across 30 different scenarios.

Nevertheless, it's worth noting that the Achilles' heel of this innovative device lies in its battery backup system. Future endeavors will focus on engineering an enhanced battery solution with prolonged charge retention, thereby mitigating the reliance on external power sources. Additionally, the device's touch interface exhibits an exceptionally high level of sensitivity, a characteristic that can be finely calibrated in forthcoming work, leveraging its datasheet for precise control.

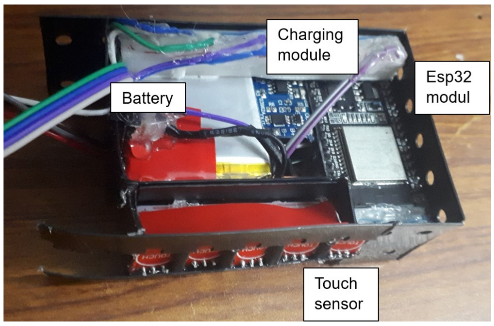
In summary, this project culminates in the successful design and development of a low-cost embedded solution, serving as an assistive technology to aid individuals in their post-total knee arthroplasty (TKA) recovery journey. The unique challenges posed by the Pakistani context, particularly in terms of technology availability, have been navigated adeptly. The Technology Readiness Level (TRL) achieved stands at completion of TRL-6 (as shown in table 4.13), with the ambition that this work will yield tangible benefits for patients in the future.



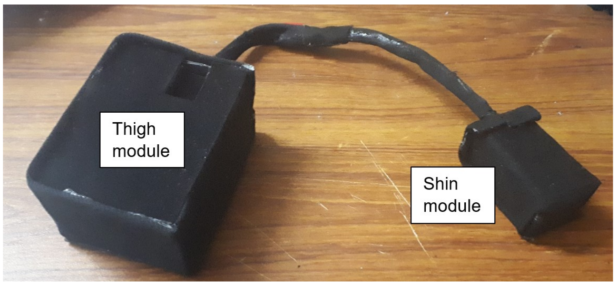
(a)



(b)



(c)



(d)

Figure 4.12: Developmental Phases and Final Assembly of the Biomechanical Monitoring Device. These images capture the sequential stages of the device's construction, leading to the completed two-part system designed for attachment to the thigh and shin. The snapshots detail the integration of components, wiring, and housing, showcasing the practical assembly process for the wearable technology for the sake of practical demonstration and testing.

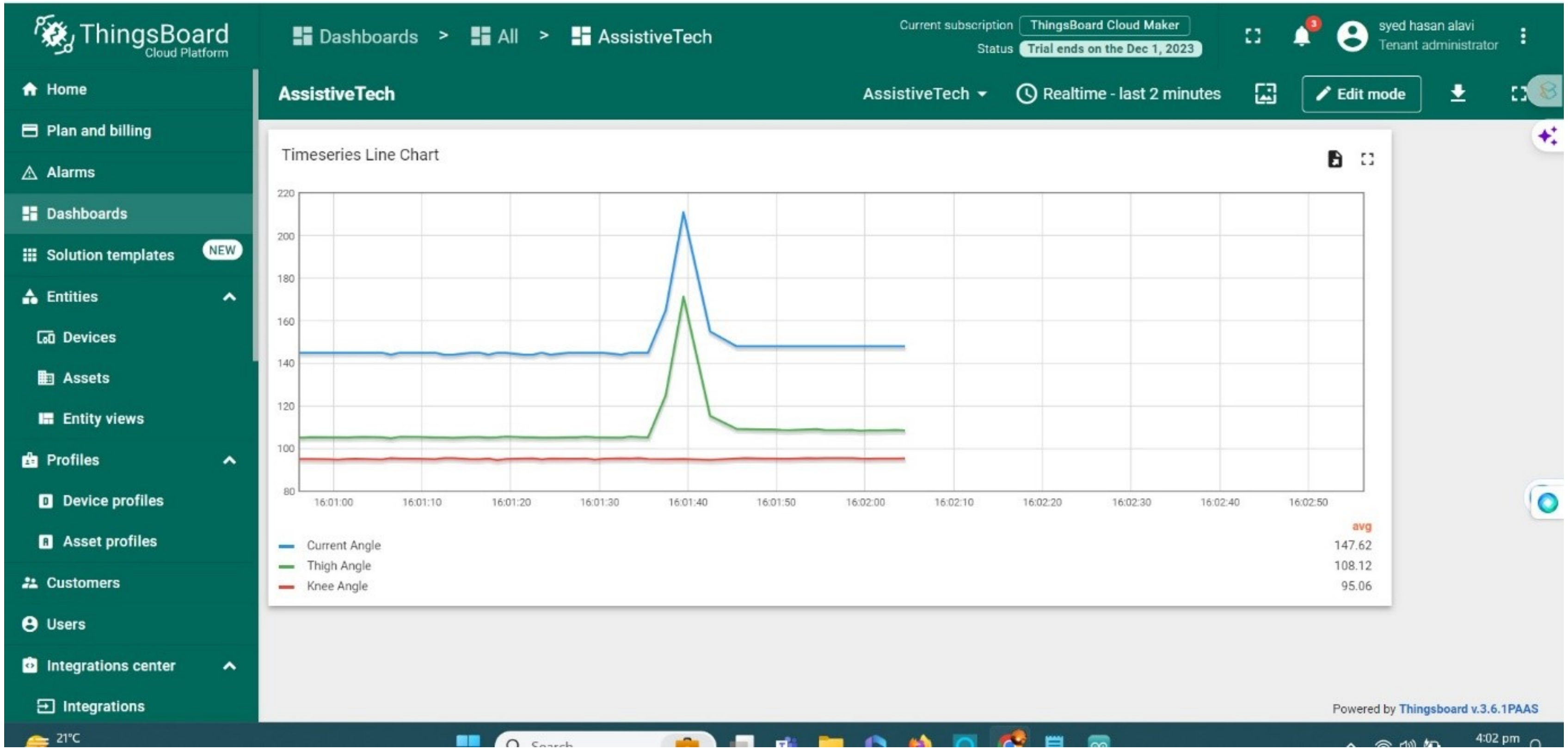


Figure 4.13: Real-time Monitoring Interface on ThingsBoard.io. This snapshot illustrates the user dashboard of the ThingsBoard.io platform, showcasing the functionality for tracking and visualizing data from device. The displayed timeseries line chart provides a clear representation of the angles monitored, including the current angle, thigh angle, and knee angle, which are stored for subsequent analysis and potential application of machine learning techniques.

4.8.1 Proposed Application

In the scenario of the ESP32-based device developed for knee transplant recovery. This device, equipped with sensors and actuators, collects data on the **patient's movements and joint angles**. The ESP32 securely communicates this data to ThingsBoard using the assigned token ID. The data is then visualized in real-time on a ThingsBoard dashboard, providing healthcare professionals with valuable insights into the patient's progress. The Rule Engine in ThingsBoard can be configured to trigger alerts if the device detects unusual patterns or potentially risky movements during the recovery process if required. The integration of design thinking principles and a structured product design and development approach has resulted in a robust and user-centric knee transplant recovery device. This methodology not only addresses the technical aspects of device development but also places a strong emphasis on human factors, usability, and real-world applicability. The iterative nature of the process allows for continuous improvement and adaptation, ensuring that the embedded device aligns with the evolving needs of both patients and healthcare providers in the context of knee transplant recovery.

4.8.2 Technology Readiness Level Analysis

Technology Readiness Level (TRL) is a systematic metric used to assess the maturity and readiness of a technology (as shown in figure 4.14). In the context of the knee transplant recovery device developed with ESP32, sensors, and ThingsBoard.io, we'll evaluate its TRL concerning its potential implementation in Pakistan.

The knee transplant recovery device is currently positioned in the completion of upper mid-range TRL levels i.e, TRL 6 (as shown in table 4.13). While the technology has advanced through conceptualization, laboratory validation, and initial prototypes, further efforts are needed to adapt and optimize the device for the unique challenges and requirements of knee transplant recovery in Pakistan. Continuous testing, user feedback, and collaboration with local healthcare stakeholders will play a crucial role in advancing the TRL and ensuring successful deployment in the Pakistani context.

Figure 4.14: Technology Readiness Level (TRL) link to figure Progression. This diagram delineates the nine developmental stages from basic principle observation (level 1) to the actual system being proven in an operational environment (level 9), providing a framework for evaluating the maturity of a technology.

TRL Level	Description	Status/Considerations
1	Basic Principles Observed	The basic principles behind the device, including the integration of sensors, microcontroller, and ThingsBoard.io for data visualization, have been observed in the laboratory setting
2	Technology Concept Formulated	The technology concept has been formulated, defining the device's functionalities and core components
3	Experimental Proof of Concept	Initial experiments and prototyping have been conducted, demonstrating the device's capabilities in controlled environments
4	Technology Validated in Laboratory	The device has been validated in a laboratory setting, showcasing its functionality and potential benefits for total knee arthroplasty recovery
5	Technology Validated in Relevant Environment	The device has undergone validation in environments relevant to knee transplant recovery, including simulated patient scenarios at BERG (biomedical engineering research group) current facility at SINES school of interdisciplinary engineering and sciences, NUST BERG.
6	System Prototype Demonstrated in Relevant Environment	A functional prototype of the knee transplant recovery device has been demonstrated in a relevant environment
7	System Prototype Tested in Operational Environment	*Feedback from potential users, healthcare professionals, and patients in Pakistan should be collected to enhance the prototype and address usability concerns. Continuous testing and refinement are required to ensure the device's reliability and effectiveness in diverse operational conditions*
8	Actual System Completed and Qualified	*Further optimizations may be necessary based on feedback, and comprehensive testing should continue to validate the system's robustness*
9	System Proven Through Successful Deployment	*Continuous monitoring, user feedback, and potential updates are essential to ensure the sustained success and improvement of the system in the Pakistani healthcare landscape*

Table 4.13: Technology Readiness Level (TRL) Progression - This table delineates the nine developmental stages from basic principle observation (level 1) to the actual system being proven in an operational environment (level 9), providing a framework for evaluating the maturity of a technology. There is successful completion of 6 TLR levels in the present study, with Additional Considerations for TLR7-9.

4.8.3 Feasibility Analysis

The feasibility study aims to assess the viability and practicality of introducing an assistive technology device for knee transplant recovery in Pakistan (as shown in table 4.14). The device, utilizing the ESP32 microcontroller, advanced sensors, and ThingsBoard.io, is designed to aid patients during the rehabilitation process. This study will consider various aspects, including technological, economic, social, and regulatory factors.

Feasibility Report

The embedded device appears to be technologically feasible within the context of Pakistan. From an economic perspective, market demand seems promising due to its cost-effectiveness compared to existing solutions, potentially resulting in a favourable return on investment. Social feasibility will depend on extensive awareness campaigns and educational efforts. Healthcare professionals appear receptive to such devices. However, regarding regulatory and legal feasibility, compliance and data security are paramount and need this ticket, but there don't seem to be any intellectual property concerns as the device is developed solely through this research.

Sr no.	Feasibility Aspect	Breakdown	Findings
1	Technological Feasibility	Hardware Availability	The hardware components, like the ESP32 microcontroller, sensors, and display modules, are generally accessible in the Pakistani technology market. However, a more indepth assessment of the local supply chain and the availability of these components in adequate quantities is necessary
		Technical Expertise	The success of the device hinges on the presence of technical expertise for tasks such as assembly, programming, and maintenance. Establishing training programs or collaborating with local technical institutions might be required to ensure a skilled workforce
		Internet Connectivity	As the device relies on ThingsBoard.io for realtime data visualization, its feasibility is tied to the accessibility and reliability of internet connectivity. Urban areas in Pakistan usually boast robust internet infrastructure, but rural regions may present challenges
2	Economic Feasibility	Cost Analysis	A comprehensive cost analysis is imperative, taking into account expenses associated with hardware components, software development, and potential customization for the local context. The affordability of the device for both healthcare institutions and individual patients is a pivotal factor
		Market Demand	It's crucial to gauge the market demand for such assistive technology devices in Pakistan. Conducting surveys or market research to assess the willingness of healthcare institutions and patients to adopt and invest in such technology is essential
		Return on Investment (ROI)	Economic feasibility is contingent on the potential return on investment. If the device proves effective in enhancing patient outcomes and reducing long-term healthcare costs, it may be economically viable for adoption
3	Social Feasibility	Acceptance & Cultural Factors	Social feasibility relies on the acceptance of this technology within the local culture. Initiatives such as public awareness campaigns and educational programs may be necessary to acquaint healthcare professionals and patients with the benefits of the device
		Patient Engagement	Ensuring patient engagement and adherence to device usage is critical. Factors like user-friendliness, cultural sensitivity, and patient education programs will greatly influence the social feasibility of the technology
		Healthcare Professional Adoption	The willingness of healthcare professionals to incorporate such technology into their practices is a determining factor. Offering training programs and workshops may be necessary to familiarize healthcare staff with the device
4	Regulatory & Legal Feasibility	Compliance with Local Regulations	Adherence to local healthcare regulations and standards is a nonnegotiable requirement. An assessment of existing regulations and potential obstacles in obtaining necessary approvals from regulatory bodies should be carried out
		Data Privacy & Security	Given the sensitivity of healthcare data, ensuring compliance with data privacy and security regulations is of utmost importance. Implementing robust security measures and obtaining necessary approvals for data collection and storage are crucial steps
		Intellectual Property Issues	Any concerns or potential conflicts related to intellectual property, particularly concerning the device's technologyand design, should be thoroughly examined to prevent legal complications

Table 4.14: Analysis of technological, economical, social and legal feasibility.

CHAPTER 5

Conclusion and Recommendations

In synthesizing the conclusions from the three areas of study - Systems Thinking, Model of Care (MoC), and assistive device development - this research presents a multifaceted approach to addressing the complexities of knee post-implant surgery outcomes. The application of systems thinking and system dynamics has provided a flexible, comprehensive framework for understanding the intricacies of healthcare challenges, especially in the context of implant surgery outcomes. This approach, adaptable across various contexts, has highlighted the importance of considering a multitude of interconnected elements and the unpredictable nature of healthcare systems. In developing the MoC, leveraging frameworks from leading healthcare systems, this research have outlined a path toward enhanced patient care in orthopedics. This includes comprehensive guides for patients, surgeons, hospital administration, and perioperative care, tailored specifically for the Pakistani healthcare context. The assistive technology developed through this research underscores the potential of low-cost, embedded devices in healthcare. Incorporating advanced sensors and edge computing, the device not only **facilitates real-time monitoring and rehabilitation** but also offers potential for future research applications, such as machine learning, to predict recovery times and identify injury risks. Collectively, these studies offer a robust foundation for improving implant surgery outcomes, marking the beginning of an ongoing journey that necessitates continued exploration, adaptation, and collaboration to meet the healthcare challenges in Pakistan and similar environments.

5.1 Limitations

In this research on improving knee post-implant surgery outcomes, this research acknowledge several limitations. Firstly, while systems thinking and system dynamics provide a comprehensive framework, they do not immediately solve the complex issues in healthcare. Practical challenges in applying these strategies within Pakistan's healthcare context may arise, requiring further context-specific investigation and adaptation. Secondly, the implementation of the developed Model of Care (MoC) is rigorous and depends heavily on the cooperation of government agencies, hospital compliance, and patient education awareness. While the MoC is grounded in international healthcare practices, its success in the local context is contingent upon effective adaptation and acceptance. Lastly, the developed assistive device faces limitations in its Technology Readiness Level (TRL), needing to undergo all three development phases before implementation in Pakistan. It requires medical association authority approvals and a manufacturing partner, presenting significant challenges in bringing this technology from concept to practical application. These limitations highlight the need for ongoing research, collaboration, and context-specific adaptations to effectively address the challenges in knee post-implant surgery outcomes in Pakistan.

5.2 Future Work

Moving forward from this research, the future work will extend the application of systems thinking and system dynamics in practical healthcare scenarios, focusing specifically on the factors impacting knee post-implant surgery outcomes in Pakistan. This will involve closely working with healthcare institutions to test and implement strategies derived from the systems analysis. The challenge lies in adapting these strategies to the unique socio-cultural and economic context of Pakistan, ensuring they are feasible and effective in the real-world setting. The Model of Care (MoC) developed in this thesis, while theoretically sound, faces its true test in practical implementation. Future efforts will concentrate on integrating the MoC into the existing workflows of select hospitals across Pakistan through pilot programs. These implementations will be closely monitored for effectiveness, requiring extensive collaboration with healthcare professionals. The objective is to adapt the MoC to the local context of each hospital, ensuring it is culturally sensitive and resource-efficient.

Training programs tailored to the needs of the healthcare staff will be a cornerstone of this implementation phase, focusing on the MoC's preoperative, intraoperative, and postoperative aspects. The effectiveness of the MoC will be evaluated through a robust monitoring framework, tracking patient outcomes, satisfaction, and complication rates. Continuous research and feedback loops will be essential for refining the MoC over time. Moreover, the future work involves technological advancements in the assistive device this research have developed. this research aim to further explore ML **machine learning** algorithms using the data collected by the device, enhancing its predictive capabilities in assessing recovery times and identifying potential injury risks. Usability studies will be conducted to refine the device's design and functionality, ensuring it meets the needs of both patients and healthcare providers. The open-source nature of the device's design invites collaboration, allowing for continuous improvement and innovation. Security measures will be a focal point, ensuring the privacy and integrity of patient data. the future work will bridge the gap between theoretical research and practical application, with a focus on continuous improvement and adaptability to the changing healthcare landscape of Pakistan. This comprehensive approach aims not only to enhance the quality of healthcare delivery but also to set new standards in patient care and recovery post knee implant surgery.

5.3 Societal Impact

The cumulative approach encompassing Systems Thinking, Model of Care (MoC), and assistive device development represents a pioneering step towards elevating knee post-implant surgery outcomes in Pakistan. By addressing the intricacies of healthcare challenges, adapting international best practices to the local context, and incorporating innovative technology, this research strives to significantly improve patient care, foster collaboration, and set new standards in healthcare delivery. The societal benefit lies in the potential transformation of orthopedic care, contributing to enhanced recovery, reduced complications, and the establishment of novel benchmarks in patient well-being post knee implant surgery.

5.4 Project Management

The table 5.1 illustrates the detailed step by step work breakdown structure to complete this research.

Sr no.	**Objective**	**WBS Work Breakdown Structure**	**Methodology/Skill Used**
1	Factors Identification	a) Literature review for factors for success	· Research
		b) Literature review for factors for failure	· Systems thinking
		c) Factors to stock variables	· Critical analysis
		d) Inference model separate for success & failure	
		e) Inference model combined - complete system	
		f) 3rd degree variables table for each 2nd degree variable	
		g) Whole system explanation	
2	Factors Analysis	a) Scenario description	· Research
		b) Scenario description to constraints	· Systems thinking
		c) Selection of variables	· Critical analysis
		d) New inference model	· Analytical reasoning
		e) Comparison between generic & specialized model	
		f) Identification & analysis of gap	
3	Tech Availability	a) Literature review for tech	· Research
		b) Market analysis for tech	· Critical analysis
		c) Listing findings	
		d) Listing findings details	
4	Tech Effectiveness	a) Rate tech based on user feedback	· Research
		b) Rate tech based on the scenario	· Critical analysis
		c) Comparison of both ratings	· Analytical reasoning
		d) Identification of tech effectiveness gap	
		e) Reasoning of tech effectiveness gap	
5	Prototype Design & MoC Development	a) Integrating design thinking & product design & development process	· Research
		b) Identification of needs & requirements based on scenario - Empathize	· PD&D
		c) Translation of needs & requirements to technical specifications - Define	· Design thinking
		d) Design thinking to list features of a tech for development - Ideate	· PM
		e) Prototyping device design – Prototype	· Creativity
		f) Development & testing of final prototype design – Test	· Embedded development skills
		g) Literature review for MoC	· IoT development skills
		h) Development of MoC	· Coding skills
		i) Validation of MoC	
6	Visualization & Data Collection Infrastructure for Future Research	a) Dashboard development	· Creativity
		b) Database integration	· Platform development skills
		c) Integration of device, dashboard & database	· System engineering
		d) Finalizing prototype & user manual development	· Writing skills
7	Analysis & Proof of Concept	a) TRL analysis	· Research
		b) Cost analysis	· Critical analysis
		c) Proof of concept	· Analytical reasoning
		d) Feasibility analysis	

Table 5.1: Plan followed for the execution of the project

APPENDIX A

Achievements

If the thesis resulted to produce any publications or any product. This can be listed here.

APPENDIX B

Sequential Code Execution

The efficient and rapid execution of sequential code is achieved through the utilization of triggers and the ESP32's interrupt system.

1. Overview:
    - The ESP32 microcontroller provides a robust interrupt system, offering up to 32 interrupt slots for each core.
    - Interrupts are categorized into hardware and software types, responding to external events or software instructions.
2. Types of Interrupts:
    - Hardware Interrupts:
    - Occur in response to external events like GPIO or touch interrupts.
    - Software Interrupts:
    - Triggered by software instructions, such as timer or watchdog timer interrupts.
3. GPIO Interrupts:
    - Attaching an Interrupt:
    - Function: attachInterrupt(GPIOPin, ISR, Mode);
    - Arguments:
    - GPIOPin: Specifies the GPIO pin to monitor.
    - ISR: The function called when the interrupt occurs.

- Mode: Defines when the interrupt triggers (LOW, HIGH, CHANGE, FALLING, RISING).
- Detaching an Interrupt:
- Function: detachInterrupt(GPIOPin);
- Argument: GPIOPin specifies the GPIO pin to detach the interrupt.

4. Interrupt Service Routine (ISR):

   Syntax:

```
void IRAM_ATTR ISR() {
        // Statements
}
```

5. Attributes:

   - ISRs are short, fast functions placed in Internal RAM for quick execution.

6. IRAM_ATTR Attribute:

   - Purpose: Code flagged with IRAM_ATTR is placed in the ESP32's Internal RAM for faster execution.
   - Reasoning: ISRs need to execute swiftly, and accessing data from internal RAM is faster than from Flash.

7. Best Practices for ISRs:

   - Keep ISRs short and fast to avoid blocking normal program execution.
   - No parameters or return values for ISRs.

APPENDIX C

Cost Analysis

The table C.1 shows cost analysis and the total cost of all items is PKR 3795 approximately 13.6$.

Item	**Price (PKR)**	**Quantity**	**Total (PKR)**
Esp32 Wroom 32 Microcontroller	1075	1	1075
Touch Sensor TTP 223	58	5	290
Piezo Active Buzzer	58	1	58
LED	14	1	14
Jumper Wires	250	1	250
OLED Display SSD 1306	539	1	539
GY521 MPU6050 Gyroscope Accelerometer Sensor Module	318	2	636
TP4056 Li-Ion Protection and Charger module	73	1	73
3.7v 600mah Lipo Battery	850	1	850
Button	10	1	10

Table C.1: Cost analysis of proposed device

Annex 'A'

office order: 0986/29/ACB/SEECS

Date April 3, 2024

Th.ECL (MS Thesis Evaluation Check List)

Student Name:

Registration:

Cover and title page of the thesis

T1. Student's name and registration number is written.

T2. Supervisor's name is mentioned.

T3. Title of the degree is written correctly.

T4. University and school's name are written correctly.

T5. Date of completion/defense (only year and month) is mentioned.

Style and formatting issues

S1. Consistent font (Times New Roman) is used throughout the thesis.

S2. Page numbering is done appropriately.

S3. Figures are readable and are aligned correctly.

S4. Captions for tables and figures use consistent format and style.

S5. Table of Contents/Figures/Tables follow proper indentation/styling.

S6. Chapter name and numbering follows consistent style.

References/Bibliography

R1. References are sorted on last name of authors (or in the order of citation in the text).

R2. References follow consistent style such as ACM or IEEE-Tran.

R3. Mandatory slots of references are filled correctly (such as Author, Title, Journal, Year).

General Issues

G1. Certificate of Originality signed by the student is present.

G2. Plagiarism report (from Euphorus) signed by supervisor is presented along with the thesis.

G3. Thesis is submitted within allowed time span for completion of thesis.

Abstract (Note: This section covers only the abstract of the thesis)

A1. There are no typing or grammatic mistakes in the abstract.

A2. Problem statement is clearly mentioned.

A3. Background to problem statement is also explained.

A4. Startling statement (preferably a paragraph) about the thesis/hypothesis is present.

A5. Implication of the startling statement is demonstrated briefly.

Results, Evaluation, and Conclusion

E1. Research is validated either empirically or analytically (Note: This doesn't cover quality of the results).

E2. Outcome of this thesis is contrasted with other similar research initiatives.

E3. Significance of this research is discussed in appropriate length.

Thesis Format

Sno	**HQ NUST Format**
1	Title Page
2	Thesis Acceptance Certificate
3	Approval Page
4	Dedicatoin
5	Certificate of Originality
6	Acknowledgement
7	Table of Contents
8	List of Abbreviation
9	List of Tables
10	List of Figures
11	Abstract
12	Main Body

Checklist for Components in Main Body

Sno	HQ NUST Fromat
1	Introduction
2	Literature Review
3	Methodology
4	Results
5	Discussion
6	Conclusion
7	Recommandation
8	Reference
9	Appendices
10	Index (Optional)

Additional Remarks:

OiC MS Thesis:

Date:

Office Order: 0986/29/ACB/SEECS

Date April 3, 2024

Th.ECL (MS Thesis Evaluation Check List)

Student Name:		
Registration:		
Cover and title page of the thesis		
T1.	Student's name and registration number is written.	
T2.	Supervisor's name is mentioned.	
T3.	Title of the degree is written correctly.	
T4.	University and school's name are written correctly.	
T5.	Date of completion/defense (only year and month) is mentioned.	
Style and formatting issues		
S1.	Consistent font (Times New Roman) is used throughout the thesis.	
S2.	Page numbering is done appropriately.	
S3.	Figures are readable and are aligned correctly.	
S4.	Captions for tables and figures use consistent format and style.	
S5.	Table of Contents/Figures/Tables follow proper indentation/styling.	
S6.	Chapter name and numbering follows consistent style.	
References/Bibliography		
R1.	References are sorted on last name of authors (or in the order of citation in the text).	
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E2.	Outcome of this thesis is contrasted with other similar research initiatives.	
E3.	Significance of this research is discussed in appropriate length.	

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