Design, Testing and Performance Optimization of Pressure Ulcer Prevention Bed for Neonates

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by

Adarsha Narayan Mallick

(2019BMZ0013)

DEPARTMENT OF BIOMEDICAL ENGINEERING

INDIAN INSTITUTE OF TECHNOLOGY ROPAR

March, 2025

Dedicated to my

Grandparents, Parents

and all my family members

Declaration of Originality

I hereby declare that the work which is being presented in the thesis entitled **Design, Testing and Performance Optimization of Pressure Ulcer Prevention Bed for Neonates** has been solely authored by me. It presents the result of my own independent investigation/research conducted during the time period from January 2020 to July 2024 under the supervision of Dr. Ashish Sahani and Dr. Durba Pal, Assistant Professor, Biomedical Engineering Department. To the best of my knowledge, it is an original work, both in terms of research content and narrative, and has not been submitted or accepted elsewhere, in part or in full, for the award of any degree, diploma, fellowship, associateship, or similar title of any university or institution. Further, due credit has been attributed to the relevant state-of-the-art and collaborations (if any) with appropriate citations and acknowledgments, in line with established ethical norms and practices. I also declare that any idea/data/fact/source stated in my thesis has not been fabricated/ falsified/ misrepresented. All the principles of academic honesty and integrity have been followed. I fully understand that if the thesis is found to be unoriginal, fabricated, or plagiarized, the Institute reserves the right to withdraw the thesis from its archive and revoke the associated Degree conferred. Additionally, the Institute also reserves the right to appraise all concerned sections of society of the matter for their information and necessary action (if any). If accepted, I hereby consent for my thesis to be available online in the Institute's Open Access repository, inter-library loan, and the title and abstract to be made available to outside organizations.

Name: Adarsha Narayan Mallick
Entry Number: 2019BMZ0013
Program: Ph.D.
Department: Biomedical Engineering
Indian Institute of Technology Ropar
Rupnagar, Punjab 140001

Date: 4th March 2025

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Certificate

This is to certify that the thesis entitled **Design, Testing and Performance Optimization of Pressure Ulcer Prevention Bed for Neonates**, submitted by **Adarsha Narayan Mallick (2019BMZ0013)** for the award of the degree of **Doctor of Philosophy** of Indian Institute of Technology Ropar, is a record of bonafide research work carried out under our guidance and supervision. To the best of our knowledge and belief, the work presented in this thesis is original and has not been submitted, either in part or full, for the award of any other degree, diploma, fellowship, associate-ship or similar title of any university or institution.

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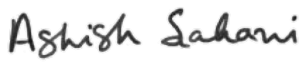

Signature of the Supervisor
Dr. Ashish Sahani
Department of Biomedical Engineering
Indian Institute of Technology Ropar
Rupnagar, Punjab 140001
Date: 4th March 2025

Dr. Durba Pal
Department of Biomedical Engineering
Indian Institute of Technology Ropar
Rupnagar, Punjab 140001
Date: 4th March 2025

Lay Summary

Pressure ulcers (PUs) represent a major health threat to neonates, particularly those in Neonatal Intensive Care Units (NICUs), where the combination of prolonged immobility and delicate skin significantly increases their vulnerability. This research addresses the urgent need for effective PU prevention strategies for neonates, with an emphasis on low- and middle-income countries (LMICs), where the rates of preterm births and related complications are notably higher. The primary objective of this study is to design, develop, and refine an anti-PU bed that caters to the specific physiological needs of neonates. The proposed solution incorporates soft robotics to create a bed that dynamically redistributes pressure, thus reducing the PU formation. Finite Element Analysis (FEA) was employed to model the interactions between a neonatal body and the bed, using elastic materials that closely mimic the properties of neonatal skin. The experimental setup included testing with a neonatal phantom model, followed by clinical evaluations conducted in NICUs to assess the bed's effectiveness. Findings from the FEA simulations and clinical trials indicated a significant decrease in areas of high pressure, thereby effectively lowering the risk of PU development. The bed's design, which includes force-sensing resistor arrays (FSRAs) for continuous real-time pressure monitoring, provides a practical and automated solution that alleviates the workload of NICU staff while enhancing neonatal care. This research underscores the potential of advanced biomedical engineering solutions to improve outcomes for neonates and advocates for the integration of these technologies into routine NICU protocols.

Abstract

In neonatal intensive care units (NICUs), the occurrence of pressure ulcers (PUs) among preterm infants is a significant clinical concern. These infants, often immobile for extended periods due to their critical conditions, are susceptible to developing PUs as a result of continuous pressure exerted by their own body weight against the bed surface. This issue is further exacerbated by the fact that neonatal skin is approximately 60% thinner than adult skin, making it more prone to damage and hampering blood flow from subcutaneous areas. Traditional methods of preventing PUs involve manual repositioning of infants by nursing staff, which is labor-intensive, inconsistent, and offers limited effectiveness, leading to additional workload and potential caregiver burnout.

To address these challenges, an innovative anti-PU bed has been developed and rigorously tested. This bed is designed to automatically vary the contact pressure on the infant's body, thereby reducing the risk of PU formation. The bed surface, made of silicone, incorporates a system of multi-channel fluid pressure actuation. This mechanism alternates between inflation and deflation cycles in different regions of the bed, effectively redistributing pressure away from any single point on the infant's body. The contact pressure is monitored using an array of force-sensing resistors (FSRAs), which detect areas of high pressure. Data from these sensors are processed through a microcontroller using an electronic circuit based on the voltage divider principle. This setup enables real-time identification of high-pressure points, which are visualized through heat maps generated using MATLAB software.

Comparative studies were conducted to evaluate the performance of the anti-PU bed against conventional bed systems currently used in NICUs. The results indicated a significant reduction in the incidence of PUs when using the anti-PU bed, highlighting its effectiveness in pressure management. The alternating pressure channel design not only mitigates the development of PUs but also significantly reduces the physical burden on nursing staff, allowing them to focus on other critical aspects of neonatal care. The anti-PU bed's performance was further validated through finite element modeling (FEM) using Abaqus, which simulated the interaction between the infant's body and the bed surface under varying pressure conditions. These simulations provided a robust understanding of how the bed design influences pressure distribution and skin integrity.

In addition to the experimental and modeling efforts, a comprehensive analysis of clinical data was undertaken, along with feedback from nursing staff who interact with these systems daily. Statistical analysis of clinical outcomes demonstrated a marked reduction in PU cases among neonates using the anti-PU bed compared to those using traditional methods. Feedback from nursing staff reinforced these findings, emphasizing the bed's role in improving the overall well-being of infants in NICUs. This study provides valuable insights into enhancing neonatal care by implementing advanced technological solutions to common clinical problems. The anti-PU bed represents a significant advancement in the prevention of pressure ulcers in vulnerable populations, offering a promising solution that combines clinical efficacy, caregiver efficiency, and improved patient outcomes.

The findings from this research have profound implications for neonatal care practices, suggesting that integrating automated pressure management systems like the anti-PU bed could become a standard preventive measure in NICUs. Future work will focus on optimizing the design for widespread clinical implementation, exploring long-term outcomes of PU prevention, and potentially expanding this technology to other at-risk patient populations. The development and deployment of such innovative solutions are critical steps toward improving the quality of care and ensuring the safety and comfort of the most vulnerable patients in our healthcare systems.

Keywords: Pressure Ulcers (PUs), Neonatal Intensive Care Units (NICUs), Force-Sensing Resistor Array (FSRA), Finite Element Modeling (FEM), Contact Pressure Monitoring, Heat maps, Clinical Data Analysis

List of Publications

Transactions/Journal Publications (from thesis)

- **A. N. Mallick**, M. Kumar, B. Basumatary, K. Arora, A. K. Sahani, "Design and Testing of Pressure Ulcers Preventive Bed for Neonates in Neonatal Intensive Care Units" IEEE Transactions on Medical Robotics and Bionics, April 2023 (I.F: 3.7), DOI: 10.1109/TMRB.2023.3265635.
- **A. N. Mallick**, B. Basumatary, M. Kumar, K. Arora, D. Pal, A. K. Sahani, "Performance Evaluation of Neonatal Anti-pressure Ulcer Bed Using a Novel Force Sensing Array" Transactions of the American Society of Mechanical Engineers (ASME), Journal of Medical Devices, DOI: 10.1115/1.4065892.
- **A. N. Mallick**, M. Bhandari, B. Basumatary, S. Gupta, K. Arora, and A. K. Sahani, "Risk Factors for Developing Pressure Ulcers in Neonates and Novel Ideas for Developing Neonatal Antipressure Ulcers Solutions." Journal of Clinical Neonatology, Affiliated to Saudi Neonatology Society, January 2023 (I.F: 0.7), DOI: 10.4103/jcn.jcn_84_22.
- **A. N. Mallick**, A. Chander, A. P. Choudhari, H. K. Chattar, A. K. Sahani, "A Review on the Role of Soft Robotics in Medical Assistive Devices" International Journal of Automation and Smart Technology, August 2023 (I.F: 0.53), DOI: 10.5875/ausmt.v13i1.2416.
- **A. N. Mallick**, S. Kumari, M. Kumar, B. Basumatary, K. Arora, D. Pal, A. K. Sahani, "Assessing the Efficacy of Anti-Pressure Ulcer Beds for Neonates with Clinical Data Analysis" Nature Scientific Reports (Under review)

Conferences (from thesis)

- **A. N. Mallick**, M. Kumar, K. Arora, and A. K. Sahani, "Finite Element Modeling of a Pressure Ulcers Preventive Bed for Neonates." IEEE-EMBS International Conference on Wearable and Implantable Body Sensor Networks (BSN), 27-30 September 2022, Ioannina, Greece, DOI: 10.1109/BSN56160.2022.9928469.

Patent (from thesis)

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- S. Maiti, M. Kumar, **A. N. Mallick**, M. Kumar, S. Ralhan, B. Mohan, A. K. Sahani, "Optimizing Preventative Strategies in Coronary Artery Bypass Grafting using Computational Fluid Dynamics" Transactions of the American Society of Mechanical Engineers (ASME), Journal of Medical Devices, (Under Revision).
- B. Basumatary, R. S. Haldar, C. Singhal, **A. N. Mallick**, A. Khokhar, R. Bansal, A. K. Sahani, "Deep Learning Approach for Gait Detection for Precise Stimulation of FES to Correct Foot Drop", IETE Technical Review (I.F: 2.4), DOI: 10.1080/02564602.2024.2344779.

Conferences

- **A. N. Mallick**, K. Arora, and A. K. Sahani, "Humidification and Heating of Oxygen for Neonates on Oxygen Therapy." in NNF Poster Innovation at 40th Annual Convention of National Neonatology Forum (NEOCON) held at Bangalore from 16th-19th December, 2021.
- **A. N. Mallick**, M. Kumar, A. Chander, R. Kumar, K. Arora, and A. K. Sahani, "Automatic Pasteurized Formula Milk Preparation Machine with Automatic Sterilized Containers." IEEE EMBC– Engineering Medicine and Biology Conference, 11-15 July 2022, Scotland Glasgow, DOI: 10.1109/EMBC48229.2022.9871811.
- **A. N. Mallick**, M. Kumar, R. Nadda, K. M. Kumar, S. Ralhan, B. Mohan, R. Repaka, A. K. Sahani, "Investigation of Failure Prevention Study of Coronary Artery Bypass Grafting Using Computational Fluid Dynamics Approach" 27th National and 5th International ISHMT-ASTFE Heat and Mass Transfer Conference, IIT Patna, DOI: 10.1615/IHMTC-2023.1980.
- B. Basumatary, R. S. Haldar, C. Singhal, **A. N. Mallick**, A. Khokhar, R. Bansal, A. K. Sahani, "Design of a Compact Wearable AI-driven Functional Electrical Stimulation System for Foot Drop" International Functional Electrical Stimulation Society (IFESS), 1-3 September 2024, University of Bath, UK.

Patents

- **A. N. Mallick**, B. Basumatary, K. Arora, A. K. Sahani, "A multi-functional neonatal formula milk dispenser for feeding babies, Application No. IN202331025526, Date of Publication: 11/10/2024.

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- **A. N. Mallick**, K. Arora, and A. K. Sahani, "A Pressure Ulcer Preventive Bed for Neonates" National Biomedical Research Competition (NBRC) organised by Society of Young Biomedical Scientist (SYBS) India (Best Poster Award).
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Nomenclature & Abbreviations

α	Material coefficient that controls the shape of the stress-strain response
λ	Principal stretches
μ	Material constant
ν	Poisson's ratio
ρ	Density
C_{bed}	Position at the centre of the pressure channels
E	Young's modulus
IL_{bed}	Position along the length and interface of the inflating-deflating pressure channels
IW_{bed}	Position along the width and interface of the inflating-deflating pressure channels
N	Order of Ogden's energy function
p	Probability of Occurances
R_{add}	Pull-down resistance
R_{FSR}	Resistance of the force sensor
S	Pressure
V_{out}	Output Voltage
AP	Alternating Pressure
BCs	Boundary Conditions
CAD	Computer Aided Design
CAE	Computer-Aided Engineering
CLP	Constant Low Pressure
CPAP	Continuous Positive Airway Pressure
CPAP	Hydrogen Embrittlement
DMC&H	Dayanand Medical College & Hospital
DRPUs	Device Related Pressure Ulcers

ECM	Engineered Conductive Materials
ECMO	Extracorporeal Membrane Oxygenation
ESP	Espressif Systems
FEA	Finite Element Analysis
FEM	Finite Element Method
FSR	Force Sensitive Resistor
FSRA	Force Sensing Resistor Array
HE	Hydrogen Embrittlement
ICUs	Intensive Care Units
IEC	Institutional Ethical Clearance
LMICs	Low- and Middle- Income Countries
NICUs	Neonatal Intensive Care Units
NSRAS	Neonatal Skin Risk Assessment Scale
PET	Polyethylene Terephthalate
PLA	Poly Lactic Acid
PSB	Pressure Sensitive Beds
PU	Pressure Ulcer
PVC	Poly Vinyl Chloride
RDS	Respiratory Distress Syndrome
RTV	Room Temperature Vulcanizing
SLA	Streolithography
TPU	Thermoplastic Polyurethane
WHO	World Health Organization
WROOM	Wireless Room

Chapter 1

Introduction & Literature Review

1.1 Neonatal and Pediatrics Population

Biomedical engineering stands at the crossroads of engineering and medicine, representing a field where technological innovation meets the critical needs of healthcare. This interdisciplinary domain encompasses the development of advanced medical devices, systems, and technologies that improve the diagnosis, treatment, and management of health conditions. The integration of engineering principles into the medical field has led to significant advancements in patient care, from the development of sophisticated imaging technologies to the creation of life-saving surgical tools. One of the most challenging and rewarding areas within this field is the design and development of medical devices for neonatal and pediatric care.

Neonates and pediatric patients present unique challenges due to their distinct physiological and anatomical characteristics. Unlike adults, neonates have smaller and rapidly changing bodies, which necessitates highly specialized medical interventions. Medical devices used in neonates must be carefully engineered to accommodate their size, developmental stage, and specific health needs. These devices include, but are not limited to, neonatal ventilators, infant incubators, pediatric heart valves, and various monitoring and diagnostic tools. The successful development and deployment of such devices require a deep understanding of pediatric physiology, advanced design capabilities, and the integration of innovative technologies. Neonates, particularly those born prematurely are among the most vulnerable patients. Their organs and systems are not fully developed, making them highly susceptible to complications and requiring precise and effective medical intervention.

A. The design of medical devices for this population addressing several critical factors:

- Size and Scale: Devices must be scaled down to fit the anatomical dimensions of neonates. This scaling is not merely a matter of miniaturization; it requires an understanding of how reduced size affects device functionality and performance.
- Physiological Adaptations: Neonates have unique physiological responses compared to adults. Their bodies may react differently to medical devices due to their metabolic rates, organ functions, and immune responses. Designing devices that can adapt to these physiological variations is essential for ensuring efficacy and safety.

- Growth and Development: Pediatric patients grow rapidly, and their medical devices must be able to accommodate this growth. This requirement poses a significant challenge for the design of devices.
- Material Compatibility: The materials used in medical devices for neonates must be bio compatible and suitable for long-term use. They must also be designed to minimize the risk of adverse reactions, such as infections or immune responses, which can be particularly problematic in neonates with delicate immune systems.
- User-Friendliness and Safety: Medical devices must be designed with both the patient and healthcare providers in mind. For instance, devices should be easy to use, maintain, and operate, while also ensuring the safety and comfort of the patient.

1.1.1 Anatomical and Physiological Characteristics of Human Skins

The Fig. 1.1 is a detailed illustration of the human skin's physiology, highlighting its structure and various components. Skin, the largest organ in the human body, performs several critical functions, including protection, sensation, thermoregulation, and more [5]. Understanding the skin's structure helps in appreciating how it carries out these vital roles. The skin is broadly categorized into three main layers: the epidermis, dermis, and subcutaneous layer (commonly known as fatty tissue) [1]. Each of these layers has distinct structures and functions as shown in Fig. 1.1.

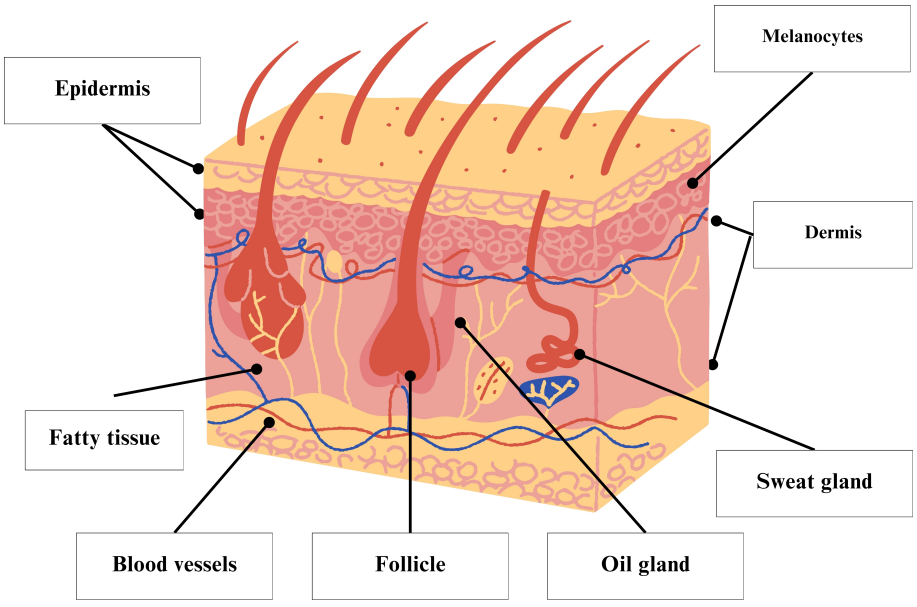


Figure 1.1: Components of human skin [1]

- Epidermis: This is the outermost layer of the skin, acting as the first barrier of defense against environmental hazards such as pathogens, chemicals, and physical injuries [6]. The epidermis is primarily composed of keratinocytes, which produce keratin, a protein that gives the skin its tough and protective quality. Another

critical component of the epidermis highlighted in the image is the melanocytes, which are responsible for producing melanin, the pigment that gives skin its color and protects it from ultraviolet (UV) radiation [7].

- Dermis: It is located beneath the epidermis, the dermis is much thicker and plays a key role in providing structural support to the skin. It is composed of dense irregular connective tissue that houses various crucial components. The dermis contains blood vessels that supply nutrients and oxygen to both the dermis and epidermis, as well as remove waste products. Sweat glands and oil glands (sebaceous glands) are also present in the dermis. Sweat glands are involved in thermo regulation by producing sweat, which cools the body when it evaporates. Oil glands secrete sebum, an oily substance that lubricates the skin and hair, preventing them from becoming dry and brittle [8], [9].
- Subcutaneous Layer (Fatty Tissue): This is the innermost layer of the skin, also known as the hypo dermis. It consists primarily of adipose tissue, which stores fat. This fatty tissue serves several purposes, such as cushioning the body's internal organs against mechanical trauma, providing thermal insulation, and serving as an energy reserve [10].

The susceptibility of neonates, especially preterm infants, to PUs is exacerbated by their unique anatomical and physiological characteristics. The skin of a neonate is considerably thinner and more fragile than that of an adult, with reduced subcutaneous fat and immature dermal layers. Preterm infants, who constitute a significant portion of NICUs admissions, have even more underdeveloped skin, making it highly susceptible to breakdown under prolonged pressure. Studies have shown that the dermal layer of a preterm neonate is less than 60% of the thickness of adult skin, which significantly increases the risk of ulceration when exposed to pressure [11]. A comparative picture of neonatal and adult skin is shown in 1.2.

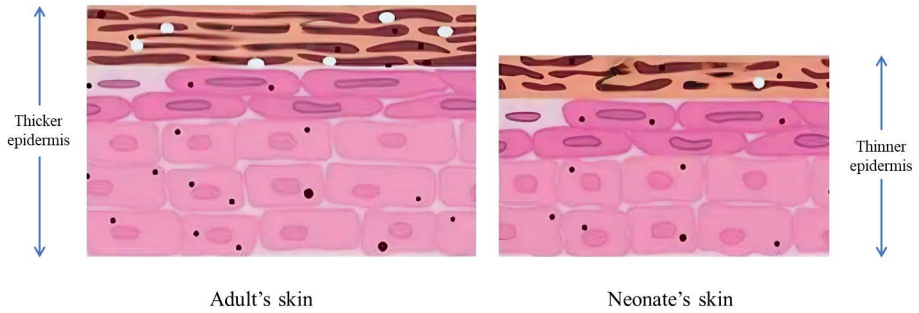


Figure 1.2: Difference between neonatal and adult skin [2], [3]

In addition to skin fragility, neonates have underdeveloped immune systems, which makes them more vulnerable to infections that can worsen PUs. Immature vasculature and reduced tissue perfusion further compound this issue, as adequate blood flow is crucial for

tissue repair and preventing ischemia-induced skin breakdown. Consequently, neonates are at a heightened risk for developing severe PUs, which can lead to complications such as sepsis and prolonged hospital stays [12].

1.1.2 Current Scenario of Neonates

As per the World Health Organization (WHO), India has the highest number of preterm births globally, accounting for approximately 15% of all births [13]. This statistic is alarming, as preterm births are closely linked to neonatal morbidity and mortality. The Fig. 1.3 presents a comprehensive overview of the neonatal healthcare scenario in India, emphasizing the challenges associated with preterm births and provides insight into the scale of the problem and the associated healthcare challenges. Preterm birth, defined as birth before 37 weeks of gestation, is a significant contributor to neonatal deaths. The Fig. 1.3 highlights that around 0.3 to 0.4 million children in India die each year due to complications arising from preterm births. These complications are often complex and multifactorial, including respiratory distress syndrome (RDS), intraventricular hemorrhage, necrotizing enterocolitis, and sepsis [14]. These conditions require immediate and intensive medical care, typically provided in Neonatal Intensive Care Units (NICUs).

A. Pie Chart Analysis

The pie chart is shown in Fig. 1.3 offers a breakdown of the causes of preterm deaths, categorized into infections, preterm complications, birth asphyxia, and others.

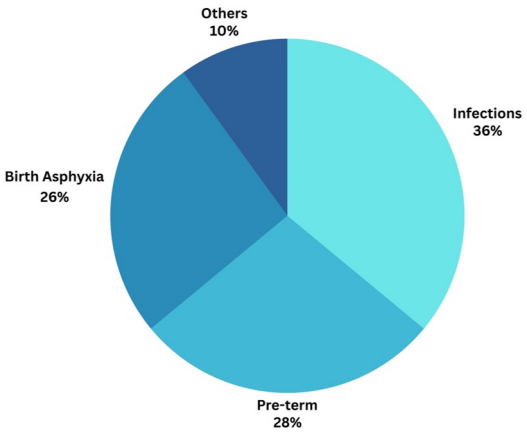


Figure 1.3: Pie chart showing the causes of pre term deaths

- Infections (36%): Infections are the leading cause of preterm deaths, indicating the vulnerability of preterm infants to pathogens due to their underdeveloped immune systems. This statistic underscores the importance of strict infection control protocols in NICUs, such as hand hygiene, sterilization of medical equipment, and controlled access to the NICU environment.

- Preterm Complications (28%): This category includes the immature lungs of preterm infants fail to produce enough surfactant, leading to breathing difficulties. Other complications include brain hemorrhages and gastrointestinal problems. The high percentage of deaths due to these complications emphasizes the need for advanced medical interventions and research into preventive strategies.
- Birth Asphyxia (26%): Birth asphyxia, or the lack of oxygen during birth, is another significant cause of neonatal death. Preterm infants are at a higher risk due to their fragile respiratory systems and immature neurological responses. This statistic highlights the critical need for skilled birth attendants and immediate resuscitation facilities at the time of birth.
- Others (10%): This segment includes a variety of less common causes, such as congenital anomalies and metabolic disorders. Although this category accounts for a smaller percentage, it still represents a significant number of neonatal deaths, stressing the need for comprehensive neonatal screening and care.

B. Healthcare Implications

The figure provides a stark reminder of the healthcare challenges in managing preterm births in India. The high mortality rate among preterm infants necessitates improvements in prenatal care, timely interventions during delivery, and enhanced postnatal care. NICUs must be equipped with the latest technology and staffed with trained professionals capable of managing complex neonatal conditions.
Moreover, public health policies should focus on preventing preterm births through better maternal healthcare, early detection of high-risk pregnancies, and promoting healthy behaviors during pregnancy. Strengthening community-based healthcare systems can also play a pivotal role in reducing preterm birth rates and improving neonatal outcomes.

1.1.3 Overview of Pressure Ulcers

Pressure ulcers, also known as decubitus ulcers or bedsores, are localized injuries to the skin and underlying tissue, typically over a bony prominence, as a result of prolonged pressure or pressure in combination with shear. The global healthcare burden of PUs is significant, affecting millions of patients annually, especially those with limited mobility such as the elderly, individuals with spinal cord injuries, and critically ill patients. Although the focus has traditionally been on adult patients, PUs are increasingly recognized as a major concern in neonatal and pediatric care, particularly in Neonatal Intensive Care Units (NICUs). A typical bed arrangement in NICUs is shown in Fig. 1.4 where a preterm infant is placed inside an incubator.

A. Prevalence of PUs in Neonatal and Pediatric Populations

The prevalence of PUs in neonatal and pediatric populations varies across different studies, but it is consistently noted that PUs are a significant issue in NICUs. A study conducted

Figure 1.4: Current scenario of a typical neonatal immobile bed arrangement with integrated parts causes the chance of PUs

in Spain's pediatric hospitals revealed that 84.1% of PUs in neonates were associated with medical devices, highlighting the role of extrinsic factors in the development of these ulcers [15]. Other studies have reported PU prevalence rates ranging from 23% to 43% in NICUs, depending on the population and the criteria used for PU identification [16].
Despite the high prevalence, PUs in neonates often go unrecognized or are misdiagnosed, primarily due to a lack of standardized assessment tools and guidelines tailored for this population. This underreporting of PUs can lead to inadequate prevention and treatment strategies, further exacerbating the issue. The literature suggests that there is a need for improved surveillance and reporting mechanisms in NICUs to better understand the true burden of PUs in neonates.

B. Risk Factors for PUs in Neonates and Pediatrics

The rising incidence of PUs among patients in NICUs, particularly those reliant on medical devices, compared to patients in standard intensive care units (ICUs), has driven extensive research into the causes and risk factors of these injuries [17]. The physiological and anatomical differences between neonatal and adult skin raise concerns about the suitability of adopting adult practices for preventing and treating PUs in premature infants. This approach has been increasingly scrutinized for its cost, efficacy, and overall effectiveness in addressing the unique challenges faced by neonates. Several risk factors contribute to the development of PUs in neonates and pediatric patients. These risk factors can be broadly categorized into extrinsic and intrinsic factors [18].

- Extrinsic Factors:

  Ulcer formation is influenced by several key extrinsic factors, including shear, friction, moisture, abnormal posture, excessive and prolonged pressure from clinical devices, and limited mobility [19]. Shear and friction primarily occur when the skin interacts with stationary surfaces, such as bed linens or medical devices, or during inter tissue plane movements like gliding. These forces can lead to

skin breakdown, especially over bony prominences. Moisture accumulation from perspiration, urine, and other bodily fluids compromises the skin barrier by causing maceration and promoting blister formation, making the skin more vulnerable to injury. Additionally, abnormal body postures result in uneven pressure distribution across anatomical points, increasing the risk of ulceration. Pressure from medical devices, including pulse oximeters, CPAP masks, and feeding tubes, is another significant contributor. While these devices are essential for neonatal care, they can exert localized pressure, leading to DRPUs. Research indicates that most pressure ulcers in neonates are associated with medical devices, particularly those used for noninvasive ventilation.

- Intrinsic Factors:

  The development of PUs in neonates is influenced by several intrinsic factors, including gestational age, birth weight, duration of hospitalization, hemoglobin levels, and nutritional status. Premature infants and those with low birth weight face a higher risk of PUs due to underdeveloped skin and reduced tissue perfusion. Studies indicate that each additional week of gestational age decreases the risk of PUs by 20.1% [20]. Despite this, the overall occurrence of PUs is lower in premature infants compared to term infants. However, the severity of PUs differs: while premature infants typically develop PUs up to stage II, term infants often experience more severe ulcers, extending to stage III [21]. Hemoglobin levels, a critical indicator of nutritional management and tissue oxygenation, play a pivotal role in PU risk. Anemia, particularly common in neonates, reduces the oxygen-carrying capacity of blood vessels, leading to tissue hypoxia and necrosis under mechanical pressure. This condition significantly increases the vulnerability of tissues to ulceration. Nutritional status is another vital factor. Adequate nutrition is essential for maintaining skin integrity and facilitating wound healing. Malnutrition or poor nutritional support impairs the body's ability to repair damaged tissue, exacerbating the risk of PU development. Conditions like edema, resulting from compromised circulation and poor nutrition, further contribute to PU formation by causing interstitial fluid accumulation and decreased tissue oxygenation [22]. Collectively, these factors underscore the importance of tailored nutritional and clinical interventions to minimize the risk of PUs in neonates.

- Predicting the Risk of Pressure Ulcer in Pediatrics:

  The medical principle, "Prevention is better than cure," holds particularly true in the context of pressure ulcers (PUs). A precise assessment of the risk factors for PU development is the critical first step in devising effective interventions to mitigate their occurrence. Accurate risk evaluation enables healthcare providers to implement tailored preventive measures, thereby reducing the burden of PUs. Among the ten validated and published scales for PU risk assessment, the Braden Q Scale, the Neonatal Skin Risk Assessment Scale (NSRAS), and the Glamorgan Scale stand out

for their proven sensitivity and specificity [23] [24]. These scales have been rigorously tested in clinical settings to ensure their reliability in identifying at-risk individuals, particularly neonates and pediatric patients. Each of these tools assigns a score based on various risk parameters, including factors such as mobility, moisture, nutrition, and skin condition. A higher score on these scales indicates an elevated risk of PU development, necessitating more stringent preventive measures. For instance, patients with higher risk scores often require specialized support surfaces, such as advanced pressure-relieving mattresses, to minimize the mechanical stress exerted on the skin and underlying tissues. By leveraging these risk assessment scales, clinicians can adopt a proactive approach, enabling early identification and management of potential PU cases. This not only enhances patient outcomes but also aligns with the overarching goal of improving the quality of care in neonatal and pediatric healthcare settings.

The Neonatal Braden Q Scale, first introduced in 1996, is an adaptation of the Braden Scale for adults, which was originally developed in 1987 to predict the risk of pressure sore development [25]. This neonatal-specific scale was designed to address the unique needs and characteristics of neonates, offering a more detailed and tailored approach compared to its adult counterpart. The Braden Q Scale evaluates multiple critical factors that influence PU risk, including body position mobility, physical activity levels, sensory perception, nutrition, tissue perfusion, oxygenation, and moisture [15]. Each of these factors is scored on a scale of 1 to 4 based on predefined guidelines, with the cumulative score reflecting the overall risk of PU development. The detailed assessment provided by this scale ensures a comprehensive understanding of the factors contributing to PU formation in neonates, enabling targeted interventions. Similarly, the NSRAS builds on the foundational Braden Scale, focusing on factors such as mobility, general physical condition, activity levels, and mental status to calculate a total PU risk score. Like the Braden Q Scale, the NSRAS provides a systematic method for assessing risk in neonates, offering healthcare professionals actionable insights for preventing PUs in this vulnerable population. By incorporating these specialized scales into clinical practice, healthcare providers can more accurately identify neonates at risk of PUs, facilitating early and effective preventive strategies tailored to their unique physiological needs.

A study carried out in several of Spain's Pediatric Hospitals built two sets of forms: one namely to assess the risk of developing PUs by patients admitted to the NICU and the other that enlisted and characterized the different preventive measures adopted by the hospitals such as skin monitoring, nutrition management, placement of pulse oximeter, and ulcer management in an attempt to study the efficacy of the said measures [26]. It also further classified the risk of PUs based on their location within the body, number of contact surfaces within the body, and the gestational age of the admitted patient. It was revealed that 84.1% of PUs were

caused by medical devices and that 54% among them were caused by noninvasive mechanical ventilation. The nasal area was highly prone to PUs followed by the occiput and other bony prominences such as heels, sacrum, elbows, and shoulder. Furthermore, each additional week of gestational age at birth reduced the risk of PUs by 20.1%. After a careful statistical analysis of all the adopted measures, kangaroo care method was the only method that fetched a significant protective effect, while other methods such as repositioning or use of support surfaces showcased nonsignificant effects. This review paper also includes studies conducted in other public care hospitals that statistically proved that a majority of PUs were caused by medical devices.[8] Adhesives used to connect clinical devices to the bodies of these neonates caused skin tissue injuries and abrasion of the stratum corneum layer when they were removed. However, silicone-based adhesives, such as RTV silicone 666, caused less skin lesions as compared to the standard acrylate-based adhesives [27]. A Cincinnati Hospital study called out several risk factors for the occurrence of PUs such as noninvasive ventilation (CPAP and ECMO), a longer period of hospitalization, medical device-related pressure injuries, excess moisture, and effect of gestational age on PU development. A greater prevalence and tendency of patients to develop stage II PUs was observed [28]. A study made from the biomechanical perspective emphasized the importance of a medical device setup, arrangement, and its role in the development of PUs in the neonates and stated that higher stresses and deformation were induced in the contacting skin tissue surfaces when wires and electrodes of medical devices were wedged under the body of newborns [29]. A US-based hospital study was carried out to determine the usefulness of pressure redistribution mattresses specifically manufactured with the intention to reduce the risk of PUs in pediatric patients [30]. This crib mattress had unique features such as movable side rails, built-in scale to measure the weight of the child, overhead features to prevent falls, and an adjustable head of the bed. A comparative analysis of the PU occurrences in patients using these mattresses and the ones that were not using them denoted that such mattresses along with bundled interventions such as use of urinary catheters, acute elevation of the head of bed, use of disposable underpads and dry-weave diapers, and the use of blanket rolls, draw-sheets, and pillows along with repositioning by nurses whenever possible could potentially prevent PUs [31].

C. PU Prone Areas and Sleeping Positions of Neonates

The figure shown in Fig. 1.5 illustrates the PU prone areas and the sleeping positions of neonates, highlighting the common regions where pressure ulcers occur in newborns. Pressure ulcers are localized injuries to the skin and underlying tissue, typically over a bony prominence, due to prolonged pressure or shear.

- Occiput (Head Region - Fig. a): The first image in the upper-left corner shows a pressure ulcer on the occiput, which is the back part of the skull. The occiput is a highly susceptible area for neonates because their skull bones are soft and

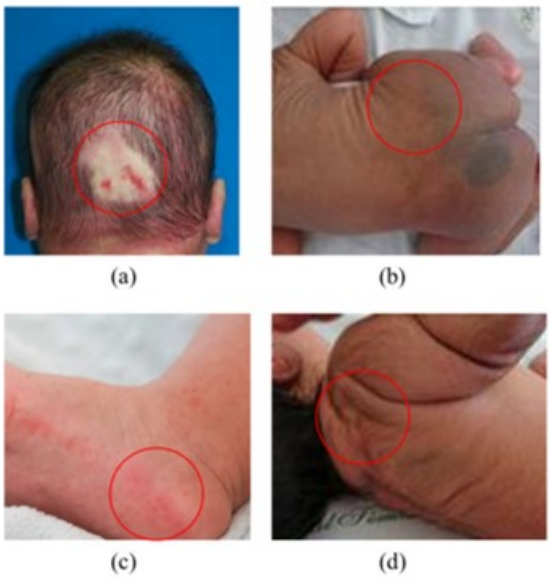


Figure 1.5: Typical neonatal cases of PUs in neonates in the regions of (a) occiput, (b) buttock, (c) toe, and (d) back of the chest [4].

undeveloped, leading to increased vulnerability. The prevalence of pressure ulcers in this region is indicated at 19%.

- Buttocks (Fig. b): The second image shows a pressure ulcer located on the buttocks. The pressure in this area typically results from lying in a supine or seated position. In the figure, it is shown that 29% of pressure ulcers occur in this region, making it one of the most common sites for PU development in neonates.

- Toe (Fig. c): The third image presents a case of PU on the toe, which, although less common, still occurs due to pressure exerted by the edge of the bed or tight swaddling. This region represents 5% of PU cases.

- Back of the Chest (Fig. d): The fourth image depicts pressure ulcers in the back of the chest, often caused by neonates lying on their backs for extended periods. The back of the chest is prone to PU development due to the constant pressure exerted in this position, with a prevalence of 14%.

To provide a visual representation of pressure ulcer occurrence and risk areas, a neonatal phantom model is shown in Fig. 1.6 with percentages marked on different body parts. The distribution of pressure ulcers is shown with:
- 29% on the buttocks: This high percentage reflects the risk associated with prolonged sitting or lying in the supine position. - 19% on the occiput: Demonstrates the vulnerability of the skull region when neonates are placed on their backs. - 16% on the back of the chest: Highlights the significant risk of ulcers due to constant pressure in this area. - 14% on the lateral aspect of the body: Lateral positions can relieve pressure from certain areas but may shift the risk to others. - 10% on the arms: This represents

areas where compression against surfaces, like armrests, can occur. - 9% on the sides of the head and ears: Neonates in lateral sleeping positions may develop PUs in this area. - 7% on the lower back: Prolonged supine positioning leads to PU development in the lower back. - 5% on the toes and feet: PUs in this region are due to poor positioning or tight swaddling. - 3% on the anterior torso: This includes areas with less direct pressure but still a risk.

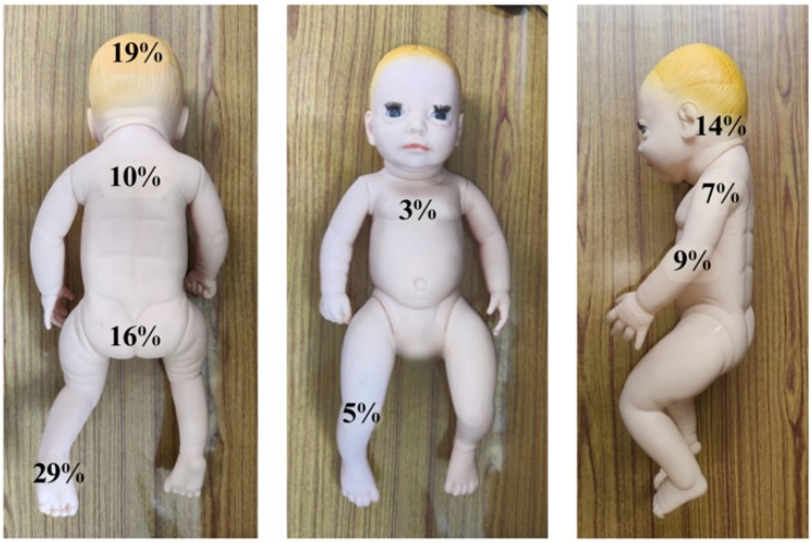


Figure 1.6: Current scenario of regions of most common occurrences of PUs in the neonates

This figure emphasizes the need for careful management of neonate positioning to prevent the occurrence of PUs. The use of pressure-relieving devices, frequent repositioning, and attention to vulnerable areas, as highlighted, can mitigate the risks. The findings presented by underscore the significance of developing neonatal beds and surfaces that minimize pressure on the most common PU-prone areas .

1.1.4 Comprehensive Literature Review on PUs in Neonates and Pediatric Patients

PUs have been extensively studied in adults, yet research on PUs in preterm babies, particularly in NICUs, remains limited. Various devices and methodologies have been proposed to address PUs in different patient populations, including neonates, pediatric patients, and adults with impaired mobility. However, the unique physiological characteristics of neonates necessitate specialized solutions that are still under development.

A. Flow Chart Analysis for PUs in Neonates

The Fig. 1.7 is a flowchart illustrating the systematic approach undertaken during the literature search focused on PUs risk assessment and antisore beds, specifically in the

context of neonatal care. The flowchart visually represents the step-by-step process, from the initial retrieval of articles to the final selection of studies included in qualitative and quantitative syntheses.

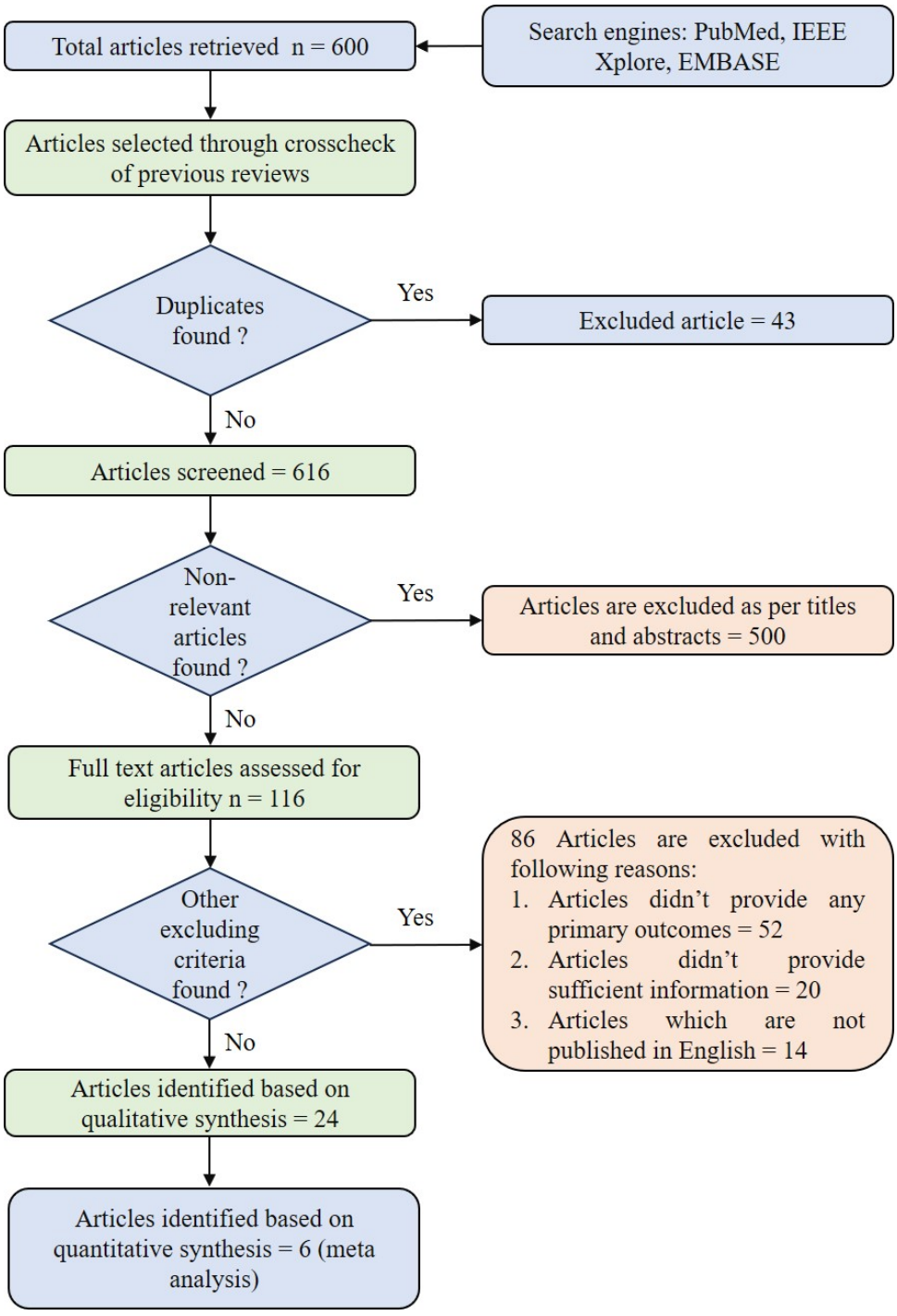


Figure 1.7: Flowchart of literature search

- Primary Aim and Search Strategy:

  The flowchart's primary objective was to identify and retrieve articles related to pressure ulcer risk assessment and antisore beds. Pressure ulcers are a significant concern in neonatal care due to the delicate nature of neonatal skin and the potential

for prolonged immobility in these patients. Antisore beds are specialized mattresses or support surfaces designed to prevent the formation of these ulcers.

To achieve this aim, a strategic search was conducted using selected keywords. These keywords were used individually or in combination to retrieve a broad range of relevant articles. The search was designed to focus on breadth rather than the details of each individual study, allowing for a comprehensive understanding of the available literature.

The search was conducted across multiple renowned scientific databases, including: PubMed, IEEE Xplore, EMBASE, and Google Scholar.

- Initial Article Retrieval and Screening:

  The search strategy retrieved a total of 600 articles from the aforementioned databases. The next step involved cross-referencing these articles with previous reviews to ensure comprehensiveness. This step is crucial as it helps in identifying any seminal works or pivotal studies that may not have been captured initially. During this phase, a duplicate check was performed. Duplicates in literature reviews refer to identical or highly similar articles retrieved from different databases or as a result of overlapping search strategies. In this case, 43 articles were identified as duplicates and were subsequently excluded, leaving 616 articles for further screening.

- Screening for Relevance:

  The next step involved screening the 616 articles based on their titles and abstracts. This step is critical in narrowing down the literature to studies that are directly relevant to the research question and here the articles were assessed for their relevance to pressure ulcer risk assessment and anti sore beds.

  A significant number of articles (500) were excluded at this stage because they did not meet the criteria of relevance. The exclusion of non-relevant articles based on titles and abstracts is a standard practice in systematic reviews to manage the volume of literature and focus on studies that are directly applicable to the research question.

- Full-Text Assessment and Eligibility Check:

  After the initial screening, 116 articles were identified for full-text assessment. This step involves a more detailed examination of the selected articles to determine their eligibility for inclusion in the qualitative and quantitative analyses.

  During this phase, the articles were assessed against specific inclusion criteria. The flowchart indicates that 86 articles were excluded for various reasons:

  No Primary Outcomes Provided (52 Articles): These studies were excluded because they did not present primary outcomes relevant to the research question. Primary outcomes are the main results measured to determine the effect of an intervention, and their absence can undermine the relevance and validity of a study in the context of a systematic review.

Insufficient Information (20 Articles): Some articles were excluded because they lacked sufficient information, which could include inadequate data reporting, missing methodological details, or incomplete results.

Non-English Publications (14 Articles): Articles published in languages other than English were excluded. This criterion is often applied in systematic reviews to ensure that all included studies are accessible and can be thoroughly evaluated by the review team.

- Synthesis of Findings:

  Finally, 24 articles were deemed suitable for qualitative synthesis, which involves a detailed analysis of the content, methodologies, and findings of the included studies. Qualitative synthesis aims to summarize and interpret the data in a way that provides insights into the research question, in this case, the effectiveness and safety of antisore beds in preventing pressure ulcers in neonates.

  Moreover, 6 articles were identified for quantitative synthesis, which typically involves meta-analysis. Meta-analysis is a statistical method used to combine the results of multiple studies to derive a pooled estimate of the effect of an intervention. In the context of this review, the meta-analysis would focus on quantitatively assessing the effectiveness of antisore beds in preventing pressure ulcers.

The flowchart provides a clear and systematic outline of the literature search process for studies related to pressure ulcer risk assessment and antisore beds. Each step in the process is methodically documented, from the initial retrieval of articles to the final inclusion of studies in the qualitative and quantitative syntheses. This structured approach ensures that the review is comprehensive, transparent, and methodologically sound, providing a reliable foundation for drawing conclusions about the effectiveness of antisore beds in neonatal care.

B. Existing PUs Prevention and Treatment Strategies

Prevention of PUs is a critical aspect of neonatal care, as treatment options are limited once ulcers develop. The primary approach to PU prevention involves minimizing pressure on vulnerable skin areas, improving tissue perfusion, and maintaining skin integrity. Several strategies have been proposed in the literature, including:

- Repositioning: Regular repositioning of neonates is a common practice in NICUs to alleviate pressure on vulnerable skin areas. However, this method has limited effectiveness and can place additional strain on nursing staff, particularly in resource-constrained settings.

- Support Surfaces: Pressure-redistribution mattresses and overlays have been developed to reduce the risk of PUs in neonates. These devices aim to distribute

pressure more evenly across the skin, reducing the risk of localized skin breakdown. Studies have shown that the use of specialized mattresses can reduce the incidence of PUs, but their availability and affordability in LMICs remain a challenge.

- Skin Monitoring: Frequent skin assessments and monitoring are essential for early identification of PUs. The use of risk assessment scales, such as the Neonatal Skin Risk Assessment Scale (NSRAS) and the Braden Q scale, has been recommended for predicting PU risk in neonates. However, these scales are not universally adopted, and there is a need for more research to validate their effectiveness in different populations.

- Moisture Management: Preventing excessive moisture buildup on the skin is critical for PU prevention. The use of absorbent materials, barrier creams, and frequent diaper changes can help reduce moisture-related skin breakdown. Silicone-based adhesives have also been shown to cause less skin damage compared to traditional acrylate-based adhesives, making them a preferred option for securing medical devices in neonates.

- Medical Device Modifications: Modifying the design and placement of medical devices can help reduce the risk of DRPUs. For example, the use of softer materials, adjustable straps, and custom-fitted devices can minimize pressure on the skin. Some studies have explored the use of sensorized soft actuators and active air mattresses for real-time pressure monitoring and redistribution, but these technologies are still in the early stages of development.

- Challenges in LMICs:

  The burden of PUs is disproportionately higher in LMICs, where healthcare systems often lack the resources and infrastructure to implement effective prevention and treatment strategies. In these regions, the prevalence of PUs is often under reported, and neonates are at a higher risk of severe complications due to limited access to advanced medical care.

  - Resource Constraints: LMICs face significant challenges in providing basic healthcare services, let alone specialized care for PU prevention. The availability of pressure-redistribution mattresses, advanced wound care products, and trained personnel is often limited, leading to sub optimal care for neonates at risk of PUs.
  - Lack of Awareness and Training: Healthcare providers in LMICs may not be adequately trained in PU prevention and management. This lack of knowledge, combined with high patient-to-nurse ratios, can result in delayed identification and treatment of PUs.

- Inadequate Medical Devices: The medical devices used in LMICs are often not designed with neonates in mind, leading to a higher risk of DRPIs. There is the need for affordable medical devices that are specifically designed for neonatal care.

C. Adult-Focused PU Prevention Devices and Their Limitations for Neonates

Several devices have been developed to prevent PUs in adults, such as sensorized soft actuators designed for wheelchair patients and active air mattresses for elderly care. For instance, a soft actuator capable of applying a uniform pressure of 3.5 kPa was used to measure interface pressure, and a peak pressure of 9.5 kPa was recorded, which is below the threshold value for PU development. This technology demonstrated flexibility, simplicity, and real-time pressure monitoring. However, while these devices showed promise for adult care, they are not directly translatable to neonatal care due to differences in skin fragility, body weight, and pressure tolerance.

Similarly, an active air mattress developed for elderly patients featured cells that could be independently controlled by pressure sensors, with a maximum internal pressure of 15 kPa. While this system helps redistribute pressure and prevent PUs, its application in neonatal care would require significant modifications due to the need for much lower pressures and more sensitive control mechanisms.

Flexible designs like these have inspired innovations in pediatric care, but their direct application to neonates is problematic. Neonatal skin is significantly thinner and more prone to damage, necessitating devices that can apply and monitor much lower pressures. Current devices, such as active air mattresses and pressure sensors, are not fully optimized for neonatal anti-sore bedding, highlighting a critical gap in available solutions.

D. Device-Related Pressure Ulcers (DRPUs) and Emerging Technologies

The prevalence of DRPUs in neonates has led to the exploration of various real-time tracking and warning systems that utilize embedded sensors and soft actuation mechanisms. Ostadabbas et al. developed an algorithm to optimize patient repositioning schedules using commercial pressure mats. Although this approach offers periodic posture repositioning, it does not reduce the workload on nursing staff. This limitation highlights the need for more automated and less labor-intensive solutions, particularly in resource-limited settings like low- and middle-income countries (LMICs).

Carrigan et al. investigated the effectiveness of a polymeric soft actuator in measuring contact pressure for neonatal patients. Using a rigid spherical shell model weighing 9 kg, they measured a peak pressure of 9.5 kPa, below the recommended threshold for PU formation. This study, along with others, underscores the potential for mobile health applications and machine learning algorithms to track critical parameters such as breathing rate, heart rate, and contact pressure in real-time, offering new avenues for PU prevention.

Various technologies have been tested to minimize DRPUs, including anti-decubitus pressure-sensitive beds (PSBs) that dynamically change body positions to prevent pressure buildup. These beds are designed to disperse contact pressure and are equipped with sensors capable of detecting very light forces, which is essential for neonates who weigh very little. While these innovations offer promise, they often require further refinement to enhance their efficacy in neonatal care.

E. Direct and Indirect Methods for Measuring Pressure Distribution

The prevention of PUs in NICUs often relies on manual repositioning, a method that is labor-intensive and prone to human error. To address this, various direct and indirect methods for measuring pressure distribution on neonatal mattresses have been proposed. Direct methods involve placing sensors or transducers directly on or under the patient's body, which may cause discomfort or irritation to the neonate's delicate skin. In contrast, indirect methods, such as using optical sensors to measure pressure distribution without direct contact, offer a less invasive alternative.

However, both direct and indirect methods have their limitations. For instance, direct methods like load cells and strain gauges may not cover the entire mattress surface or capture pressure variations over time. On the other hand, indirect methods such as infrared thermography may involve bulky equipment unsuitable for NICU environments.

Research comparing different pressure distribution measurement techniques has shown that pressure mapping systems, which use many embedded sensors, provide more detailed information than load cells or strain gauges. Stinson et al. demonstrated that pressure mapping systems could accurately capture the interface pressure between neonates and mattresses, offering valuable data for PU prevention.

F. Cost-Effective Solutions and Performance Enhancement in LMICs

One of the significant challenges in preventing PUs in neonates, particularly in LMICs, is the high cost of advanced pressure measurement systems. Low-cost solutions, such as resistive sensors, have been proposed to address this issue. These sensors are inexpensive, easy to use, and capable of monitoring pressure variations over time, making them suitable for resource-limited settings.

Furthermore, research by Bai et al. on 254 NICU patients found that using pressure redistribution visco elastic foam significantly reduced the risk of PU development. This finding highlights the importance of selecting appropriate materials for neonatal mattresses to prevent skin breakdown.

However, despite these advances, most existing methods for measuring pressure distribution in neonatal care remain either invasive, expensive, or unsuitable for neonatal skin. This gap underscores the need for more research to develop efficient and reliable methods to design anti-PU beds that cater specifically to neonates.

1.1.5 Mechanisms on Designing and Developing Anti-sore Bed

The Fig. 1.10 depict an analysis of literature and patents related to anti-sore bed mechanisms, particularly those used to prevent PUs in neonates and it summarizes the different types of anti-sore bed mechanisms identified in the research, the specific devices or technologies developed, and their prevalence in the literature. The images also illustrate the classification of these mechanisms as passive, active, or both, and present this data in tabular and graphical forms as shown in Fig. 1.10.

A. Broad Classification of Solutions

Prevention of PUs constitutes a variety of mattresses, classified as low-tech devices or constant low pressure (CLP), high-tech devices or alternating pressure (AP), and other support surfaces [32]. The CLP devices construct the body shape of the patient to distribute its weight over a large area and include standard and alternative foam mattresses/overlays such as convoluted and cubed, gel filled, air filled, water filled, fiber, or bead filled. The AP devices provide the pressure periodically beneath the patient's body with mechanical techniques and include air fluidized beds, low air loss beds, or AP overlays/mattresses. Based on the operation of these mattresses, they are classified as static mattresses, dynamic mattresses, and overlay mattresses [33].

Static mattresses redistribute the pressure around the whole body and are very handy to use and to set up, while dynamic/ripple mattresses are designed as an alternative inflating and deflating strips bed underneath the patient [34]. The noise of electric pumps and the breakdown of mechanical system owing to its rigorous use form some of its drawbacks. The third category includes the overlay mattress that is placed on a static mattress or on a dynamic mattress or sometimes even both. It is quick to install. However, it does not provide the same level of protection as a replacement mattress. It is suitable for a short period of time and also for acute illness. It prevents the patient to get in or out of the bed as it raises the height of the mattress [35].

B. Literature and Patents on Anti-sore Bed Mechanisms

The first image presents a table summarizing 28 articles relevant to anti-sore bed mechanisms, categorizing them based on the nature of the mechanism (passive, active, or both) [36], [37], [38], [39]. Each entry in the table provides the name of the literature or patent, the publishing year, and the first author or inventor associated with the work.

- Passive Mechanisms:
  - The QUATTRO ACUTE Mattress: This entry discusses a passive mechanism involving the QUATTRO ACUTE mattress, a product designed to prevent pressure ulcers through a specialized mattress surface. Passive mechanisms

Table 1.1: Retrieved articles on anti-sore bed mechanisms according to the area of research.

Anti-PU bed mechanism	Literature name/Patent name	Publishing year / Patent year	First author/Inventor
Passive	The QUATTRO ACUTE mattress and pressure ulcer prevention	2003	Sylvie Hampton [40]
	Hospital-Acquired pressure ulcer prevalence: Evaluating Low-Air-Loss Beds	2011	Jane Johnson [41]
	Neonatal absorbency pad and related methods [patent]	2015	Jennifer J. Bracci [42]
Active	The theracute alternating pressure relieving mattress	2001	Heather Newton [43]
Both	A smart bed platform for monitoring & ulcer prevention	2011	R. Yousefi [44]
	Design of anti bed sore hospital bed	2014	C. Czar [45]

rely on materials or structural design features that reduce pressure without requiring active mechanical or electronic intervention.

  - Hospital-Acquired Pressure Ulcer Prevalence: This study evaluates the effectiveness of low-air-loss beds in preventing hospital-acquired pressure ulcers, another example of a passive system.
  - Neonatal Absorbency Pad and Related Methods: This patent describes an absorbent pad for neonates, designed to manage moisture and reduce the risk of pressure ulcers, representing another passive intervention.

- Active Mechanisms: The Theracute Alternating Pressure Relieving Mattress: Active mechanisms involve systems that dynamically adjust the support surface, typically through mechanical means like alternating pressure systems. The Theracute mattress is an example, actively altering pressure points to prevent prolonged stress on any one area.

- Both Passive and Active Mechanisms: A Smart Bed Platform for Monitoring & Ulcer Prevention: This platform integrates both passive and active elements, employing sensors for monitoring and active adjustments to prevent ulcers. Design of Anti-Bed Sore Hospital Bed: This entry represents a bed design incorporating both passive structural features and active pressure-relieving technologies.

The most acceptable way of preventing neonatal PUs is to get the patients moving often and prevent them from sleeping or lying in the same position for a long period of time on a particular side of the body [46]. Since there are no specified solutions designed for neonates, previously designed antisore beds for adults have been included in this study as

a means to understand the technology gap and highlight the scope for future development [47].

A study done on sleeping mattresses of premature babies by Carol Turnage-Carrier [48] on 5 bed surfaces which includes crib mattress with foam, standard crib mattress, mattress with gel donut, mattress with gel, and mattress with water pillow stated that except the standard crib mattress all of the four surfaces had significantly lower interface pressures i.e., less than 100 mm Hg.

A patented device with multiple layers of sponge, air, and paper sheet layer used for reduction of pressure ulcers [49]. Depending on the patient's weight, the air mattress and sponge layers are arranged to enhance the patient's body's surface area in contact with the bed. The intermediate layer is a rubber layer designed to offer ventilation utilising dry air or dry air mixed with ozone gas, essential/volatile oil, and/or antibacterial vapours for parts of the mattress that come into contact with a patient's body. The purpose of the second sponge layer is to distribute air beneath the patient's body. If the mattress becomes wet from sweating or incontinence, the paper sheet layer is set up to sound an alert.

Smart bed platform developed by Yousefi et al. [50] evidently denotes a combination of machine intelligence, sensor network, and computers that is capable of providing support to the healthcare staff in improving patient care and PU prevention, also carrying out epidemiological analysis efficiently. The design beholds two types of sensors, resistive and capacitive over the entire bed surface in order to measure surface body pressure. Patient profile was generated based on initial and fused sensor data that capture matrices such as moisture content, pressure map, temperature, and blood pressure.

The Nimbus pediatric system, designed for examination to be at risk of pressure injury or existing pressure damage provides alternating pressure relief with self- regulating weight, size, and position adjustment of the patient [51].

A patented device that is for relieving pressure invented by Jennifer B et al. has several different layers that include -1. Sponge layer for conduction of electricity 2. Air electric conducting sheet 3. Intermediate layer having air release units 4. Second sponge layer having sensor matrix for the detection of mattress with second moisture [42].

Carrigan et al. [52] have developed a sensor-based soft actuator array. Controlling interface pressure was accomplished by monitoring the internal pressure of the actuator. The said system automatically distributed the interface pressure using the pressure-modulating algorithm. After applying the weight on the surface, there were changes in pressure at the center of the surface. Conclusively, a system with the interpolated surface achieves the best pressure distribution.

An array of capacitor plates is used for sensing the pressure, as shown in Fig. 1.8. Wherein, the applied pressure can be obtained based on the capacitance value [53]. Sensor-to-sensor variation and baseline drift were some of the limitations associated with this version.

Chenu et al. [54] have developed a seating system based on an embedded system that measures the pressures in real time and estimates the risk for internal overstrains. The

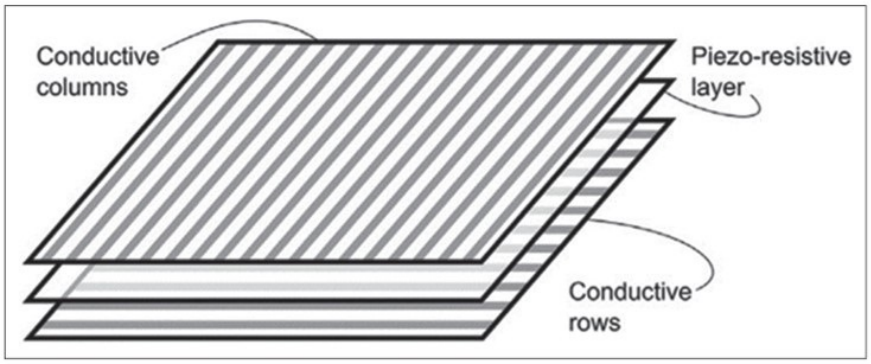


Figure 1.8: Schematic of the sensor array

textile map is put onto the chair's seat area, usually all around the cushion. The system has been intentionally developed for the paraplegic population, to monitor their interface pressures for prevention of ulcers as shown in Fig. 1.9 Interface pressure, the loading between a patient's skin and the support surface, is measured to determine the relative efficiency of performance of various support surfaces.

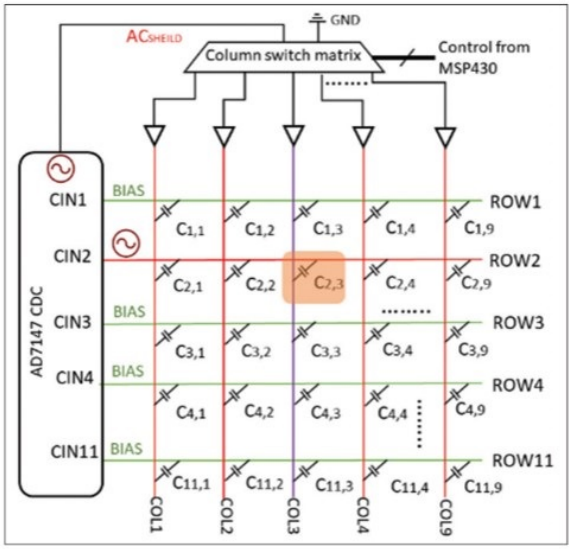


Figure 1.9: Three layers that constitute the TexiCare textile sensors

C. Bar Graph on Anti-sore Bed Mechanisms

The Fig. 1.10 is a bar graph that visualizes the distribution of reported devices according to the type of anti-sore bed mechanism: passive, active, or both.

- Passive Mechanisms: The graph shows a higher number of passive devices, with six entries. This dominance suggests that many approaches to preventing pressure ulcers in neonates rely on passive technologies, likely due to their simplicity, cost-effectiveness, and ease of integration into neonatal care settings. Passive systems typically involve specialized mattress materials, low-air-loss surfaces, or absorbent pads designed to distribute pressure and manage moisture effectively.

- Active Mechanisms: There is only one entry for active mechanisms, which could imply that while active systems are recognized for their effectiveness in pressure ulcer prevention, they may be less commonly implemented in neonatal care, possibly due to higher costs, complexity, or the need for ongoing maintenance.

- Both Passive and Active Mechanisms: The graph also indicates three entries for mechanisms that incorporate both passive and active features. This hybrid approach can provide the benefits of both strategies, combining the pressure distribution properties of passive systems with the dynamic adjustments of active systems. These mechanisms may offer a more comprehensive solution to pressure ulcer prevention but may also be more resource-intensive.

The data presented in these images reflect a research landscape where passive mechanisms are the most commonly explored and implemented strategies for preventing pressure ulcers in neonates. This trend might be attributed to the balance of effectiveness, cost, and ease of use that passive devices offer. However, the incorporation of active components or the development of hybrid systems represents a growing area of interest, especially as technology advances and the need for more sophisticated neonatal care solutions becomes apparent.

Understanding the different approaches and their applications is crucial for developing effective, evidence-based strategies to minimize the occurrence of pressure ulcers in vulnerable neonatal populations. The integration of both passive and active elements may represent the future direction in this field, aiming to provide both preventive and therapeutic benefits in the management of pressure ulcers.

The second image effectively visualizes the data presented in the first image by translating the detailed tabular information into a simplified bar graph format. It predicts the prevalence of different anti-sore bed mechanisms by summarizing the number of devices reported in the literature. The graph shows a clear predominance of passive mechanisms, consistent with the entries in the table, and highlights the distribution of active and combined mechanisms, thus reinforcing the trends identified in the first image. This visual correlation between the table and the graph emphasizes the research focus on passive solutions while also acknowledging the emerging interest in more dynamic and integrated approaches.

1.1.6 Competition Landscape & Analysis

The Fig. 1.11 presents a detailed competitive landscape analysis for different devices used to manage or prevent pressure ulcers, specifically in the context of neonates. The analysis is crucial in identifying the strengths and limitations of various devices and technologies available in the market, focusing on several parameters essential for effective pressure ulcer management.

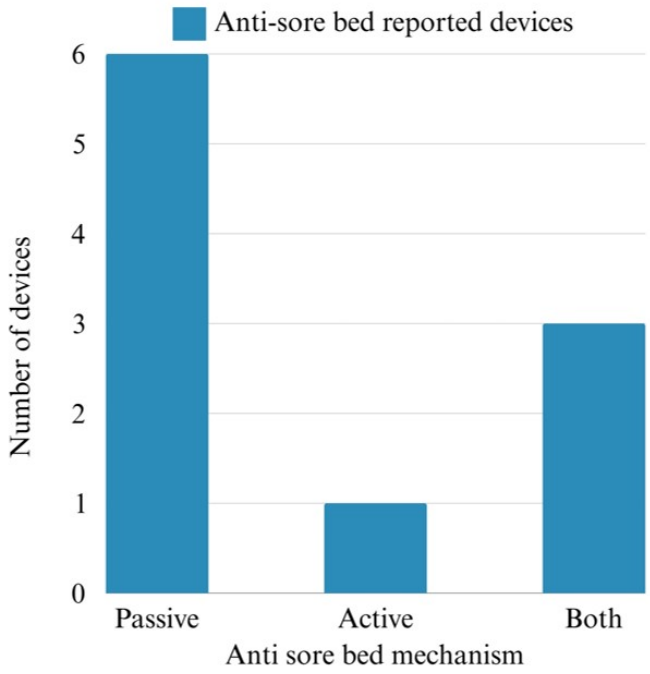


Figure 1.10: Simple bar graph denoting the various mechanisms followed by anti-sore beds

Serial No.	Devices	Pressure channels	Noise free	Mattress quality	Portable	Consistent	Adults	Neonates
1	Auto Logic 110	✗	✗	✗	✓	✓	✓	✗
2	Hicks AM-08	✓	✗	✓	✗	✓	✓	✗
3	IRIS	✗	✗	✓	✓	✓	✓	✗
4	Gel pillow & mattress	✗	✗	✗	✗	✗	✗	✓

Figure 1.11: Competitive existing devices and parameter analysis

A. Parameters Assessed

The Fig. 1.11 evaluates four different devices across seven critical parameters:

- Pressure Channels: This parameter assesses whether the device has alternating pressure channels, which are essential for reducing pressure on the skin by periodically shifting the body weight. Alternating pressure channels help in redistributing the pressure on different parts of the body, thus minimizing the risk of pressure ulcer formation.

- Noise-Free Operation: This criterion evaluates the noise level produced by the device during operation. A noise-free or low-noise device is particularly crucial in neonatal care settings to ensure that the infant is not disturbed during sleep, which is vital

for their growth and development.

- Mattress Quality: The quality of the mattress is another vital factor, as a good mattress should provide adequate support and comfort, thereby reducing the risk of pressure ulcers. High-quality mattresses typically have materials that conform to the body's contours, providing even support and reducing localized pressure.
- Portability: Portability refers to the ease with which the device can be moved or transported. In neonatal care, where space may be limited and the need for mobility high, a portable device can be particularly advantageous.
- Consistency: This parameter assesses whether the device consistently delivers its intended function over time. Consistency in pressure relief is critical for preventing pressure ulcers.
- Suitability for Adults: Some devices may be versatile enough to be used for both adults and neonates. However, this parameter specifically looks at whether the device is appropriate for adult patients.
- Suitability for Neonates: Given the unique physiological characteristics of neonates, including their delicate skin and low body weight, this parameter evaluates whether the device is specifically designed or adaptable for neonatal use.

B. Comparison of Devices

The existing devices are shown in Fig. 1.12.

- Auto Logic 110: This device does not have alternating pressure channels, operates with noise, and has poor mattress quality. However, it is portable and consistent in its function, making it suitable for adults but not for neonates. The absence of pressure channels and the noise it generates make it less desirable in a neonatal setting.
- Hicks AM-08: This device features alternating pressure channels and good mattress quality, but it is not noise-free and lacks portability. While it is consistent and suitable for adults, it is not ideal for neonates due to its noise level and lack of portability.
- IRIS: Like the Auto Logic 110, this device lacks alternating pressure channels, is noisy, and has inadequate mattress quality. However, it is portable and consistent, making it more suitable for adult care than for neonates.
- Gel Pillow & Mattress: This device does not have alternating pressure channels, is noisy, and has poor mattress quality. It is also not portable, but it is consistent. The device is better suited for adults but does not meet the requirements for neonatal care.

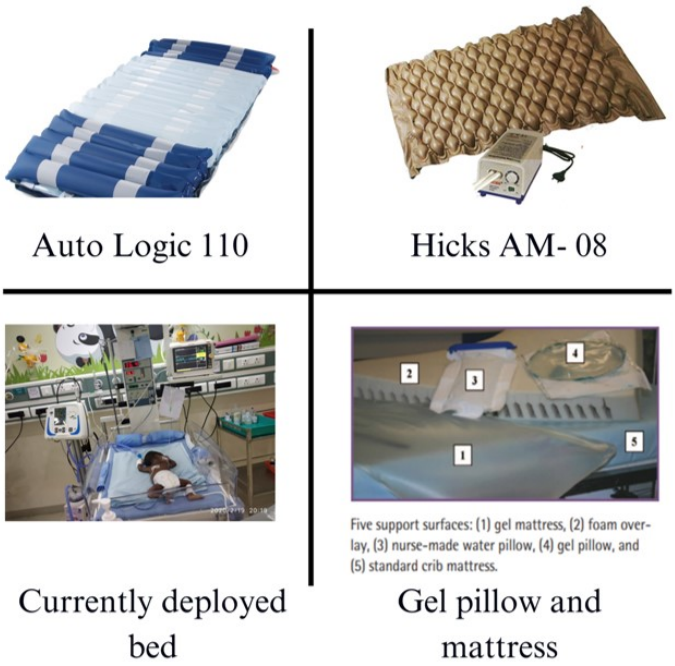


Figure 1.12: Competitive landscape for the existing devices

Limitation of the solutions:
The incapability of measurement of factors such as nutrition levels, sleep, or friction and shear levels that are an integral aspect of the etiology of PUs is believed to be one of the major limitations of the existing solutions. The current methods employed to reduce the incidence of neonatal PUs also have certain inhibitions such as incapacity of repositioning (seen as somewhat effective way to protect ulcerations) owing to limitations in the availability of nurses. Support surfaces such as low air loss beds, sheepskin, gel pads, viscous fluid mattresses, heel suspension of the bed using pillows, and air, water, or gel mattresses are limited by their sheer availability, scientific evidence proving their overall efficacy for pediatric patients, and maintenance costs. Pressure injuries tend to include tissue damage inflicted on the skin due to mechanical forces and medical devices. Congenital pressure injuries or traumatic birth injuries (due to significantly diminished or near absence of amniotic fluid presence in the mothers, skin injuries due to intrauterine transfusions or amniocentesis) are also an integral aspect of the cause of PUs in neonates. Thus, there is a pressing need for the development of pediatric specific anti-PU solutions to prevent the occurrence of neonatal pressure injuries.

1.1.7 Gaps in the Literature

Significant gaps remain in the prevention of PUs in NICUs, particularly when preterm babies are in vulnerable sleeping positions. While advanced technologies exist to prevent PUs, their high cost limits accessibility, especially in LMICs. There is a critical need for affordable, pressure-redistribution devices designed specifically for NICUs, where preterm infants are often at higher risk due to prolonged time in one position. Additionally, training programs tailored to healthcare providers in resource-limited settings are essential

to improve prevention and care practices.

Despite progress in understanding PU risk factors, the absence of standardized tools for accurately predicting risk in neonates remains a major gap. Assessment tools like the NSRAS and Braden Q require further refinement for use across diverse NICUs populations. Furthermore, there is limited research on DRPUs, even though medical devices contribute significantly to skin breakdown in NICUs. Future studies should prioritize interventions targeting these high-risk situations, focusing on both short- and long-term outcomes to better understand how PUs impact the growth and development of preterm infants.

1.1.8 Thesis Objectives

- **Design and Development of an Anti-Sore Bed Using Soft Robotics** The anti-sore bed for neonates was designed using soft robotics, incorporating alternating pressure channels that inflate and deflate to prevent the development of pressure ulcers (PUs). The soft robotic materials provide a gentle and adaptive interaction with neonates' delicate skin, ensuring continuous pressure redistribution, which is crucial in NICUs where neonates, especially preterm infants, are often immobile for extended periods. This design aims to minimize tissue damage by preventing prolonged exposure to high-pressure points.
- **Finite Element Method (FEM) Analysis and Validation** A comprehensive FEM analysis was performed using ABAQUS CAE software to simulate the interaction between the neonatal body and the anti-PU bed. The model used hyperelastic material properties for neonatal skin to accurately simulate how the bed redistributes pressure across the body. The analysis validated the bed's design by confirming that the alternating inflation and deflation of pressure channels effectively reduced the risk of developing PUs by minimizing prolonged pressure points.
- **Design and Testing of the Anti-Sore Bed with a Neonatal Phantom Model** After completing the design, the anti-sore bed was tested using a neonatal phantom model to replicate the physical properties of neonates. The bed's innovative multi-channel inflation system ensures alternating pressure distribution across the neonate's body, reducing the risk of prolonged high-pressure areas that could lead to PUs. This system automates the pressure redistribution process, minimizing the manual labor required by nursing staff to frequently reposition infants, while ensuring real-time monitoring and adjustments through the integration of a force-sensing resistor array (FSRA). This objective was crucial for confirming the practicality of the bed in real-world NICU scenarios.
- **Performance Optimization Using Force Sensor Resistor Arrays (FSRA)** To enhance the performance of the anti-PU bed, Force Sensor Resistor Arrays (FSRAs) were integrated into the system for accurate real-time monitoring of pressure distribution. The FSRA works by using a voltage divider circuit connected

to an ESP WROOM 32-bit microcontroller, allowing for precise measurements and dynamic adjustments in pressure distribution across the bed. The calibration process involved the use of dummy weights to simulate real-world conditions, ensuring the system could reliably prevent PUs by monitoring and adjusting pressure points in real time.

- **Clinical Assessment of the Efficacy of Anti-sore Beds in NICUs** A clinical study was conducted in NICUs to assess the efficacy of the anti-sore bed in preventing PUs. The study focused on preterm infants with gestational ages between 28 to 34 weeks and birth weights from 0.50 to 1.35 kg. Results demonstrated that neonates placed on air-inflatable mattresses had a significantly lower risk of developing PUs compared to conventional beds. The automated pressure redistribution system extended the time between necessary position changes, reducing the workload on healthcare staff and improving the comfort of the infants. Statistical analysis confirmed that neonates using conventional beds had a fourfold higher risk of developing PUs. This clinical assessment confirmed the bed's effectiveness and highlighted its potential to significantly improve care in NICUs.

1.1.9 Thesis Outlines

The research objectives of the present work are structured and elaborated upon across five chapters, as outlined below:

Chapter 1 provides an overview of the significance of preventing PUs in neonates, particularly in NICUs, where preterm infants are highly vulnerable to developing PUs due to their fragile skin and immobility. It introduces the challenges faced in NICUs regarding prolonged pressure exposure and outlines the need for innovative solutions to mitigate the risks. The chapter sets the foundation for the thesis by discussing the current state of PU prevention technologies, their limitations, and the research objectives aimed at developing a novel anti-pressure ulcer bed tailored for neonates. **Chapter 2** focuses on the design and development of an anti-PU bed using soft robotics technology. The design incorporates alternating pressure channels to prevent PUs by redistributing pressure across the neonate's body, ensuring gentle and adaptive interactions with their delicate skin. The chapter details the design process, including the selection of materials, system components, and soft robotic elements, which allow for the dynamic redistribution of pressure. Testing of the bed using a neonatal phantom model is also described, emphasizing its ability to prevent prolonged high-pressure points and reduce the workload for NICU staff. **Chapter 3** presents the performance evaluation of the anti-PU bed through the integration of a novel Force Sensing Resistor Array (FSRA). The FSRA system is designed to provide real-time monitoring and dynamic pressure adjustments across the bed to ensure optimal pressure redistribution. The chapter covers the technical details of the FSRA setup, including calibration, sensor selection, and data acquisition

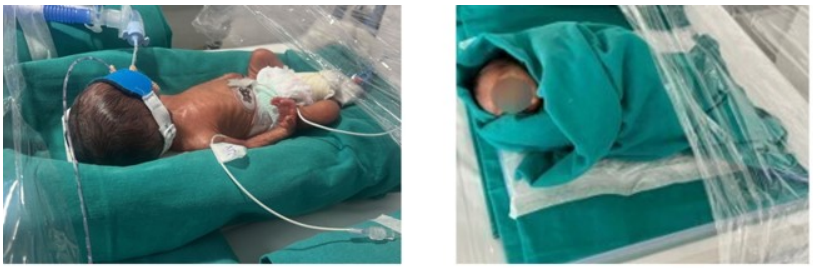
methods. Performance optimization using real-time data is discussed, along with validation of the system's ability to precisely measure pressure distribution and reduce the risk of PU development. **Chapter 4** evaluates the clinical efficacy of the anti-PU bed through a comprehensive analysis of data collected from NICUs. The clinical study focuses on preterm infants with gestational ages between 28 to 34 weeks and compares the incidence of PUs in neonates placed on the anti-PU bed versus conventional beds. Statistical analysis of the clinical data, including pressure monitoring results and the frequency of repositioning, is presented to demonstrate the bed's effectiveness in reducing PU risk. The chapter highlights the significant reduction in PU incidence and discusses the broader impact on neonatal care and healthcare efficiency. The final **Chapter 5** summarizes the key findings of the research, emphasizing the success of the anti-pressure ulcer bed in preventing PUs in neonates. It highlights the importance of the novel design using soft robotics and FSRA for real-time monitoring and performance optimization. The chapter discusses the broader implications for NICU care, including improved outcomes for preterm infants and reduced workloads for healthcare staff. It also identifies potential future research directions, such as further refinement of the bed design and expanding its application to other vulnerable patient populations.

Chapter 2

Design and Testing of Pressure Ulcers Preventive Bed for Neonates in Neonatal Intensive Care Units

2.1 Introduction

Pressure ulcers (PUs) in neonatal intensive care unit (NICU) patients result from localized skin and tissue damage due to intense, prolonged pressure often exacerbated by shear forces, friction, or a combination of these factors. This typically occurs when soft tissues are compressed between bony areas and a contact surface [55]. In low- and middle-income countries (LMICs), high infant mortality rates are linked to an estimated 15 million preterm births annually (before 37 weeks of gestation) [56]. Key contributors to these statistics include infections (36%, encompassing sepsis, pneumonia, tetanus, and diarrhea), preterm birth (28%), and birth asphyxia (23%) [57]. Premature birth rates in LMICs are approximately 12%, compared to 9% in high-income countries, with lower-income families being more vulnerable to preterm deliveries [58], [59]. PUs, though often overlooked, are significant hospital-acquired conditions, especially among critically ill patients, neonates, and children. In NICUs, preterm infants are at elevated risk for PUs due to prolonged immobility, which can lead to infection, pain, and extended hospital stays [60]. Compared to adults, preterm infants exhibit distinct anatomical, physiological, pulmonary, and developmental characteristics [61]. The skin of preterm neonates has a dermal layer that is less than 60% as thick as that of adults, making them particularly susceptible to PUs [56]. Constant pressure on these delicate areas, typically over bony prominences, can impede blood flow from subcutaneous tissues, creating pressure points [62]. The presence of PUs can significantly threaten the survival of neonates by leading to severe complications such as sepsis and clinical instability. The current beds have no smart feature to overcome the PUs from the neonates as they are slept on the NICUs bed with cotton clothes. The typical arrangement of beds in NICUs for neonates that causes the chance of PUs in different postures is shown in Figs. 2.1 (a) and 1(b). Typical neonatal cases of PU are shown in Figs. 2.1 (c)–1(f), which corresponds to 19%, 16%, 29%, and 10% for the occiput, buttock, toe, and back of the shoulders, respectively [63].



(a) (b)

Figure 2.1: Immobile neonatal bed with attached parts that increases the risk of PUs in (a) anterior position, (b) lateral recumbent position).

In pediatric hospitals, maintaining the skin integrity of preterm infants is a complex issue often misunderstood, leading to challenges in assessing PU risk factors, staging, or detection. These facilities often lack adequate guidelines, information, tools, qualified nursing staff, infrastructure, and awareness regarding PU prevention and management [59]. NICU staff often manually reposition patients to manage PUs, a method that is labor-intensive and has limited efficacy. Ostadabbas et al. [64] used an algorithm for a patient's optimal repositioning schedule to evaluate the stresses on human skin by comparing the time and frequency of the pressure-sensitive beds (PSBs). The suggested method leverages data from a commercial pressure mat assembled on the bed's surface to offer each patient a sequence of the next positions and the time of repositioning. Hence, this technique doesn't reduce the workload of the nursing staff although it provides an periodic posture repositioning of the patients. Literature reports various methods to mitigate device-related pressure ulcers (DRPUs), such as real-time tracking and warning systems with embedded sensors, soft actuation mechanisms, monitoring of maximum response force, and changes in bed materials[65]. Carrigan et al. [66] modeled a neonate as a rigid spherical shell weighing 9.0 kg, placed on the center of a polymeric soft actuator to measure contact pressure. Their pressure modulation algorithm identified a peak pressure of 9.5 kPa, below the recommended threshold. Gefen et al. [67] conducted experiments on rats to study time-dependent PU formation, finding that higher pressures led to quicker PU development, whereas lower pressures required more time. A mobile health application utilizing machine learning algorithms has been developed to monitor breathing rates, heart rates, activity, and contact pressure in critically ill neonates using PSBs [68]. A neonatal patient simulator for PSBs identified PU development in areas including the head, thorax, right arm, abdomen, pelvis, heel, lower limbs, and feet [69]. Some systems use air bladders to regulate airflow across the support surface, creating alternating pressure zones to prevent PUs. This real-time system divides the bed into five zones with a maximum internal pressure of 15 kPa and a maximum reactive force of 78 N, adjusting air pressure via pressure sensors [70], [71]. Sensitive to pressures as low as 7 grams, these systems can distribute pressure across even lighter body parts, such as arms and feet, by optimizing the foam material used in PSBs [72]. There are other technologies, such as passive pressure map/distribution tools and active lifting devices (e.g., beds with

moving parts), air mattresses, pillows, foam wedges, and soft cushions, are currently available and used to dynamically change the body position of patients [73]. Passive pressure relief, which involves using bedding or seat cushions with no active components, is more common due to cost and durability. Over time, compression and distortion of those materials reduce their effectiveness in reducing PUs [74]. Anti-decubitus PSBs are active air beds able to perform various motions and patterns and stop pressure build-up. But, these beds are not able to control the body pressure between sensors and states of PSBs [71].

There are limited PU prevention devices specifically designed for preterm infants in NICUs. Many existing anti-PU technologies are complex, expensive, and lack the sensitivity required for lightweight neonates and preterm infants. This study explores experimental and finite element (FE) simulation frameworks to analyze and prevent DRPUs in newborns. Both phantom models and actual neonatal patients were used to test the designed anti-PU bed. FE simulation frameworks were applied to verify and analyze the anti-PU bed's design and functionality with the developed prototype model.

2.2 System Level Framework

As we saw in the previous discussion, the currently available solutions for neonatal anti-PU beds are inadequate. In the current work, we have designed and developed the anti-PU beds with different sizes of pressure channels and conducted both experimental work and simulations to validate their performance.

2.2.1 Generic System Level Design

Rectangular Shaped Pressure Channel Bed Design:

The preliminary prototype was designed with a CAD model of dimension 600 mm x 450 mm and produced using an SLA 3D printer to mimic the currently deployed bed in hospitals. Each pressure channel has a dimension of 450 mm x 50 mm in rectangular form. The silicone rubber sheet is used as inflating material and glued using the RTV 666 anabond silicone (works as air-tight features at the interface of pressure chambers) with the base of the bed.

Square Shaped Pressure Channel Bed Design:

In order to accommodate more pressure channels beneath the skin of neonates, the pressure channels are designed as square-shaped pressure channels. Here, the material used is poly vinyl chloride (PVC). The dimension of each square channel has been taken as 80 mm x 80 mm in consultation with our clinical collaborator [58].

2.2.2 Electronic Circuit Design for Bed

A detailed block diagram of the control and actuator system is shown in Fig. 2.2, where the electrical control signals as well as the pneumatic flow throughout the system are defined.

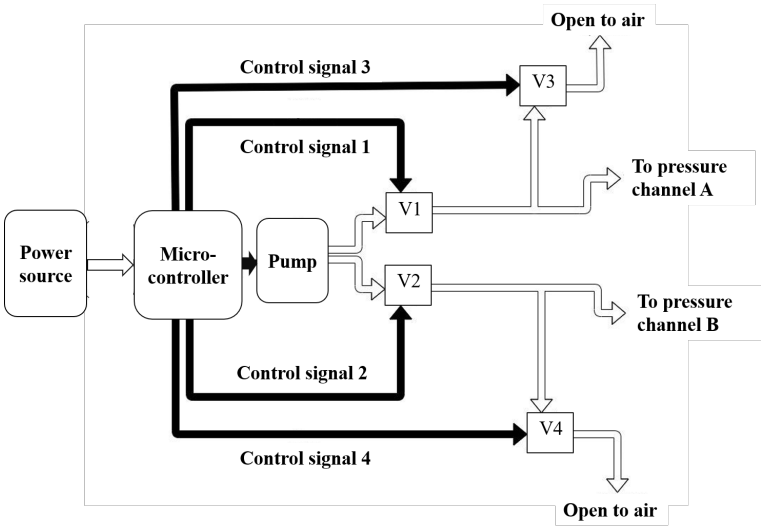


Figure 2.2: Block diagram of the control and actuator system depicting electrical and pneumatic control flow.

The pressure channels of the bed have pneumatic control through multiple ionix solenoid valves and these are operated by 24 V DC. Sobo double-nozzle air pump is used for the actuation mechanism and this is operated by 220 V AC. The periodic ON & OFF of the solenoid valves and pumps are operated by a 6-channel 5 V relay module. These valves, pumps, and relay modules are controlled by the Arduino Uno R3 ATmega328P microcontroller. This microcontroller automates the whole actuation process. All pressure channels are grouped into two alternately. The solenoid valves named V1 & V2 control airflow to the pressure channels, and V2 & V3 make way for air to exit the pressure channels. The V1 & V4 are activated simultaneously and V2 & V3 are activated together such that alternate channels are inflating and deflating continuously. The silent pump drives air into the pressure channels commanded by the microcontroller, and a control algorithm in the microcontroller turns the solenoid valves on/off in order to inflate and deflate the pressure channels at regular intervals of time.

An electronic circuit controlling the actuation mechanism for the prototype developed anti-PUs bed is shown in Fig. 2.3 (a). After a successful actuation mechanism with electronic components, the automatic inflation and deflation process was implemented as shown in Fig. 2.3 (b). The square- shaped pressure channel bed design with smaller blocks of size 80 mm x 80 mm each is as shown in Fig. 2.3 (c) and clinical trials of infants have been carried out at the NICUs of Dayanand medical college & hospital, Ludhiana (DMC & H) is shown in Fig. 2.3 (d).

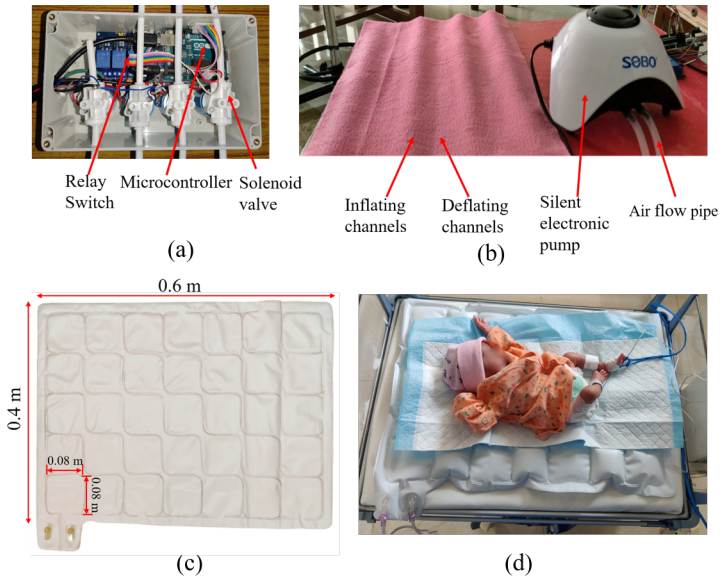


Figure 2.3: The various prototype models of (a) electronic circuit controlling the actuation mechanism (b) prototype developed for anti-PU bed with rectangular inflating and deflating channels (c) the bed designed shows the square shaped pressure channels (d) the final device deployed in NICUs for infant testing.

2.2.3 Finite Element Modeling Framework

In order to prevent human life losses and ease of production, enterprises now employ FEM to identify a cost-effective solution to an expensive proposal or to validate an erroneous model. The anti-PU bed design, simulation, and testing were carried out using the Abaqus software, and all measurements were considered in SI units.

Skin, fat, and bone are treated as a continuum in the FE neonatal bed. The constant neonatal body weight against the bed surface was investigated for the cyclic air pressure. The contact surfaces, gravity, and interactions have been considered, and a two-step pressure calculation was performed. The developed anti-PU FE model is used for linear and cyclic pressure loading. It is also adaptable to diverse load types, desired tests (displacement or pressure), and a set of geometric parameters such as wall thickness, chamber size, and mesh refinement. These inputs make a complete, ready-to-run Abaqus input file.

Simulation of Rectangular Shaped Pressure Channels:

In our previous work [58], we have simulated a neonatal bed with rectangular-shaped pressure channels in Abaqus with and without pressure in the channels. The mechanical parameters such as pressure and deformation for baseline are constant throughout the body contact w.r.t time due to the self-weight. The neonatal skin contact with an anti-PU bed varies alternatively in terms of mechanical parameters. These parameters vary alternatively with time in parabolic form due to the application of cyclic pressure on the neonatal body. The FE simulated anti-PU bed minimizes the pressure concentration and automatically varies contact position which is able to reduce the chance of PUs.

Simulation of Square-Shaped Pressure Channels:

First, a CAD 3D model of the bed, skin, fat, and bone of a neonate was created. The dimension of the bed is taken as per the currently used NICU beds in hospitals, i.e., 600 mm x 450 mm. The shape of each pressure channel is taken as square-sized chambers (measurements are taken in consultation with our clinical collaborator), and the dimension of each pressure channel is 39 mm x 39 mm. The bed was created with alternately inflating and deflating small pressure channels to accommodate more areas of the baby. The geometrical FE model is shown in Fig. 2.4 (a) and (b) showing the skin, fat, and bone were modeled as thin plates with given thicknesses as a preterm baby [75]. Fig. 2.4 (c) showing a pictorial design of a NICU bed. The portions showing "A" is taken as inflating chambers and "B" is taken as deflating chambers and vice-versa.

The materials are selected which are able to mimic the neonatal body (fat, skin, and bone) and the actual bed properties. The neonatal body and the polylactic acid (PLA) used as the bed's foundation are continuum, linearly elastic, and isotropically homogeneous materials. The material properties of the neonatal body parts and the bed are shown in Table 2.1 [4].

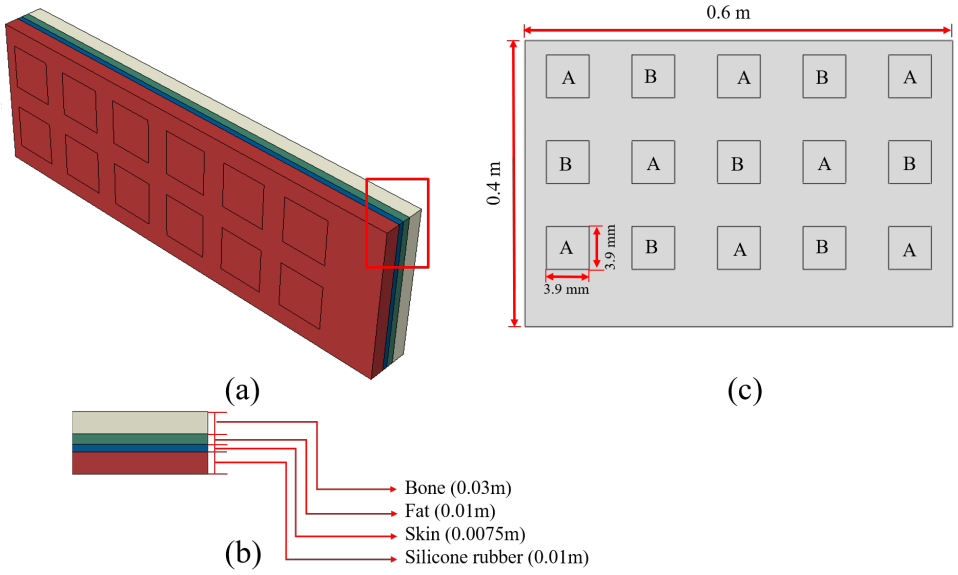


Figure 2.4: Geometrical aspects of (a) a FE model for bed and the neonatal body parts, (b) dimensions of the bed and neonatal body parts, and (c) dimensions of the bed and pressure chambers.

Table 2.1: Material Properties Used for PUs Bed and Neonatal Body.

Material	Young's modulus (kPa)	Poisson's ratio (-)	Density (kg.m^{-3})
Bone (body)	7	0.3	1750
Fat and Skin	1	0.42	1050
Silicone rubber (bed)	170	0.28	2329
Base of the bed	320	0.35	1190

An Ogden first-order (N = 1) polynomial model was selected for the silicon bed used in the present simulation with parameters μ_1= 10 MPa, and α_1= 25. The generalized Ogden's energy function for hyper elastic materials is written as [76]:

$$W(\lambda_1, \lambda_2, \lambda_3) = \sum_{p=1}^{N} (\mu_p/\alpha_p)(\lambda_1^{\alpha_p} + \lambda_2^{\alpha_p} + \lambda_1^{\alpha_p} - 3) \tag{2.1}$$

Where μ_p, α_p are material constants, and N is the order of the polynomial. Here, the materials used for the neonatal model and bed are incompressible.

The mesh-independent study was performed as it plays a vital role to estimate the closer value in FE analysis. Here, we conducted the test for various mesh sizes in the range of 10- 50 mm with an interval of 0.5 mm for fat, skin, bone, body, silicone rubber (bed), and the base of the bed. It is found that the value of the output is not changing, which means the model has meshed insensitive for the element size of 10 mm with an 8-node linear brick, reduced integration, and hourglass control (C3D8R) element type. The number of nodes and elements have shown in Table 2.2.

Table 2.2: FE Mesh Model Parameters for PUs Bed and Neonatal Body.

Model parts	Number of nodes (-)	Number of elements (-)
Fat	30783	18926
Bone (body)	23897	13978
Skin	16606	8505
Silicone rubber	28857	17400

The whole body model of the neonatal phantom has been considered as a single unit while applying loading and boundary conditions. Air pressure was applied to the cavity areas while all other surfaces are fixed with the base of the bed. The weight of the baby has been taken to be 1000 g (1.0 kg), corresponding to the value of gravity is 9.8 Newton as shown in Fig. 2.5 (a). Pressure is applied hydro statically to the inner surfaces of the chambers with a closed continuum model alternatively as shown in Fig. 2.5 (b) and (c) respectively. The neonatal phantom lying on a flatbed was simulated.

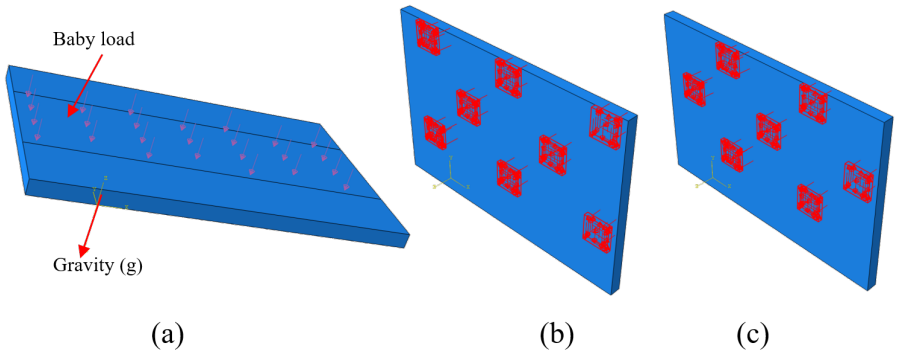


Figure 2.5: Loading condition of (a) baby weight and gravity in the downward direction, and alternating fluid pressure in (b) pressure chamber-A, and (c) pressure chamber-B.

The sides of the neonatal bed which are in contact with the base support are fixed as shown in Fig. 2.6. Such an arrangement will ensure that the silicone rubber sheet is tightly coupled to the bed surface and this contact was created in such a way that it ensures that the boundaries of the model are not displaced. Here, the baby sliding motion is not considered, which could account for frictional force and shear strain.

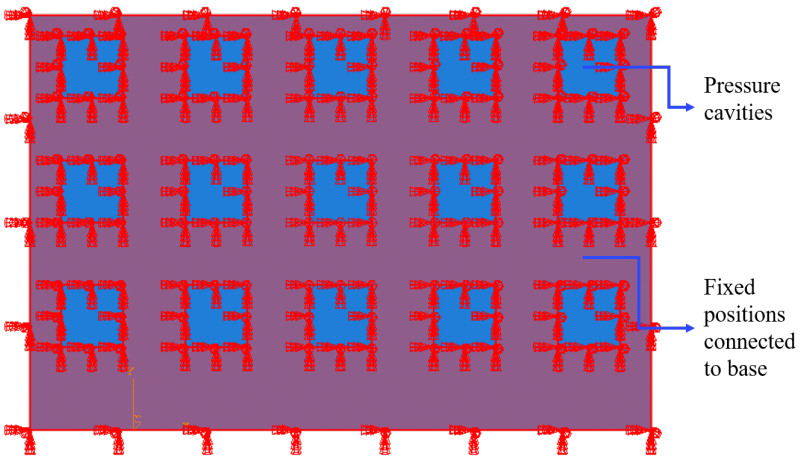


Figure 2.6: The contact of the lower part of the silicone sheet fixed with the base of the model.

2.3 Setup for Experimental Validation

The designed anti-PU bed with a periodically changing alternating pressure channel mechanism was calibrated. The outputs of the force sensors were checked for accuracy by placing them on the PU-prone areas of a neonatal mannequin during testing. To calibrate the force sensor, various weights such as 50, 100, 150, and 200 g are used. These weights are taken as calibration samples as force in Newton and the cor- responding resistances were noted in the range of Kilo-Ohm. The force developed due to these weights is calculated using the MATLAB software polyfit function. The logarithmic graph shows the calibration of deployed force sensor FSR-406 as shown in Fig. 2.7 (a). It shows the variation of resistance w.r.t. force applied on the sensor. When there is no force, the resistance becomes very high, i.e., in the range of Mega-Ohm. By increasing the force on the sensor the resistance gradually decreases. Hence, there is an inverse relationship between force and resistance.

The dummy weights are kept in various positions on the inflating, deflating, and interface portions to accurately calibrate them for the phantom model. The bar graph in Fig. 2.7 (b) shows the average force values in different positions with 4 to 5 tests for each weight. Here, the three positions across the bed (position-1: P1), along the direction of the bed (position-2: P2), and at the interface of the inflation and deflation channels (position-3: P3) are considered. In the bar graph, the mean values of the readings have been plotted. The standard deviation and variance for all the tests have been recorded. For all three conditions, the p-values are recorded and shown in Table 2.3 and are less than 0.05. Hence,

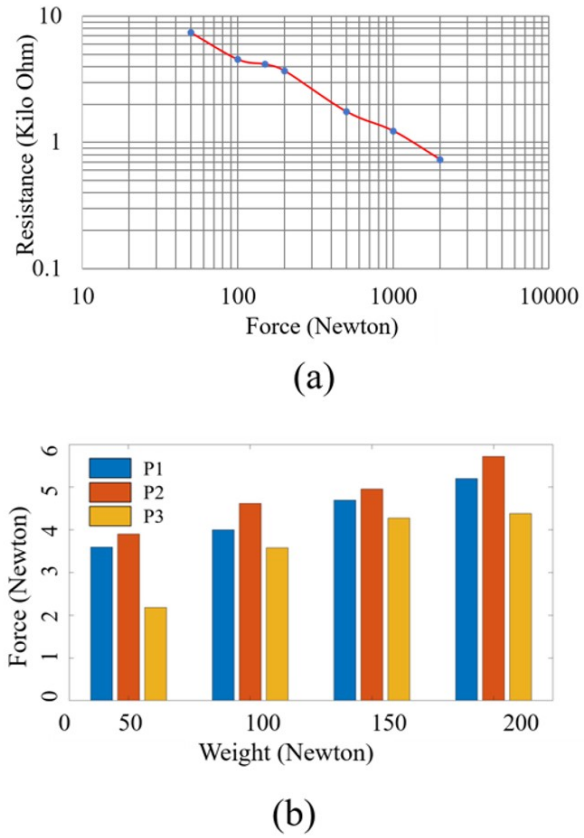


Figure 2.7: Graphical representation showing (a) calibration of force sensor FSR-406 (b) bar graph showing the force value for the various positions of weight.

there is a significant difference between the tests that are performed in mutual orientations. The force sensors are connected to the microcontroller to measure the pressure and force as shown in Fig. 2.8 (a). There is a smaller force sensor of the same technical specifications connected with the microcontroller to sense the very low-pressure variation at the toe regions. The readings are taken from the force sensors as analog values and then converted to force and pressure. To smooth the sensor output values plots, an average rolling function is used to match the FE simulation results obtained from Abaqus software [58].

Table 2.3: p-values Obtain from Mutual Orientations of the Force Sensors.

Weight (Newton)	P1 vs P2 (-)	P2 vs P3 (-)	P1 vs P3 (-)
50	0.007	0.0004	0.00004
100	0.0002	0.000008	0.0009
150	0.003	0.006	0.0007
200	0.0001	0.002	0.00013

The force sensors are installed under the bony surfaces of the premature neonatal phantom such as the back side of the head, buttocks, and other bony prominences as shown in Fig. 2.8 (b). Testing of the final device with the neonatal phantom was shown in Fig. 2.8 (c). The aim of this mannequin test was to determine how the contact pressure distribution

can contribute to a comfort assessment for neonatal monitoring in incubators on beds with different posture orientations. This mannequin test was technological proof to reveal details about the trial process and practical considerations that helped prepare for clinical testing, such as the baby positions. The weight of the phantom has been taken as 1.0 kg to represent a preterm baby in NICUs [77], and the material has been chosen to be a soft silicone material. Although it doesn't simulate the actual infants' tissue, it is deployed in the experiment primarily for weight purposes and, to some extent for its ability to mimic neonatal skin. The force sensors are deployed under the bony surfaces of a neonate in the hospital to test the final device as shown in Fig. 2.8 (d). Here, we have carried out clinical testing on a single neonate. Furthermore, our future works will continue this study on multiple neonates.

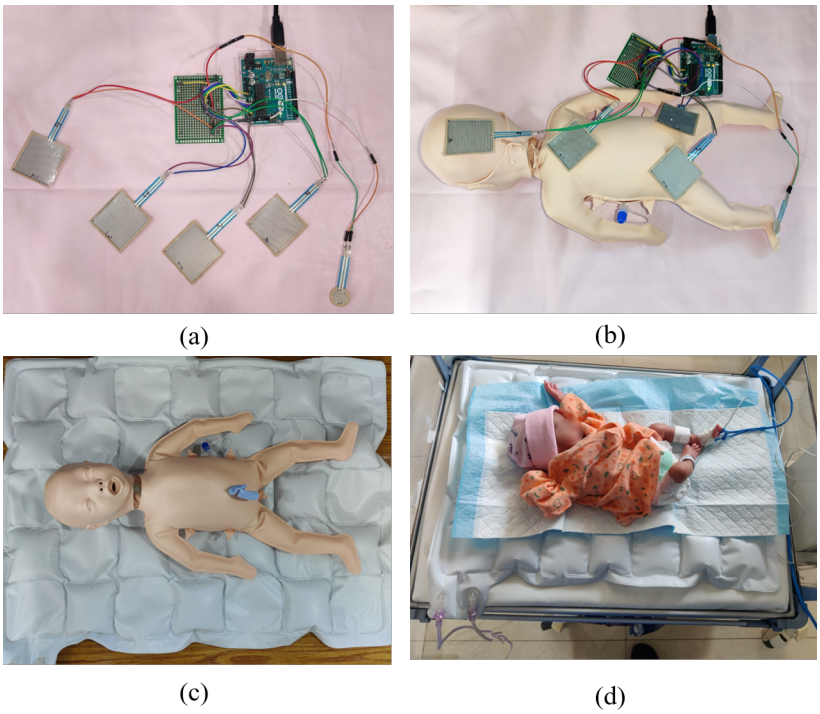


Figure 2.8: Hardware connection of (a) force sensors FSR-406 (b) placement of these sensors on the premature neonatal phantom model in lay down position (c) testing of the final device with the model (d) force sensors are tested on neonates at hospitals.

2.4 Results and Discussions

The design and testing of the PUs preventive bed involve subjecting the mannequin to rectangular and square-shaped pressure channels of the bed with variations to contact pressure w.r.t. time. Upon conducting the hospital trials, the final device a square-shaped pressure channel bed was tested on neonates. These tests provided valuable insights into the efficacy of the device and which were also validated by FE simulation analysis.

Therefore, after testing both beds, the outputs are plotted. The electronic pump is used to actuate the bed at regular intervals. One cycle of the inflation and deflation process has

to be taken as 30 seconds (sec) for smooth recording of the data, and the microcontroller can change this actuation time span as per our requirement. The data was recorded for 3 to 4 minutes, and it started before the placement of the phantom for calibration of the bed. The final data was recorded after the removal of the start data. The recorded data has been analyzed and plotted in Microsoft excel. The force variation w.r.t. time in both rectangular and square-shaped pressure chamber beds for the phantom model as shown in Fig. 2.9 (a) and (b) respectively and square-shaped pressure chamber bed for neonatal human baby as shown in Fig. 2.9 (c).

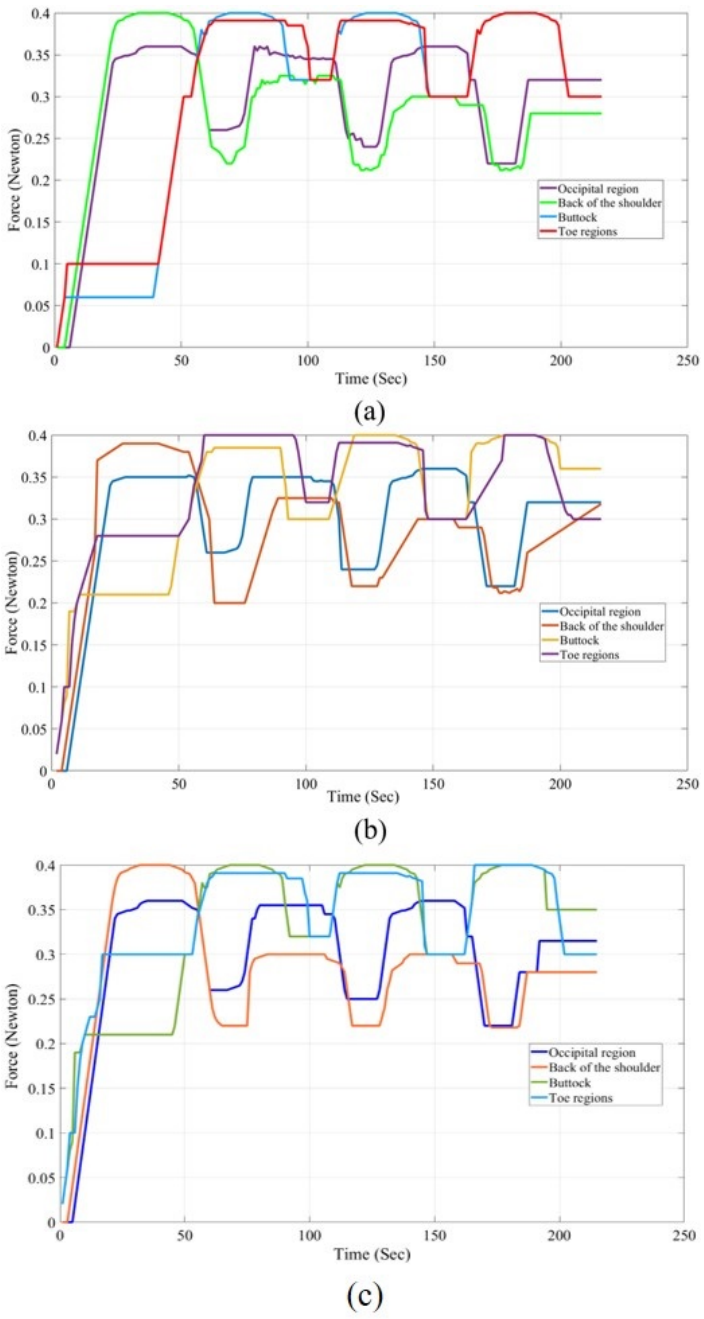


Figure 2.9: Variation of forces in (a) rectangular-shaped pressure channel and (b) square-shaped pressure channel on the phantom model (c) square-shaped pressure channel on neonatal baby with respect to time.

The plot of the square-shaped pressure chamber bed is more distinct as the pressure chambers are smaller than the rectangular-shaped pressure chamber bed. The data from four sensors placed beneath the PUs-prone areas like the occipital region, back of the shoulder, buttock, and toe regions. The maximum force obtained from the sensor is 0.4 Newton. These plots depict some cycles of inflation and the deflation process.

FE analysis was carried out on 64-bit Windows 10 Pro workstations with 32 cores 2.10 GHz Intel and Xeon CPU 6130 processors and 160 GB of RAM. To verify the demonstration, FEA was performed to check the risk assessment for PUs analysis. Hence, the neonatal model is simulated to measure the average pressure developed which can be the reason for the development of PUs [4]. The 4.26 kPa average contact pressure is the threshold value for causing PUs in the human body reported by various research papers for as little as 1-2 hours [55], [70], [78].

The pressure on the skin at no air pressure was taken as the baseline. The contour plot shown in Fig. 2.10, signifies the self-weight of the baby. Here, the simulation has been carried out for 15 minutes without alternating pressure channels and it shows the baseline of the pressure points. The continuous self-weight of the baby can cause the PUs in the various parts of the body. The average pressure exerted on the baby is found to be 3.3 kPa which is greater than the threshold value [55]. As per literature [79] the minimum applied pressure for PUs generation is 3.5 kPa for 15 minutes of clock time. Here, the same exposure time is considered to check the exerted pressure values for the PU generation which is 3.3 kPa. The contour plot for the preeminence without alternating air channels, i.e., the baseline model is shown in Fig. 2.10 due to the self-weight of the baby.

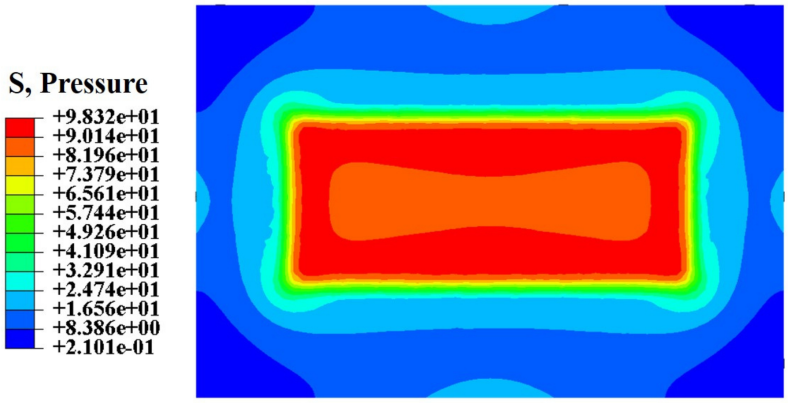


Figure 2.10: Pressure exerted due to self-weight of baby without alternating air channels (baseline model).

The contour plot for the cyclic pressure applied to the neonatal phantom in FE analysis is shown in Fig. 2.11 (a) and (b) signifies two different time steps of an overall alternating profile. Therefore, it is observed that when chamber A of the bed are inflated, the other portions, i.e., chamber B are deflated periodically.

It is found that when we activate alternating pressure channels the pressure increases in inflated regions and decreases in deflated regions compared to the baseline. The pressure

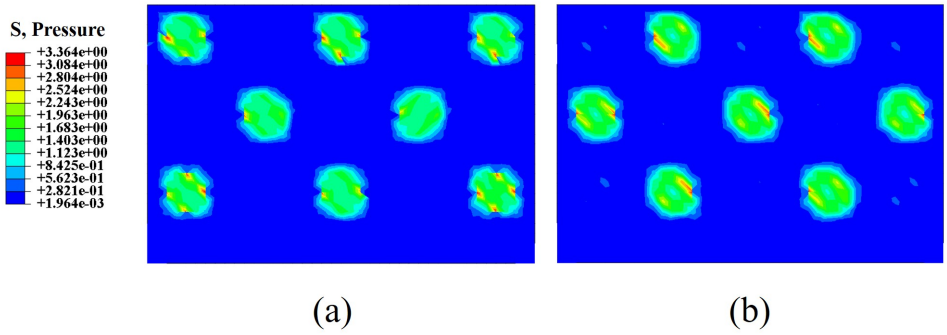


Figure 2.11: Distribution of pressure for (a) chamber-A, and (b) chamber-B.

gradient distribution across the thickness (skin, fat, and bone) of the FE neonatal model corresponds to alternating pressure chamber as shown in Fig. 2.12 (a) and (b). The alternating pressure gradient signifies the change in contact of the bed with the skin w.r.t. time. As the inflation and deflation channels will be alternating, no high-pressure points will be formed under the skin for a long time which is the primary way to reduce PU in neonates. This means the use of simple bed results in constant pressure generation, and an anti-PUs bed results in pressure variation in the contact position of the bed with the neonatal baby model.

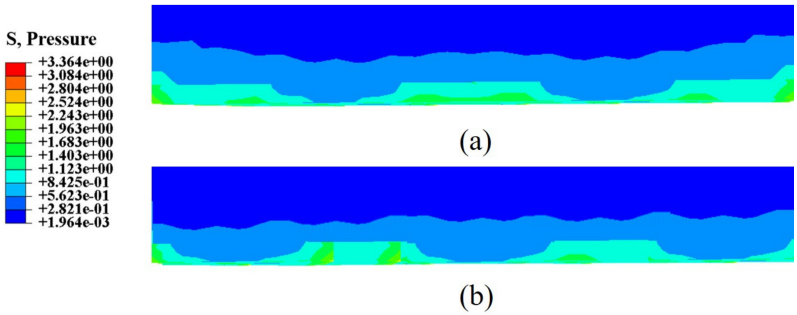


Figure 2.12: Variation of pressure gradient through the thickness of the neonatal FE model of (a) chamber-A, and (b) chamber-B.

The anti-PU bed model has been designed to apply air pressure alternatively on the backside of the neonatal phantom and neonates in the hospitals. The results of our experiment show that the pressure remains constant for an extended period, with negligible variation when the alternating pressure channels are absent. This indicates that the anti-PU bed model effectively regulates pressure and reduces the risk of developing pressure ulcers.

The experimental analysis shows that the maximum forces generated for the neonatal phantom and for the neonatal baby are 0.400 N and 0.405 N and the corresponding pressure values are obtained at 2.62 kPa and 2.66 kPa, respectively. Each area of the square-shaped

pressure channel is 39 x 39 mm^2. In the FEA simulation, the generated pressure value is 2.68 kPa. The percentage errors are 2.29% and 0.75% for the phantom model and the real human baby respectively corresponding to simulation results. The value of developed pressure as per experimental and simulation studies is under a safe limit to avoid PUs in neonates [69], [72]. Therefore, it is observed that the developed anti-PUs bed using experiments and corresponding simulation-based analysis is able to reduce the PUs, and we are confident in its ability to provide a safe and effective solution for the prevention of pressure ulcers in neonates. This work mainly focused on anti-PUs bed design and testing. It only considers the PUs prevention based on changing the continuous contact between the neonatal baby's skin and bed surface by taking the normal weight of the baby on the bed surface, not the shear forces due to the rolling or sliding motion of the baby.

2.5 Conclusion and Future Scope

The hardware prototype designed here provides an alternative to the existing bed in NICUs. The alternating pressure profile obtained from the force sensors gives an overview of implementing this bed in hospitals. In the FE simulation, the bed was tested for newborns with and without pressure in the channels. The mechanical parameters such as pressure and force for baseline are constant throughout the body contact w.r.t time due to the self-weight. The contact pressure with an anti-PU bed varies alternatively was shown in terms of mechanical parameters. These parameters change alternately over time because of the application of fluid cyclic pressure in the multichannel two-stage system. The FE-simulated anti-PU bed minimizes the pressure concentration and automatically varies contact position, reducing the chance of PUs. This concludes the purpose of the design and analysis of anti-PU beds and, also the reduction of efforts made by nurses.
In our future work, we will perform the tissue-level analysis of skin on PUs due to sliding and frictional forces between the skin and the bed surfaces. In addition, our devices will be tested on multiple infants and have to be compared with the existing beds to characterize the reduction in PUs objectively. The ethics clearance for such studies has already been taken. The results of that study are planned to be quite comprehensive and published in a separate one in our future work. Through our continued efforts, we aim to refine our approach further and develop practically effective solutions for preventing and treating PUs in neonates.

Chapter 3

Performance Evaluation of Neonatal Anti-pressure Ulcer Bed Using a Novel Force Sensing Array

3.1 Introduction

First four weeks of life, after birth, are crucial for premature survival. This period is known as the neonatal or newborn stage [80]. Special care and attention are needed to ensure their survival and well-being. Newborns face various challenges and severity to their health and survival, especially in low and middle-income countries (LMICs), where the burden of infectious diseases, malnutrition, and poor health systems are high [58]. One of the most common and unpreventable complications that can affect newborns are pressure ulcers (PUs). It is also known as bedsores or decubitus ulcers that cause skin and underlying tissue injuries, which result in prolonged pressure on the skin [81], [82]. PU can cause pain, infection, delayed wound healing, and reduced quality of life, and these are especially prevalent in hospitalized neonates in neonatal intensive care units (NICUs). PUs are caused by various factors that increase the risk of developing skin breakdowns due to immobility, medical devices, moisture, friction, shear, and contact pressure [83], [84].

The prevalence of PUs in newborns range from 3% to 27% reported in different studies [85], [86], [87] . However, these studies may underestimate the true burden of PU in newborns, as they are based on visual inspection and subjective assessment of skin integrity, which may not detect early signs of tissue damage or hidden wounds. Furthermore, there is a lack of standardized definitions and criteria for diagnosing and staging PU in neonates, which may lead to inconsistency and variability in reporting and comparing results.

Several methods have been proposed in the literature to measure and monitor the pressure distribution on hospital beds for different purposes, such as preventing PUs, optimizing patient comfort, evaluating mattress performance, or assessing patient posture. In tackling PUs, NICU staff frequently rely on manual repositioning of neonates. Yet, this method's efficacy is constrained, prompting the need for more nursing personnel to cope with the resulting workload increase. The methods adopted for the prevention of PUs can be broadly classified into two categories: direct methods and indirect methods [88], [89]. Direct methods involve placing sensors or transducers directly on or under the patient's

body or between the patient's body and the mattress surface. In this methods, the force or pressure applied by the patient's body on the mattress surface, and transducers used in between, may cause discomfort to the skin of the baby. These sensors can measure various physical quantities related to pressure distribution, such as force, strain, and displacement. Indirect methods involve placing sensors or transducers away from the patient's body or outside the mattress surface. Here, the measurable physical parameters, such as pressure distribution based on temperature, light, or radiation, may cause irritation and other health-related issues, e.g., improper sleeping. These sensors can measure physical quantities related to pressure distribution indirectly through other phenomena, such as light reflection or absorption. Each method has its advantages and limitations in terms of accuracy, sensitivity, reliability, cost, complexity, invasiveness, and suitability for neonatal skin.

A method based on optical sensors that can measure the pressure distribution on mattresses without contacting the patient's skin can reduce the risk of infection and skin damage. Comparison of the antiPU system and with other indirect methods, such as infrared thermography, which require large or heavy equipment that may not fit in the limited space or weight capacity of NICU beds, which can range from 0.5 m^2 to 1.5 m^2 and 50 kg to 150 kg, respectively [90]. The comparison of different methods for measuring pressure distribution on neonatal mattresses, such as load cells, strain gauges, and pressure mapping systems. It has been found that direct methods, such as load cells and strain gauges, use some sensors that may not cover the entire mattress surface or capture the pressure variation over time. For example, a typical load cell system can have only four sensors at the corners of the mattress, which may miss the pressure peaks at the bony prominences of the neonate's body. Stinson et al. suggested that pressure mapping systems, which use many sensors embedded in a thin mat, can provide more accurate and detailed information on the pressure distribution and interface pressure between the neonate and the mattress [91]. The developed PUs preventive beds reported by various authors have similar types of issues and challenges. A low-cost pressure measurement system based on resistive sensors, which can be used in LMICs where the average health expenditure per capita is less than $100. Comparison of preventive bed systems for PUs with other direct methods, such as load cells, piezoelectric transducers, and magnetic resonance imaging, which can cost up to $10,000 per unit and may not be affordable or accessible in LMIC [92]. The various micro channels for fluid flow and the fluid–structure interactions have been reported to measure the pressure at the inlet and outlet using sensors for biomedical devices [93]. Bio-inspired pressure-sensitive color changing thin films are reported, which are based on displacement and intensity measurement techniques [94]. Al-Dahiree et. al. [95] reported on the design and shape optimization of load cell based on active and passive strain gauge which is sensitive to 20 grams (g). Bai et al. [96] reported the observations on 254 patients of NICUs and found that 88% reduced the risk of pressure injury development due to the use of pressure redistribution visco elastic, polyurethane memory foam. Nizami et al. [69] used pressure-sensitive mats to simulate

the respiratory rate for neonates and found the 1.57% RMS error. Van Donselaar and Chen [97] developed a frequency-based pressure mat that is sensible to very small weight (7 g) for clinical test and estimated the different material assessments will not affect the pressure values. In terms of bed performance enhancement, Jesus et al. [98] used the thru force-sensing resistor (FSR) system to be more receptive to lighter forces with consideration of contact to see the effect of weight, position, geometry (taken as a T-shape object), and location. This was a more sensitive analysis as compared to earlier available literature, and it will help to enhance the raw data. However, this method is more accurate but does not take the neonatal model or the clinical test of the bed. So, there is still scope for performance enhancement of these anti-PU beds with the considerations of neonatal baby model implementation.

Therefore, there is a need for efficient and reliable methods to design anti-PU beds for neonates by measuring and monitoring the pressure distribution on interfacial contact positions of bed and neonates (as shown in Fig. 1). This in-depth work can help to identify the areas of high risk for skin breakdown, evaluate the effectiveness of preventive interventions, and guide the appropriate treatment strategies. However, most of the existing methods for measuring pressure distribution are either invasive, expensive, complex, or unsuitable for neonatal skin.

In this study, we propose a novel force-sensing resistor array (FSRA) that works on the piezoelectric effect is integrated into the NICU mattresses for performance evaluation of the designed anti-PU bed design [83]. The deployed FSRA is a low-cost, easy-to-use, and flexible solution that can measure and monitor the pressure variation over time when subjected to an alternating inflating and deflating pressure channels. The sensor array consists of 48 small force sensors that are arranged in a matrix configuration on a flexible substrate. The sensor array can detect the pressure exerted by the neonate's body on each sensor and transmit the data to a microcontroller for processing and analysis. The sensor array can also provide real-time feedback through a heat map that indicates the level of pressure on each sensor; based on that, the pressure points can be reduced and help to prevent PUs.

3.2 Materials and Methods Used for Experimental System Framework

The objective of this study is to assess the efficacy of the anti-PU bed using the FSRA and compared with the standard pressure mapping system designed for a neonatal phantom. The heat map is used for the visualization of the pressure distribution on the mattress surface, which can accurately measure and monitor the pressure variation over time. The following are the steps used for the experimental (expt.) system framework and methodology adopted.

3.2.1 Square-Shaped Pressure Channel Bed Design

To accommodate more pressure channels beneath the skin of neonates, the channels are designed in a smaller number of square-shaped pressure channels [83]. The dimensions of square pressure channels are meticulously determined to cater to the typical proportions of preterm infants. The usual lengths of preterm neonates vary in the range of 273–368 mm, and for the head and chest circumferences vary in the range of 203–254 mm [99], [100]. The length of the phantom taken in this work lies within this range. The circumference of the bony prominences, i.e., head and chest of the phantom, is nearly 200 mm. So, the maximum channel size could be 200 mm only. By making the pressure channel size same as the circumference/ diameter with inflation and deflation, causes the movement of head and chest, as a result it creates discomfort to the neonatal baby due to inflation and deflation. So, the minimum size of the channels is considered as one fourth of the circumference of head/chest to accommodate more pressure channels as well as proper pressure distribution. This is the maximum channel size possible based on the circumference of the phantom with consideration of neonatal comfort and to restrict the movement of head due to the actuation mechanisms. However, if we consider the pressure channel size smaller than this, then the pressure distribution is comparatively less sensitive to actuation mechanisms as we have tested this type of pressure channel bed in clinical trials. Hence, with consideration of the above demographic data, clinical insights, and consultations with our expert neonatologists of Dayanand Medical College & Hospital, Ludhiana, the size was specified for the sensing elements to be 50 x 50 mm^2 . Furthermore, these dimensions are specifically tailored to address the heightened susceptibility of bony prominences to PUs. Understanding the criticality of bony prominence sizes in preterm infants is paramount in mitigating the risk of PUs. Thus, the decision regarding the size of pressure channels is methodically made to ensure adequate coverage and alleviate potential complications. A comparative image has been shown in Fig. 3.1.

In this work, 24 pressure channels are accommodated under the neonatal phantom model that provides enough pressure variation in the pressure channels. Here, the materials used in designing the beds are polyvinyl chloride and thermoplastic polyurethane [101].

3.2.2 Force Sensor Array Mattress Design

To measure the pressure variations accurately at every point of channel for a neonatal phantom model, the sensor array mattress was designed as shown in Fig. 3.2 (a). The cross-sectional view of different layers is shown in Fig. 3.2 (b). The specifications of A, B, C, D, E, F, G, H, and I layer materials and thickness grade of FSRA are summarized in Table 3.1. Here, PET and ECM represent polyethylene terephthalate and engineered conductive materials, respectively. To imbue PET with conductive properties, it involves the infusion of conductive materials such as carbon or graphene into the PET polymer matrix [102]. The size of each sensor in the mattress coincided with the size of the pressure channels in the bed. Therefore, the pressure variations in the channels during the inflating

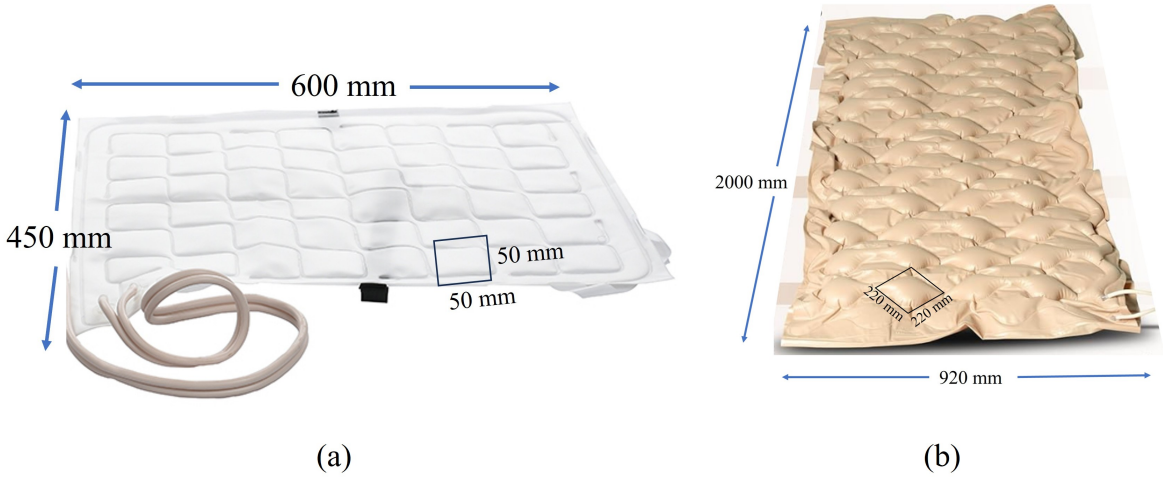


Figure 3.1: The developed bed with proper dimensions (a) for the neonates, and (b) for the adults.

and deflating process can be recorded quantitatively.

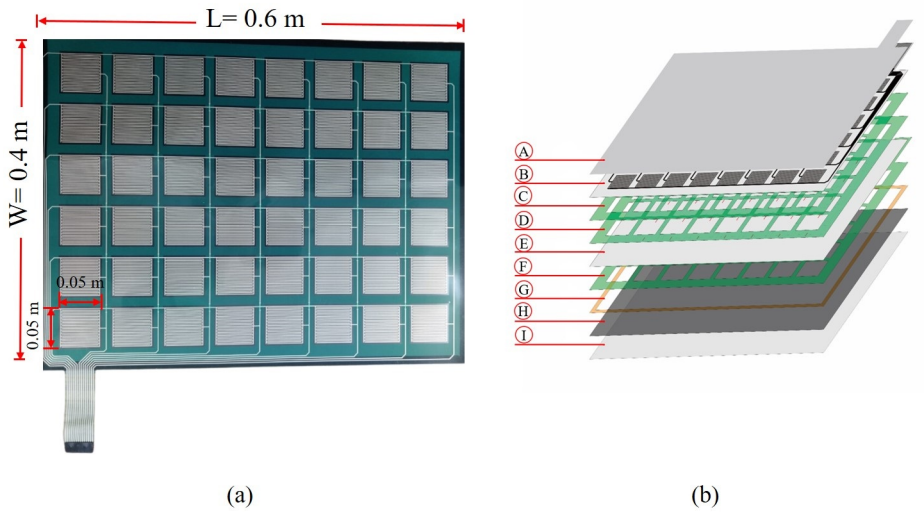


Figure 3.2: The deployed model of (a) the force sensor array mattress with appropriate dimensions, and (b) different layers of FSRA.

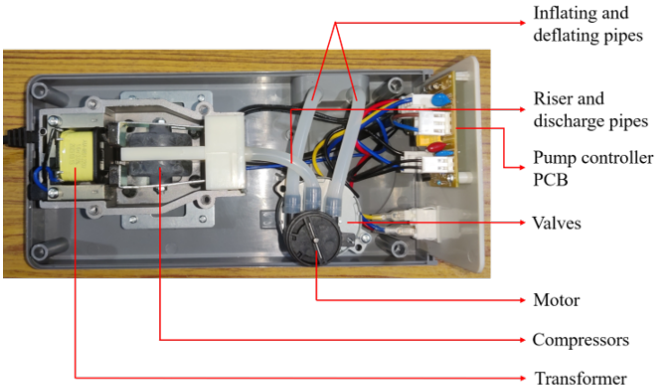
3.2.3 Electronic Circuit Design of an Air Pump for Alternately Actuation Mechanism.

The electrical components of the air pump and the control signals for pneumatic flow are shown in Figs. 3.3 (a) and 3.3 (b), respectively. The main components of this alternating air pump are a compressor, valves, nozzles, riser pipes, and discharge pipes. The compressor generates pulses of compressed air that are delivered to the valve. The valve alternately opens and closes, allowing the air to be compressed to reach the nozzle. The nozzle injects the compressed air and creates bubbles that rise and the bubbles reduce the weight of the gas and make it easier to lift through. The pipe carries the air to the

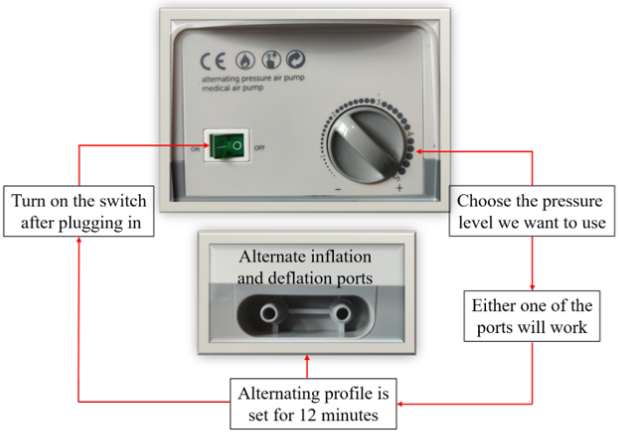
Table 3.1: Detail description of various layer materials of FSRA

Layers	Name & description	Material
A	Circuit layer	0.125mm PET film
B	Printed top layer	ECM CI-1001
C	First dielectric layer	ECM DI-7502
D	Second dielectric layer	ECM DI-7502
E	Printed jump layer	ECM CI-1001
F	Third dielectric layer	ECM DI-7502
G	Printed top adhesive	3M7533
H	FSR layer	0.1mm PET film
I	Back adhesive	3M9495LE adhesive

pressure channels of the beds alternately. The pump is set for 12 min of alternating profile. The pump controller has five levels with different pressure values and is operated with a 220 V AC supply. After a successful actuation mechanism with electronic components, the automatic inflation and deflation process was implemented with an open-loop system.



(a)



(b)

Figure 3.3: Electronic circuit of (a) an alternating air pump showing the different parts of the pump (b) shows the operation and working principle.

3.2.4 Calibration of Both FSRA and Designed Anti-PU Bed.

The two-time step for alternating positions is explained in Fig. 3.4 (a) showing the pressure channels "A" inflating and "B" deflating; Fig. 3.4 (b), showing the pressure channels B inflating and A deflating. The anti-PU bed with a periodically changing alternating pressure channel mechanism was calibrated by checking the output of each FSRA sensor for accuracy. The calibration process involved by placing the sensors below the neonatal phantom model during testing [103], [104] and the static characteristics of these sensors have been analyzed. We have utilized a variety of dummy weights (brash chromed slotted weights) for repeatability, including 50, 100, 500, and 1000 g as calibration samples and the force developed due to these weights was calculated. The corresponding resistances were noted in the range of kilo-Ohm (kΩ) using the Fluke 15B+ digital multimeter. Each of the 48 sensors in the FSRA was calibrated with the sample weights, and the output values were taken multiple times to obtain an inverse relationship between force and resistance. The resistance values varied for all sensors in the range of Mega-Ohm (MΩ) when no weight was applied. Multiple tests have been carried out for each sensor, and the averaged values are plotted in logarithmic scales. The logarithmic graph shows the resistance values for calibration of the deployed FSRA as shown in Fig. 3.6 (a) where C1–C8 represents the calibration curve for the sensors in columns 1–8.

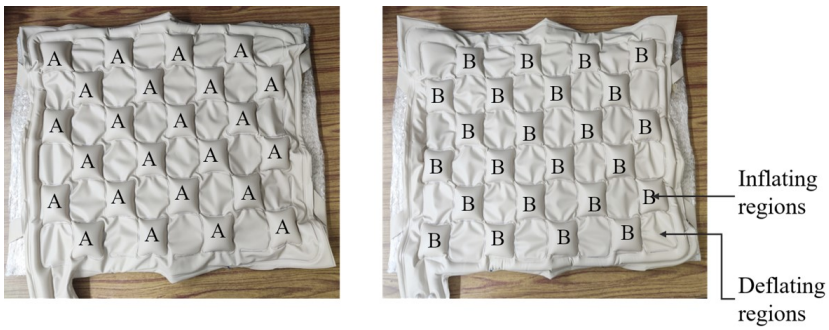


Figure 3.4: Two different positions of bed (a) showing the pressure channel "A" are inflating and "B" is deflating (b) showing the pressure channel "B" are inflating and "A" are deflating.

Each point on the lines corresponds to the average value of multiple tests that have been carried out for calibration. It shows the non linearity behavior of the sensing elements, i.e., the variation of resistance with respect to the force applied on the sensor. By increasing the force on the sensor, the resistance gradually decreases. Hence, there is an inverse relationship between force and resistance.

To calibrate the bed for the phantom model, which is a simulated body shape, we used some dummy weights that mimic the mass of a real body. We placed these weights in different sections of the bed, such as the inflating section, the deflating section, and the interface section where they connect. The force values were measured by performing

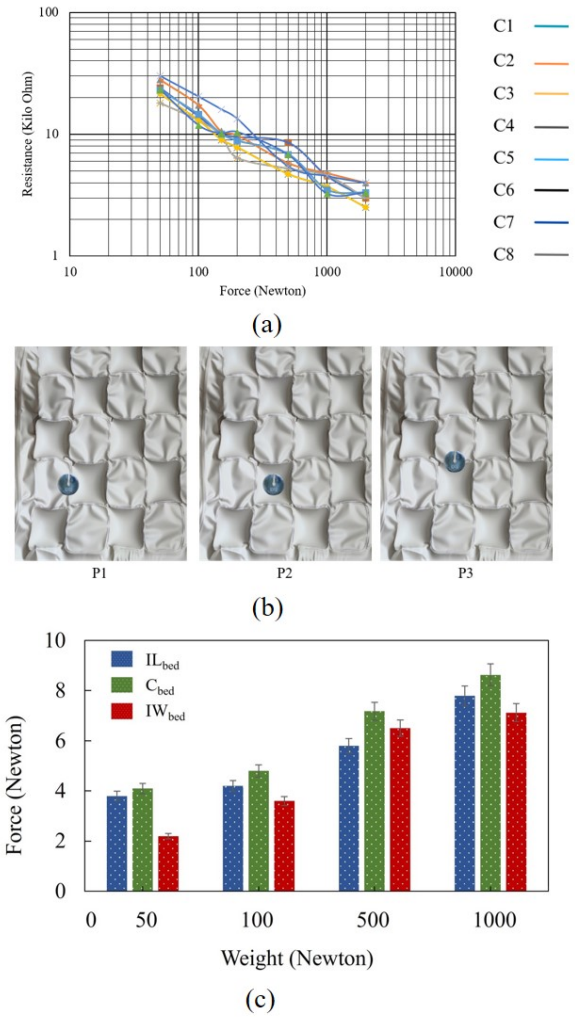


Figure 3.5: Graphical representation showing (a) calibration of FSRA (b) positions at IL_{bed}, C_{bed}, and IW_{bed} (c) error bar graph showing the force value for the various positions of weights.

multiple tests, with each weight considering three positions on the bed. IL_{bed} is along the length and interface of the inflating–deflating, C_{bed} is at the center, and IW_{bed} is along the width and interface of the inflating–deflating pressure channels as shown in Fig. 3.4 (b) [83]. The error bar graph in Fig. 3.4 (c) illustrates the average force values recorded at the mentioned positions, with three tests conducted for each weight. The mean values from these readings are plotted in the graph. We measure the standard deviation and variance of the results for all tests, the p-values for the three scenarios are compared, and displayed in Table 3.2. They are all below 5% and the error bars in the graph are also not overlapping, which indicate that the tests have significant differences when we alter the orientations.

The study of FSR was considered based on static analysis. The study did not account for the time gap between the loading and unloading of the weights, and the oscillations reading is not taken into account. Therefore, the setting time for the FSR measurement does not mean in our case static type analysis, which also simplifies and is accountable

Table 3.2: *p*-values obtained from mutual orientations of the force sensors

Weight	IL vs C	C vs IW	IL vs IW
50	0.005	0.0074	0.0008
100	0.0022	0.00008	0.0029
500	0.003	0.008	0.0077
1000	0.001	0.009	0.00096

for fulfilling the primary purpose of the paperwork analysis.

3.2.5 Experimental Setup of FSRA.

A single FSR measures the amount of force applied on it, and multiple FSRs can be combined into a matrix array with electronics circuits to measure the distributed force. Here, FSRA is designed with a thru mode connection to be receptive to lighter weights and a greater number of sensors. The circuit configuration of a thru-mode array and the voltage divider circuit of a single FSR sensor are shown in Figs. 3.6 (a) and 3.6 (b), respectively. In this thru-mode connection, 48 resistors are connected in six rows and eight columns. The wheat stone bridge is circuited in this configuration. However, due to circuit complexity and delay in response, it has been discarded from real-time implementation. Hence, to obtain the pressure values of each FSR sensor, the FSRA is connected to a voltage divider circuit, as shown in Fig. 3.6 (b), with a pull-down resistor of 10 kΩ.

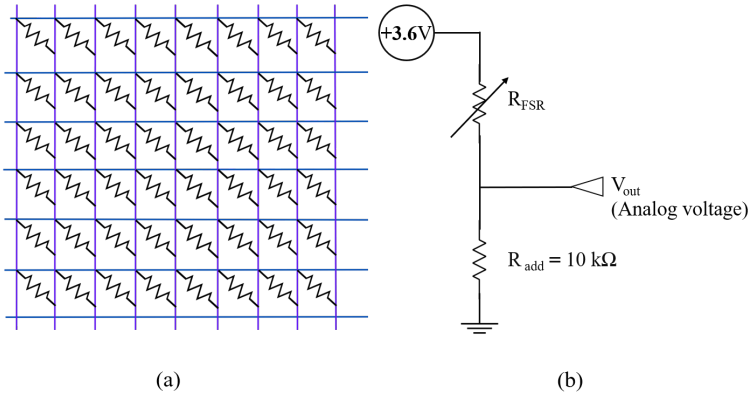


Figure 3.6: Configuration of (a) Thru mode circuit of FSRA and (b) the voltage divider circuit of a single FSR.

3.2.6 Configuration of Experimental Setup.

The thru mode, i.e., series connection of FSRA circuit, is designed using the voltage divider circuit. Two 74HC4051 multiplexers are used in this circuit to select the particular sensor in the FSRA as shown in Fig. 3.7 (a). Each mux has eight output pins, i.e., Y0–Y7. Therefore, one mux is used for connecting six rows, and the other one is used for connecting eight columns, such that 48 sensor values can be collected from the thru-mode FSRA. This circuit has six select pins, three in each mux, i.e., (S0–S2). Hence, there are $2^6 = 64$ combinations. Out of which, only 48 select lines or signals are enabled here.

The aim of designing this circuit is to simplify the 48 different voltage divider circuits. To accurately measure the individual sensor values, a curve fit function was deployed, and the electronic circuit in the hardware connection with printed circuit board is shown in Fig. 3.7 (b). The microcontroller ESP WROOM 32 is used for the analog-to-digital conversation of the values received from the sensors. The microcontroller is powered with 3.6 V, and a 10 kΩ resistor is used. The hardware setup with the designed anti-PUs bed with FSRA is shown in Fig. 3.8.

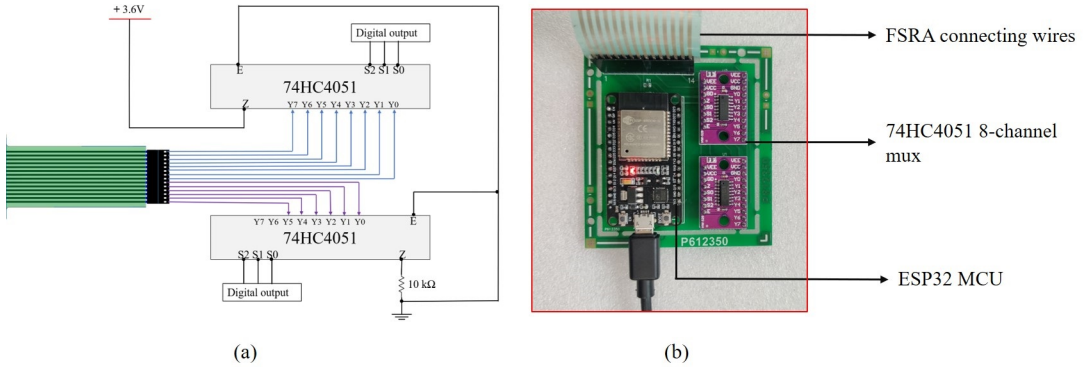


Figure 3.7: Layout of (a) 74HC4051 with the ESP WROOM 32 MCU (b) designed PCB of FSRA with hardware connection.

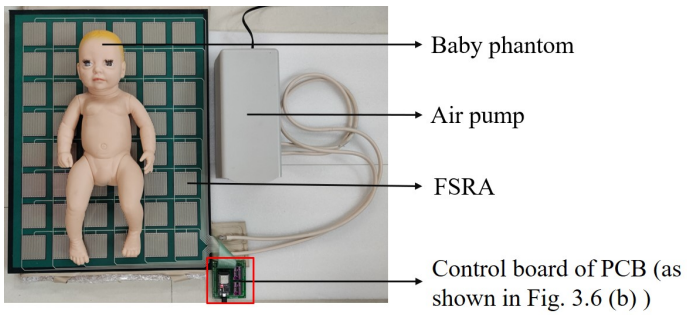


Figure 3.8: Hardware setup with the designed anti-PUs bed..

3.2.7 Voltage Divider Circuit of FSRA.

It produces a variable voltage that the analog-to-digital converter of the ESP WROOM 32 microcontroller can read. The output voltage is measured as the voltage drop across 10 kΩ.

The output voltage is obtained, derived by 3.1:

$$V_{out} = \frac{R_{add}}{R_{FSR} + R_{add}}.V_{in} \tag{3.1}$$

where R_{add} is pull-down resistance, and R_{FSR} is the resistance of the force sensor. With Eq. 3.1, the variation of R_{FSR} can be obtained by measuring the output voltage V_{out}. Here, the circuit's output voltage increases with an increase in the applied force and vice

versa.

Case 1: When there is no pressure on the FSRA, that is, no loading condition. The resistance of FSR is extremely high (around 10 MΩ); hence, the output voltage obtained is shown in the equation 3.2:

$$V_{out} = (10k\Omega/(10k\Omega + 10M\Omega))3.6V = 0.0036V \approx 0V \tag{3.2}$$

Case 2: When there is significant pressure on the FSRA, that is, high loading condition. The resistance of the FSR dropped to 300 (approximately); hence, the output voltage obtained is shown in the equation 3.3:

$$V_{out} = (10k\Omega/(10k\Omega + 300\Omega))3.6V = 3.49V \approx 3.6V \tag{3.3}$$

Hence, from Eqs. 3.2 and 3.3, it is observed that the output voltage varies from 0 to 3.6 V depending on the force applied to the FSRA. In the electronic circuit, the output we are getting from each and individual sensor corresponds to the resistance of that FSR in the FSRA, and it is designed using the voltage divider circuit. To ensure that the data acquisition device can always read the voltage variation according to the resistance change, an optimal value of Radd must be determined. Based on the expt. data, the resistance range of a single FSR varies from several MΩ to 200 kΩ, corresponding to an applied force between 0.2 and 20 N. However, a thru-mode FSRA shifts the range between 820 kΩ and 40 kΩ for the same interval. By considering these values and Eq. 3.1, the resistance of individual FSR sensors can be determined. Extremely large or small Radd can produce a small readable resistance range.

3.3 Validation Using Finite Element Simulation Framework

Now-a-days, the finite element analysis (FEA) tools provide a cost-effective solution to analyze the severity and to enhance the productivity and efficiency of biomedical devices. The FEA simulation framework demonstrated the FSRA with neonatal phantom by using with and without an anti-PU bed. The expt. demonstrated FSRA work has modeled on a virtual platform by utilizing FE software ABAQUS. The geometry, material specifications, load, boundary conditions (BCs), and mesh sensitivity analysis are the steps used in FEA. An Ogden first-order ($N = 1$) polynomial model was selected for the bed used in the present simulation with parameters μ_1= 10 MPa and α_1=25. The generalized Ogden's energy function for hyper elastic materials is written as [30]

$$W(\lambda_1, \lambda_2, \lambda_3) = \sum_{p=1}^{N} (\mu_p/\alpha_p)(\lambda_1^{\alpha_p} + \lambda_2^{\alpha_p} + \lambda_3^{\alpha_p} - 3) \tag{3.4}$$

where μ_p and α_p are material constants, and N is the order of the polynomial. Here, the materials considered have a continuum and incompressible behavior. The material properties for the phantom include a Young's modulus of 1 GPa, a Poisson's ratio of 0.3,

and a density of 1750 kg.m^{-3}. For the FSRA, Young's modulus is 260 GPa, Poisson's ratio is 0.38, and the density is 1190 kg.m^{-3}.

The neonatal model was designed using this link.1 The neonatal phantom, FSRA, and bed model are representative of the expt. demonstrated work as shown in Fig. 3.9 (a). The BCs are applied to the bed and FSRA as shown in Fig. 3.9 (b). BCs applied here are fixed types. In fixed type BCs, the translational (U_x, U_y, U_z) and rotational (UR_x, UR_y, UR_z) degrees-of-freedom are zero.

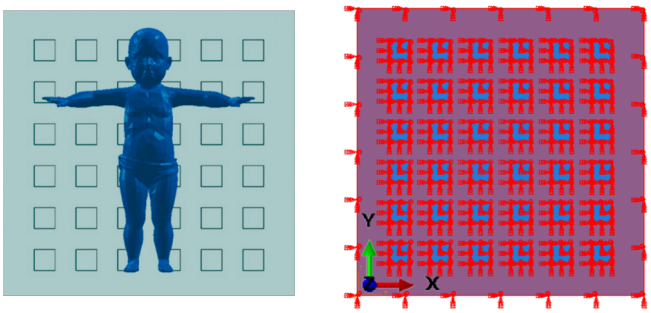


Figure 3.9: Geometrical representation of (a) neonatal phantom model used for simulation (b) fixed boundary condition applies to the lower part of the FSRA.

The loading is the weight (1.0 kg) of the phantom baby acting on the bed and FSRA sensor. The resistance to this self-weight is the stress or pressure developed at the interface that can be measured on the force sensor. The pressure is defined as the force per unit area in the FEA. The mesh-independent study was performed as it plays a vital role in estimating the closer value in FE analysis. Here, the mesh sensitivity test was conducted for various mesh sizes in the 10–50 mm range, with an interval of 0.5 mm for the neonatal model and FSRA. It is found that the value of the output is not changing, which means the model has meshed insensitive for the element size of 10 mm with an eight-node linear brick, hybrid integration, and hourglass control (C3D10H) element type. The neonatal FE model consists of 73,392 nodes and 44,302 elements. The FSRA FE model includes 19,319 nodes and 9481 elements. The bed is made up of 23,270 nodes and 10,988 elements.

3.4 Results and Discussion

To evaluate the performance of the anti-PU bed using the FSRA, the mannequin is used as a surrogate of a premature baby weighing 1 kg [105]. Here, this work signifies the performance enhancement of design and tested alternately inflated and deflated anti-PU bed, published research work, Mallick et al. [83]. The FSRA is placed under the mannequin, and the electronic air pump was deployed for the automatic actuation mechanism of the pressure channels of the bed at regular intervals and carried out for multiple cycles to record the data.

The heat maps are plotted in two-dimensional presentations utilizing MATLAB software to classify the pressure variation in these two cases. For proper visualization, a 6 x 6

matrix sensor is considered for the results, as this signifies the actual pressure exerted by the neonatal phantom as shown in Figs. 3.10 (a) and 3.10 (b).

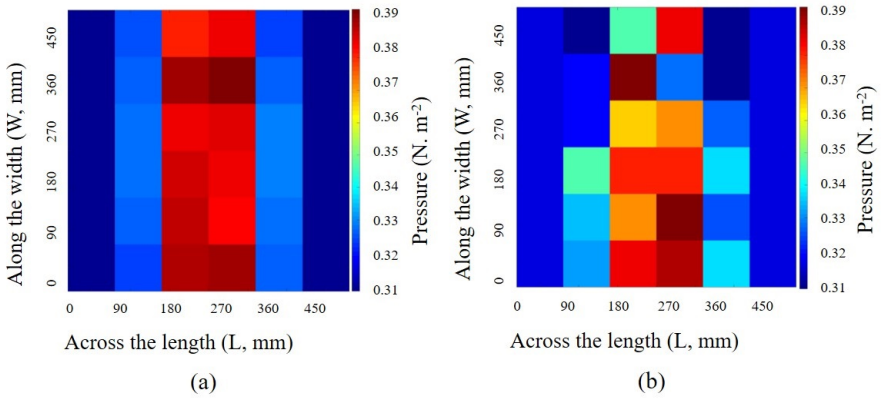


Figure 3.10: Distribution of the pressure (Newton per unit area) on the FSRA hardware setup (a) without the anti-PU bed (b) with the anti-PU bed.

Here, the X-axis signifies the variation of pressure across the length of the phantom represented as L, and the Y-axis signifies the width as W. This heat map shows the average value of each pressure sensor during the time taken into consideration for data recording. The pressure sensors of the FSRA, located directly below the phantom, exhibit higher values compared to the others. The data were recorded for 45 min to record three to four cycles of the alternating profile, and the average value of pressure for each sensor was plotted in the heat map of MATLAB software. Fig. 3.10 (a) signifies the baseline pressure value of the neonatal phantom model that is placed in the FSRA (no alternating pressure channels are activated). Hence, the pressure value of each sensor is constant throughout the total period and is found to be 0.39 N, i.e., it shows the self-weight of the phantom. Fig. 3.10 (b) indicates the individual pressure value of each FSRA pressure sensor measured on the anti-PU bed. The alternating pressure channels are not affected by the pressure measurements as all the pressure channels have separate sensing elements/sensors and they are individually placed. The pressure in the pressure channels varies sinusoidally throughout the time taken into consideration for data recording. In the heat map, each pixel corresponds to an FSR sensor of the FSRA and shows the average pressure value exerted on it. It is observed that the occipital region, back of the shoulders, buttocks, and toe regions are more prone to PUs.

The results of the expt. work show that the maximum force generated for the neonatal phantom is 0.39 N, and the corresponding pressure values are obtained at 1.56 kPa. To establish relevant changes, statistical testing has been performed using weights of 0.8 kg and 1.5 kg phantoms with the FSRA (other than 1 kg with a force value 1.56 kPa). The corresponding force values were found to be 1.52 kPa and 1.68 kPa. This shows variation of neonatal weight with respect to pressure variation on anti-PUs bed. The threshold value for causing PUs in the human body reported by various research papers for as little as 1–2 h as 4.26 kPa of average contact pressure [106], [107].

The FEA was used to validate the demonstrated expt. work. The FSRA sensor has a given material property and thickness over which the phantom weight was placed. The distribution of the pressure on the FSRA without an anti-PU bed (alternating air pressure was not applied in the channels) and with an anti-PU bed is shown in Figs. 3.11 (a) and 3.11 (b), respectively. Here, the conventional bed has not been analyzed. Only with and without altering the pressure channel role has been described.

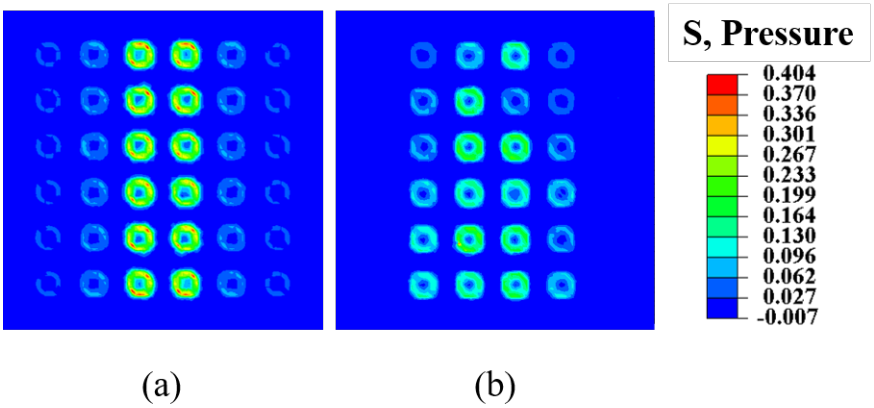


Figure 3.11: Distribution of the pressure (Newton per unit area) on the FSRA in FE analysis model (a) without anti-PU bed (b) with anti-PU bed.

It is observed that the pressure is uniform without an anti-PU bed, and its value is higher as compared to an anti-PU bed. The pressure peaks are reduced in Fig. 3.11 (b), and its value is distributed using an anti-PU bed and heat map result contours of expt. are comparable as shown in Figs. 3.10 (a) and 3.10 (b) which can maintain minimum pressure. The distribution of pressure without and with anti-PU bed on the occipital region, back of the shoulder, buttock, and toes are shown in Figs. 3.12 (a)–3.12 (h), respectively.

It is observed that without an anti-PU bed, the peak value of pressure is developed on the occipital region as shown in Fig. 3.12 (a) and it gets reduced by using the anti-PU bed for the A as inflating and B as deflating position (shown in Fig. 3.4) in Fig. 3.12 (b). Similarly, without using an anti-PU bed, the peak pressure on other PUs prone areas (back of the shoulder, buttock, and toes) are depicted as shown in Figs. 3.12 (c), 3.12 (e), and 3.12 (g), respectively. Using an anti-PU bed, the peak pressure gets reduced on PUs prone areas are depicted as shown in Figs. 3.12 (d), 3.12 (f), and 3.12 (h), respectively.

The values of peak pressure recorded by FSRA sensor in expt. work are 0.39, 0.386, 0.392, and 0.389 N for without anti-PU bed and 0.34, 0.336, 0.342, and 0.339 N for anti-PU bed on head, shoulder, buttock, and toes, respectively. In the FEA study, the pressure developed is 0.395, 0.381, 0.400, and 0.391 N without the anti-PU bed and 0.345, 0.331, 0.350, and 0.341 N for the anti-PU bed on the head, shoulder, buttock, and toes, respectively. Approximately 12% reduction in pressure difference is recorded after using an anti-PU bed in both expt. and FEA work. For the neonatal model, the expt. results recorded a force of 0.385 N, while the FEA output was 0.400 N. For the FSRA, the expt. results showed a force of 0.39 N, and the FEA output was 0.404 N.

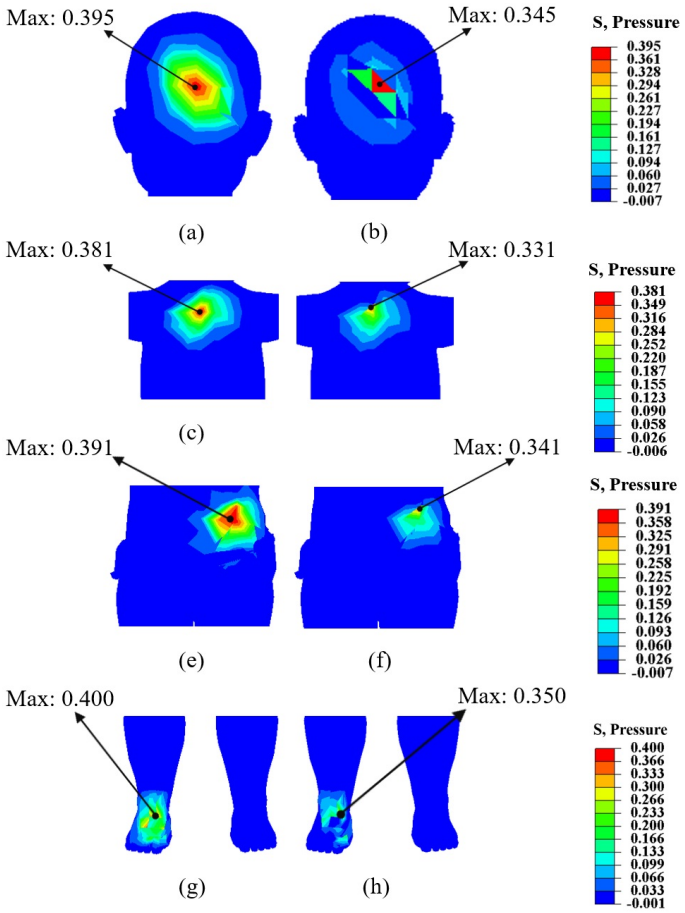


Figure 3.12: Distribution of pressure (Newton per unit area) with and without anti-PU bed on occipital, buttock, toes, and back of the shoulders from (a) to (h) respectively.

It is observed that the generated pressure value due to the designed anti-PUs bed, as per the expt. study and the corresponding performance evaluation shown by heat map, is under the safe limit to avoid PUs in neonates [69], [72]. This work focused mainly on improving the anti-PU bed design and testing performance reported in our previous research paper [83]. Here, the clinical aspects of occurrences of PUs at different positions such as anterior position, lateral recumbent position of neonates, and PUs prone areas like occipital, back of the shoulders, buttock, and toe regions have been incorporated. Additionally, the validation of the design through FEA of the real-time phantom model ensures both the reliability and efficacy of the new bed under simulated and real conditions, a depth of analysis that the previous work lacks. The earlier study provides basic design and initial testing of the anti-PUs bed with the implementation of very few force sensors. In FEA, the in-depth pressure analysis through the cross section (skin, fat, and bone) of the neonatal model was done.

Here, the FSRA system, equipped with multiplexers, accurately measures the force exerted on each sensor individually by different parts of the neonatal model. The pressure differences were recorded, and we utilized heat maps with a 6 x 6 matrix for better visibility.

3.5 Conclusions

The hardware prototype of the designed anti-PU bed provides an effective solution for the prevention of PUs in premature neonates in NICUs. The alternating pressure values in the pressure channels shown by the heat map, which were obtained from the FSR, give an overview of the implementation of this bed. The mechanical parameters, such as pressure and force for the baseline model, are constant throughout the body contact with respect to time due to the self-weight. These parameters change alternately over time because of the application of cyclic pressure in the multichannel, two-stage system. The contact pressure with an anti-PU bed varies alternatively to reduce the pressure points. The use of FSRA and the performance evaluation reported here for the anti-PU bed conclude the design to minimize pressure points with greater accuracy and automatically vary contact position to reduce efforts made by nursing staff. The FE analysis successfully validated the experimentally demonstrated work. In our future work, we will perform thermal management analysis related to body temperature, which is responsible for skin failure. In addition to this, our calibrated anti-PU bed will be tested for more newborn babies for objective and commercialization purposes.

Chapter 4

Assessing the Efficacy of Anti-Pressure Ulcer Beds for Neonates with Clinical Data Analysis

4.1 Introduction

Pressure ulcers (PUs) are localized injuries to the skin and underlying tissue is a significant challenge in the patients of the healthcare system [108]. It is also known as bedsores or decubitus ulcers, and pressure injuries, and it is more serious, particularly among neonates hospitalized in the neonatal intensive care unit (NICU). It is caused by long-time continuous contact of skin between the bony prominence and the contact surface due to compression effect [109]. Furthermore, it is caused due to continuous unrelieved pressure that restricts blood flow to the different areas of the body and lymphatic arteries results in leading to tissue necrosis, and cellular hypoxia [110]. The other factors such as high and persistent pressure from shear, friction, or a combination of these. In the case of hospitalized neonates (vulnerable infants), especially preterm and low birth-weight babies (body weight less than 1.50 Kg), are at a heightened risk of developing PUs. Because of their delicate or underdeveloped skin, insufficient perfusion, impaired movement, compromised neurological reactivity, fluid retention, dampness, and medical equipment [111]. The occurrence of PUs in neonates can lead to various complications, including pain, infections, delayed recovery, and prolonged hospital stays, impacting both the infant's well-being and the healthcare system's resources. It is reported that in neonates, the toe (29%), occipital (19%), buttock (16%), and backside of the shoulder (7%) are the most frequent regions where the PU is most commonly observed due to prolonged stays in hospitals [112]. In general, as per scientific reports, the PU incidence in NICUs ranges from 3.70 to 21.60%, with a frequency of 23% [113], [114]. Moreover, PUs have been attributed to 11 billion usd in costs worldwide each year, and in the US, their consequences account for 60,000 of the 2.5 million hospitalized patients' mortality annually [115]. These findings emphasize the importance of implementing steps to prevent and control PUs, particularly in neonates, including both term and preterm babies admitted to the NICU. Adults are prone to sustain PU over bony prominences where there is less

subcutaneous fat, which facilitates the uniform distribution of pressure applied to the skin throughout a wide surface area and facilitates minimizing the pressure at a certain point [116]. However premature babies have relatively little or no subcutaneous fat until after 34 weeks of gestational age. Also, the skin structure of preterm neonates is a bit different from that of adults. In preterm neonates, the outer layer of the epidermis, the stratum corneum, has 4–5 layers of cells, which is composed of 20 layers in adults [117]. In preterm, mitotically active cells are present in a single layer that forms the stratum basale, the foundational layer of the epidermis. Further, over time, the cells in this layer move outward, losing their nucleus, growing keratin, and flattening as they reach the stratum corneum's external layer. Lipoprotein secretions from the spaces between cells serve as the epidermal barrier's "cement" [118]. The thinness of the external layer in preterm neonates makes them more vulnerable; therefore, PUs may appear anywhere on their bodies. The extent and depth of tissue damage have been classified into four stages by the National PUs Advisory Panel (NPUAP), the European PUs Advisory Panel (EPUAP), and the Pan Pacific pressure injury alliance (PPPIA) [119]. In stage I, there is non-blanchable erythematous skin; it may be tender, soft, warmer, or colder than the tissue underneath; in stage II, the thickness of the skin is partially lost or blisters or ulcers may appear; in stage III, the skin thickness is entirely lost, and subdermal components are visible; and in stage IV, there is a complete tissue loss exposing muscle, tendon, or bone. Furthermore, NPUAP has described two additional stages: stage five, "unclassifiable," indicating that there is a complete disappearance of skin or tissue thickness and depth that is unknown. In the sixth stage, "suspected deep tissue injury," also with an undetermined depth, there is a blood-filled blister or a purple or maroon patch of discolored, intact skin [120]. Additionally, the existence of it could pose a significantly increased risk of sepsis and clinical instability to the neonate's survival. Therefore, PUs prevention in neonates is of utmost importance to ensure optimal neonatal care and promote better health outcomes. Early intervention and effective preventive measures can significantly reduce the incidence and severity of PUs, thereby enhancing the overall quality of care provided to these fragile infants. Various prevention methods have been explored to address this issue. One such approach that has garnered attention is the use of anti-PU beds, i.e. air-inflatable mattresses. This operates by periodically actuating alternately inflating and deflating, ensuring that no single surface remains in direct contact with the neonate's delicate skin. These specialized beds aim to redistribute pressure, minimize the risk of tissue damage caused by prolonged contact with the same pressure points, and minimize contact pressure [59]. The efficacy of anti-PU beds in PU prevention, a realworld clinical study, and their significance in reducing the workload of nursing staff by reducing the frequency of position changes have been performed and investigated in this paper. For this, the data has been collected from the nursing staff of hospitals for anti-PU beds and conventional beds and then analyzed using statistical approaches. The data was analyzed to identify the potential differences in PU incidence. From the analysis and study, it was observed that the chance of PUs gets reduced by utilizing the anti-PU bed in

NICUs. In addition, the potential challenges faced and the overall neonatal care practices associated with PU prevention by healthcare professionals are described for utilizing these preventive measures. The rationale behind this study is to bridge the existing knowledge gap concerning PUs in neonates and their prevention strategies. This research, a valuable insight to inform nursing staff and contribute to the improvement of neonatal health outcomes. The study helps in the guidance and support of healthcare professionals in delivering the highest standard of care to neonates, promoting their health, and fostering a nurturing environment for their development.

4.2 Materials, Methods and Statistical Data Analysis Approach

The complete development and setup of the anti-PU bed and the method to perform the clinical studies on the neonates are described in this section. This section consists of two stages in which the first step is to set up development for clinical testing and data generation. In the second stage, the statistical approach is described as utilized for the clinical data.

4.2.1 Clinical Testing and Data Collection Framework

The clinical testing and data collection framework consists of the following steps:

Device Design and Deployment

The anti-PU bed employed in this study is a specialized air-inflatable mattress equipped with alternating pressure channels, referred to as case-I, whereas the conventional bed setup is named case-II. The currently deployed conventional bed in NICUs of (DMC & H, Ludhiana is shown in Fig. 4.1. Case-I mattresses were strategically deployed for infants to ensure proper alternating pressure distribution. It was designed to accommodate neonates of varying sizes, allowing for optimal pressure distribution and prevention of PUs. The mattress is constructed using bio compatible materials, such as TPU (Thermoplastic Polyurethane) and PVC (Polyvinyl Chloride), ensuring its safety for use in a medical setting as shown in Fig. 4.2 (a) and 4.2 (b) respectively.

Figure 4.1: The deployed conventional bed currently deployed in the NICUs.

(a) (b)

Figure 4.2: The prototype deployed an anti-PU bed in NICUs of DMC & H Ludhiana with (a) TPU material, and (b) PVC material.

The alternating pressure channels are uniformly sized 5×5 cm^2 , providing consistent and controlled pressure relief across the neonates' skin surfaces. To seamlessly integrate the anti-PU bed into existing NICUs, its dimensions were designed to match those of the standard NICU station beds, measuring 60×45 cm^2, as shown in Fig. 4.3.

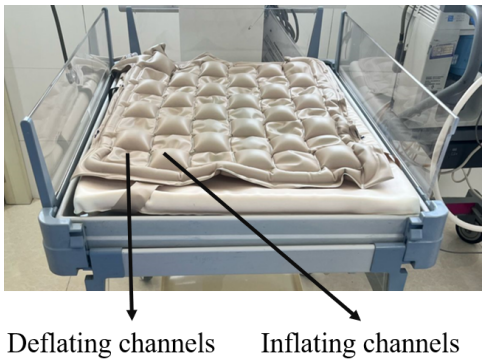


Figure 4.3: Positioning of alternative air channels on the anti-PU bed in the NICU stations of DMC & H Ludhiana.

This standard size allowed easy fitting and utilization in the NICU environment. During implementation, clinicians utilized an absorbable medical underpad sheet before placing the neonates on the mattress. This additional layer added a protective barrier and enhanced comfort for the infants. The electronic circuit used in the actuation mechanism is shown in Fig. 4.4 (a). A silent electronic pumping mechanism was employed as a pump to maintain the alternating pressure channels. The pump featured a regulator system to control the airflow speed to the mattress, ensuring precise and adaptable pressure modulation, as shown in Fig. 4.4 (b).

These pumps are user-friendly operation allow for easy adjustment and customization as per the infants' needs. Two silicone pipes connected to the mattress facilitated the seamless actuation of the alternating and deflating channels. These pipes ensured smooth airflow management within the mattress, further enhancing the pressure relief mechanism. To accommodate various NICU setups, the pump was designed with both hanging and standing systems, providing flexibility in its placement without disrupting other equipment

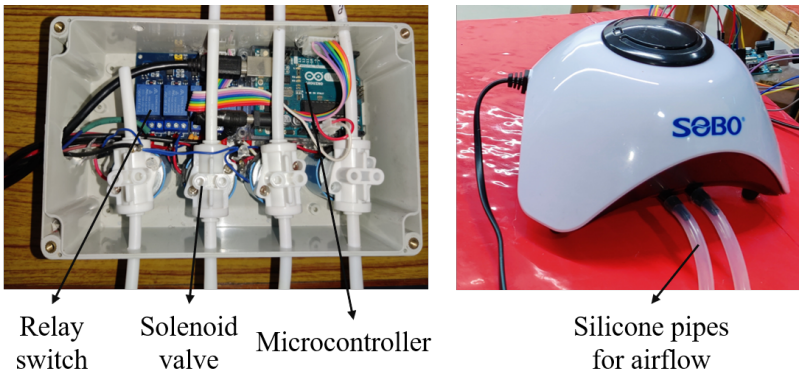


Figure 4.4: Positioning of (a) electronic circuit used for actuation mechanism and (b) silent pump and connecting silicone pipes for airflow patterns

in the NICU environment. One actuation cycle was set to 8 minutes for inflation and deflation purposes.

Study Settings and Participants

This research employs a prospective observational study design to assess the efficacy of air inflatable mattresses in preventing PUs among premature infants in the NICUs of DMC & H Ludhiana, a tertiary care facility with specialized neonatal care services. The participants included infants with a gestational age (refers to the number of weeks of pregnancy at the time of birth) of 28 weeks to 34 weeks and birth weight of 0.50 Kg to 0.35 Kg. The demographic characteristics of the participants are summarized in Table 4.1. The postnatal age at admission (Agep), type of mechanical ventilation (Ventm), and other parameters are described.

Table 4.1: Demographic characteristics of the participants.

Variables	N1	N2	N3	N4	N5	N6	N7	N8
Age_p (days)	1	8	1	21	6	4	1	1
Gender	F	M	F	M	F	M	F	M
Ethnic group	w	b	b	w	w	w	w	w
Birth gestation (weeks)	31	27	29	37	38	39	36	30
Birth weight (Kg)	1.99	1.30	0.82	2.57	2.40	3.50	2.34	1.22
Length (cm)	35	26	34	47	48	46	49	37
Head circumference (cm)	30.5	39	24	33	33	34	35	27
Analgosedation (Yes/No)	Yes	No	Yes	Yes	Yes	Yes	No	No
Mechanical ventilation	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
$Vent_m$	HFO	CPAP	CPAP	TS	HFO, HFNC	No	CPAP	HFNC
Total NICU stay (days)	10	45	50	9	9	5	4	23
Outcome	DAMA	D/S	D/S	D/S	Mortality	D/S	D/S	D/S

Data Collection Procedure and Ethical Considerations

Clinical data and nursing staff feedback were collected throughout 15 to 30 days for each admitted infant. The data collection process was carried out once every three days in a

week to ensure comprehensive observation.

Data collection took place over 6 months. This time frame allows for a substantial sample size and sufficient data to assess the efficacy of air-inflatable mattresses in preventing PUs among premature infants in the NICUs. The 6-month data collection period is chosen to capture a representative sample of neonates admitted to the NICUs during different seasons and to account for any potential variations in clinical practices or patient demographics that may occur over time. Ethical approval for the study was obtained from the Institutional Ethical Clearance (IEC) Committee of DMC & H Ludhiana. Informed consent was obtained from parents or legal guardians before enrolling the infants in the study. The neonatal baby on the anti-PU ed with the data collection setup is shown in Fig. 4.5.

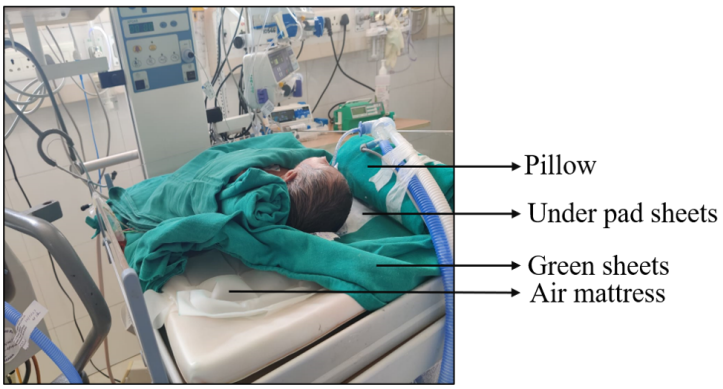


Figure 4.5: Neonatal baby on the anti-PU bed with data collection setup at NICUs.

4.2.2 Statistical Formulas to Analyze the Collected Data

To compare the efficacy of case-I (an anti-PU) bed in preventing PUs to the case-II (conventional) beds, descriptive statistics were used to present nursing staff perspectives and the incidence of PUs among neonates. Categorical data from the questionnaires were summarized using frequencies and percentages, while continuous data (e.g., frequency of position changes) were presented as mean ± standard deviations. The statistical formulas used to analyze the collected data as follows:

Chi-square test

The Chi-square test was utilized to analyze the association between the type of bed (used for case-I and case-II) and the incidence of PUs (Yes/No) in neonates. The null hypothesis (H0) assumed No significant difference in the incidence of PUs between these two cases, while the alternative hypothesis (H1) suggested a significant difference. The chi-square statistics:

$$\text{Expected frequency} = \frac{\text{Row total} \times \text{Column total}}{\text{Grand Total}} \tag{4.1}$$

We sum the contributions from each cell to get the overall chi-square value.

Contribution from anti-PU, Yes cell+ contribution from conventional, Yes cell+ contribution from anti-PU, No cell+ contribution from conventional, No cell. The Chi-square statistic formula is:

$$\chi^2 = \sum \frac{(O-E)^2}{E} \tag{4.2}$$

Where O is the observed frequency, and E is the expected frequency

Independent Samples $t-$test

An independent sample $t-$test was conducted to compare the mean duration of position changing between neonates for both cases using the expression:

$$t = \frac{x_1 - x_2}{\sqrt{\frac{s_1^2}{n_1} + \frac{s_2^2}{n_2}}} \tag{4.3}$$

Where x_1 and x_2 are the mean duration of position change, s_1 and s_2 are the standard deviations, and n_1 and n_2 are the sample sizes of case-I and case-II respectively.
Additionally, the $t-$test was used to compare the efficacy of air-inflatable mattresses in reducing the frequency of position changes between the two groups. The null hypothesis (H0) posited no significant difference in the frequency of position changes, while the alternative hypothesis (H1) suggested a significant difference.

Relative Risk Calculation

The formula for standard error (SE) is:

$$SE = \sqrt{\frac{1}{a - \frac{1}{a+c}} + \frac{1}{b - \frac{1}{b+d}}} \tag{4.4}$$

Where a = number of events for case-II (in this case, number of neonates with PUs in the conventional bed group named case-II(a)), b = number of non-events in the case-II (total number of neonates in the conventional bed group minus the number of events), c = number of events for case-I (in this case, number of neonates with pressure ulcers in the anti-PU bed group named case-I(a)), d = number of nonevents for case-I (total number of neonates in the anti-PU bed group minus the number of events).
The relative risk (RR) was calculated to quantify the risk of developing PUs in the conventional bed group compared to the anti-PU bed group. It is defined as the risk ratio in the conventional bed group to the risk in the anti-PU bed group. The logarithm of the relative risk (LRR) formulations:

$$LRR = ln(RR) \pm 1.96 \times SE \tag{4.5}$$

Degree of Freedom (*df*)

For the $t-$test, df is calculated as $df = n_1 + n_2 - 2$, where n_1 and n_2 are the sample sizes of the two groups. For the Chi-square test, the $df = (R-1) * (C-1)$, where R is the number of rows and C is the number of columns in the contingency table.

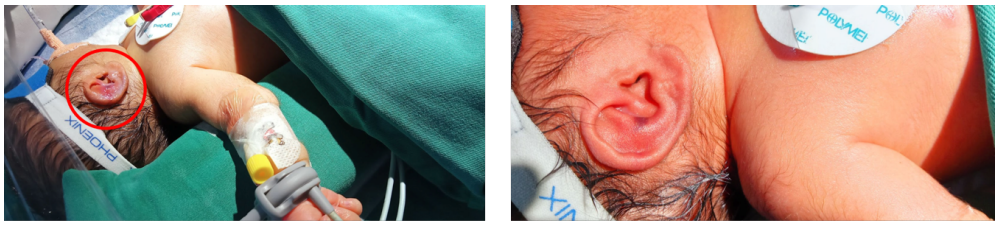
4.3 Results and Discussions

The clinical study involved neonates by considering case-I and case-II. Case-II consists of a conventional bed with a non-air inflatable mattress with neonatal postures changed by the nursing staff. A total of 44 neonates were included in the study, with 32 neonates assigned to the case-I and 12 neonates to the case-II.

Table 4.2: Total number of neonates in the study for both cases.

Category	PUs (Yes)	PUs (No)	Total neonates
Case-I	1	31	32
Case-II	4	8	12
Total	5	39	44

The anti-PU bed group with and without PU is named case-I(a) and case-I(b) respectively. The conventional bed group with and without PU is named case-II(a) and case-II(b), respectively. The developed PUs in a neonate of birth weight 1990 g (1.9 Kg) and 31 weeks of gestation during the clinical study as shown in Fig. 4.6 (a). The PUs in stage III developed in the neonates while lying in conventional beds shown by zoomed view as shown in Fig. 4.6 (b).



(a) (b)

Figure 4.6: The PUs in stage III developed in the neonates while lying on the (a) conventional bed, and (b) zoomed view.

The frequency of position changes with time duration on both case beds for the neonatal baby for conventional and anti-PU beds, shown in Fig. 4.7 as a scatter plot by yellow and blue circles. The conventional bed neonates show the fast duration of a position change by nursing staff, which is approximately 2–3 hours. Utilizing the anti-PU bad, the frequency of position change by nursing staff is 3–6 hours. The study was performed for 48 hours, in which the last 10 hours may cause the PUs shown here on the x-axis. 4 neonatal out of 12 placed on conventional beds suffer from PUs due to a long duration of continuous contact (approximately nearby or more than 3 hours as shown in Fig. 4.7 showing the

yellow color). One neonatal baby out of 35 neonates placed on an anti-PU bed suffered from PUs as shown by the blue colour due to places up to or a maximum of 6 hours.

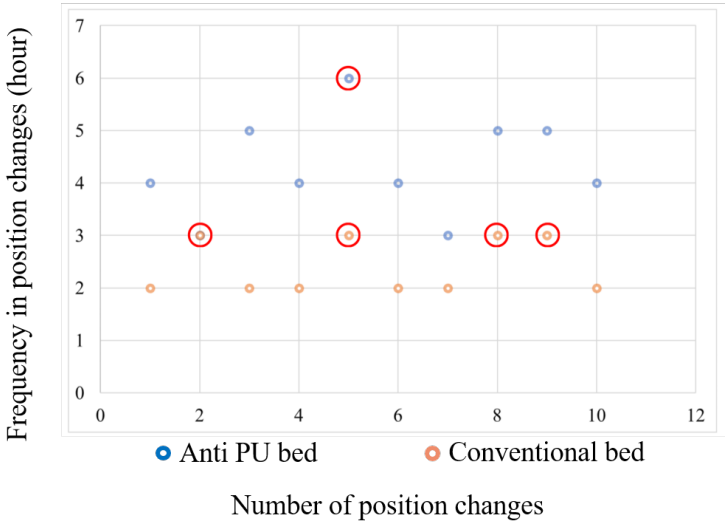


Figure 4.7: The PUs in stage III developed in the neonates while lying in conventional beds.

For case-I(a), case-I(b), case-II(a), and case-II(b) the total number of rows and columns is 32, 32, 12, 12, and 5, 39, 5, 39 respectively. The grand total for all the cases is 44 as summarized in Table 2. The total number of rows and columns is the expected frequency for PUs for case-I(a), case-I(b), case-II(a), and case-II(b) are calculated using Eq. 1 denoted by E11, E12, E21, E22 and its calculated value is 3.636, 28.364, 1.364, and 10.636 respectively. The observed frequency for case-I(a), case-I(b), case-II(a), and case-II(b) is 1, 31, 4, and 8 respectively, and the corresponding expected frequency.

The Chi-square test was conducted to assess the association between the occurrence of PUs and the treatment group (case-I vs. case-II). Utilizing Eq. 2 the value of 2 is 2.350, 0.309, 3.499, and 0.578 respectively and its sum is 6.736. The Chi-square test revealed a significant association between the occurrence of PUs and the treatment group (2 = 6.736, p $<$ 0.05). The contingency table showed that 1 neonate in the anti-PU bed group and 4 neonates in the conventional bed group developed PUs. Neonates in the conventional bed group were significantly more likely to develop PUs compared to those in the anti-PU bed group.

The $t-$test revealed a significant difference in the mean duration of position changing between the two cases ($t-$value = 5.28, p $<$ 0.05). Substituting the value of x_1 is 4.3, x_2 is 2.4, n_1 is 32, n_2 is 12, s_1^2 is 0.4452, and s_2^2 is 0.42 in the Eqn. 3 and the calculated value of t is 5.28. The neonates under consideration in case-I had a significantly longer duration of position change than those in case-II. For the $t-$test, the degrees of freedom (df) for the sample sizes of the two cases are found to be 42. For the chi-square test, the df for the given number of rows and columns in the contingency table is 1. Both statistical tests were performed at a significance level (α) of 5%, indicating a threshold for statistical significance. For case-I, we have recorded the time duration of position changes

of neonates by the nursing staff. The mean duration of position changing was 4.3 hours (SD = 0.445), while for case-II, it was 2.4 hours (SD = 0.4). The number of neonates in case-II who developed PUs is 4 and the number of neonates in case-I who developed PUs is 1. Using Eqn 5 the value of the relative risk calculated is 4. Now, to calculate the 95% confidence interval (CI) for the relative risk, we need to determine the standard error (SE) of the natural logarithm of the relative risk (ln(RR). Using Equ. 4, the SE is 0.6228. The lower bound is 1.38 and the upper bound is 0.17 and the calculated ln(RR) value is 2.59. The RR was 4 with a 95% CI of 0.17 to 2.59. This indicates that neonates those are in the observation in case-II had a 4 times higher risk of developing PUs compared to case-I. The 95% confidence interval for the relative risk 0.17 to 2.59 suggests that we are 95% confident that the true relative risk lies within this interval.
In summary, the design and deployment of the anti-PU bed in this study prioritized safety, comfort, and usability. By using bio-compatible materials, ensuring consistent pressure distribution, and incorporating a user-friendly pump system, the anti-PU bed aimed to effectively prevent PUs in neonates and seamlessly integrate into existing NICU setups.

4.4 Conclusions

This research contributes to the growing body of evidence on neonatal skin health and pressure ulcer prevention strategies. The study findings support the efficacy of air-inflatable mattresses in reducing PU incidence and improving neonatal skin health in the NICU setting. The implementation of air-inflatable mattresses can have significant implications for neonatal care, enhancing comfort, reducing pressure ulcer occurrence, and potentially leading to improved health outcomes for premature infants. As a preventive measure, these specialized beds and mattresses offer a valuable addition to the repertoire of neonatal care practices. By fostering evidence-based improvements in neonatal care protocols, this research aims to create a nurturing environment that promotes the well-being and development of premature infants. Ultimately contributing to better neonatal health outcomes and the overall quality of care in the NICU.

4.5 Ethics and Consent

The Institutional Ethics Committee (IEC) of Dayanand Medical College and Hospital, Ludhiana, approved this clinical study (Ref. No. DMCH/R&D/2020/173, dated 09/12/2020). As the participants are minor, written consent has been obtained from the guardians of the patients for publishing images, and clinical data.

Chapter 5

Summary and Future Scope

5.1 Summary

The comprehensive research presented in this thesis culminates in the design and analysis of an innovative hardware prototype—a specialized anti-PU bed designed for NICUs. This bed offers a promising alternative to conventional beds currently used in NICUs by incorporating a multichannel, two-stage system that cyclically adjusts the pressure distribution across the infant's body. The alternating pressure profile, as captured by force sensors, provides critical insights into the bed's potential implementation in hospital settings.

FE simulations were conducted to evaluate the mechanical performance of the bed under different conditions, including scenarios with and without pressure in the channels. These simulations revealed that the mechanical parameters, such as pressure and force, remain constant throughout body contact over time in a baseline scenario due to the self-weight of the newborn. In contrast, the anti-PU bed showed a dynamic variation in contact pressure, alternating due to the fluid cyclic pressure applied in the system. This alternating pressure distribution effectively minimizes pressure concentration points, automatically shifts contact positions, and thereby significantly reduces the risk of PUs. The findings underscore the bed's efficacy in both minimizing the occurrence of PUs and easing the workload of nursing staff.

The FE-simulated anti-PU bed not only validates the experimental results but also confirms the bed's design objectives—namely, the reduction of pressure concentration points with high accuracy and the provision of automatic contact position variation. These features are essential for reducing the incidence of PUs in neonates, particularly those who are premature and thus more susceptible to skin breakdown.

The study also contributes valuable knowledge to the field of neonatal care, particularly in the context of neonatal skin health and PU prevention strategies. The research findings strongly support the use of air-inflatable mattresses as an effective intervention for reducing PU incidence and enhancing neonatal skin health. The implementation of such specialized mattresses in NICUs has far-reaching implications, potentially improving health outcomes and enhancing the overall quality of care for premature infants.

5.2 Scope for future studies

The possible immediate extensions of the current work for the future include:

- Looking forward, this research paves the way for several future investigations. Planned studies include tissue-level analysis of neonatal skin to understand the effects of sliding and frictional forces between the skin and bed surfaces. Additionally, there will be a focus on thermal management analysis related to body temperature, which plays a crucial role in skin integrity and PU prevention. The calibrated anti-PU bed will also undergo further testing with a larger cohort of infants to objectively assess its effectiveness and pave the way for commercialization.

- Ethical clearance for these studies has already been obtained, and the results are anticipated to be robust and comprehensive, warranting separate publication. Through continued efforts, the research aims to refine the approach further and develop practically effective solutions for preventing and treating PUs in neonates, ultimately contributing to better neonatal health outcomes and improved quality of care in NICU settings.

References

[1] Lawton Sandra. Skin 1: the structure and functions of the skin | Nursing Times. *Nursing Times [online]*, 115(12):30–33, 2019. URL https://www.nursingtimes.net/clinical-archive/dermatology/skin-1-the-structure-and-functions-of-the-skin-25-11-2019/.

[2] Adult Skin. Basic Differences between Adult Infant skin.

[3] JW Fluhr, R Darlenski, N Lachmann, C Baudouin, P Msika, C De Belilovsky, and J-P Hachem. Infant epidermal skin physiology: adaptation after birth. *British journal of dermatology*, 166(3):483–490, 2012.

[4] Flávia Pereira Reginatto, Damie DeVilla, Fernanda M. Muller, Juliano Peruzzo, Letícia P. Peres, Raquel B. Steglich, and Tania F. Cestari. Prevalence and characterization of neonatal skin disorders in the first 72 h of life. *Jornal de Pediatria*, 93(3):238–245, 2017. ISSN 00217557. doi: 10.1016/j.jped.2016.06.010.

[5] Marty O Visscher, Andrew N Carr, Jason Winget, Thomas Huggins, Charles C Bascom, Robert Isfort, Karen Lammers, and Vivek Narendran. Biomarkers of neonatal skin barrier adaptation reveal substantial differences compared to adult skin. *Pediatric Research*, 89(5):1208–1215, 2021.

[6] Monty Lyman. *The remarkable life of the skin: an intimate journey across our surface*. Random House, 2019.

[7] Takao Someya and Masayuki Amagai. Toward a new generation of smart skins. *Nature Biotechnology*, 37(4):382–388, 2019. ISSN 15461696. doi: 10.1038/s41587-019-0079-1. URL http://dx.doi.org/10.1038/s41587-019-0079-1.

[8] Niels Vandamme and Geert Berx. From neural crest cells to melanocytes: cellular plasticity during development and beyond. *Cellular and Molecular Life Sciences*, 76(10):1919–1934, 2019. ISSN 14209071. doi: 10.1007/s00018-019-03049-w. URL https://doi.org/10.1007/s00018-019-03049-w.

[9] Minela Aida Maranduca, Daciana Branisteanu, Dragomir Nicolae Serban, Daniel Constantin Branisteanu, Gabriela Stoleriu, Nicuta Manolache, and Ionela Lacramioara Serban. Synthesis and physiological implications of melanic pigments (review). *Oncology Letters*, 17(5):4183–4187, 2019. ISSN 17921082. doi: 10.3892/ol.2019.10071.

[10] Marty O. Visscher, Andrew N. Carr, Jason Winget, Thomas Huggins, Charles C. Bascom, Robert Isfort, Karen Lammers, and Vivek Narendran. Biomarkers of neonatal skin barrier adaptation reveal substantial differences compared to adult

skin. *Pediatric Research*, 89(5):1208–1215, 2021. ISSN 15300447. doi: 10.1038/s41390-020-1035-y. URL http://dx.doi.org/10.1038/s41390-020-1035-y.

[11] Pablo García-Molina, Evelin Balaguer-López, Francisco Pedro García-Fernández, María de los Ángeles Ferrera-Fernández, José María Blasco, and José Verdú. Pressure ulcers' incidence, preventive measures, and risk factors in neonatal intensive care and intermediate care units. *International Wound Journal*, 15(4):571–579, 2018. ISSN 1742481X. doi: 10.1111/iwj.12900.

[12] Annisa Rahma and Majella E. Lane. Skin Barrier Function in Infants: Update and Outlook. *Pharmaceutics*, 14(2):1–25, 2022. ISSN 19994923. doi: 10.3390/pharmaceutics14020433.

[13] Lulu M Muhe, Elizabeth M McClure, Assaye K Nigussie, Amha Mekasha, Bogale Worku, Alemayehu Worku, Asrat Demtse, Beza Eshetu, Zemene Tigabu, Mahlet A Gizaw, et al. Major causes of death in preterm infants in selected hospitals in ethiopia (sip): a prospective, cross-sectional, observational study. *The Lancet Global Health*, 7(8):e1130–e1138, 2019.

[14] Li Liu, Shefali Oza, Dan Hogan, Yue Chu, Jamie Perin, Jun Zhu, Joy E Lawn, Simon Cousens, Colin Mathers, and Robert E Black. Global, regional, and national causes of under-5 mortality in 2000–15: an updated systematic analysis with implications for the sustainable development goals. *The Lancet*, 388(10063):3027–3035, 2016.

[15] Pablo García-Molina, Evelin Balaguer-López, Francisco Pedro García-Fernández, María de los Ángeles Ferrera-Fernández, José María Blasco, and José Verdú. Pressure ulcers' incidence, preventive measures, and risk factors in neonatal intensive care and intermediate care units. *International Wound Journal*, 15(4):571–579, 2018.

[16] Christos Triantafyllou, Evangelia Chorianopoulou, Eleni Kourkouni, Theoklis E Zaoutis, and Georgia Kourlaba. Prevalence, incidence, length of stay and cost of healthcare-acquired pressure ulcers in pediatric populations: a systematic review and meta-analysis. *International Journal of Nursing Studies*, 115:103843, 2021.

[17] Mona Mylene Baharestani and Catherine R Ratliff. Pressure ulcers in neonates and children: an npuap white paper. *Advances in skin & wound care*, 20(4):208–220, 2007.

[18] Habeeb Sahib Naher and Amal Talib Al-Sa'ady. Review on bacterial etiology of neonatal infections. *EurAsian Journal of Biosciences*, 14(2), 2020.

[19] Deanna E Johnson. Recognizing congenital pressure injuries: a case series. *Journal of Wound Ostomy & Continence Nursing*, 46(1):65–68, 2019.

[20] Dilini I Imbulana, Brett J Manley, Jennifer A Dawson, Peter G Davis, and Louise S Owen. Nasal injury in preterm infants receiving non-invasive respiratory support:

a systematic review. *Archives of Disease in Childhood-Fetal and Neonatal Edition*, 103(1):F29–F35, 2018.

[21] Tino Adrian Jucker, Simon Annaheim, Elodie Morlec, Martin Camenzind, Anna-Barbara Schlüer, Barbara Brotschi, and René Michel Rossi. Innovative air mattress for the prevention of pressure ulcers in neonates. *Journal of wound care*, 33(9):652–658, 2024.

[22] Osama Elshahat Mostafa, Nazik MA Zakari, and Marwa Al Salem. Evaluation of nurses' attitudes, behaviors, and barriers toward pressure ulcer prevention in neonatal and pediatric intensive care units. *Frontiers in Pediatrics*, 12:1455950, 2024.

[23] Biagio Nicolosi, Felice Curcio, Maria Aurelia Gheorghe, Prisco Ranieri, and Eustachio Parente. Risk assessment of pressure injuries in newborns. appropriateness of glamorgan and nsras scales: a scoping review. *infermieristica journal*, 3(1):45–60, 2024.

[24] Princess K Ahedor. *Development and Evaluation of a Nurse Practitioner-Directed Multidisciplinary Pressure Ulcer Prevention Protocol and Its Impact on Pressure Ulcer Rates in a Long-Term Care Setting.* PhD thesis, Wilmington University (Delaware), 2024.

[25] Catherine Noonan, Sandy Quigley, and Martha AQ Curley. Using the braden q scale to predict pressure ulcer risk in pediatric patients. *Journal of pediatric nursing*, 26 (6):566–575, 2011.

[26] Maíla Fidalgo de Faria, Maria Beatriz Guimarães Ferreira, Márcia Marques dos Santos Felix, Isadora Braga Calegari, and Maria Helena Barbosa. Factors associated with skin and mucosal lesions caused by medical devices in newborns: observational study. *Journal of clinical nursing*, 28(21-22):3807–3816, 2019.

[27] Marty Visscher and Teresa Taylor. Pressure ulcers in the hospitalized neonate: rates and risk factors. *Scientific reports*, 4(1):7429, 2014.

[28] Ayelet Levy, Kara Kopplin, and Amit Gefen. Device-related pressure ulcers from a biomechanical perspective. *Journal of Tissue Viability*, 26(1):57–68, 2017.

[29] Charleen Deo Singh and Noordeen Shoqirat. Pressure redistribution crib mattress: A quality improvement project. *Journal of Wound Ostomy & Continence Nursing*, 46(1):62–64, 2019.

[30] Suzanne E Courtwright, Kari A Mastro, Christa Preuster, Navid Dardashti, Sandra McGill, Myrlene Madelon, and Donna Johnson. Reducing hospital-acquired pressure ulcers using bundle methodology in pediatric and neonatal patients receiving extracorporeal membrane oxygenation therapy: An integrative review and call to action. *Journal for Specialists in Pediatric Nursing*, 22(4):e12188, 2017.

[31] Karoon Agrawal and Neha Chauhan. Pressure ulcers: Back to the basics. *Indian Journal of Plastic Surgery*, 45(02):244–254, 2012.

[32] Drew Payne. Pressure ulcer prevention with a new mattress. *Nursing And Residential Care*, 19(11):613–615, 2017.

[33] Drew Payne. Under pressure: relieving ulcers with mattresses. *Nursing And Residential Care*, 20(5):201–205, 2018.

[34] Chunhu Shi, Jo C Dumville, Nicky Cullum, Sarah Rhodes, Elizabeth McInnes, En Lin Goh, and Gill Norman. Beds, overlays and mattresses for preventing and treating pressure ulcers: an overview of cochrane reviews and network meta-analysis. *Cochrane Database of Systematic Reviews*, (8), 2021.

[35] Mette Boeg Horup, Knaerke Soegaard, Tue Kjølhede, Aase Fremmelevholm, and Kristian Kidholm. Static overlays for pressure ulcer prevention: a hospital-based health technology assessment. *British Journal of Nursing*, 29(12):S24–S28, 2020.

[36] Ronald D Wortman, Michael P Rechin, Roland E Flick, and John K Whitney. Mattress for relieving pressure ulcers, August 18 1998. US Patent 5,794,289.

[37] Lena Gunningberg, C Lindholm, M Carlsson, and P-O Sjödén. Effect of visco-elastic foam mattresses on the development of pressure ulcers in patients with hip fractures. *Journal of wound care*, 9(10):455–460, 2000.

[38] Govind U Raiphale, Abhishek P Godse, Kshiteej S Dhotre, and Omkar N Chakor. A review on design and development of anti-bedsore bed for patients. *IOSR J Mech Civ Eng*, 13(4):57–62, 2016.

[39] Siva Soonthornkiti and Petch Jearanaisilawong. Design of anti-bedsore hospital bed. *Journal of Research and Applications in Mechanical Engineering*, 1(4):15–20, 2013.

[40] Sylvie Hampton. The quattro acutetm mattress and pressure ulcer prevention. *British journal of nursing*, 12(11):697–701, 2003.

[41] Jane Johnson, Darcie Peterson, Betty Campbell, Regina Richardson, and Dana Rutledge. Hospital-acquired pressure ulcer prevalence-evaluating low-air-loss beds. *Journal of Wound Ostomy & Continence Nursing*, 38(1):55–60, 2011.

[42] Jennifer J Bracci. Neonatal absorbency pad and related methods, May 5 2015. US Patent 9,023,003.

[43] Heather Newton. The theracute alternating pressure replacement mattress. *British Journal of Nursing*, 10(13):883–886, 2001.

[44] Rasoul Yousefi, Sarah Ostadabbas, Miad Faezipour, Mehrdad Nourani, Vincent Ng, Lakshman Tamil, Alan Bowling, Deborah Behan, and Matthew Pompeo. A smart bed platform for monitoring & ulcer prevention. In *2011 4th international conference*

on biomedical engineering and informatics (BMEI), volume 3, pages 1362–1366. IEEE, 2011.

[45] Czar Czamwahyudy, Nur Dinah2 Nurul Syahirah3 Sharifah Nur, and Farehan4 Siti Aishah5 Siti Atiqah. Multi-fowler techno bed: A solution for pressure ulcer patients. *Technology*, 1(1):16–22, 2015.

[46] Ivy Swanson Razmus and Suzanne M Keep. Neonatal intensive care nursing pressure injury prevention practices: a descriptive survey. *Journal of Wound Ostomy & Continence Nursing*, 48(5):394–402, 2021.

[47] Ivy Razmus and Suzanne Keep. Neonatal intensive care nursing pressure injury prevention practices: A descriptive survey. *World Council of Enterostomal Therapists Journal*, 42(3), 2022.

[48] Carol Turnage-Carrier, Kathleen M McLane, and Mary Ann Gregurich. Interface pressure comparison of healthy premature infants with various neonatal bed surfaces. *Advances in Neonatal Care*, 8(3):176–184, 2008.

[49] Mamduh A El-messeiry and Abdulaziz Binsaeed. Mattress for relieving pressure ulcers, January 5 2016. US Patent 9,226,863.

[50] Yu-Wei Liu, Yeh-Liang Hsu, and Wei-Yi Chang. Development of a bed-centered telehealth system based on a motion-sensing mattress. *Journal of Clinical Gerontology and Geriatrics*, 6(1):1–8, 2015.

[51] Irene Jones, Carol Tweed, and Maggie Marron. Pressure area care in infants and children: Nimbus® paediatric system. *British Journal of Nursing*, 10(12):789–795, 2001.

[52] Wei Carrigan, Pavan Nuthi, Charu Pande, Caleb P Nothnagle, and Muthu BJ Wijesundara. A pressure modulating sensorized soft actuator array for pressure ulcer prevention. In *International Design Engineering Technical Conferences and Computers and Information in Engineering Conference*, volume 58158, page V003T13A004. American Society of Mechanical Engineers, 2017.

[53] Marcus Yip, David Da He, Eric Winokur, Amanda Gaudreau Balderrama, Robert Sheridan, and Hongshen Ma. A flexible pressure monitoring system for pressure ulcer prevention. In *2009 Annual international conference of the IEEE engineering in medicine and biology society*, pages 1212–1215. IEEE, 2009.

[54] Olivier Chenu, Nicolas Vuillerme, Marek Bucki, Bruno Diot, Francis Cannard, and Yohan Payan. Texicare: An innovative embedded device for pressure ulcer prevention. preliminary results with a paraplegic volunteer. *Journal of Tissue Viability*, 22(3):83–90, 2013.

[55] Joseph E Grey and Stuart Enoch. ABC of wound healing: Pressure ulcers. *Bmj*, 332(Suppl S6):0606226, 2006. doi: 10.1136/sbmj.0606226.

[56] Li Liu, Shefali Oza, Dan Hogan, Yue Chu, Jamie Perin, Jun Zhu, Joy E. Lawn, Simon Cousens, Colin Mathers, and Robert E. Black. Global, regional, and national causes of under-5 mortality in 2000-15: an updated systematic analysis with implications for the Sustainable Development Goals. *Lancet (London, England)*, 388(10063): 3027–3035, dec 2016. ISSN 1474-547X. doi: 10.1016/S0140-6736(16)31593-8. URL https://pubmed.ncbi.nlm.nih.gov/27839855/.

[57] Adarsha Narayan Mallick. Automatic Pasteurized Formula Milk Preparation Machine with Automatic Sterilized Containers. 2022.

[58] Adarsha Narayan Mallick, Mukesh Kumar, Kamaldeep Arora, and Ashish Kumar Sahani. Finite Element Modeling of a Pressure Ulcers Preventive Bed for Neonates. pages 1–4, IEEE–EMBS International Conference on Wearable and Implantable Body Sensor Networks (BSN), 2022. doi: 10.1109/bsn56160.2022.9928469.

[59] Adarsha Narayan Mallick Meghana Bhandari Bijit Basumatary Shivani Gupta, Kamaldeep Arora and Ashish Kumar Sahani. Risk Factors for Developing Pressure Ulcers in Neonates and Novel Ideas for Developing Neonatal Antipressure Ulcers Solutions. *Journal of Clinical Neonatology*, 2023. doi: 10.4103/jcn.jcn_84_22.

[60] Nor Fazli Adull Manan, Mohd Hanif Mohd Ramli, Mohd Nor Azmi Ab Patar, Cathy Holt, Sam Evans, Mahmoud Chizari, and Jamaluddin Mahmud. Determining hyperelastic parameters of human skin using 2D finite element modelling and simulation. *SHUSER 2012 - 2012 IEEE Symposium on Humanities, Science and Engineering Research*, pages 805–809, 2012. doi: 10.1109/SHUSER.2012.6268996.

[61] Barbara Delmore, Michelle Deppisch, Cynthia Sylvia, Crystal Luna-Anderson, and Ann Marie Nie. Pressure Injuries in the Pediatric Population: A National Pressure Ulcer Advisory Panel White Paper. *Advances in Skin and Wound Care*, 32(9): 394–408, 2019. ISSN 15388654. doi: 10.1097/01.ASW.0000577124.58253.66.

[62] Adarsha Narayan Mallick, Mukesh Kumar, Rahul Nadda, K Manoj Kumar, Sarju Ralhan, Bishav Mohan, Ramjee Repaka, and Ashish Sahani. Investigation of failure prevention study of coronary artery bypass grafting using computational fluid dynamics approach. In *Proceedings of the 27th National and 5th International ISHMT-ASTFE Heat and Mass Transfer Conference December 14-17, 2023, IIT Patna, Patna-801106, Bihar, India*. Begel House Inc., 2024.

[63] Rosina Ksoo, Meenakshi Bhatt, Harish Chellani, and Sugandha Arya. Congenital cutis laxa with ileus and cleft lip and palate. *Journal of Clinical Neonatology*, 8(4): 248–249, 2019.

[64] Sarah Ostadabbas, Rasoul Yousefi, Mehrdad Nourani, Miad Faezipour, Lakshman Tamil, and Matthew Q. Pompeo. A resource-efficient planning for pressure ulcer prevention. *IEEE Transactions on Information Technology in Biomedicine*, 16(6): 1265–1273, 2012. ISSN 10897771. doi: 10.1109/TITB.2012.2214443.

[65] Jaki Law. Transair® paediatric mattress replacement system evaluation. *British journal of nursing*, 11(5):343–346, 2002.

[66] Wei Carrigan, Pavan Nuthi, Charu Pande, Caleb P. Nothnagle, and Muthu B.J. Wijesundara. A Pressure Modulating Sensorized Soft Actuator Array for Pressure Ulcer Prevention. *Proceedings of the ASME Design Engineering Technical Conference*, 3, nov 2017. doi: 10.1115/DETC2017-68191.

[67] A. Gefen, N. Gefen, E. Linder-Ganz, and S. S. Margulies. In vivo muscle stiffening under bone compression promotes deep pressure sores. *Journal of Biomechanical Engineering*, 127(3):512–524, 2005. ISSN 01480731. doi: 10.1115/1.1894386.

[68] Shermeen Nizami, Amna Basharat, Arslan Shoukat, Uzair Hameed, Syed Ali Raza, Amente Bekele, Randy Giffen, and James R. Green. CEA: Clinical Event Annotator mHealth Application for Real-time Patient Monitoring, 2018. ISSN 1557170X.

[69] Shermeen Nizami, Amente Bekele, Mohamed Hozayen, Kim Greenwood, Joann Harrold, and James R. Green. Comparing time and frequency domain estimation of neonatal respiratory rate using pressure-sensitive mats. *2017 IEEE International Symposium on Medical Measurements and Applications, MeMeA 2017 - Proceedings*, pages 239–244, 2017. doi: 10.1109/MeMeA.2017.7985882.

[70] Malindu Ehelagastenna, Ishan Sumanasekara, Hishan Wickramasinghe, Indrajith D. Nissanka, and Gayani K. Nandasiri. Towards the Development of an Alternating Pressure Overlay for the Treatment of Pressure Ulcers Using Miniaturised Air Cells. *Proceedings 2020, Vol. 64, Page 33*, 64(1):33, nov 2020. ISSN 2504-3900. doi: 10.3390/IECAT2020-08522. URL https://www.mdpi.com/2504-3900/64/1/33.

[71] Atsushi Takashima, Akitsugu Misaki, Shin Ichiro Takasugi, and Motoji Yamamoto. Characteristic analysis of an air cell for active air mattress of prevention for pressure ulcer. *Advanced Robotics*, 28(7): 497–504, apr 2014. ISSN 0169-1864. doi: 10.1080/01691864.2013.876937. URL https://kyushu-u.pure.elsevier.com/en/publications/characteristic-analysis-of-an-air-cell-for-active-air-mattress-of.

[72] Rik Van Donselaar and Wei Chen. Design of a smart textile mat to study pressure distribution on multiple foam material configurations. *ACM International Conference Proceeding Series*, pages 0–4, 2011. doi: 10.1145/2093698.2093827.

[73] EuniceO Osuala. Innovation in prevention and treatment of pressure ulcer: Nursing

implication. *Tropical Journal of Medical Research*, 17(2):61, 2014. ISSN 1119-0388. doi: 10.4103/1119-0388.140411.

[74] Klaus Ejner Andersen. Decubitus prophylaxis : A prospective trial on the efficacy of alternating pressure air mattresses and water mattresses. (December), 2015.

[75] Rakshita Panchal, Luke Horton, Peyman Poozesh, Javad Baqersad, and Mohammadreza Nasiriavanaki. Vibration analysis of healthy skin: toward a noninvasive skin diagnosis methodology. *Journal of Biomedical Optics*, 24(1):1, jan 2019. ISSN 15602281. doi: 10.1117/1.JBO.24.1.015001. URL /pmc/articles/PMC6985698//pmc/articles/PMC6985698/?report=abstracthttps://www.ncbi.nlm.nih.gov/pmc/articles/PMC6985698/.

[76] Nor Hashimah Sulaiman and Daud Mohamad. A Jaccard-based similarity measure for soft sets. *SHUSER 2012 - 2012 IEEE Symposium on Humanities, Science and Engineering Research*, pages 659–663, 2012. doi: 10.1109/SHUSER.2012.6268901.

[77] Sri Purwiyanti, Sri Ratna Sulistiyanti, Fx Arinto Setyawan, Billy Mulia Wibisono, Ketut Sasmita Atmaja, and Helmy Fitriawan. Multisensors System for Real Time Detection of Length, Weight, and Heartbeat of Premature Baby in the Incubator. *Proceedings of 2018 International Conference on Electrical Engineering and Computer Science, ICECOS 2018*, 17:85–88, 2019. doi: 10.1109/ICECOS.2018.8605208.

[78] Kristin A. Cummins, Richard Watters, and Treasa Susie Leming-Lee. Reducing Pressure Injuries in the Pediatric Intensive Care Unit. *Nursing Clinics of North America*, 54(1):127–140, 2019. ISSN 00296465. doi: 10.1016/j.cnur.2018.10.005. URL https://doi.org/10.1016/j.cnur.2018.10.005.

[79] Eran Linder-Ganz and Amit Gefen. Stress analyses coupled with damage laws to determine biomechanical risk factors for deep tissue injury during sitting. *Journal of Biomechanical Engineering*, 131(1):1–13, 2009. ISSN 01480731. doi: 10.1115/1.3005195.

[80] Rachael Zimlich. What Is the Neonatal Period? The First Four Weeks of a Child's Life. *Verywell health*, 2021. URL https://www.verywellhealth.com/neonatal-period-5176591.

[81] AdarshaNarayan Mallick, Meghana Bhandari, Bijit Basumatary, Shivani Gupta, Kamaldeep Arora, and AshishKumar Sahani. Risk factors for developing pressure ulcers in neonates and novel ideas for developing neonatal antipressure ulcers solutions. *Journal of Clinical Neonatology*, 12(1):27, 2023. ISSN 2249-4847. doi: 10.4103/jcn.jcn_84_22.

[82] Mona Mylene Baharestani and Catherine R. Ratliff. Pressure ulcers in neonates and

children: an NPUAP white paper. *Advances in skin wound care*, 20(4):208–220, 2007. ISSN 15277941. doi: 10.1097/01.ASW.0000266646.43159.99.

[83] Adarsha Narayan Mallick, Mukesh Kumar, Bijit Basumatary, Kamaldeep Arora, and Ashish Kumar Sahani. Design and Testing of Pressure Ulcers Preventive Bed for Neonates in Neonatal Intensive Care Units. *IEEE Transactions on Medical Robotics and Bionics*, 5(2):421–428, 2023. ISSN 25763202. doi: 10.1109/TMRB.2023.3265635.

[84] Pablo Garci Molina, Alba Alfaro Lopez, Sara Maria, Garcia Rodriguez, Celia Brontons Paya, Mari Carmen, Rodriguez Dolz, and Eveln Balaguer Lopez. Neonatal pressure ulcers : prevention and treatment. pages 29–39, 2017.

[85] Patricia Scheans. Neonatal pressure ulcer prevention. *Neonatal network : NN*, 34: 126–132, 2015. ISSN 1539-2880. doi: 10.1891/0730-0832.34.2.126. URL https://pubmed.ncbi.nlm.nih.gov/26803094/.

[86] Deepakshyam Krishnaraju and Sivakumar Palaniswamy. Phototherapy bed surface to support neonatal skin preservation. *Neonatal Intensive Care*, 32(3):45–49, 2019. ISSN 10622454.

[87] Hyunwoo Park, Kyuyoung Kim, Soon-Jae Kweon, Osman Gul, Jungrak Choi, Yong Suk Oh, Inkyu Park, and Minkyu Je. A wireless and wearable body-pressure-monitoring system for the prevention of pressure-induced skin injuries. *IEEE Transactions on Biomedical Circuits and Systems*, 2023.

[88] C. F. Babbs, J. D. Bourland, G. P. Graber, J. T. Jones, and W. E. Schoenlein. A pressure-sensitive mat for measuring contact pressure distributions of patients lying on hospital beds. *Biomedical Instrumentation and Technology*, 24(5):363–370, 1990. ISSN 08998205.

[89] Ignacio Ghersi, Mario Mariño, and Mónica Teresita Miralles. Smart medical beds in patient-care environments of the twenty-first century: a state-of-art survey. *BMC Medical Informatics and Decision Making*, 18(1):1–12, 2018. ISSN 14726947. doi: 10.1186/s12911-018-0643-5.

[90] Chen Zhu, Yizheng Chen, Yiyang Zhuang, Guozhong Fang, Xuefeng Liu, and Jie Huang. Optical Interferometric Pressure Sensor Based on a Buckled Beam with Low-Temperature Cross-Sensitivity. *IEEE Transactions on Instrumentation and Measurement*, 67(4):950–955, apr 2018. ISSN 00189456. doi: 10.1109/TIM.2018.2791258.

[91] May D Stinson, AP Porter-Armstrong, and PA Eakin. Pressure mapping systems: reliability of pressure map interpretation. *Clinical rehabilitation*, 17(5):504–511, 2003.

[92] Beverley McKeon and Rolf Engler. Pressure measurement systems. *Springer Handbooks*, pages 179–214, 2007. ISSN 25228706. doi: 10.1007/978-3-540-30299-5_

4/COVER. URL https://link.springer.com/referenceworkentry/10.1007/978-3-540-30299-5_4.

[93] Feng Shen, Mingzhu Ai, Zonghe Li, Xinran Lu, Yan Pang, and Zhaomiao Liu. Pressure measurement methods in microchannels: advances and applications. *Microfluidics and Nanofluidics 2021 25:5*, 25(5):1–31, apr 2021. ISSN 1613-4990. doi: 10.1007/S10404-021-02435-W. URL https://link.springer.com/article/10.1007/s10404-021-02435-w.

[94] Jiawei Chen, Yingzheng Liu, Zhaomin Cao, and Di Peng. Pressure field measurements using bio-inspired pressure-sensitive film with adjustable sensitivity and range. *Experiments in Fluids*, 62(3):1–11, mar 2021. ISSN 14321114. doi: 10.1007/S00348-021-03155-1/FIGURES/12. URL https://link.springer.com/article/10.1007/s00348-021-03155-1.

[95] Omar Sabah Al-Dahiree, Mohammad Osman Tokhi, Nabil Hassan Hadi, Nassar Rasheid Hmoad, Raja Ariffin Raja Ghazilla, Hwa Jen Yap, and Emad Abdullah Albaadani. Design and Shape Optimization of Strain Gauge Load Cell for Axial Force Measurement for Test Benches. *Sensors 2022, Vol. 22, Page 7508*, 22(19):7508, oct 2022. ISSN 1424-8220. doi: 10.3390/S22197508. URL https://www.mdpi.com/1424-8220/22/19/7508/htmhttps://www.mdpi.com/1424-8220/22/19/7508.

[96] Dorothy Li Bai, Tsai Wen Liu, Hsiu Ling Chou, and Yeh Liang Hsu. Relationship between a pressure redistributing foam mattress and pressure injuries: An observational prospective cohort study. *PLOS ONE*, 15(11):e0241276, nov 2020. ISSN 1932-6203. doi: 10.1371/JOURNAL.PONE.0241276. URL https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0241276.

[97] Rik Van Donselaar and Wei Chen. Design of a Smart Textile Mat to Study Pressure Distribution on Multiple Foam Material Configurations. pages 0–4, 2011. doi: 10.1145/2093698.2093827.

[98] Karen Flores De Jesus, Marvin H Cheng, Lei Jiang, and Ezzat G Bakhoum. Resolution Enhancement Method Used for Force Sensing Resistor Array. 2015, 2015.

[99] Ronald HJ van Gils, Linda SGL Wauben, and Onno K Helder. Body size measuring techniques enabling stress-free growth monitoring of extreme preterm infants inside incubators: A systematic review. *Plos one*, 17(4):e0267285, 2022.

[100] Quick Find and Embroidery Designs. Prem2Pram - Premature Baby Clothes Store. pages 2–3.

[101] Adarsha Narayan Mallick, Amanpreet Chander, A Pratap, Hemant Kumar Chattar,

and Ashish Sahani. A Review on the Role of Soft Robotics in Medical Assistive Devices. 13(1), 2023.

[102] Minju Seon, Youngdae Lee, and Chanwoo Moon. Medical robotic bed to prevent pressure sores. *Applied Sciences (Switzerland)*, 11(18), 2021. ISSN 20763417. doi: 10.3390/app11188459.

[103] Halit Eren. Calibration Process. *Handbook of Measuring System Design*, (July), 2005. doi: 10.1002/0471497398.mm999.

[104] Wael Othman, Kojo E. Vandyck, Carlos Abril, Juan S. Barajas-Gamboa, Juan P. Pantoja, Matthew Kroh, and Mohammad A. Qasaimeh. Stiffness Assessment and Lump Detection in Minimally Invasive Surgery Using In-House Developed Smart Laparoscopic Forceps. *IEEE Journal of Translational Engineering in Health and Medicine*, 10(February):1–10, 2022. ISSN 21682372. doi: 10.1109/JTEHM.2022.3180937.

[105] Lifesaving Solutions, https://laerdal.com/in/. 2021.

[106] Cynthia A. Fleck. Pressure ulcers. *Diagnosis of Aging Skin Diseases*, 332(February): 233–252, 2008. doi: 10.1007/978-1-84628-678-0_19.

[107] Malindu Ehelagastenna, Ishan Sumanasekara, Hishan Wickramasinghe, Indrajith D. Nissanka, and Gayani K. Nandasiri. Design of an alternating pressure overlay for the treatment of pressure ulcers. *MERCon 2021 - 7th International Multidisciplinary Moratuwa Engineering Research Conference, Proceedings*, pages 202–207, jul 2021. doi: 10.1109/MERCON52712.2021.9525787.

[108] JE Gray, S Enoch, and KG Harding. Abcs of wound healing: pressure ulcers. *BMJ*, 332:472–5, 2006.

[109] A. J. Figueredo and P. S. A. Wolf. Assortative pairing and life history strategy – a cross-cultural study. *Human Nature*, 20:317–330, 2009. doi: https://doi.org/10.1007/s12110-009-9068-2.

[110] Laura E Edsberg, Joyce M Black, Margaret Goldberg, Laurie McNichol, Lynn Moore, and Mary Sieggreen. Revised national pressure ulcer advisory panel pressure injury staging system: revised pressure injury staging system. *Journal of Wound, Ostomy, and Continence Nursing*, 43(6):585, 2016.

[111] H Orsted, T Ohura, and K Harding. Pressure, shear, friction and microclimate in context. *A consensus document. Wounds International, London, UK*, 2010.

[112] Ivy Razmus, Lynette Lewis, and David Wilson. Pressure ulcer development in infants: state of the science. *Journal for Healthcare Quality*, 30(5):36–42, 2008.

[113] Christine A Schindler, Theresa A Mikhailov, Kay Fischer, Gloria Lukasiewicz, Evelyn M Kuhn, and Linda Duncan. Skin integrity in critically ill and injured children. *American Journal of Critical Care*, 16(6):568–574, 2007.

[114] Kumiko Fujii, Junko Sugama, Mayumi Okuwa, Hiromi Sanada, and Yuko Mizokami. Incidence and risk factors of pressure ulcers in seven neonatal intensive care units in japan: a multisite prospective cohort study. *International wound journal*, 7(5): 323–328, 2010.

[115] Jan Kottner, Doris Wilborn, and Theo Dassen. Frequency of pressure ulcers in the paediatric population: a literature review and new empirical data. *International journal of nursing studies*, 47(10):1330–1340, 2010.

[116] Anne V Loewenthal. Reducing the incidence of hospital-acquired pressure ulcers by enhancing the role of unit-based skin champions. 2016.

[117] Miriam D Fox. Wound care in the neonatal intensive care unit. *Neonatal network*, 30(5):291–303, 2011.

[118] GN Stamatas, J Nikolovski, MC Mack, and N Kollias. Infant skin physiology and development during the first years of life: a review of recent findings based on in vivo studies. *International journal of cosmetic science*, 33(1):17–24, 2011.

[119] PAN Pacific. Prevention and treatment of pressure ulcers: quick reference guide. *National Pressure Ulcer Advisory Panel*, 75, 2014.

[120] Paul B Keller, Jan Wille, Bert van Ramshorst, and Christian van der Werken. Pressure ulcers in intensive care patients: a review of risks and prevention. *Intensive care medicine*, 28:1379–1388, 2002.

Chapter A

Arduino code for multiple force sensors (FSR-406)

```
float fsrReading0;
float fsrReading1;
float fsrReading2;
float fsrReading3;
float fsrReading4;

float fsrVoltage;
unsigned long fsrResistance;
unsigned long fsrConductance;
long fsrForce;
void setup(void)
{
Serial.begin(9600);
}
float calculateforce(float rawvalue)
{
fsrVoltage = map(rawvalue, 0, 1023, 0, 5000);
if (fsrVoltage == 0)
{
fsrForce=0;
}
else
{
fsrResistance = 5000 - fsrVoltage; // fsrVoltage is in millivolts so 5V = 5000mV
fsrResistance *= 10000; // 10K resistor
fsrResistance /= fsrVoltage;

fsrConductance = 1000000; // we measure in micromhos so
fsrConductance /= fsrResistance;

if (fsrConductance <= 1000)
{
```

```
fsrForce = fsrConductance / 80;
}
else
{
fsrForce = fsrConductance - 1000;
fsrForce /= 30;
}
}
return fsrForce;
}

void loop(void)
{
fsrReading0 = analogRead(A0);
fsrReading1 = analogRead(A1);
fsrReading2 = analogRead(A2);
fsrReading3 = analogRead(A3);
fsrReading4 = analogRead(A4);

Serial.print(“sensor0”);
Serial.print(“\t”);
Serial.print(“sensor1”);
Serial.print(“\t”);
Serial.print(“sensor2”);
Serial.print(“\t”);
Serial.print(“sensor3”);
Serial.print(“\t”);
Serial.println(“sensor4”);

Serial.print(calculateforce(fsrReading0));
Serial.print(“\t”);
Serial.print(calculateforce(fsrReading1));
Serial.print(“\t”);
Serial.print(calculateforce(fsrReading2));
Serial.print(“\t”);
Serial.print(calculateforce(fsrReading3));
Serial.print(“\t”);
Serial.println(calculateforce(fsrReading4));
}
```

Chapter B

Code for connection of 74HC4051 mux with ESP32 with FSRA

```
//Mux control pins
int s0 = 25; //MUX2 having 9 to 14 channel
int s1 = 26; //MUX2 having 9 to 14 channel
int s2 = 27; //MUX2 having 9 to 14 channel
int s3 = 12; //MUX1 having 1 to 8 channel
int s4 = 13; //MUX1 having 1 to 8 channel
int s5 = 14; //MUX1 having 1 to 8 channel

//Mux in "Z" pin
int Z_pin = 35;

void setup()

pinMode(s0, OUTPUT);
pinMode(s1, OUTPUT);
pinMode(s2, OUTPUT);
pinMode(s3, OUTPUT);
pinMode(s4, OUTPUT);
pinMode(s5, OUTPUT);

pinMode(Z_pin, OUTPUT);

digitalWrite(s0, LOW);
digitalWrite(s1, LOW);
digitalWrite(s2, LOW);
digitalWrite(s3, LOW);
digitalWrite(s4, LOW);
digitalWrite(s5, LOW);

Serial.begin(9600);
```

```
void loop()

//Loop through and read all 48 values
for(int i = 0; i < 48; i ++)
Serial.print("Value at channel ");
Serial.print(i);
Serial.print(" is : ");
Serial.println(readMux(i));
delay(300);



float readMux(int channel){
int controlPin[ ] = s0, s1, s2, s3, s4, s5};

int muxChannel[48][6]={
{0,0,0,0,0,0}, //channel 0 [1][9]
{0,0,0,0,0,1}, //channel 1 [2][9]
{0,0,0,0,1,0}, //channel 2 [3][9]
{0,0,0,0,1,1}, //channel 3 [4][9]
{0,0,0,1,0,0}, //channel 4 [5][9]
{0,0,0,1,0,1}, //channel 5 [6][9]
{0,0,0,1,1,0}, //channel 6 [7][9]
{0,0,0,1,1,1}, //channel 7 [8][9]

{0,0,1,0,0,0}, //channel 8 [1][10]
{0,0,1,0,0,1}, //channel 9 [2][10]
{0,0,1,0,1,0}, //channel 10 [3][10]
{0,0,1,0,1,1}, //channel 11 [4][10]
{0,0,1,1,0,0}, //channel 12 [5][10]
{0,0,1,1,0,1}, //channel 13 [6][10]
{0,0,1,1,1,0}, //channel 14 [7][10]
{0,0,1,1,1,1}, //channel 15 [8][10]

{0,1,0,0,0,0}, //channel 16 [1][11]
{0,1,0,0,0,1}, //channel 17 [2][11]
{0,1,0,0,1,0}, //channel 18 [3][11]
{0,1,0,0,1,1}, //channel 19 [4][11]
{0,1,0,1,0,0}, //channel 20 [5][11]
{0,1,0,1,0,1}, //channel 21 [6][11]
{0,1,0,1,1,0}, //channel 22 [7][11]
{0,1,0,1,1,1}, //channel 23 [8][11]
```

```
{0,1,1,0,0,0}, //channel 24 [1][12]
{0,1,1,0,0,1}, //channel 25 [2][12]
{0,1,1,0,1,0}, //channel 26 [3][12]
{0,1,1,0,1,1}, //channel 27 [4][12]
{0,1,1,1,0,0}, //channel 28 [5][12]
{0,1,1,1,0,1}, //channel 29 [6][12]
{0,1,1,1,1,0}, //channel 30 [7][12]
{0,1,1,1,1,1}, //channel 31 [8][12]

{1,0,0,0,0,0}, //channel 32 [1][13]
{1,0,0,0,0,1}, //channel 33 [2][13]
{1,0,0,0,1,0}, //channel 34 [3][13]
{1,0,0,0,1,1}, //channel 35 [4][13]
{1,0,0,1,0,0}, //channel 36 [5][13]
{1,0,0,1,0,1}, //channel 37 [6][13]
{1,0,0,1,1,0}, //channel 38 [7][13]
{1,0,0,1,1,1}, //channel 39 [8][13]

{1,0,1,0,0,0}, //channel 40 [1][14]
{1,0,1,0,0,1}, //channel 41 [2][14]
{1,0,1,0,1,0}, //channel 42 [3][14]
{1,0,1,0,1,1}, //channel 43 [4][14]
{1,0,1,1,0,0}, //channel 44 [5][14]
{1,0,1,1,0,1}, //channel 45 [6][14]
{1,0,1,1,1,0}, //channel 46 [7][14]
{1,0,1,1,1,1}, //channel 47 [8][14]
//reject the below values
// {1,1,0,0,0,0}, //channel 48
// {1,1,0,0,0,1}, //channel 49
// {1,1,0,0,1,0}, //channel 50
// {1,1,0,0,1,1}, //channel 51
// {1,1,0,1,0,0}, //channel 52
// {1,1,0,1,0,1}, //channel 53
// {1,1,0,1,1,0}, //channel 54
// {1,1,0,1,1,1}, //channel 55
// // {1,1,1,0,0,0}, //channel 56
// {1,1,1,0,0,1}, //channel 57
// {1,1,1,0,1,0}, //channel 58
// {1,1,1,0,1,1}, //channel 59
// {1,1,1,1,0,0}, //channel 60
```

```
// {1,1,1,1,0,1}, //channel 61
// {1,1,1,1,1,0}, //channel 62
// {1,1,1,1,1,1}, //channel 63
};

//loop through the 6 sig
for(int i = 0; i < 6; i ++)
{
digitalWrite(controlPin[i], muxChannel[channel][i]);
}

//read the value at the Z pin
float val = analogRead(Z_pin);
float fsrForce = val;
//float voltage = map(val,0,1024,0,5000);
//float fsrForce = map(val,0,5000,0,50);
return fsrForce;

}
```

Chapter C

Technical Justification for Using ESP32 Instead of Arduino Uno in the FSRA Control Board

The ESP32 microcontroller unit (MCU) was chosen over the Arduino Uno for the FSRA (Force Sensing Resistor Array) control board due to its superior hardware capabilities, including more GPIO pins, higher processing power, built-in Wi-Fi and Bluetooth, and enhanced analog-to-digital conversion (ADC) features. Below is a detailed technical analysis of why ESP32 is a better choice than Arduino Uno for this application.

C.1 GPIO Availability and Multiplexing Capability

The FSRA control board requires handling multiple sensor inputs, which necessitates the use of multiplexers (74HC4051). The ESP32 provides a larger number of General-Purpose Input/Output (GPIO) pins compared to the Arduino Uno, allowing for efficient control of multiple sensors.

C.1.1 ESP32 GPIO Specifications:

a. **34 to 39 (Input only) – Suitable for reading sensor data.**

b. **0 to 33 (Input/Output) – Used for digital control, including selecting multiplexer channels.**

c. **Multiple PWM-supported GPIOs – Useful for advanced signal processing.**

C.1.2 Arduino Uno GPIO Specifications:

a. **14 digital I/O pins (D0–D13).**

b. **6 analog input pins (A0–A5).**

c. **Limited PWM pins (6 PWM-capable pins only).**

Given that FSRA requires reading from multiple sensors, the ESP32's higher GPIO count allows direct interfacing with more multiplexers without additional expansion modules.

C.2 Analog-to-Digital Converter (ADC) Capabilities

FSRA sensors generate analog signals that need to be converted into digital values for processing.

C.2.1 ESP32 ADC Capabilities:

It provides 4096 levels of granularity (compared to 1024 in Arduino Uno) i.e. 12-bit ADC resolution and it allows for simultaneous readings from different sensors i.e. Multiple ADC channels (up to 18 ADC-capable GPIOs).

C.2.2 Arduino Uno ADC Capabilities:

It provides only 1024 levels of granularity (lower precision) i.e. 10-bit ADC resolution and Only 6 ADC channels – Limits the number of sensors that can be read simultaneously.

For FSRA applications, a higher resolution ADC means more accurate force readings, making ESP32 the preferred choice.

C.3 Multiplexing Efficiency with 74HC4051

The circuit diagram in the first image uses 74HC4051 8-channel analog multiplexers, which require digital control signals to select different input channels. ESP32 provides sufficient GPIOs to control multiple multiplexers simultaneously. Faster digital switching due to a higher CPU clock speed (240 MHz vs. 16 MHz in Arduino Uno). Lower power consumption per switching operation (useful for battery-powered applications).

C.4 Processing Power and Memory

FSRA-based applications often require real-time signal processing, which is computationally demanding.
ESP32: 240 MHz dual-core processor (Tensilica Xtensa LX6), 520 KB SRAM + 4 MB Flash Memory, Supports floating-point operations and advanced DSP functions.
Arduino Uno: 16 MHz ATmega328P microcontroller,2 KB SRAM + 32 KB Flash Memory, Limited floating-point processing capability.
The ESP32's higher processing power allows faster sensor data acquisition, filtering, and real-time processing, which is crucial for accurate FSRA readings.

C.5 Power Efficiency and Voltage Compatibility

The ESP32 operates at 3.3V logic, while the Arduino Uno operates at 5V logic. The FSRA sensors and 74HC4051 multiplexer are compatible with 3.3V, making ESP32 a

better voltage match. ESP32 supports deep sleep modes, reducing power consumption when not actively reading sensors.

C.6 Wireless Connectivity for FSRA data transfer

Unlike the Arduino Uno, the ESP32 has built-in Wi-Fi and Bluetooth connectivity, making it ideal for remote monitoring and IoT-based applications. Data from the FSRA can be sent wirelessly to a cloud server or a smartphone application. Enables real-time force distribution monitoring in biomedical or industrial applications.

If an Arduino Uno were used, additional modules like ESP8266 or HC-05 Bluetooth would be required, increasing complexity and cost. Thus, using an ESP32 MCU significantly enhances the performance and scalability of the FSRA system, making it an optimal choice over the Arduino Uno.