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A CONCEPT PAPER: “THE DEVELOPMENT OF SKY ARMS: A NOVEL SYSTEM FOR ALLEVIATING EDEMA USING THE 4D DEVELOPMENT MODEL”

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Abstract:

Millions of people worldwide suffer from oedema, a condition that frequently shows up as swelling in the upper extremities and is characterized by an abnormal buildup of fluid in tissues. Efficient management of oedema is crucial for alleviating symptoms and improving patient outcomes, typically achieved through elevating the limbs to aid in fluid drainage. However, current methods, such as traditional arm slings and bandages connected to IV stands, have significant drawbacks, including limited adaptability, discomfort, inadequate support, and environmental issues due to frequent bandage changes. This concept paper introduces Sky Arms, an innovative device designed to revolutionise the management of upper limb oedema. Sky Arms is a limb elevation device incorporating cutting-edge materials, digital technology, dynamic customisation, and data-driven feedback. It will be developed using the 4D Development Model to provide a user-friendly, secure, and adaptable experience. This study explores the features of Sky Arms, the role of the 4D Model in enhancing therapy effectiveness, the potential impact on patient care and recovery, and the opportunities for collaboration in the social sciences, education, and innovation. Sky Arms offers a promising solution to the persistent problem of oedema through the implementation of the 4D Development Model. This study highlights its innovative methodology and potential benefits, advocating for interdisciplinary cooperation to bring this technology to fruition. Sky Arms represents a significant advancement in oedema treatment, offering the potential for improved patient outcomes, a higher quality of care, and reduced healthcare costs.

Keywords:

Alleviation, 4D Development Model, Fluid Retention, Innovation, Medical Devices, Upper Limb Oedema

Introduction

A sizable number of people worldwide suffer from oedema, a condition marked by the abnormal buildup of fluid in tissues (Scallan et al., 2010; Hettrick & Aviles, 2022). Swelling in the upper limb is a common manifestation of oedema, causing discomfort, stiffness, and limited movement. Efficient management of oedema is crucial for relieving symptoms and improving patient outcomes. One approach involves elevating the affected limb to facilitate the return of fluid to the central circulation (Besharat et al., 2021). However, current methods of oedema management, such as manual arm slings or bandages connected to intravenous (IV) stands, have several drawbacks that hinder effective patient care (Borman, 2018). Conventional arm slings, typically made of cloth, have limited flexibility and can cause discomfort when worn for extended periods. This discomfort can lead to improper alignment and hinder the outflow of fluid. Moreover, manual slings may not provide sufficient support, especially for heavier limbs, reducing their effectiveness (Baker et al., 2010). On the other hand, bandages connected to IV stands may offer greater stability, but they can be easily displaced, increasing the risk of falls and compromising patient safety. Additionally, the frequent changing of dressings generates more waste, raising concerns about the environmental impact and long-term sustainability of these conventional approaches (Miller, 2021).

This concept paper introduces the Sky Arms device, an innovative solution designed to revolutionise the management of upper limb oedema in response to the challenges posed by this condition. The Sky Arms device is developed using the 4D Development Model, which incorporates state-of-the-art materials, digital technology, personalised customisation, and data-driven feedback. This approach ensures that the system addresses the limitations of current methods by providing a user-friendly, secure, and customisable platform for elevating the upper limb. The main objectives of this concept paper are to highlight the unique features of the Sky Arms device, utilising the 4D Development Model to enhance the effectiveness of oedema treatment; explore the potential impact of the Sky Arms device on patient care and recovery; and examine opportunities for interdisciplinary collaboration in the fields of social sciences, education, and innovation.

Background of the Study

Oedema, a prevalent illness, is characterized by the abnormal accumulation of fluid in the body's tissues, resulting in swelling and discomfort. Possible causes include heart failure, kidney illness, or chronic venous insufficiency (Scallan et al., 2010). Oedema may also occur during surgical procedures or traumatic injuries, leading to localized oedema. When it affects the upper extremities, it can cause significant discomfort, pain, and stiffness, restricting mobility and interfering with everyday activities. Effective management of oedema in the upper limb is vital for relieving symptoms and improving overall quality of life (Borman, 2018).

Oedema is caused by the abnormal buildup of fluid in the interstitial, which is the area found beneath the skin or in body cavities such as the lungs. Visible swelling occurs when there is an accumulation of 2.5 to 3 litres of fluid in the interstitial space, either in a specific area or

throughout the body (Scallan et al., 2010). Normally, the lymphatic system removes the excess fluid and channels it into the veins. However, if the lymphatic drainage system becomes overwhelmed, the fluid remains in the interstitial space, causing the affected limb to appear swollen. Oedema is primarily caused by four factors: reduced plasma oncotic pressure, elevated plasma hydrostatic pressure, increased vascular permeability, and impaired lymphatic drainage. Factors such as starvation, burns, brain injury, liver disease, or high levels of protein in the urine can decrease plasma oncotic pressure. In some cases, there may be an increase in capillary hydrostatic pressure due to excessive fluid volume or blockage of veins, leading to elevated intravenous pressure. Inflammation and increased vascular permeability can contribute to the development of localized or widespread oedema. When there is an increase in capillary permeability in injured areas, proteins migrate into the interstitial space and generate osmotic pressure, which draws fluid towards the area. Additionally, the production of inflammatory cytokines increases capillary permeability in cases of ischemia and viral diseases (Lent-Schochet, 2023).

Multiple strategies are available for managing oedema. Swelling may persist for an extended period, especially if the joint has been immobilized for a prolonged duration. It may take several months for the swelling to diminish. Not all patients with oedema require medication therapy. Occasionally, limiting sodium intake and elevating the lower limbs above the level of the left atrium may be sufficient. However, the majority of patients will need to use diuretics along with nonpharmacologic therapy, such as reducing salt intake. The choice of diuretic, route of administration, and dosing regimen will depend on the underlying condition, its severity, and the urgency of the situation (King, 2017).

Elevating the injured hand above heart level is a fundamental method for managing oedema. This can be achieved by using a pillow or cushion for support while sitting or resting, and by keeping the hand elevated during movement. Healthcare providers and medical professionals should be mindful of how long a limb is elevated to prevent stiffness in the upper extremity (Miller et al., 2017; Abbal et al., 2023). Another effective therapy for hand oedema is contrast bathing. This technique involves alternating between cold and warm water to promote blood circulation and relieve oedema. The patient should immerse their hand in cold water for one minute (or a comfortable duration) to form a fist, and then transition to warm water for three minutes. This process should be repeated for a total of 10 minutes, ending with warm water. However, individuals with open wounds or circulatory impairments in the hand or upper limb should avoid this technique. Nurses should supervise the treatment to prevent any potential harm (Breger et al., 2009).

Massage therapy can also help reduce swelling in the affected hand. The hand should be elevated above heart level, while the elbow is supported on a firm surface. Applying firm pressure and stroking the hand from the fingertip to the elbow can effectively reduce swelling by promoting drainage. Using a lubricating cream can enhance the massage procedure. Occupational therapists or physiotherapists can administer this treatment, and nurses should assess the condition of the skin afterwards (Patel et al., 2022).

Traditional Methods of Oedema Management

The traditional method of controlling oedema in the upper limb involves raising the affected limb above the level of the heart. This helps with fluid removal and reduces swelling. Typically, manual arm slings or bandages are used and attached to drip stands. However, these approaches

have certain limitations that can affect their effectiveness and patient comfort. Adjusting manual arm slings can be challenging, making it difficult to find the optimal angle for efficient fluid drainage. Prolonged use of these slings can lead to discomfort and the development of pressure sores, causing patients to deviate from their prescribed treatment (Sibbald et al., 2020). Bandages secured to intravenous poles are inherently unstable and prone to slipping, increasing the risk of falls and accidents. Additionally, the constant need to replace these dressings generates a significant amount of medical waste, raising concerns about sustainability and the environment (Hettrick & Aviles, 2022).

Conventional therapies for oedema include the use of compression garments, manual lymphatic drainage, and pharmaceutical therapy. However, compression garments can be uncomfortable and challenging to apply, resulting in poor patient compliance. Manual lymphatic drainage, although effective, is time-consuming and not accessible to everyone. Pharmacological therapies, such as diuretics, carry inherent risks and may not be suitable for all individuals (Ely et al., 2006).

Incidence and Management of Hand Injuries

A study conducted at Beacon Hospital in Petaling Jaya revealed that approximately 90 out of every 100,000 patients suffer from hand injuries. Chinese patients make up the majority of cases, followed by Malays and Indians. The number of cases is increasing. Raising the injured hand is essential for reducing pain and swelling, as well as for the rehabilitation process and regaining full functionality. However, consistently raising the injured hand can be challenging. Conventional slings often cause discomfort and may discourage patients from using them. Moreover, they can negatively affect shoulder mobility, leading patients to prefer shorter periods of immobilisation. Applying and removing a sling can also be difficult for patients with hand injuries, making it hard for them to comply with the treatment. As a result, some hand surgeons may recommend elevating the hand using nearby objects like cushions. However, this approach carries the risk of patients not adhering to the need for elevation. Minimizing inflammation is crucial to prevent limitations in joint movement and stiffness in the fingers and wrists (Miller, 2021).

The Need for Innovative Solutions

Considering the limitations of traditional approaches and the significant impact of oedema on patients' well-being, there is a clear need for innovative treatments. Current therapies often lack flexibility, causing discomfort and reducing patient compliance. Makeshift remedies, such as using bandages attached to drip stands, are unstable and increase the risk of falls and injuries (Smith et al., 2024). Additionally, regularly replacing bandages leads to the accumulation of medical waste and raises concerns about environmental sustainability (Plona et al., 2022).

Sky Arms device is an advanced technique developed to alleviate oedema. By integrating advanced materials, digital technology, dynamic customisation, and data-driven feedback into the 4D development model, it overcomes the limitations of older approaches. This comprehensive technique provides a user-friendly and adaptable platform for elevating the upper limbs, thereby improving the effectiveness of oedema treatment. Sky Arms device aims to enhance patient care and recovery outcomes, reduce the burden on healthcare providers, and promote sustainability. Sky Arms device improves patient compliance with the treatment plan by offering a pleasant, secure, and customisable platform for elevating limbs. As a result, it increases the efficiency of fluid evacuation and reduces oedema. The system's real-time

monitoring and dynamic adjustments ensure that patients consistently receive optimal support throughout the treatment process, minimizing complications and facilitating a faster recovery.

In summary, Sky Arms device represents a significant advancement in the management of upper limb oedema. This groundbreaking procedure addresses the limitations of traditional procedures and has the potential to improve patient care, optimize recovery outcomes, reduce the burden on healthcare providers, and promote sustainability. By fostering interdisciplinary collaboration, Sky Arms device can facilitate further research and development in the fields of healthcare, social sciences, and innovation. The goal is to enhance the quality of life for individuals suffering from oedema.

Problem Statement

Elevating the hand is crucial for effectively managing oedema caused by hand injuries, as it can alleviate pain and discomfort. However, a significant challenge in managing oedema is that patients often fail to adhere to recommended elevation regimens. One common reason for this lack of compliance is the absence of appropriate orthotics specifically designed to assist in hand elevation (Tan, 2021). Traditional slings are generally not recommended because they may cause shoulder problems and exacerbate the situation by allowing the hand to hang below the level of the heart (Murrell, 2003).

The persistent use of slings to elevate the affected hand remains a serious issue. Studies have shown that 38% of patients find traditional slings uncomfortable, leading to a significant number of patients discontinuing their use (Kroeze et al., 2019). Additionally, immobilizing the shoulder with a sling can have a negative impact on shoulder mobility. As a result, there has been a shift towards shorter periods of immobilization, particularly after procedures involving the glenohumeral joint (Muraoka et al., 2019). After sustaining an injury or undergoing surgery on the upper extremities, patients face significant challenges when it comes to independently applying and removing slings. This difficulty hampers their ability to engage in everyday activities or participate in hand rehabilitation. Consequently, many hand surgeons opt not to use slings and instead recommend that patients elevate their hands using shoulder movement, hold them over their heads during movement, or support them with items such as blankets or small pillows when at rest. These procedures can be physically and mentally demanding for patients, increasing the likelihood of non-compliance (Miller, 2021).

Hand elevation is a common practice in therapeutic settings in Malaysia, where blankets and small cushions are often used. However, this technique has various issues. Patients frequently fail to readjust the position of their hands properly after activities such as using the toilet or eating. The hot and humid climate in Malaysia exacerbates discomfort, causing patients to remove the supports due to perspiration. This prolongs the recovery time and hinders the reduction of oedema. An orthopaedic device designed to allow convenient hand elevation in Malaysian conditions could effectively address these concerns by immobilizing the hand and reducing the risk of upper-limb stiffness caused by manual elevation.

Although there are treatments available for oedema, significant gaps still remain. Traditional procedures are uncomfortable and inconvenient, leading to poor patient compliance and hindering the effectiveness of treatment (Fullarton et al., 2004; Yu et al., 2020). Additionally, existing systems do not have the capability to actively monitor and adjust for individual variations in swelling, which makes it difficult to achieve optimal management. Currently, the

available options do not effectively tailor treatment to meet the specific needs of each patient, resulting in inconsistent outcomes (Hettrick & Aviles, 2022). These gaps highlight the need for an innovative solution that prioritizes comfort, real-time monitoring, and personalised treatment.

There is an urgent need for a groundbreaking solution that addresses these shortcomings by providing a more pleasant, efficient, and personalized approach to managing oedema. An effective solution should utilize state-of-the-art technology to continuously monitor and adapt to the patient's condition in real-time, ensuring the best possible therapy and improved patient outcomes. The Sky Arms device, developed using the 4D Development Model, aims to fill these gaps by incorporating cutting-edge materials, digital technology, customizable features, and data-driven feedback. This approach will fulfil the following requirements:

- i. Improved comfort and adherence: Intelligent fabrics will be used to provide optimal compression while ensuring comfort, thereby promoting better patient compliance.
- ii. Real-time monitoring and adjustment: Wearable sensors and mobile applications will enable continuous monitoring and immediate adjustments based on the patient's condition.
- iii. Personalized treatment: Patient data will be collected and used to customize treatment protocols according to everyone's unique needs and physiological responses.

The main objectives of this innovation are to simplify the setup process of Sky Arms device for nurses, reduce the setup time compared to manual arm slings, and effectively reduce hand oedema in patients, thereby enhancing their overall quality of life. By addressing these critical shortcomings, Sky Arms device has the potential to significantly improve patient care, compliance, and treatment outcomes for hand oedema.

Significance of the Innovation Project

The objective of the Sky Arms innovation project is to create a new way to manage hand oedema that overcomes the limitations of existing solutions. Sky Arms device aims to offer a more comfortable, efficient, and personalized approach by incorporating advanced materials, digital technology, and data-driven feedback. Implementing this solution will improve patient adherence, enable continuous monitoring and adjustments, and ultimately lead to better treatment outcomes and faster recovery for individuals with hand oedema.

The Sky Arms device is a highly innovative development in the treatment of oedema, offering several potential advantages. This new approach can effectively reduce hand oedema in patients, thereby decreasing the risk of infection and enhancing overall quality of life. The sustainable materials used in Sky Arms device are durable and have a longer lifespan, minimizing their ecological impact and reducing the amount of waste generated from frequent replacements. This method significantly reduces the workload of nurses by including an adjustable strap that can be easily customized to fit the patient's hand size, eliminating the need for time-consuming manual configurations. As a result, nurses can save valuable time and focus on other important tasks in the hospital. Additionally, Sky Arms device can help reduce healthcare costs by shortening recovery periods and preventing complications from prolonged therapy. This device also provides enhanced educational opportunities for healthcare workers through innovative training and simulation technologies. Furthermore, it promotes social and

technological innovation, stimulating further research and development in related fields. Therefore, the Sky Arms device has the potential to greatly improve patient care, optimize healthcare efficiency, and ensure the long-term sustainability of medical practices.

Research Methodology

Sky Arms is a device for managing hand and arm oedema that has been developed using the 4D development methodology, which includes four stages: Define, Design, Develop, and Deliver.

Define Stage

The Define stage aims to identify the limitations and shortcomings of existing methodologies. Sky Arms device aims to improve the efficiency, user-friendliness, and security of elevation systems by addressing issues such as limited adjustability, discomfort, and unreliable attachment techniques that pose safety risks. Additionally, Sky Arms device addresses the environmental impact of frequent bandage changes, and the labour-intensive tasks faced by nurses when using conventional methods.

Design Stage

In the Design process, Sky Arms device prioritizes patient comfort and healthcare provider efficiency, taking into consideration the challenges at hand. The product includes an adjustable strap for individual height preferences, a steel support that can be securely moved and locked into place for stability and flexibility, and a device consisting of a hook and strap for convenient attachment and detachment. The use of resilient, launderable fabrics ensures extended durability and reduces unnecessary waste.

Develop Stage

During the Develop phase, a fully functional prototype of Sky Arms device was created. The prototype will undergo testing to evaluate its functionality, adaptability, and user experience. This allows for improvements to be made before mass manufacturing.

Deliver Stage

In the Deliver phase, Sky Arms device will be deployed in real-world settings through clinical trials to assess its effectiveness in controlled circumstances. Healthcare personnel will receive extensive training on the proper installation and use of Sky Arms device. Following this, Sky Arms device will be incorporated into current procedures and practices in hospitals and home care environments.

Comparative Analysis

The diagram below illustrates a comparison between the manual arm sling currently used for patients with hand oedema in the hospital setting (figure 1) and the innovative Sky Arms Device (figure 2), which aim to enhance the quality of services for these patients.



Figure 1: Current Arm Sling

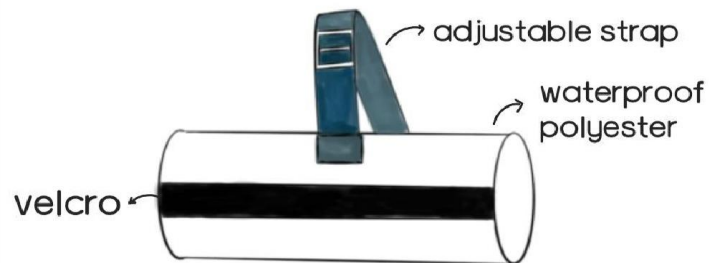


Figure 2: Sky Arms Device

Potential Benefits of Sky Arms Device

Sky Arms device is a comprehensive method for managing swelling in the hands and arms. The goal is to decrease the intensity and duration of swelling by using effective and comfortable treatments. This strategy improves patient compliance and satisfaction by offering user-friendly and non-invasive alternatives. By providing healthcare practitioners with up-to-the-minute data, it facilitates well-informed judgments and modifications, promoting interdisciplinary research and development that crosses the divides between technology, healthcare, and social sciences. The pioneering design of Sky Arms device has a multitude of benefits for both patients and healthcare providers.

Patients benefit from enhanced comfort provided by an adjustable strap and padded cuff, improved security due to a sturdy steel support and brake system, facilitated healing through consistent elevation that promotes proper lymphatic drainage, and reduced risk of infection due to easy cleaning and disinfection capabilities.

Sky Arms device enhances the efficiency of healthcare professionals by reducing the time spent on adjusting and monitoring arm elevation. It also improves patient outcomes by ensuring consistent and effective oedema management. Additionally, it reduces the workload of skilled nursing staff by allowing them to focus on more complex patient needs. Moreover, it promotes environmental sustainability through its durable design, which reduces the frequency of replacements and minimizes waste.

Conclusion

Sky Arms device utilizes the 4D development model to address the persistent problem of oedema. This concept paper highlights the innovative methodology and potential impact of the device, emphasizing the need for collaboration among the fields of social sciences, education, and innovation to effectively develop this revolutionary technology. The Sky Arms device represents a significant breakthrough in oedema treatment, as it overcomes the limitations of current therapies using cutting-edge technology and a patient-centred approach. By addressing gaps in knowledge and practice, this project has the potential to significantly improve patient outcomes, enhance the quality of care, and reduce healthcare costs.

Ethical Considerations

This study will adhere strictly to all ethical protocols for conducting research with human subjects. These protocols include obtaining informed consent from participants and ensuring the confidentiality of their information. Before commencing the study, it will undergo a comprehensive review and approval process by an Institutional Review Board.

Estimated Cost for Each Item

Items	Price	Quantity	Cost
Wheels (50mm) with	RM 3.50	3	RM 10.50
Swivel Fix Brake	RM 3.50	3	RM 10.50
Stainless steel stand (1.1-2M X 0.4M)	RM 52.99	1	RM 52.99
Adjustable Limb Restraint Strap	RM 4.39	1	RM 4.39
Adjustable Cuff	RM 8.90	1	RM 8.90
Screw 4 flat head	RM 1.76	3	RM 5.28
Total cost			RM 92.56

***RM (Ringgit/ Malaysia currency)**

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Call to Action

We invite researchers, healthcare experts, educators, and innovators to join us in a discussion about the Sky Arms system and explore potential collaborations. Together, we can drive progress in patient care and health technology.

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