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Modified Bandage Backpack for Immobilization in Patients with Clavicle Fractures

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ABSTRACT

Clavicle fractures often occurred at the center due to lack of muscle and ligament protection. Management of clavicle fractures could be done operatively or non-operatively, with arm slings being the most common tool. However, arm slings tended to be less stable, so bandage backpacks were developed as an alternative. Although more stable in fixation, bandage backpacks still had weaknesses that required the development of new designs that were more comfortable and safe. This study aimed to develop a modified bandage backpack product for patients with clavicle fractures. This research used the Research and Development (R&D) method. The research procedure used the ADDIE model consisting of 5 stages including analysis, design, development, implementation, and evaluation stages. Product validation was carried out by four media experts consisting of 2 nursing lecturers and 2 emergency room nurses who were members of BAPENA PPNI Blitar City. Results from expert validators showed a feasibility score of 92%. The results of this modified bandage backpack product assessment met the criteria as very feasible with some suggestions and input. The modified bandage backpack product was expected to be used as an alternative treatment for patients with clavicle fractures.

Keywords: Modified bandage backpack; fixation; clavicle fracture

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INTRODUCTION

A midshaft clavicular fracture is the most common type of clavicle fracture because the middle part of the bone is less protected by muscles or ligaments, making it prone to breaking due to trauma (1). Patients typically experience severe pain, swelling, and restricted movement, which can interfere with daily activities (2). Treatment can be either operative (for fractures with significant displacement) or non-operative (such as arm slings or elastic bandages) (3). The operative method has a lower non-union risk (2.6%) compared to non-operative treatment (5.9–15.1%), especially if patients resume physical activity too soon (4).

A study conducted at Sanglah General Hospital (2013–2017) revealed that 718 cases of clavicular fractures predominantly occurred in the productive age group (25–64 years), with traffic accidents being

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the leading cause. This is because individuals in this age group are highly active and mobile. Most patients (88.3%) opted for non-operative treatment, primarily using arm slings (5). However, this method is considered less stable and carries risks such as prolonged pain or incomplete healing (6). To address these limitations, a backpack-style bandage device was developed, offering better stability. This device is commercially available, designed like a backpack, and made of fabric and foam.

The device aims to stabilize the shoulder position, improve clavicle bone alignment, and provide immobilization. However, it still has drawbacks, including inflexible lower straps that may feel tight for some users. Additionally, it lacks a wound cover for the clavicle, which poses a bleeding risk in open fractures, even if dressed. The device is also expensive, though cheaper versions are marketed as "posture supports" despite being the same product. Therefore, this research focuses on improving the backpack bandage by adding cross-straps for wound support and elastic materials to enhance comfort and healing effectiveness.

METHODS

The method used in this study is the Research and Development (R&D) method. This research and development method is employed to produce an exclusive product and assess its feasibility. The product developed in this study is a modified bandage backpack intended for patients with clavicle fractures. The research utilized the ADDIE development model, which consists of five stages: Analysis, Design, Development, Implementation, and Evaluation.

This research was conducted at BAPENA PPNI, Blitar City, and carried out in stages, including a preparation and planning phase from August to December 2024, followed by the implementation and reporting phase from January to April 2025. The implementation phase involved activities such as expert validation, the first trial, data collection, and the preparation and presentation of the final report. The research subjects consisted of four expert validators, comprising two university lecturers and two members of BAPENA PPNI Blitar City. The lecturers are recognized experts in their respective fields, while the BAPENA PPNI members are practicing nurses currently serving in the Emergency Department.

RESULT

Table 1. An Expert Validation Result

No.	Validation	Score	Standard Criteria	Explanation
1.	Expert 1 (Mr. AN)	90	$P = \frac{90}{85} x100 = 100\%$	Very Worthy
2.	Expert 2 (Mr. AS)	69	$P = \frac{69}{85} x100 = 81\%$	Very Worthy
3.	Expert 3 (Mrs. WM)	76	$P = \frac{76}{85} x100 = 89\%$	Very Worthy
Total		**235**	$\mathbf{p = \frac{235}{255} x100 = 92\%}$	**Very Worthy**

Based on the table, it can be seen that the total assessment score from expert validators is 235. The criteria used to determine the quality and feasibility level of the product are obtained by comparing the total score with the maximum possible score (255).

$$\mathrm{P} = \frac{235}{255}\mathrm{x}100\% = 92\%$$

According to Arikunto (2010), as cited in Ayu's research stated that if the analysis result falls within the standard range of 81%–100%, the product is classified as highly feasible for use (7). This classification is based on scores that meet the evaluation criteria in several aspects, including design, comfort, practicality, and ease of use. However, feedback, criticism, and suggestions from expert validators will be accepted by the researcher as valuable input for evaluation.

DISCUSSION

Expert Competency Analysis – Media Specialists

The expert competency analysis indicated that all media specialists possessed adequate knowledge regarding clavicle fracture management, particularly emphasizing immobilization, pain control, and wound care as the primary components of conservative treatment. This finding is consistent with established clinical guidelines, which identify immobilization as a key factor in maintaining fracture alignment and promoting optimal healing in non-displaced or minimally displaced clavicle fractures (8). The experts' perspectives confirm that the conceptual framework underlying the development of the modified bandage backpack aligns with current orthopedic practices.

Recent evidence comparing conventional immobilization devices for clavicle fractures indicates that commonly used bandage systems such as figure-of-eight braces and slings have inherent limitations. Studies have demonstrated that broad arm slings are associated with improved patient comfort and ease of application, which are important factors in optimizing patient compliance during the immobilization period (9). Moreover, novel sling designs such as *poly-slings* have been shown to significantly reduce pain scores compared to traditional figure-of-eight braces, suggesting that discomfort and restricted positioning remain challenges with conventional bandaging systems (10). While evidence remains limited, current literature highlights clinicians' preference for sling-based immobilization due to better tolerance and patient satisfaction, which indirectly reflects on compliance and usability concerns with older devices.

Furthermore, expert opinions that surgical intervention depends on fracture severity and clinical judgment reinforce the continued relevance of conservative treatment options. Given that a substantial proportion of clavicle fractures are managed non-operatively, innovations that improve immobilization quality and patient adherence are clinically significant, particularly in emergency and primary care settings (11). Overall, the expert analysis supports the feasibility and clinical relevance of the modified bandage backpack, although further clinical evaluation is necessary to assess its effectiveness compared to standard immobilization methods.

Analysis of Existing Products

Interviews with media experts confirmed that several immobilization devices are currently used in the conservative management of clavicle fractures, including arm slings, figure-of-eight bandages, and mitella slings. This finding is consistent with contemporary orthopedic literature, which identifies these devices as standard non-operative treatment options, particularly for non-displaced or minimally displaced fractures (6,12). The widespread use of these devices highlights their clinical relevance; however, their effectiveness is influenced by usability, comfort, and the ability to maintain proper immobilization over time.

Arm slings are commonly preferred due to their simplicity and ease of application. Nevertheless, studies have reported limitations such as inconsistent sizing, inadequate shoulder retraction, and limited stabilization of the clavicle, which may reduce immobilization effectiveness and prolong discomfort (9). These shortcomings can negatively affect patient compliance, particularly during prolonged use, as insufficient support may lead to improper positioning and persistent pain.

Figure-of-eight bandages and mitella slings provide better fixation and promote shoulder retraction, which is beneficial for maintaining clavicle alignment. However, both devices require proper application techniques and user skill. Several studies indicate that incorrect application can lead to discomfort, skin irritation, and reduced compliance, especially when patients or caregivers lack adequate training (12,13). These limitations underscore the need for an immobilization device that combines effective fixation with ease of use and standardized sizing, providing the rationale for the development of a modified bandage backpack.

Target Needs Analysis

Interviews with media experts revealed that a tool intended for clavicle fracture patients should provide adequate fixation, comfort, and ease of use. Fixation is essential to stabilize the injury area, as instability can increase the risk of severe pain, damage to surrounding tissues, bleeding, wound infection, and improper or failed bone healing (non-union) (14).

Product Design

The product developed in this study is a modified bandage backpack designed specifically for immobilization in patients with clavicle fractures. The device adopts a backpack-strap configuration, allowing bilateral shoulder support and controlled shoulder retraction to enhance clavicular stabilization. This design addresses key limitations of conventional immobilization devices by integrating ergonomic principles to improve comfort, stability, and ease of use. Ergonomic orthopedic devices have been shown to improve patient tolerance and adherence, which are critical factors in successful conservative fracture management (15).

The backpack-based structure enables more even distribution of pressure across the shoulders and upper back, reducing localized discomfort commonly reported with figure-of-eight bandages and traditional slings. Additionally, the modified design minimizes dependency on advanced bandaging skills, allowing easier application by healthcare providers, caregivers, or patients themselves. Studies have emphasized that simplified device application and standardized fitting are essential to maintain proper immobilization and prevent complications related to improper positioning or poor compliance (16).

This study follows a Research and Development (R&D) framework, focusing on the systematic creation and refinement of a novel assistive medical device. The R&D approach is widely recommended in health technology innovation as it supports iterative design based on

expert input, usability considerations, and clinical relevance (17). By translating clinical needs and expert recommendations into a practical product design, the modified bandage backpack represents a feasible and innovative solution for conservative clavicle fracture management. Further stages of development should include usability testing and clinical trials to evaluate effectiveness and patient outcomes.

Design Stage

At the design stage, the researcher developed the Modified Bandage Backpack based on findings from the analysis of existing products and expert input. This stage focused on translating clinical needs and identified product limitations into a functional and user-centered design. A structured product assessment sheet was compiled to guide the design process, ensuring that key aspects such as comfort, stability, ease of use, and immobilization effectiveness were systematically addressed. Design-driven approaches in health technology emphasize the importance of aligning product features with clinical functionality and user requirements to optimize outcomes (18).

The Modified Bandage Backpack is primarily constructed from sponge foam covered with soft fabric, selected to enhance comfort and reduce skin irritation during prolonged use. Elastic fabric is incorporated into the lower and cross straps to allow controlled flexibility while maintaining sufficient tension for stabilization. Velcro fasteners are strategically placed to facilitate easy adjustment, standardized fitting, and secure fastening. Previous studies have highlighted that soft materials, adjustable components, and simplified fastening mechanisms improve patient tolerance and adherence to orthopedic immobilization devices (19,20).

Compared to existing bandage backpacks, this design introduces key modifications, including an additional cross-strap to secure the wound cover and the use of elastic material in the lower strap. These enhancements are intended to improve shoulder stabilization, maintain clavicle alignment, and provide effective immobilization, which are critical factors in preventing secondary displacement and minimizing complications during fracture healing (9). By improving both biomechanical support and usability, the design stage establishes a strong foundation for subsequent development and evaluation phases of the modified bandage backpack.

Development Stage

The development stage in the ADDIE model involves realizing the product design into a tangible form. During this stage, the conceptual framework is transformed into an implementable product. Once

completed, the product is evaluated by expert validators using a prepared assessment sheet. Based on their feedback and suggestions, the product is revised accordingly to ensure its readiness for implementation (21).

Product Feasibility

The feasibility assessment was conducted during the implementation phase. The product was trialed by media experts, who evaluated it using an assessment form prepared by the researcher.

Based on the total score from expert validators, which amounted to 235 out of a maximum of 255, the product's quality and feasibility level can be determined.

$$P = \frac{235}{255} x100\% = 92\%$$

According to Arikunto (2010), as cited in Ayu's research (7), if the analysis results fall within the 81%–100% range, the product is classified as highly feasible for use. This conclusion is drawn from evaluation aspects including design, comfort, practicality, and ease of use. Nevertheless, feedback, critiques, and suggestions from expert validators are accepted by the researcher as valuable input for further evaluation.

CONCLUSION

At the analysis stage, it was found that a device intended to assist patients with clavicle fractures must be able to provide fixation, be comfortable, and easy to use to support recovery. This product is an improved version of the previously existing bandage backpack. The improvements include the addition of a cross-strap to secure the wound cover and the use of elastic material for the lower strap. The evaluation results for the Modified Bandage Backpack indicated that the product was rated as highly feasible, along with several suggestions provided by expert validators. This demonstrates that the product has strong potential for further development. Based on expert validator assessments, the Modified Bandage Backpack received a score of 92%, indicating that it is highly feasible for use.

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