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Research article

Research on product design of FAHP bone marrow aspiration needle

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A B S T R A C T

Bone marrow aspiration is a crucial medical procedure to obtain bone marrow samples for diagnosis and treatment. However, traditional bone marrow aspiration needles face several challenges such as operational difficulties, inadequate sample acquisition, and patient discomfort. To address these issues, we aimed to design a bone marrow aspiration needle product by using fuzzy analytic hierarchical process (FAHP). The FAHP method was used to identify key factors in the design of the bone marrow aspiration needle, including technicality, usage, and application characteristics. The importance weights and priorities of each factor were determined through questionnaires and interviews with experts. A new bone marrow aspiration needle product was developed based on the results of the FAHP. The new product design considers the weights and priorities assigned to key factors, resulting in improved convenience during operation and a higher success rate of sample acquisition. This was achieved by optimising the structure and material selection of the needle. This study presents a novel bone marrow puncture needle product that effectively integrates the importance and priority of the key factors. It successfully enhances operational performance and patient experience, thereby offering an innovative solution to improve the success rate and therapeutic effect of bone marrow punctures.

1. Introduction

Bone marrow aspiration and biopsy are essential diagnostic procedures with extensive applications in the evaluation of a range of diseases. These procedures are commonly used to diagnose abnormalities in the blood system, identify malignancies in non-haematological tissues, detect metabolic disorders, and evaluate treatment responses to conditions such as chemotherapy and bone marrow transplantation. Furthermore, bone marrow aspiration and biopsy play a crucial role in staging haematological malignancies and assisting in the diagnosis of suspected infections in patients with unexplained fever. Tomasian et al. [1] emphasised that pain during bone marrow aspiration can be minimised using various methods, such as local anaesthesia, distraction techniques, and specialised needle designs. Additionally, patient education and effective communication regarding the surgery can help alleviate anxiety and enhance pain management during the procedure. However, studies focusing on the design of needle-based products are limited. Currently, most needles available in the market are function-oriented and share similar technical characteristics. Nevertheless, user experience varies significantly, highlighting the importance of considering both medical attributes and patient experience when designing medical products. This study addressed the design issues associated with traditional bone marrow puncture needles,

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focusing on the challenges related to sample acquisition, patient experience, and handling. Traditional bone marrow puncture needles pose technical difficulties that can hinder medical staff from overcoming operational challenges and potentially impede the smooth progress of the procedure [2]. Inadequate sample acquisition is also a concern that may compromise clinical diagnostic accuracy. Additionally, patients may experience pain during the procedure, which diminishes their overall treatment comfort and negatively affects their treatment experience.

In the global manufacturing industry, there is growing emphasis on quality assurance methods to address product failures and ensure patient safety [3]. The medical device industry is experiencing rapid advancements in design, materials, and technology, offering new solutions to challenging healthcare problems [4]. However, traditional innovation channels in this industry face limitations owing to the diverse and unique needs of the multiple stakeholders involved. The value-driven innovation process aims to balance stakeholders' opinions and address specific requirements for effective medical device design [5]. By integrating failure, risk, and quality assurance analyses, a comprehensive approach can be developed to ensure product quality and promote global manufacturing practices in the healthcare sector. Fu et al. [6] proposed a fuzzy logic programming-based approach for designing anti-epidemic products considering household conditions and economic benefits. Their research highlighted the need for adaptable design strategies to effectively respond to emerging health crises. Building on this [7], we emphasize the importance of an appropriate monitoring design to ensure the safety of medical products, stressing the need for accurate data collection and real-time information for healthcare professionals. Hagedorn et al. [8] presented an information model for the user-centered design of medical devices, emphasising the integration of stakeholder perspectives and user requirements. This study underscores the importance of considering user needs and preferences during the design process. Overall, these studies demonstrate the interconnectedness of design considerations, ranging from adaptability and safety to user-centered approaches, in addressing public health challenges and enhancing the effectiveness of medical products. In addition to public health crises, industrial product design also plays a crucial role in meeting consumer needs in the context of market constraints. Lin et al. [9] focused on designing a pillbox for chronic disease treatment using a fuzzy decision model to optimise medication adherence. Liu et al. [10] employed an Analytic Hierarchy Process (AHP) to guide the design of household medical products for rhinitis, thus enhancing the scientific basis of design strategies. Moreover, the application of machine learning in intelligent manufacturing, particularly in the design of medical products and intelligent hospital systems, has attracted significant attention. Liu et al. [11] investigated the use of machine learning with big data for intelligent medical disease diagnosis and classification, highlighting its accuracy and potential for improving medical diagnostics. Medina et al. [12] proposed a standard product design process model to support medical device development, considering the complexity and regulatory environment of medical devices. Miclaus et al. [13] discussed the interaction between design and safety in medical device development, emphasising the incorporation of quality and risk management processes. Moultrie et al. [14] presented a maturity grid assessment tool for environmentally conscious design in the medical device industry, addressing the industry's growing concerns regarding environmental impacts. Ricles et al. [15] examined the regulatory landscape and challenges in regulating 3D-printed medical products, highlighting the potential of additive manufacturing technologies. Additionally, the patient-centric design of pharmaceutical drug products has gained increasing attention as a crucial factor in promoting healthy aging, improving patient quality of life, and extending life expectancy. Stegemann et al. [16] emphasised the need to consider patient needs in drug product design to ensure compliance, safety, and effectiveness. Overbeeke et al. [17] explored the design and implementation of patient preference studies in the medical product life cycle, underscoring the need for collaboration among stakeholders and the potential applications of patient preferences in decision-making. Yue et al. [18] focused on the evaluation and improvement of older family medical product designs by utilising the AHP to enhance the assessment method and promote tailored medical products for the older dults.

Our research focused on improving the design of bone marrow aspiration needles to enhance surgical accuracy and patient experience. Hyperthermia has attracted increasing attention as a potential therapeutic approach. Previous studies have utilised Laplace transforms and experimental data to analyse thermodynamic models and investigate tissue temperature and thermal damage caused by laser irradiation [19]. Other related studies include the analysis of fractional-order heat transfer in skin tissues [20] and application of fractional-order biological heat transfer models in spherical tissues [21]. These studies have provided valuable background information for current bone marrow aspiration needle design, particularly when considering the effects of temperature on biological tissues and selecting important design variables for hyperthermia therapy. Additionally, finite element analysis of nonlinear biological heat transfer models influenced our work, particularly in understanding the impact of external heat sources on tumour cell therapy [22].

In summary, these studies collectively emphasize the interconnectedness of design considerations in medical product development, ranging from adaptability, safety, and user-centered approaches to advanced technologies. By integrating these aspects, medical products can effectively inform design decisions, enhance the effectiveness of medical product design, and improve patient outcomes.

The paper is organised as follows. Section 2 provides an introduction to the background and methods, including the current research status of bone marrow aspiration needles, factor analysis, and related concepts of FAHP. Section 3 describes the research process. Section 4 discusses the design of bone marrow aspiration needles, using it as an example to explore improvements in various factors. Finally, Section 5 presents the conclusions, summarises the research findings, discusses potential areas for future studies, and identifies the limitations of this study.

2. Methods and background

2.1. Status of bone marrow aspiration needles

A bone marrow aspiration needle is a specialised medical device used to perform bone marrow aspiration. It is a needle-like tool designed to penetrate human bones to obtain a sample of bone marrow fluid or tissue or for therapeutic purposes, such as bone marrow stem cell transplantation. These needles are typically made of stainless steel or other corrosion-resistant materials to prevent contamination and adverse reactions in patients. The size and shape of the needle may vary depending on the manufacturer and intended use; however, it generally has an elongated shape with a sharp tip. One end of the needle is usually connected to an aspirator or syringe, allowing collection of bone marrow fluid during the puncture. During the bone marrow aspiration procedure, doctors insert a needle into the anaesthetised skin and soft tissue, penetrating the skeletal cortex to reach the bone marrow cavity. Doctors can extract a sample of bone marrow fluid or tissue using an attached device for further laboratory tests or treatment.

The use of bone marrow aspiration needles requires the expertise of highly trained medical professionals and is typically performed by orthopaedic surgeons, haematologists, oncologists, or other relevant specialists. To minimise intraoperative pain, patients are typically administered local anaesthesia before the procedure. The bone marrow aspiration needle serves as a crucial medical instrument that enables doctors to effectively diagnose and treat specific blood disorders, tumours, and immune system issues.

2.1.1. Medical product design

Product design encompasses the entire process of creating new products or improving existing ones, from the initial concept to the final product. This involves a series of steps, including design, development, and implementation, to meet specific requirements and goals. While the appearance of a product is important, product design also considers factors such as functionality, performance, materials, manufacturing processes, and user experience. Medical product design focuses on creating and developing products such as medical equipment, devices, appliances, auxiliary equipment, and supplies. The ultimate objective of medical product design is to enhance medical care and improve patient experience, while ensuring the safety, efficacy, and reliability of products [10,23].

2.1.2. Factor analysis

Factor analysis is a statistically significant method used to analyse the interrelationships between multiple variables and explore the underlying structure within the data. It simplifies complex datasets by grouping observed variables into fewer and more explanatory potential factors. These latent factors represent common variances between variables, enabling us to comprehend the inherent structure of the data and uncover patterns and hidden relationships. In a recent study, the performance of primary axis factorisation and maximum likelihood factor analysis were compared, highlighting their respective advantages for different types of factor patterns and sample sizes [24]. Gaskin reviewed the factor analysis decisions and evaluated their application in nursing research, providing recommendations for future use [25]. Furthermore, Green et al. proposed a revised parallel analysis method that aimed to enhance the accuracy of determining the number of factors [26]. The goal of factor analysis is to determine the appropriate number of factors and their corresponding factor loadings, which indicate the strength of the relationship between each variable and each potential factor. These factor loadings can be used to explain variability in the data and identify common factors that influence the original variable. However, the factor analysis has limitations. For instance, selecting the correct number of factors can be difficult and different interpretations of these factors can yield different outcomes. Therefore, when conducting factor analysis, researchers must carefully consider factors such as the research objective, data characteristics, and explanatory power.

2.1.3. Fuzzy analytic hierarchial process (FAHP)

FAHP is a decision support method that integrates fuzzy mathematics and hierarchical analysis to address complex multicriteria decision problems. The FAHP organises decision-making issues into a hierarchy consisting of objective, criterion, and sub-criterion layers. Each level includes relevant decision factors that form a set of guidelines or scenarios. The AHP was proposed by Professor T. L. Saaty of the University of Pittsburgh in the early 1970s and later people added fuzziness to it to form the FAHP [27].

The concept of fuzzy mathematics was introduced in the FAHP to quantify decision makers' fuzzy preferences for guidelines and protocols. Decision makers often use vague language, such as 'very important', 'somewhat important', or 'generally important', to express their preferences for different guidelines and options. These fuzzy evaluations are then converted into mathematical fuzzy values. Specific computational methods are employed to process these values and determine the weight of each factor and final decision outcome. The FAHP has been widely applied and extended to various fields. Erkan et al. utilised the AHP and FAHP methods to compare the efficacy of barcode and RFID systems in warehouse data collection [28]. Kubler et al. conducted a comprehensive review of the application and development of FAHP and provided an online testbed to assist researchers in applying, modifying, and extending the FAHP [29]. Reig-Mullor et al. proposed an extended FAHP model (E-FAHP) that incorporated nonlinear fuzzy numbers to enhance the representation of fuzzy comparison matrices [30]. Rouyendegh and Erkan employed FAHP to select the appropriate academic staff [31].

2.1.4. Mathematical theorems for fuzzy matrices

The establishment of the FAHP matrix is a systematic and critical process that involves quantifying experts' fuzzy cognition of design factors [32]. First, the hierarchical structure of the bone marrow puncture needle design is determined and the key factors are organised according to their hierarchical relationships. Fuzzy linguistic variables are then created for each factor to capture the experts' fuzzy perceptions of their relative importance. These fuzzy linguistic variables can use terms such as 'very important', 'important', 'general', 'less important', and 'not important' [33]. Subsequently, an expert panel performs pairwise comparisons to provide a fuzzy comparison of the relative importance of each pair of factors [34]. The results of these comparisons form a fuzzy comparison matrix, in which each element reflects the relative priority of one factor over the other. Finally, the fuzzy comparisons of the experts form a complete matrix that serves as the basis for subsequent fuzzy calculations. This process helps to incorporate expert subjective knowledge into design, making design decisions more objective and explainable.

An n-dimensional square matrix R can be defined as follows:

$$R = (r_{ij})_{n\times n} = \begin{bmatrix} r_{11} & r_{12} & \dots & r_{1n} \\ r_{21} & r_{22} & \dots & r_{2n} \\ \vdots & \vdots & \vdots & \vdots \\ r_{n1} & r_{n2} & \dots & r_{nn} \end{bmatrix} \tag{1}$$

1) If matrix R satisfies $0 \leq r_{ij} \leq 1$, (i, j = 1, 2,⋯, n), then R is a fuzzy matrix.
2) If matrix R satisfies condition 1 and $r_{ij} + r_{ji} = 1$, (i, j = 1, 2,⋯, n), then R is a fuzzy complementary matrix.
3) If matrix R satisfies conditions 1 and 2 and $r_{ii} = 0.5$, (i = 1, 2, …, n) and $r_{ij} = r_{ik} - r_{jk} + 0.5$, (i, j, k = 1, 2, …, n), then R is called a consistent fuzzy matrix.

2.2. Computational steps of FAHP

1) FAHP score table (Table 1)

The table is analysed in defining the fuzzy analytic hierarchy table XU [35].

2) Construction of the FAHP scoring matrix

The aforementioned 0.1–0.9 scale method is used to compare the evaluation factors in pairs and the FAHP scoring matrix A is obtained as follows:

$$A = \begin{bmatrix} a_{11} & a_{12} & \dots & a_{1n} \\ a_{21} & a_{22} & \dots & a_{2n} \\ \vdots & \vdots & \vdots & \vdots \\ a_{n1} & a_{n2} & \dots & a_{nn} \end{bmatrix} \tag{2}$$

Matrix A satisfies the requirements of the fuzzy complementary matrix, that is, $0 < a_{ij} < 1$, $a_{ij} + a_{ij} = 1$, and $a_{ij} = 0.5$, (i = j).

3) Sum the matrix A row by row

$$a_i = \sum_{k=1}^{n} a_{ik}, (i, k = 1, 2 \cdots n) \tag{3}$$

4) Find the weight determinant WI of each factor

$$w_i = \frac{1}{n} - \frac{1}{2\alpha} + \frac{a_i}{n\alpha}, \tag{4}$$

$$WI = [w_1\ w_2\ \cdots w_n]^T, \tag{5}$$

where $\alpha = \frac{n-1}{2}$.

5) Consistency CI test. Build the weight matrix W

Table 1
FAHP score table.

Scoring criteria
0.1 Factor i is absolutely unimportant than factor j
0.2 Factor i is much less important than factor j
0.3 Factor i is less important than factor j
0.4 Factor i is slightly less important than factor j
0.5 Factor i is as important as factor j
0.6 Factor i is slightly more important than factor j
0.7 Factor i is more important than factor j
0.8 Factor i is more important than factor j
0.9 Factor i is absolutely more important than factor j

$$w_{ij} = \alpha(w_i - w_j) + 0.5 \tag{6}$$

$$W = \begin{bmatrix} w_{11} & w_{12} & \dots & w_{1n} \\ w_{21} & w_{22} & \dots & w_{2n} \\ \vdots & \vdots & \vdots & \vdots \\ w_{n1} & w_{n2} & \dots & w_{nn} \end{bmatrix} \tag{7}$$

$$CI(A, W) = \frac{\sum_{i=1}^{n}\sum_{j=1}^{n}|w_{ij} - a_{ij}|}{n^2} \tag{8}$$

The smaller the CI value, the better the consistency. Generally, $CI < 0.1$ means that the consistency requirements are met.

3. Research process

The research steps in this study were conducted using the FAHP, as shown in Fig. 1. Firstly, a reasonable design scheme for the bone marrow aspiration needle was established based on the elements of the objective layer. Secondly, the factors influencing the product design of the bone marrow aspiration needles were identified and organised through research and factor analysis. These factors were used as elements of the standard layer. Thirdly, the criterion layers of product design were decomposed into more specific sub-criterion

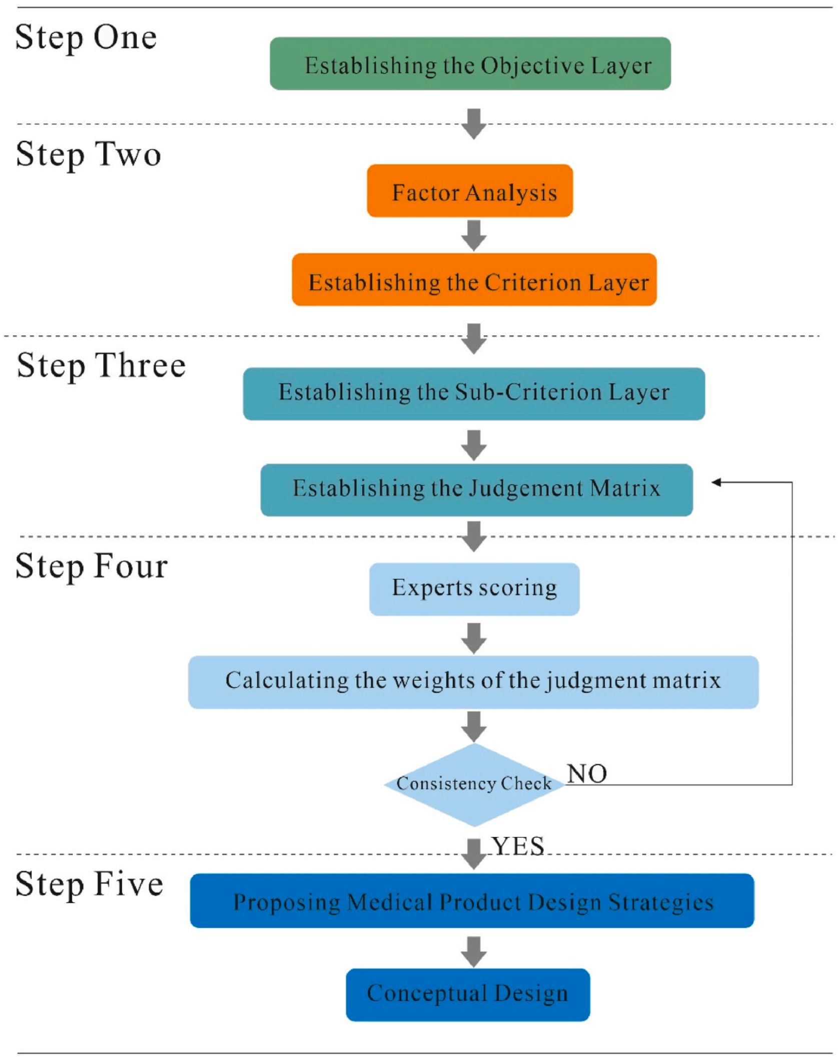

Fig. 1. Flow chart of the bone marrow aspiration needle optimisation design.

layers. The design elements of each sub-criterion layer were described in detail and a judgment matrix was constructed based on these descriptions. Fourthly, a panel of experts was established to compare and score the importance of directly relevant factors at each level. A comparison matrix was then created based on the scores of the experts, which were used to calculate the weight of each design element. After calculating the weights, a consistency test was conducted to ensure consistency of opinions within the expert group and the reliability and credibility of the results. Conclusions were then drawn based on the results of factor sorting. Subsequently, design practice commenced, wherein the product design and development process was initiated, guided by the conclusions and design requirements. During the design practice, the product was implemented and built incrementally, considering the factors identified in the ranked results. This ensured that the quality and performance of the product satisfied the expected standards. Throughout practice, any issues or areas for improvement that arise were addressed through continuous adjustment and enhancement, design optimisation, and by bringing the product to an optimal state. The optimisation process may involve material selection, functional improvements, and production process optimisation, among other aspects, to ensure that the product is comprehensive and aligned with market demand. Ultimately, through design practice and optimisation, we aimed to create competitive medical products that fulfill user needs and exhibit superior performance.

This study aimed to develop a more reasonable design scheme for bone marrow aspiration needles. Based on the preliminary interviews and research results, the factors were refined and classified to establish a criterion layer. This classification can be extended to derive more detailed design factors and establish sub-criterion layers. Myelaspiration is an effective diagnostic method; therefore, most patients are neutral to these products. Visiting patients who have undergone surgery can provide relevant information. For surgeons, surgical outcomes are the primary focus of the product design. Adjectives were collected from a product perspective by reviewing the literature on bone marrow aspiration and analysing relevant data. The adjectives collected from interviews with users and research were analysed, resulting in four attributes that affect the design of bone marrow aspiration needles: technicality, usage characteristics, stability, and application characteristics. Sixteen subcategory adjectives associated with bone marrow aspiration needles were selected.

The factors were organised in a layered structure, with A serving as the top layer, including its sublayers. This is illustrated in Fig. 2, with namely A1 Innovation, A2 Efficiency, A3 Reliability, A4 Revolutionary, etc. The sublayers were further divided into four groups.

In this study, a scale of 0.1–0.9 [35] was utilised to assign numerical values and define the importance between the two comparison elements. The specific scales and their significance levels are listed in Table 1. Additionally, an expert group of 11 individuals was formed to ensure the applicability of the research results. This group included 6 graduate students in product design, 3 patients requiring bone marrow aspiration, and 2 experts in the medical product development and medical fields. Each indicator was scored by the experts. The final result is shown in Tables 2–7.

The use of a fuzzy analytic hierarchy in the decision-making process aims to overcome the limitations of human subjective factors and improve the decision-making accuracy. Its main purpose is to eliminate subjective biases. In this method, the consistency of the judgment matrix plays a crucial role, and a consistency index (CI) of less than 0.1 is typically used to assess the reasonableness of the judgment matrix. Ensuring consistency is essential for the effectiveness of Fuzzy Hierarchy. Based on the above consistency test, it can be observed that the CI is less than 0.1 and passes the consistency test.

In practice, many decision-making processes pose challenges in quantitatively describing the comparisons between factors. In such cases, the FAHP proves to be effective. It helps to hierarchise complex decision-making systems by comparing the importance of various related factors layer-by-layer. This method provides a quantitative basis for analysis and decision-making. By introducing fuzzy computing, this approach can handle uncertainty and ambiguity more effectively, thereby improving problem-solving in real decision-making scenarios. As shown in Fig. 3, it is evident that B3 Material Comfort, C3 Precision in operation, and C4 Quality and Safety carry relatively high weights. These aspects should be considered in subsequent design processes.

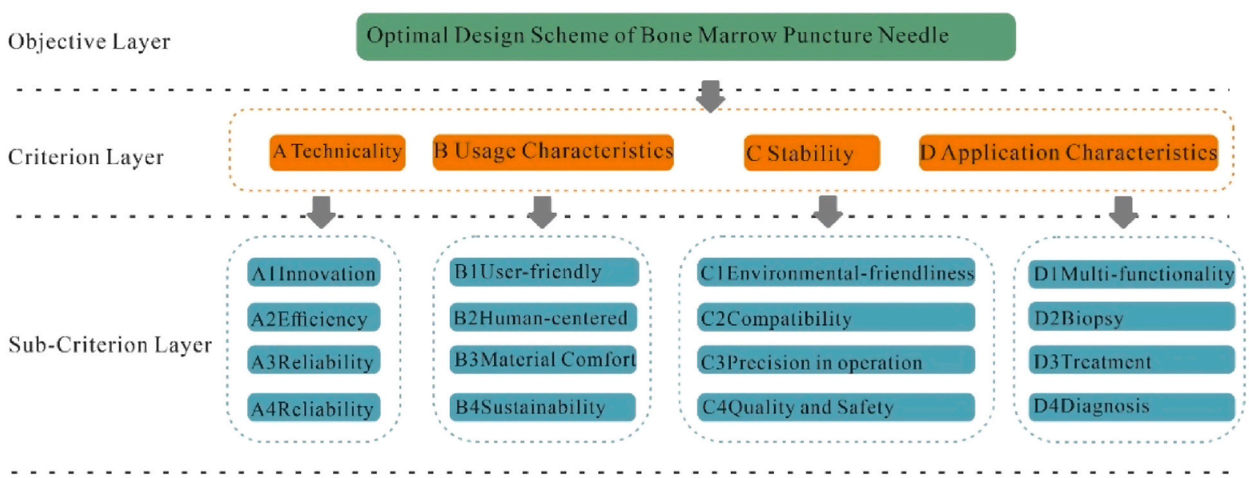

Fig. 2. Factor stratification.

Table 2
Criterion layer FAHP analysis table.

	A Technicality	B Usage Characteristics	C Stability	D Application Characteristics	Weight (wi)
A Technicality	0.5	0.4	0.3	0.6	0.2167
B Usage Characteristics	0.6	0.5	0.4	0.6	0.2667
C Stability	0.7	0.6	0.5	0.7	0.3333
D Application Characteristics	0.4	0.4	0.3	0.5	0.1833

Modified weight matrix for calculation: bone marrow aspiration needle optimisation design; consistency CI = 0.0188.

Table 3
Technical sublayer analysis table.

	A1 Innovation	A2 Efficiency	A3 Reliability	A4 Revolutionary	Weight (wi)
A1 Innovation	0.5	0.4	0.2	0.5	0.1833
A2 Efficiency	0.6	0.5	0.3	0.6	0.25
A3 Reliability	0.8	0.7	0.5	0.8	0.3833
A4 Revolutionary	0.5	0.4	0.2	0.5	0.1833

Modified weight matrix for calculation: optimised design of the bone marrow aspiration needle Technicality; consistency CI = 0.

Table 4
Analysis table using characteristic sublayers.

	B1 User-friendly	B2 Human-centered	B3 Material Comfort	B4 Sustainability	Weight (wi)
B1 User-friendly	0.5	0.7	0.2	0.9	0.3
B2 Human-centered	0.3	0.5	0.2	0.4	0.15
B3 Material Comfort	0.8	0.8	0.5	0.8	0.4
B4 Sustainability	0.1	0.6	0.2	0.5	0.15

Weight matrix for calculation after correction: optimised design of bone marrow aspiration needle characteristics; consistency CI = 0.075.

Table 5
Analysis table of stability sublayers.

	C1 Environmental-friendliness	C2 Compatibility	C3 Precision in operation	C4 Quality and Safety	Weight (wi)
C1 Environmental-friendliness	0.5	0.4	0.2	0.3	0.15
C2 Compatibility	0.6	0.5	0.2	0.3	0.1833
C3 Precision in operation	0.8	0.8	0.5	0.5	0.35
C4 Quality and Safety	0.7	0.7	0.5	0.5	0.3167

Modified weight matrix for calculation: optimised design of bone marrow aspiration needle Stability; consistency CI = 0.025.

Table 6
Application characteristics sublayer analysis table.

	D1 Multi-functionality	D2 Biopsy	D3 Treatment	D4 Diagnosis	Weight (wi)
D1 Multi-functionality	0.5	0.4	0.4	0.4	0.2
D2 Biopsy	0.6	0.5	0.6	0.5	0.2833
D3 Treatment	0.6	0.4	0.5	0.5	0.25
D4 Diagnosis	0.6	0.5	0.5	0.5	0.2667

Weight matrix for calculation after correction: optimal design of bone marrow aspiration needle application characteristics; consistency CI = 0.0188.

4. Discussion

The extraction of factor weights from bone marrow aspiration needle products has been introduced as a novel approach in previous studies. Previous studies have analysed products using preschool AHP [36–38]; however, the specific factor weights were not modified during the research process, which has certain limitations. Compared with previous studies, this study offers a versatile solution to the problem of details in medical product design based on concreteness. The results of the FAHP in this study provided a clear determination of the comprehensive weight and ranking of the bone marrow aspiration needle design factors. The calculation results of the criterion layer indicated that C: stability > B: use characteristics > A: technicality > D: application characteristics. The stability and use characteristics of the product ranked among the top two factors.

As the properties of the criterion layer expanded, we observed a slight change in the ordering of the sub-criterion layer properties, indicating that with the introduction of more factors or dimensions, the original sub-criterion may undergo fine-tuning in terms of

Table 7
Intermediate layer weight table.

Sublayers	Global weights	Sibling weights	Criterion layer
A1 Innovation	0.0397	0.1833	A Technicality
A2 Efficiency	0.0542	0.25	
A3 Reliability	0.0831	0.3833	
A4 Revolutionary	0.0397	0.1833	
B1 User-friendly	0.08	0.3	B Usage Characteristics
B2 Human-centered	0.04	0.15	
B3 Material Comfort	0.1067	0.4	
B4 Sustainability	0.04	0.15	
C1 Environmental-friendliness	0.05	0.15	C Stability
C2 Compatibility	0.0611	0.1833	
C3 Precision in operation	0.1167	0.35	
C4 Quality and Safety	0.1056	0.3167	
D1 Multi-functionality	0.0367	0.2	D Application Characteristics
D2 Biopsy	0.0519	0.2833	
D3 Treatment	0.0458	0.25	
D4 Diagnosis	0.0489	0.2667	

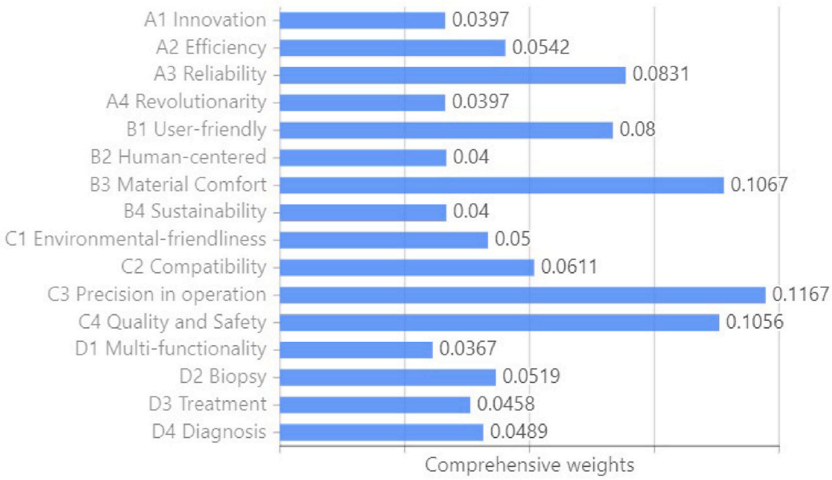

Fig. 3. Factor weight histogram.

importance. Fig. 3 illustrates that B3 Material Comfort, C3 Precision during operation, and C4 Quality and Safety of the bone marrow aspiration needles are relatively important factors. Therefore, when designing medical products, the choice of material plays a crucial role. In response to these problems, we proposed specific design strategies.

4.1. Material comfort

Improving the patient experience during surgery can enhance patient satisfaction [39,40]. The use of comfortable materials can enhance patient experience. These studies offer valuable insights and strategies to enhance the surgical experience of patients. By conducting these studies, medical teams can gain a better understanding of patient needs and improve surgical supplies, ultimately leading to improved patient satisfaction and surgical outcomes.

The main materials used in bone marrow aspiration needles include stainless steel, cobalt-chromium alloy, silica gel, polyethylene, polypropylene, and other metallic materials. In this section, we discuss the selection criteria for these materials in physiotherapy devices and analyse their advantages and disadvantages, with a specific focus on the study objectives and patient safety and experience. To enhance the patient's experience, we chose a soft silicone material that was compatible with the patient's skin. Silicone elastomers, which are highly flexible and malleable materials commonly used in the production of medical devices, offer several advantages such as high-temperature resistance, corrosion resistance, hypoallergenic properties, and good biocompatibility. They are particularly suitable for medical devices that require flexibility and plasticity and their use can improve patient comfort and reduce the risk of trauma. As illustrated in Fig. 4, A represents the syringe insertion part, B denotes the threaded part, and C signifies the spiral knob part, all of which are constructed from blue PVC. Additionally, D is composed of silicone, while the needle is crafted from stainless steel.

4.2. Precision in operation

Precision in the operation of the procedure ranked second in factor analysis, making it a crucial factor to consider during the design process. During research and finishing of traditional needles, we observed that controlling the strength during surgery is essential. Being too light may result in improper puncture, whereas being too heavy may lead to bone breakage or surgical failure. To address this issue, we introduced a controllable spiral device at the CD position, as shown in Fig. 4. This device allows thread rotation to control the

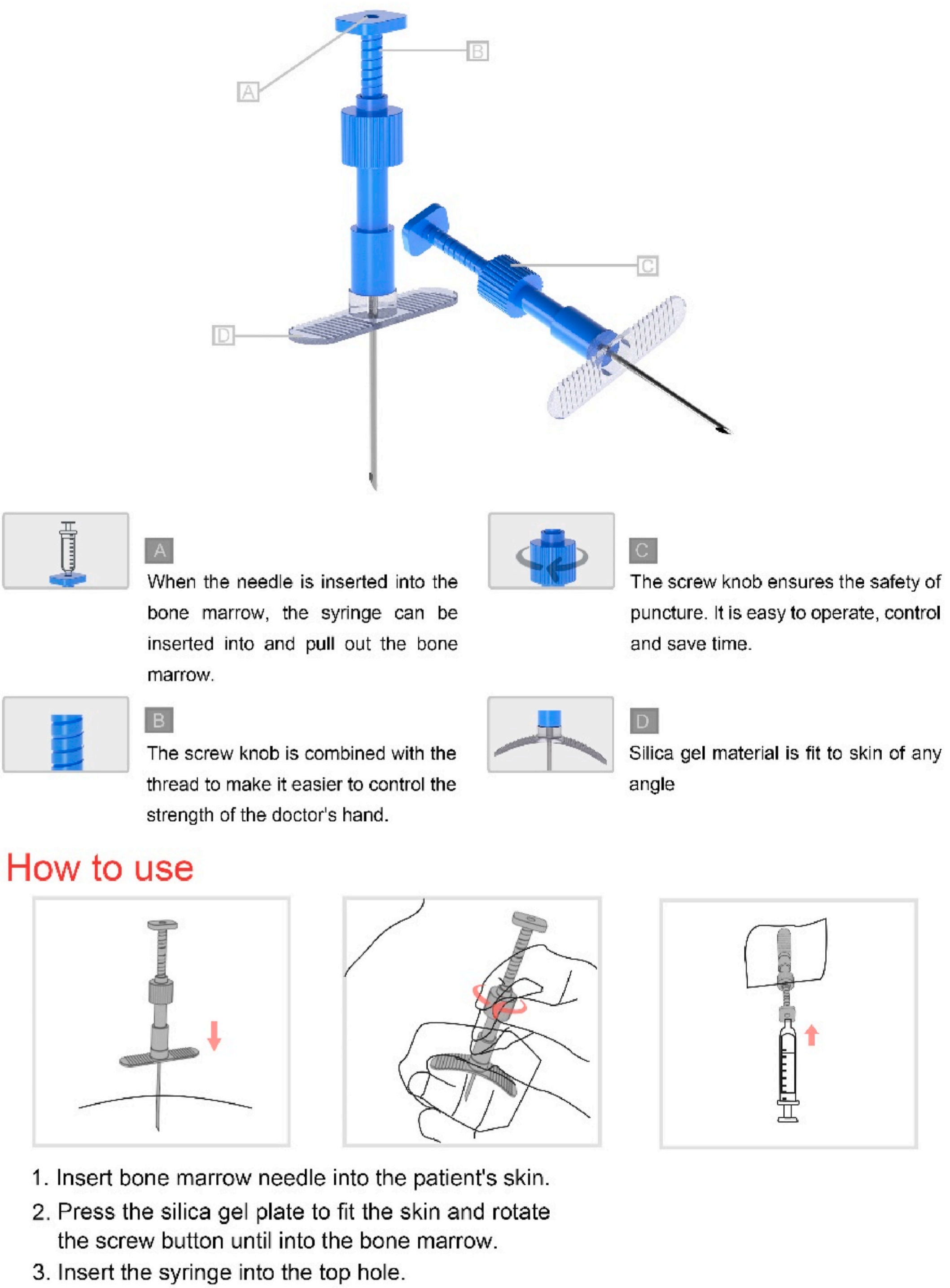

Fig. 4. Bone marrow aspiration needle.

needle, enabling adjustments that improve the success rate of bone marrow aspiration surgery.

These improvements can enhance surgical accuracy, minimise the risk of surgical failure, and provide patients with safer and more effective treatments. By precisely controlling the depths of needle entry and exit, the medical staff can improve the surgical process, minimise patient damage, and enhance the success rate and treatment effectiveness of the operation. Therefore, these improvements have practical significance in bone marrow aspiration surgery and positively contribute to patient health and recovery.

4.3. Quality and Safety

Needle quality and safety are crucial considerations for the design and use of medical devices. Needles are widely used in various surgical and diagnostic procedures in medical practice and their quality and safety directly affect patient health and treatment outcomes. Safety is a key aspect to consider in needle design because medical devices should prioritise maximising patient safety during use. To ensure safety, the needle should possess an anti-slip design. The handle of the puncture needle should be designed with a non-slip feature to enable the medical staff to securely hold and operate the needle during surgery. In Fig. 4C and D, stripes can be added to increase the friction.

It is essential to ensure that the needle has sufficient strength and durability. One way to achieve this is to thicken the stainless steel of the needle, which prevents breakage or damage during medical procedures. Therefore, it is crucial to consider the quality and safety of needles when designing medical devices. By optimising the design and manufacturing processes and adhering to strict quality control standards, we can ensure that the needle is highly effective in medical practice and guarantees the safety and health of patients. Additionally, continuous monitoring and improvements are necessary to enhance the quality and safety of needles, ultimately contributing to the overall improvement of medical services.

5. Conclusion

By applying the FAHP method, we identified the key factors of bone marrow aspiration needle design and determined the importance weights and priorities of factors such as material selection, needle size, handle design, and slip resistance. We not only successfully designed an improved bone marrow puncture needle product but also explored innovative research paths in the field of medical device design. This study provides unique innovative methods for the design and optimisation of future medical devices. The new design considers the weight and priority of these key factors and addresses the limitations of the traditional needles. Through the optimisation of needle size and material selection, the newly designed bone marrow aspiration needle offers improved ease of operation and a higher success rate for sample acquisition. Fig. 5 shows a cross-sectional view of the bone marrow aspiration surgery.

In addition, the improved handle design and anti-slip performance enhance the operating experience of doctors and reduce patient's pain during procedures. This leads to more precise and safe procedures, while increasing patient satisfaction. Through prototyping and experimental validation, we confirmed significant improvements in the operational performance and patient experience with FAHP-based designs. Compared with traditional bone marrow aspiration needles, the new bone marrow aspiration needles demonstrated better clinical effectiveness.

In this study, a novel bone marrow aspiration needle product was designed using the FAHP method, considering the weight and priority of the key factors. The design successfully improved the operational performance and patient experience. This design can be widely implemented in clinical practice to enhance the success rate and treatment effects of bone marrow aspiration. Further research is needed to validate the effectiveness of the design in different clinical settings and to refine and optimise the product according to the ongoing needs and challenges in medical practice. Although this study provided valuable insights for researchers and designers

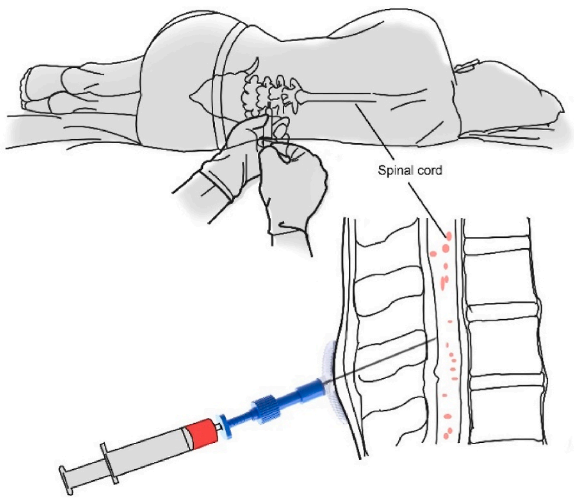

Fig. 5. Cross-sectional view of the bone marrow aspiration surgery.

regarding the bone marrow aspiration needle design, it had some limitations. The study focused on analysing specific bone marrow aspiration needle products; however, different brands and models may vary in appearance and design. Therefore, the experimental results may not be universally applicable to all types of needle products and should be used as a reference in the research process.

Future studies should explore a wider range of medical products and include different user groups to further refine the product design and factor selection, thereby enhancing their applicability and practicality. Although this study focused on bone marrow aspiration needles, the research methods and findings can be referenced in the design and practice of other medical devices. We believe that this study provides significant contributions to the field of bone marrow aspiration needle design and will positively impact future research and practice.

Data availability statement

The data that support the findings of this study are available from the corresponding author, [HBP], upon reasonable request.

Ethics declarations

The study protocol was approved by the research ethics board at Sanming Integrated Medicine Hospital (approval No. 2023-KY-006), and written informed consent was obtained from all patients before the study commenced. The study was conducted in accordance with the revised principles of the Helsinki Declaration. All methods in this study were performed in compliance with relevant guidelines and regulations.

CRediT authorship contribution statement

Lin Wang: Writing – review & editing, Writing – original draft, Visualization, Software, Methodology, Formal analysis, Data curation, Conceptualization. **Jianying Xiong:** Supervision, Project administration. **Chenglu Ruan:** Writing – review & editing, Project administration, Funding acquisition.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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