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Research article

B-FMEA-TRIZ model for scheme decision in conceptual product design: A study on upper-limb hemiplegia rehabilitation exoskeleton

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ABSTRACT

Upper-limb rehabilitation devices are essential in restoring and improving the motor function of hemiplegic patients. However, developing a product design that meets the needs of users is challenging. Current design tools and methods suffer from limitations such as a single model, poor synergy between integrated models, and subjective bias in analysing user needs and translating them into product attributes. To address these issues, this study proposes a new structural design decision-making model based on Behaviour Analysis (B), Failure Mode Effect Analysis (FMEA), and Teoriya Resheniya Izobreatatelskikh Zadatch (TRIZ theory). The model was developed and applied to design an upper-limb rehabilitation exoskeleton for hemiplegia. In this paper, an empirical investigation was conducted in several rehabilitation hospitals in Xuzhou City and used user journey mapping to identify potential failure points in the behaviour process. Then, the fault models were ranked according to the Fuzzy Risk Priority Number (FRPN) calculated by FMEA and used TRIZ theory to determine principles for resolving contradictions and generating creative design solutions for the product. By integrating B, FMEA, and TRIZ theory, it eliminated subjective bias in product design, improved the design decision-making process, and provided new methods and ideas for designing assistive rehabilitation devices and similar products. The framework of the proposed approach can be used in other contexts to develop effective and precise product designs that meet the needs of users.

1. Introduction

The increasing prevalence of stroke disability and the ageing of society has led to a significant rise in the number of hemiplegic rehabilitation patients [1]. In response, the development of rehabilitation medical products has received increasing attention from all walks of life. However, compared with the rapid development of the medical industry, the development and design of rehabilitation products are relatively lagging [2]. The upper limbs of the human body are engaged in various complex and fine activities, and their motor function directly affects daily human life. However, the functional and formal design of rehabilitation products for patients with

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upper limb hemiplegia still requires optimisation because of the relatively low degree of physical disability and the lack of attention such patients receive. Patients with upper limb hemiplegia require more effective, reliable, and fault-free rehabilitation products to meet their differentiated rehabilitation needs. Therefore, developing appropriate rehabilitation products has become a critical factor [3–5].Rigorous scientific design and development methods are essential to ensure the design and development of more suitable, reliable, and effective rehabilitation medical products. Various tools and methods have been applied in the product design process, such as Behaviour Analysis, the KANO model, Technique for Order Preference by Similarity to an Ideal Solution (TOPSIS), Analytic Hierarchy Process (AHP), Failure Mode Effect Analysis (FMEA), Quality Function Deployment (QFD), and Teoriya Resheniya Izobreatatelskikh Zadatch (TRIZ theory). Among these, the B, FMEA, and TRIZ theory are crucial for improving product quality, reducing failure risk, and meeting user need. Scholars have integrated various methods to improve them and make the research process more comprehensive [6]. For example, Dezan et al. [7] used Bayesian networks and FMEA as decision logic to improve the safety of autonomous vehicles. Melgoza et al. [8] proposed a tool that integrates attribute lists, QFD, and TRIZ theory to realise the customised design of biomedical devices. Previous multidisciplinary research on the fusion of methods and product innovation design lacks a paradigm model that integrates user needs analysis, product design decisions, and creative solution generation. User needs analysis and product attribute transformation determination are often characterised by a lack of objectivity and a quantitative basis [9]. However, previous multidisciplinary research on the fusion of methods and product innovation design lacks a paradigm model that integrates user needs analysis, product design decisions, and creative solution generation.

Therefore, this study proposes an integrated approach for analysis, decision-making, and problem-solving in product design and development to address this gap. It demonstrates the effectiveness of this approach through a case study of an upper-limb rehabilitation exoskeleton for hemiplegia. The structure of this paper is as follows. Section 2 provides a more detailed literature review to justify the necessity of the integrated approach, introducing the background of the three key technologies (B, FMEA, and TRIZ theory) using an integrated approach. Section 3 presents the methodology and flowchart of the proposed integrated model. Section 4 describes a case study of an upper limb rehabilitation exoskeleton for hemiplegia. Finally, Section 5 concludes the paper.

2. Literature review

2.1. User behaviour analysis

The American psychologist Hunter Walter introduced the concept of user behaviour, and incorporated the ’what’ and ’how’ of psychology into the objective study of user behaviour. User behaviour is a series of phased user activities connected over time in a particular environment. Through decomposition, observation, interviews, and other methods of user behaviour, the objective user needs can be derived from the different stages of activities.

A bidirectional causal relationship exists between user behaviour and needs, where user behaviour is attributed to user needs, representing the most objective manifestation of user behaviour [10]. Therefore, exploring user behaviour can reveal the needs of users. To understand user behaviour, it is crucial to analyse the user behaviour, and the type of need that leads to the occurrence of user behaviour. User journey mapping is a beneficial tool to visually present the process of user behaviour and achieve a particular need. Creating user journey maps is beneficial for exploring specific user information, objectively and effectively breaking down user behaviour, analysing potential failure points at each stage, using them as a starting point for product design, and allowing for the exploration of specific user information more objectively.

2.2. Failure mode and effect analysis (FMEA)

Risk analysis is crucial in the product design process. FMEA is a systematic procedure that can be used to identify potential failure modes, and failure causes, and their impacts on the performance of components, systems and processes [11–13]. FMEA is able to analyse and improve failure modes at various system levels, including components, parts, and subsystems, and can be used to enhance the reliability of products, processes, and systems.

Currently, the FMEA is widely used in various research fields. Zandi et al. [14] applied FMEA to risk management in the agricultural sector. They combined the use of TOPSIS and AHP and added severity, time, cost, and quality ranking to analyse the risk of investment projects while considering these factors. Rastayesh et al. [15] used FMEA as the basis for analysing failures in hybrid energy systems. In addition, some scholars [16–18] have combined fuzzy methods with FMEA to transform qualitative information into quantitative parameters, effectively eliminating the uncertainty and fuzziness of subjective experience in conventional FMEA risk analysis.

2.3. Theory of Finding and solving problems

TRIZ theory was initially proposed as a method for engineering innovation problems by Soviet scientist Genrich Altshuller, who analysed millions of high-quality inventions and design patents from various countries. TRIZ theory includes tools for analysing and defining problems, analysing and defining contradictions, defining specific engineering problems, and defining and using inventive principles. TRIZ theory [19] analyses the technical challenges and solutions encountered during product invention, analyses the inherent principles and principles, and aims to serve as a guiding tool for people involved in product development, design, and other related activities.

Applying TRIZ theory to analyse the critical problem conflict types in design objectives and using standard engineering parameters and inventive principles to resolve the corresponding conflicts can yield specific design implementation plans. This method compensates for the shortcomings of a single innovation design theory and quickly identifies design directions and feasible solutions. In previous research, there has been a significant amount of effective integration of TRIZ theory with other design methods [20,21]. When developing products with original innovation and life cycle optimisation, a complex set of objective functions should be planned for simultaneously. Ahmed et al. [22] proposed a design process model for safety-critical systems, which consists of three methods: Axiomatic Design (AD), TRIZ theory, and Fault Tree Analysis (FTA). AD was used to identify functional coupling, TRIZ theory was used to decouple using technical and physical contradictions and inventive principles, and FTA was used for the reliability analysis of solutions.

In summary, TRIZ theory has a solid theoretical foundation and complete analytical methods that can provide problem-solving tools for engineering problems. By analysing the principles and rules inherent in technical difficulties and their solutions found in the product invention process, TRIZ theory aims to be a guiding tool for people to use in product development, design, and related work processes.

3. Methodology

This study integrates user journey map, fuzzy FMEA, and TRIZ theory to propose a B-FMEA-TRIZ design decision-making model based on the complementary advantages of user behaviour analysis, failure mode and effects analysis, and theory of inventive problem-solving. This model analyses the user behaviour at each stage of the product usage process, identifies potential failure points, conducts fuzzy FMEA for fault diagnosis, ranks the failure modes, and utilises TRIZ theory to inspire solutions to conflicts.

This study proposes a novel method for product design decision-making by integrating the B-FMEA-TRIZ model from the perspectives of user behaviour analysis, risk assessment, and problem-solving. The novelty of this model lies in the following aspects. The model's name derives from the initial letters of each stage, as shown in Fig. 1. The model comprises the following three stages.

Stage 1 User Behaviour Analysis. This stage aims to analyse the potential faults in the current behaviour process. The journey map describes the user's behaviour process to identify potential faults through on-site observation and personnel interviews. First, cluster analysis was conducted on the potential target population characteristics of the product, not limited to individuals, but considering their social background, physical condition, and other factors to construct a comprehensive role prototype. Then, real-life snapshots were taken when the typical roles interacted with the product in an autonomous situation, covering the entire process from start to finish, focusing on the process mode and behaviour changes. Finally, by combining the initial expectations and interview results, the users' behaviour and needs at different stages were analysed and integrated into a visually intuitive representation, which the participants confirmed to identify potential faults.

Stage 2 Fault Diagnosis. Fuzzy FMEA analysis is utilised to diagnose potential faults, which are both quantitative and structured. Interviews are conducted to identify potential faults, causes, and impacts. An evaluation questionnaire based on potential failures was then compiled to collect opinions from selected participants. Finally, the fault model is ranked based on the FRPN values [23]. This stage aims to predict and detect errors in the behavioural process and prevent failures from occurring by identifying critical fault models and providing design decisions and risk assessments for potential failures. Stage 3: Conceptualization of Innovative Solutions. TRIZ theory is utilised to generate corresponding innovative solutions. The most critical failure modes concerning the basic design requirements were identified. Then, based on the characteristics of the failure, the corresponding TRIZ parameter table and 40 inventive principles are adopted, mapping the causes of failure to TRIZ theory and improving parameters and worsening parameters through systematic steps. Finally, the TRIZ Contradiction Matrix was utilised to generate TRIZ inventive principles corresponding to the design case.

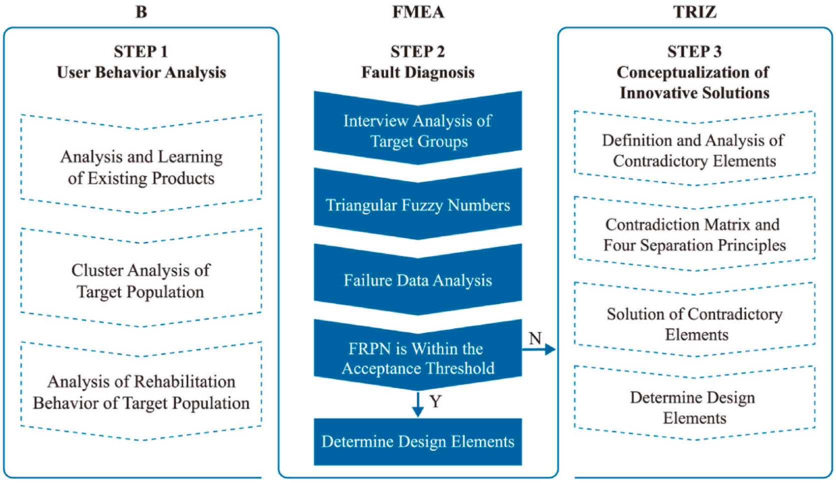

Fig. 1. Integrated design decision model.

This study proposes a novel model B-FMEA-TRIZ for product design decision-making from user behaviour analysis, risk assessment, and problem-solving perspectives. The novelty of this study can be summed up as follows.

(1) Clarify potential failures at each stage through the user behaviour journey map and analyse the causes and impacts of each failure model.
(2) Evaluate product failures through FMEA, thereby enhancing the accuracy of the design.
(3) Use TRIZ theory and analysis methods to generate appropriate innovative principles for the product design process, guide problem-solving, and reduce design subjectivity.

4. Case study

This study proposes the B-FMEA-TRIZ design decision model, which integrates behavioral analysis, fuzzy FMEA, and TRIZ theories to provide structured guidance for conceptual design. Next, it is used to guide the conceptual design of an exoskeleton for upper limb hemiplegia rehabilitation, which involves three phases: (1) user behavior analysis; (2) fault diagnosis; and (3) conceptualization of innovative solutions.

4.1. User behaviour analysis

The main task of this stage is to identify potential failures during the user journey. Firstly, the specific methods and processes of upper limb rehabilitation training for hemiplegic patients were studied by consulting relevant books and videos [24–26]. Then, the following research subjects were selected from three rehabilitation hospitals in Xuzhou: (1) Patients with unilateral upper extremity hemiplegia who have two or more years of experience using rehabilitation equipment and (2) physicians and nursing staff with more than five years of experience. Finally, a case analysis of users was conducted through observations, interviews and user journey mapping. Twenty middle-aged (45–59 years old) patients with similar conditions, in stable recovery, with muscle strength of grade 3 or below, clear consciousness, and no cognitive dysfunction, who were in the middle age (45–59 years old), were selected as the target subjects for behavioural observation and interviews from the patients with unilateral upper limb hemiplegia who were undergoing rehabilitation in three hospitals in Xuzhou, to collect the sample data.

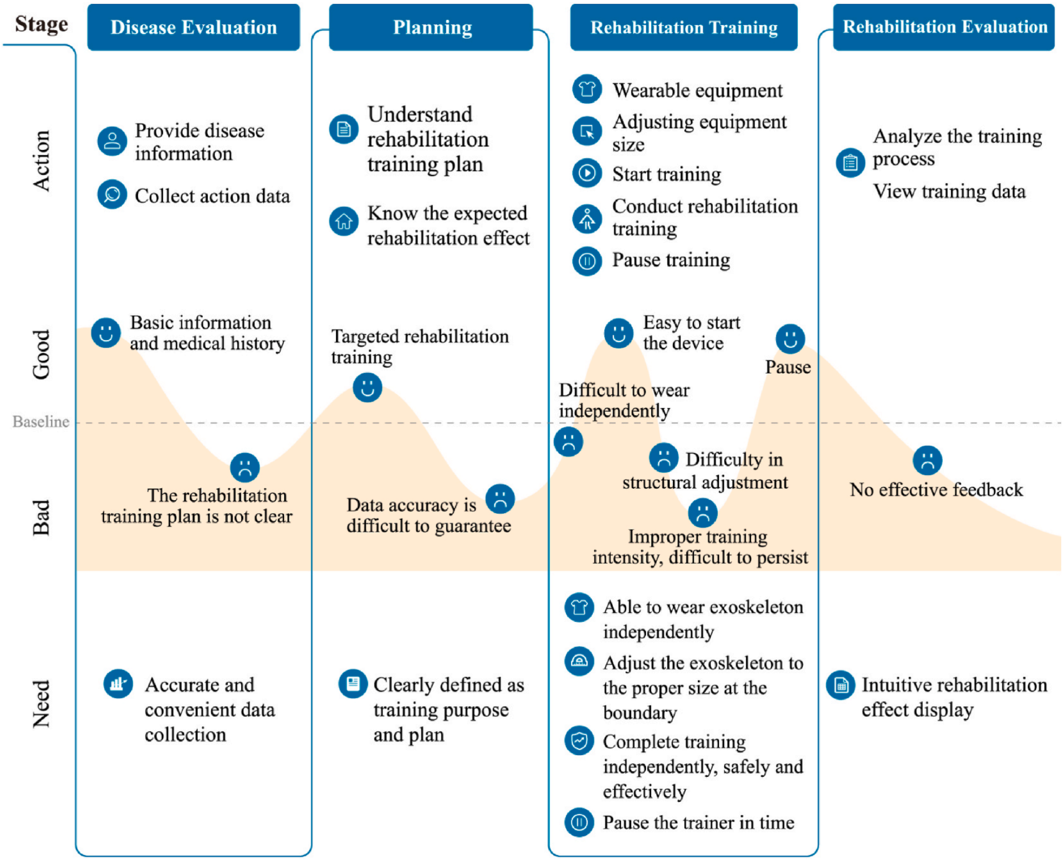

Fig. 2. User behaviour journey.

Table 1
Fault points in the user behaviour stage.

Stage	Disease Evaluation	Planning	Rehabilitation Training	Rehabilitation Evaluation
Failure Point	(F1)Acquisition of patient's condition information;	(F2) Know the expected recovery effect;	(F3) Understand the rehabilitation training plan; (F4) Wear and adjust the exoskeleton; (F5) Adjust the training intensity; (F6) Monitoring vital signs and abnormal movements; (F7) Pause the trainer;	(F8) Analyse the training effect

During the user behaviour observation process, the observer avoided interference with user behaviour and promptly recorded the user behaviour activities of the upper limb hemiplegia rehabilitation exoskeleton users. At the same time, combined with semi-structured interviews, some necessary behaviours and contradictory behaviours were interviewed to deepen the understanding of the motives behind user behaviours and related needs such as user preferences. The common user behaviours of each patient were comprehensively organized, and the necessary behaviours that appeared in all users were defined and depicted on the final user journey map. A universal user journey map for the upper-limb hemiplegia rehabilitation exoskeleton was created, as shown in Fig. 2.

After user observation, conducting interviews, and behaviour assessment, user needs and pain points were identified, as well as eight main failure points during product usage were recognised, as shown in Table 1. In the next stage, these failures are further diagnosed.

4.2. Fault diagnosis

Twenty hemiplegic patients were interviewed to identify and analyse eight potential business failure points for failure conditions, causes, and impacts, as shown in Table 2.

Based on the causes and effects of the provided failure models, an expert questionnaire was developed by extrapolating each question involving the failure modes one by one in accordance with the principles and methods of scaling, and the subject matter instructor was asked to critically review the questionnaire to ensure that it had a high degree of logical validity. Each failure case was analysed, and measured using the Likert scale, with required occurrence probability, severity, and detection level metrics.

After the data collection was completed, the questionnaire data were imported into SPSS statistical software. On the one hand, the results of reliability analysis showed that the Cronbach's α coefficient of the questionnaire was 0.834, which indicated that the questionnaire had a high quality of reliability; on the other hand, the results of the KMO and Bartlett's spherical test showed that the value of the KMO was 0.874, $P < 0.001$, which indicated that it was suitable for factor analysis. Further correlation test between each dimension of the questionnaire and the total score showed that the correlation coefficients between each dimension of the questionnaire and the total score ranged from 0.625 to 0.841, which was a significant positive correlation, indicating that the content

Table 2
Failure mode and effect analysis of upper limb rehabilitation exoskeleton.

Item	Potential Failure Points	Failure Conditions	Causes of Failure	Effects of Failure
F1	Acquisition of patient's condition information	The patient's basic information, medical history, previous treatment and current status of motor function are not clear;	The information acquisition method is lagging and inaccurate	The training does not match the patient's actual symptoms, and the rehabilitation effect is poor
F2	Know the expected rehabilitation effect	The expected rehabilitation effect is not clear	Inadequate motivation	Without goals, patients tend to give up rehabilitation training
F3	Understand the rehabilitation training plan	The rehabilitation training plan is not clear	Inadequate information transmission	It is difficult to control the training progress, and the training is chaotic
F4	Wear and adjust the exoskeleton	Unable to wear exoskeleton equipment independently; Improper size of exoskeleton	The exoskeleton structure is too cumbersome and cumbersome; Unreasonable size adjustment structure	Waste other human resources; The exoskeleton does not fit the patient's joints, which is not conducive to rehabilitation training
F5	Adjust training intensity	Unable to adjust training intensity in different areas	The strength of the rehabilitation exoskeleton is not flexible; Different parts of patients have different degrees of rehabilitation	Inefficient rehabilitation
F6	Monitoring vital signs and abnormal movements	Unable to find abnormal vital signs and correct abnormal movements in time	Equipment information monitoring and adjustment are not timely;	Training risk increases; Abnormal exercise may be harmful to the rehabilitation of patients
F7	Pause trainer	The pause control key cannot provide a fast response	The form of pause control key is unreasonable	May cause secondary injury to patients
F8	Analyse training effect	Lack of summary and analysis of training effect	Incomplete rehabilitation process	The content and intensity of rehabilitation training are not flexible

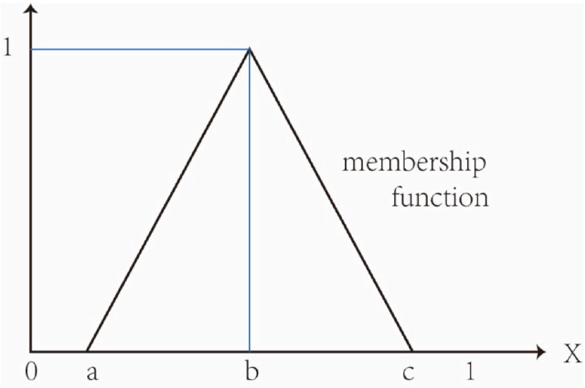

Fig. 3. Triangular membership function.

measured by each dimension was consistent with the overall direction of the questionnaire; the correlation coefficients between each dimension of the questionnaire ranged from 0.362 to 0.639, which was lower than the correlation between the dimensions and the total score, indicating that the direction measured by each dimension was consistent, yet relatively independent, with good validity. Therefore, the reliability and validity of the questionnaire meet the requirements of data analysis.

The FMEA calculation was conducted as follows.

Step 1: To identify the weights of risk factors OSD (O for occurrence probability, S for severity level, D for detection level) in FMEA, divide the risk factor weights into five different levels: EI (extremely important), VI (very important), I (important), LI (less important), and NI (not important).

Step 2: Using triangular fuzzy numbers, all membership functions of linguistic input data were standardised within the range of {0,1} [27], and the triangular membership function is shown in Fig. 3.

The membership function is shown in formula (1), as reported by Refs. [28,29].

$$EI(X)=\begin{cases}4x-3, & 0.75<x<1\\ 1, & x=1\\ 0, & others\end{cases}$$
$$VI(X)=\begin{cases}4x-2, & 0.5<x<0.75\\ 1, & x=0.75\\ -4x+4, & 0.75<x<1\\ 0, & others\end{cases}$$
$$I(X)=\begin{cases}4x-1, & 0.25<x<0.5\\ 1, & x=0.5\\ -4x+3, & 0.5<x<0.75\\ 0, & others\end{cases} \tag{1}$$
$$LI(X)=\begin{cases}4x, & 0<x<0.25\\ 1, & x=0.25\\ -4x+2, & 0.25<x<0.5\\ 0, & others\end{cases}$$
$$NI(X)=\begin{cases}1, & x=0\\ -4x+1, & 0<x<0.25\\ 0, & others\end{cases}$$

Step 3Evaluate the risk associated with these failure modes and prioritise failures by calculating the fuzzy Risk Priority Number (FRPN). A questionnaire was developed to assess failures in upper limb rehabilitation devices and to collect opinions from medical staff in rehabilitation hospitals. Step 4: $S_{itj} = (q_{itj}, o_{itj})$ represents a triangular fuzzy number that evaluates the importance of the occurrence, severity, and detection related to the t-th research object's needs and the i-th type of failure mode in FMEA. Therefore,

S_i is defined as the fuzzy mean of each type of failure mode for the t-th research object, where n is the number of participating research objects.

$$S_i = \sum\nolimits_{t=1}^{n} S_{it} / n \tag{2}$$

The $S_{it} = \left(q_{itj}, \quad o_{itj}, \quad p_{itj} \right)$ is calculated by the following equations:

$$Q_{it} = \sum\nolimits_{j=1}^{n} q_{itj} / n \tag{3}$$

$$O_{it} = \sum\nolimits_{j=1}^{n} o_{itj} / n \tag{4}$$

$$P_{it} = \sum\nolimits_{j=1}^{n} p_{itj} / n \tag{5}$$

Assuming no weight difference between the failure model categories of OSD, the comprehensive fuzzy number of the kth occurrence, severity, and detection classification is determined by the number of participants involved in the survey.

$$Q_{it} = \sum\nolimits_{j=1}^{k} q_{it} / k \tag{6}$$

$$O_{it} = \sum\nolimits_{j=1}^{k} o_{it} / k \tag{7}$$

$$P_{it} = \sum\nolimits_{j=1}^{k} p_{it} / k \tag{8}$$

Step 5 Defuzzification of Output Data. When output results are more easily interpretable, it is recommended to use crisp data to represent them. Let X represent the defuzzified values of composite fuzzy number for each class of occurrence, severity, and detection (Q_i, O_i, *and* P_i). The defuzzified values were calculated using the following formula.

$$X = (Q_i + O_i + O_i + P_i) / 4 \tag{9}$$

Step 6 Calculate the severity, occurrence, and detection levels of each business failure mode in FMEA using the cumulative scores of the respondents. Simultaneously, calculate the Fuzzy Risk Priority Number (FRPN) of each business failure mode, as shown in Equation (10):

$$FRPN = S \times O \times D, \tag{10}$$

Step 7 Sort the importance of each category of occurrence, severity, and detection in FMEA based on the data calculated in Step 6. The integrated triangular fuzzy numbers of the OSD are calculated using equations (2)–(5), and then Q_i, O_i, and P_i are calculated using equations (6)–(8). The fuzzy values of the integrated triangular fuzzy numbers of the OSD are obtained using Equation (9), and the FRPN value of each failure point is calculated using Equation (10). The importance of each failure point was then ranked, as shown in Table 3.

Table 3
Prioritisation of failure modes and effects of an upper limb rehabilitation exoskeleton.

Item	Fuzzy value of Occurrence Probability	De-fuzzy Value of Severity	Detective Deblurring Fuzzy Value	Fuzzy Risk Priority Index (FRPN)	Importance Ranking
F1	0.5271	0.4956	0.5044	0.1318	7
F2	0.5827	0.5591	0.5636	0.1836	5
F3	0.5631	0.5756	0.5111	0.1657	6
F4	0.7311	0.6964	0.6320	0.3218	1
F5	0.6427	0.6729	0.6191	0.2677	2
F6	0.5484	0.7582	0.5578	0.2319	3
F7	0.5249	0.7476	0.4769	0.1871	4
F8	0.4716	0.4556	0.4898	0.1052	8

Finally, the higher the FRPN value, the higher the requirement for taking improvement measures. Therefore, key fault situations F4, F5, and F6 with FRPN values greater than 0.2 were selected for improvement.

4.2.1. Conflict analysis of exoskeletons

According to Table 3, the highest priority item for critical failure conditions is F4: Wearing and adjusting the exoskeleton. One cause of failure The exoskeleton structure is too bulky and cumbersome, requiring the exoskeleton to be lightweight, but this will reduce its stability. Another cause of failure is, the size adjustment structure is unreasonable and requires improving the exoskeleton's adaptability, which may increase the device's complexity. These two conflicts can be defined as the parameters to be improved, namely, parameter 1 (object mass) and parameter 35 (adaptability and versatility), and the parameters that will deteriorate, namely, parameter 13 (structural stability) and parameter 36 (device complexity).

The second priority item is F5: Adjusting training intensity. One failure cause is that The rehabilitation exoskeleton's strength adjustment is not flexible, which requires the exoskeleton to be more flexible and maneuverable. However, this will increase the difficulty of monitoring. Another cause of failure is that Different parts of the patient's body have different rehabilitation levels, which requires improving the device's ability to respond to external changes, which will increase the device's complexity. These two conflicts can be defined as the parameters to be improved: parameter 38 (degree of automation) and parameter 35 (adaptability and versatility). The parameters that will deteriorate are parameter 37 (difficulty of monitoring and testing) and parameter 36 (device complexity).

The third priority item is F6: Monitoring vital signs and abnormal movements. One cause of failure, the weak visibility of information monitoring and prompting, requires improving the visibility of information prompts. These two conflicts can be defined as the parameter to be improved, namely, parameter 27 (reliability), and the parameter that will deteriorate, namely, parameter 37 (difficulty of monitoring and testing).

The failure points were analysed and organised and then transformed into TRIZ theory standard problem descriptions. The corresponding inventive principles for resolving the conflicting contradictions were obtained, as shown in Table 4.

4.2.2. TRIZ solution based on the Contradiction Matrix

Based on the inventive principles in Table 4 and practical requirements, this study proposes the following solutions are proposed.

(1) According to inventive principles 2, 1, and 5, the feature principle of maintaining stability in the traditional backpack form is extracted, the upper arm group is segmented, and the forearm group is merged.
(2) According to inventive principles 1, 7, and 15, the group is segmented, and the sliding parts are embedded to achieve size adjustment as needed.
(3) According to inventive principle 24, the training intensity of the robot is adjusted according to heart rate information obtained through an external control system. (4) According to inventive principle 3, connect the two motors at the upper arm in series and parallel the motors at the upper and lower arms to achieve partial control.
(5) According to inventive principles 24 and 23, angle displacement sensors, acceleration sensors, and heart rate acquisition systems are used to capture real-time motion data and present them in the form of auditory or visual prompts.

4.2.3. Exoskeleton design for upper limb hemiplegia rehabilitation

Based on the innovative design concepts mentioned above, the design solution for the upper limb hemiplegic rehabilitation exoskeleton is as follows: According to the form of upper limb hemiplegic rehabilitation training activities, a simple shoulder strap is used as a support for the movement, and flexible fixation devices replace some of the rigid fixation devices in traditional rehabilitation robotic arms. This achieves controllable stability and a lightweight design. The above fixed way ensures the fixation of the shoulder and normal movement of the arm. All drive control devices were installed at the shoulder node position, avoiding the traditional method of setting drive control devices at the shoulder and elbow joints, which can cause interference from the weight of the device on motion control. The biceps and triceps brachii are the largest muscle groups in the entire arm and play a crucial role in arm circumference and strength. The muscle groups in the upper arm are more numerous than those in the forearm [30,31].

In this case study, to facilitate single-handed wearing, the upper arm is divided into blocks for fixation, and the forearm is worn as a single unit. Also, in order to facilitate the adjustment of the exoskeleton and meet the requirements of safe and effective human-machine interaction, the width of the rear frame can be adjusted using sliding parts and coil springs, and the driving box on the front plane can be adjusted using vertical axis hinges, within the prescribed range of ergonomic dimensions.The upper arm is divided into several sections and embedded in the stretchable component, and the length of the upper arm can be adjusted using sliding buckles. Fig. 4 shows a schematic diagram of the wearing and adjustment of the exoskeleton for upper limb hemiplegia rehabilitation.

The heart rate acquisition system obtains the user's heart rate information and sends it to an external control system that adjusts the robot's training intensity based on the acquired heart rate information. Adaptive adjustment of training intensity allows patients to increase the challenge while adapting to the current training intensity. It provides appropriate assistance when the patient's body load is exceeded, encouraging them to participate in rehabilitation training and maximise neural remodelling actively. Different exercise modes and exercise groups were set for different injury sites of the upper limb. The two motors controlling the large arm were connected in series, and the motors of the large and small arms were connected in parallel to achieve partial control and exercise for different recovery stages.

Angle displacement sensors, acceleration sensors, and heart rate acquisition systems are installed at the shoulder and elbow to capture motion data in real-time, which are wirelessly transmitted back to the terminal. Due to tactile defects in hemiplegic patients, other forms of feedback can be used for interaction, such as converting tactile expression into auditory or visual expression, voice prompts, and intensity display bars to compensate for the lack of tactile senses.

Fig. 5 shows the final optimised design of the upper-limb hemiplegia rehabilitation exoskeleton.

Table 4
Solution of TRIZ theory conflicts.

Failure Points	Improve Parameters	Leading to Deterioration Parameters	Principles of Invention
F4 Wearing and adjusting exoskeleton	1 Mass of an object	13 Structural stability	NO2. Extraction NO1. Division principle NO5. Consolidation principle
	35 Adaptability and versatility	36 Device complexity	NO1. Division principle NO7. Nesting principle NO15. Dynamic principle
F5 adjust training intensity	38 degrees of automation	37 Difficulty of monitoring and testing	NO24. Intermediary principle
	35 Adaptability and versatility	36 Device complexity	NO3. Local mass principle
F6 Monitoring vital signs and Abnormal movement	27 Reliability	37 Difficulty of monitoring and testing	NO24. Intermediary principleNO23. Feedback principle

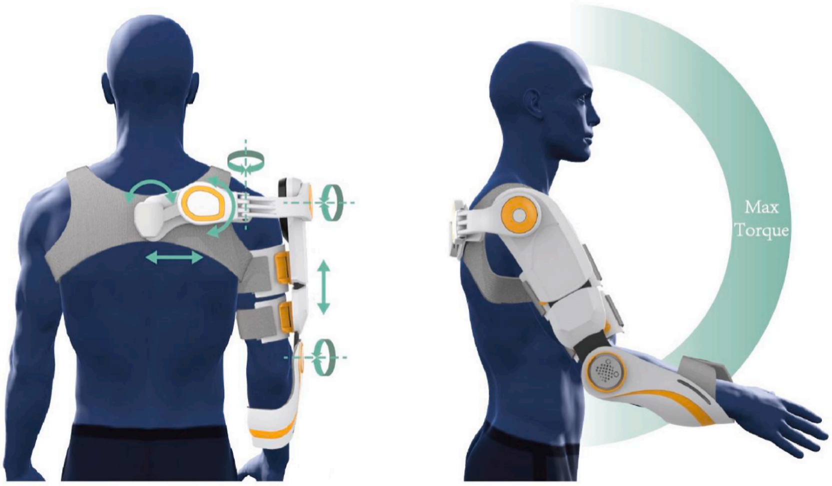

Fig. 4. Schematic diagram of wearing and adjusting exoskeletons.

5. Discussion

This study proposes an innovative B-FMEA-TRIZ product design integration method based on the scientific, generic, innovative and efficient nature of product design decisions. The method aims to help designers develop innovative products from a new perspective. The applicability and effectiveness of the proposed method are verified through a design practice study. Compared with other conventional design decision-making methods, this method demonstrates obvious advantages.

The proposed B-FMEA-TRIZ method provides a comprehensive product design decision framework by combining user behaviour analysis, risk assessment and problem-solving strategies. Unlike conventional methods that rely only on the designer's experience or a single theoretical guide, the method in this study integrates fuzzy FMEA and TRIZ theories, and is able to accurately translate user requirements into specific design improvement points. This interdisciplinary integration not only deepens the understanding of user requirements, but also improves the reliability of risk assessment, which ultimately leads to the generation of innovative solutions.

Furthermore, through in-depth analysis and clustering of product target population characteristics, this study captured and processed the fuzzy concepts in user expressions and sought commonalities in user behaviours. This approach not only narrows the differences between 'user-user' and 'user-product', but also deepens the understanding of potential failure points and provides an effective means to scientifically evaluate the user-experience journey map. It also provides an effective means of scientifically evaluating user experience journey maps.

Moreover, by integrating different design theories, this study demonstrates a new way to compensate for the shortcomings of a single theory and to generate a universal design theory. The proposed B-FMEA-TRIZ methodology, and in particular the application of TRIZ in solving design problems, provides designers with a highly efficient tool to help them quickly generate solutions when facing complex design challenges.

Finally, although the TRIZ method provides principled guidance in solving conflicting problems in design, it is still a great

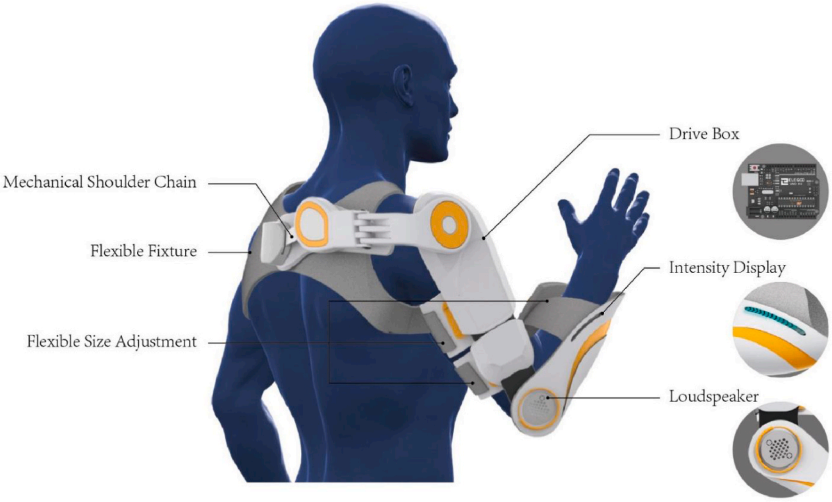

Fig. 5. The final optimised design of the exoskeleton used for upper limb hemiplegia rehabilitation.

challenge to translate these principled guidance into concrete product conceptual solutions. The B-FMEA-TRIZ approach adopted in this study provides a new perspective to overcome this challenge by emphasizing the importance of cross-domain knowledge and promoting creative thinking.

In conclusion, the B-FMEA-TRIZ product design integration approach not only embodies an innovation in product design decision-making methods, but also proves its effectiveness through empirical studies. This approach provides designers with a new tool to better understand user needs, assess design risks, and create innovative solutions that ultimately advance the field of product service design.

6. Conclusions

This study develops a comprehensive product innovation design model B-FMEA-TRIZ incorporating user behaviour analysis, FMEA, and TRIZ theory. The combination of these methods provides qualitative and quantitative insights for improving product design and manufacturing processes. By analysing user behaviour and identifying potential failure points, FMEA enables the prioritisation of failure modes and provides a quality improvement tool to prevent product design failures. TRIZ theory offers inventive principles to generate innovative solutions for conflicting issues. The feasibility of B-FMEA-TRIZ method is verified through a case study regarding the product design of upper limb rehabilitation exoskeleton for hemiplegia patients. User behaviour from four successive stages was extracted, and failure points were identified using FMEA. TRIZ theory was then applied to transform these failure points into standard problem descriptions, and corresponding solutions were proposed. Based on these analyses, this study designed an upper limb rehabilitation exoskeleton that accounted for the product's structure, function, and appearance. The B-FMEA-TRIZ model has implications for the design of medical devices and can serve as a reference for future research.

There are also some limitations to this study that need to be addressed. In particular, the clustering analysis of product target population characteristics requires further refinement, and the verification and evaluation of design cases are also necessary. The limitations of this study may be addressed in future research to improve its effectiveness.

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Ethics statement

This study was reviewed and approved by the Ethics Committee of the School of Electrical and Mechanical Engineering, Jiangsu Normal University, with the approval number: [JDLL2003001]. All participants provided informed consent to participate in the study.

Data availability statement

The original contributions presented in the study are included in the article. The authors do not have permission to deposite data into a publicly available repository and can be contacted further for inquiries.

CRediT authorship contribution statement

Duanshu Song: Conceptualization, Funding acquisition, Methodology, Project administration, Writing – original draft, Writing – review & editing. **Li Liu:** Data curation, Methodology, Software, Writing – original draft, Writing – review & editing. **Tong Zhu:** Resources, Validation, Writing – review & editing. **Shanchao Zhang:** Resources, Supervision, Writing – review & editing, Visualization. **Yuexin Huang:** Formal analysis, Methodology, Project administration, Resources.

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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Appendix A. Supplementary data

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