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Research Article

DEVELOPMENT OF MEDICAL DEVICE DESIGN METHOD CONSIDERING HUMAN-CENTERED DESIGN

K. Kikuta
D. Misaki*
Department of Mechanical Systems Engineering, Faculty of Engineering, Kogakuin University Shinjuku Campus, 1-24-2 Nishisinjuku, Shinjuku-ku, Tokyo, 1638677, Japan

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ABSTRACT:
According to the Ministry of Health, Labour and Welfare, accidents due to medical malpractice have occurred in Japan because of the mishandling of medical devices. The emphasis is placed primarily on the function and cost of medical devices at the design stage; however, their usability is not considered. Therefore, human-centered design (HCD) is important and needs to be employed. The main goal of HCD is to enhance the ease of product usage, to maximize user satisfaction and enhance device safety. The product usability mainly depends on the shape of the device, and thus, analyses should be performed based on the feature quantity of the shape. This study focuses on the method that digitizes the change in the shape, by extracting the shape information, in addition to deriving the design plan using the engineering design variable. In HCD, divergence and convergence of ideas is important. Therefore, the design plan is derived using the generative design for the divergence of the idea. Through this, several design plans were derived in this study, based on a plan that quantified the matching distance using image processing. Lastly, we derived the design plan and then analyzed the data on device shape, through digitization.

Keywords: *Human centered design, Design method, Medical device*

1. INTRODUCTION

In recent years, the number of patients in Japan have increased, [1] resulting in an increase in the number of surgical operations. However, there are several cases in which patients have been injured or killed in medical accidents during surgeries. According to a survey by the Japan Council for Quality Health Care, the number of such adverse events reported has increased between FY 2017 and FY 2018 [2], with medical errors being one of the major causes. Malpractice has accounted for 70% of such adverse events in the United States [3]. Moreover, malpractice is reported to cause nearly 100,000 fatal accidents every year [4]. Malpractice is the third leading cause of death, following heart disease and cancer, in the United States [5]. Several medical devices are designed based on engineering indices, making it difficult to consider their usability [6]. Therefore, the Food and Drug Administration (FDA) demands the evaluation of usability and human factors in development stage of medical devices [7]. Therefore, the important factors to be considered include device durability, compactness, and simplicity of use [8]. The term “usability”, as defined by the International Organization for Standardization (ISO), is the extent to which a product can be used to achieve a specific goal with effectiveness, efficiency, and satisfaction in a specific context. The term “human factors”, as defined by the American Standards Association and Medical Device Development Association, refers to the application of knowledge on human ability (physical, sensory, emotional, and intellectual) and the restrictions in the

* Corresponding author: D. Misaki
E-mail address: misaki@cc.kogakuin.ac.jp

design and development of tools. ISO 9241-210 defines human-centered design as an approach to system design and development aimed at improving the usability of interactive systems by applying knowledge and techniques related to human factors and usability. The advantages of improving the human factors and usability of medical devices includes enhancement in productivity, avoidance of stress, risk reduction, among others. The FDA states that it is an important point in human engineering (HFE) and usability engineering (UE) to understand how people and technology interact with each other and to study how a user interface affects technology [9]. In addition, what is important in order to execute HFE and UE in the development of medical device are user, environment using the device and device user interface. It has been shown that problems regarding usability can be addressed to some extent by using the device over a long period of time. However, the device efficiency is difficult to improve after the design stage [10]. In addition, it has been shown that adverse medical events can be prevented through effective design [11]. Shah et al. also showed that the involvement of healthcare professionals in the design of medical devices is a necessary step for functional improvement [12, 13].

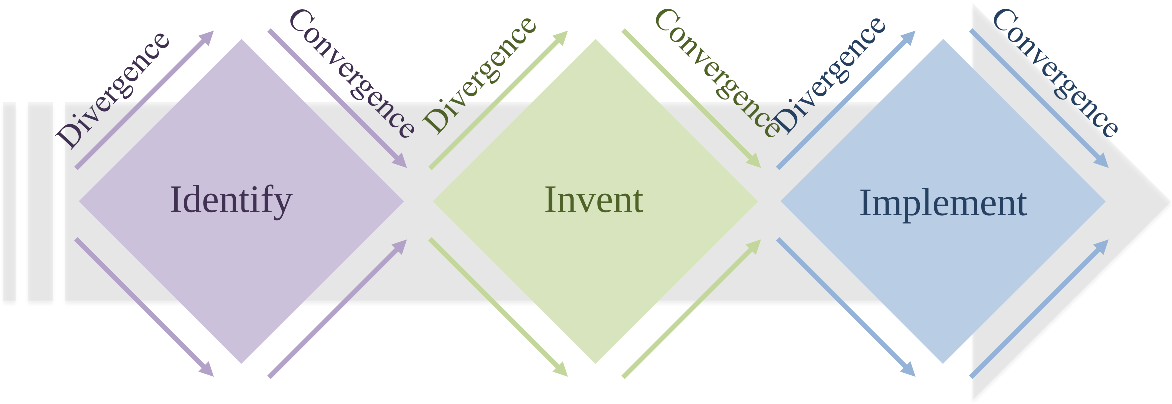


Fig. 1. Divergence and convergence in biodesign process [16]

According to Thomas et al., there is no formal framework for engineers to gain medical knowledge and understand the clinical environment for designing medical devices [14]. Moreover, it is difficult to incorporate the opinions of users and the user environment, because design teams for medical devices seldom comprise specialists in the medical field [15]. Therefore, it is necessary to incorporate the engineering and usability perspectives in the early stage of design. Yock et al. developed the biodesign process to solve these problems [16]. Figure 1 shows the biodesign process. The purpose of biodesign is to take into consideration the needs of users at the stage of designing medical device, by forming a team of specialists in various fields, such as medicine and engineering. As biodesign is based on design thinking, the divergence and convergence of ideas are important. Idea divergence is the proposal of multiple ideas. The convergence of ideas is to narrow down candidates from multiple ideas, create a prototype of the refined idea and repeat this process to derive the best idea. However, this process is likely to be expensive because it involves a team of experts from various fields. In addition, as it takes time to diverge ideas, it increase the time taken to complete the final product. Therefore, it is important to develop a method that can diverge and converge ideas within a short duration. For these reasons, although biodesign is an effective tool, it cannot easily derive multiple ideas. In this paper, we propose to use CAD and artificial intelligence (AI) to diverge ideas. However, it is difficult for AI to consider human's usability. Information on the shape of the device is acquired through image processing. Gloud has proposed the following important principles in system design to improve usability [17]: early focus on users and tasks, empirical measurement, and iterative design. The first step is to focus on the users and the tasks. The designer must understand who the user is. This understanding is based on cognition, behavior, and physical characteristics. The understanding of the user can help to partially solve the usability problems. Early in the development phase, the target users must actually use the simulation and prototype to work with the tool, observe and record the performance and response, and analyze it. Finally, if a user finds a problem, it needs to be addressed. Thus, the device needs to be redesigned by repeating these steps. The convergence of ideas is evaluated from the viewpoint of engineering index and affordability based on safety factors, weight, and image processing for the derived idea. Previous studies have shown signs of physical discomfort during and after the use of laparoscopic devices [18-21]. In particular, the handle part of the forceps has various shapes, and most of these shapes cause the user some discomfort [22]. Therefore, it is necessary to consider a new shape for the handle of forcep. Human-centered design (HCD) refers to the idea of designing a device with a focus on its usability. The main porpose of HCD is to improve the ease of use in order to maximize user satisfaction and enhance the safety of the device [23]. For this purpose, the concept of affordance is required. “Affordance” is a term coined by Gibson, and is described as the "meaning" and "value" that the environment imparts to animals [24, 25]. When a person uses an object, he or she can understand how to use it just by looking at the environment and the object. Norman used Gibson's affordance theory in his design [26]. He stated that door handles are perceived by human as objects to be "pushed" or "pulled", causing misunderstandings and misuse. Therefore, this paper states that a design should not only be understandable by human users, but should also prevent misunderstandings and misuse.

In this study, the development of a process for efficient and novel medical device design is proposed, and its efficiency is verified. First, the idea based on engineering design variables is derived using generative design. This yields the design variables and the basic shape of the medical device, considering specifically the important functions required from such a device. In the next step, the usability of the derived idea is evaluated, and the optimum idea is selected. To perform this evaluation, it is desirable to conduct a test by having a medical professional actually use the device. However, it is necessary to use other methods of evaluation as well because the aforementioned idea is expensive and time-consuming. Moreover, it is necessary to reproduce human recognition by the program, to quantitatively evaluate the affordance. Lastly, each idea should be evaluated computationally using image processing.

2. PROPOSED METHOD

In this study, we propose a medical-device design method considering HCD, by referring to biodesign (Fig. 2). Divergence, which is important in biodesign, is performed using generative design in AUTODESK Co. Generative design derives multiple solutions from one three-dimensional CAD datum. Use this to exude idea. In the next step, several ideas are converged to a single idea. In addition to the engineering evaluation, an evaluation on the affinity is performed using image processing. In the image processing, feature points are extracted from a two-dimensional image, and the matching amount is calculated.

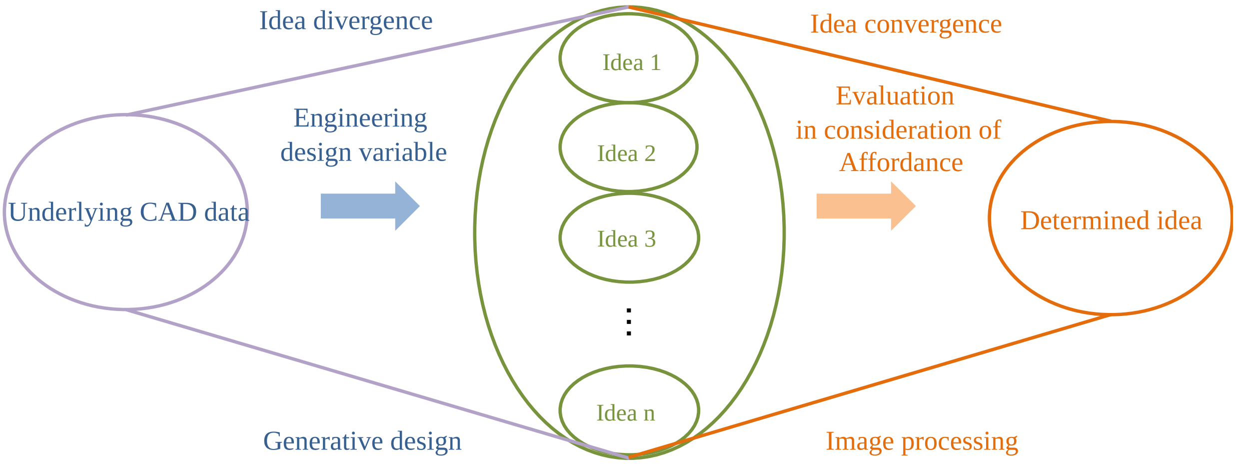


Fig. 2. Proposed design method for medical device considering HCD based on design thinking

3. GNERATIVE DESIGN

Generative design is one of the important CAE tools which can combine the level set method and the topology optimization method. First, we input 3D data on the shape of an existing medical device or its idea, and then derive various solutions according to the design variables, such as safety factor and mass. First, three-dimensional CAD data of the handle part of the base forceps were prepared. In this study, we referred to the handle of forceps used in oral endoscopic surgery. The width of commercial handle of the forceps is 125 mm, its height is 156 mm, and the finger-hanging part is 30 mm in diameter [27]. The handle of the designed forceps is shown in Fig. 3. The material of the forceps was aluminum, and a 5-N force was applied to each finger. The gravity direction is specified as the direction of the Z axis. The set load and gravity direction are shown in Fig. 4 (a). There are also places where you want to leave space when you change. In this case, the obstacle geometry was installed. Furthermore, there are some parts for which the shape needs to be maintained when making changes. They are designated as the holding geometry. The specified geometry is shown in Fig. 4 (b).

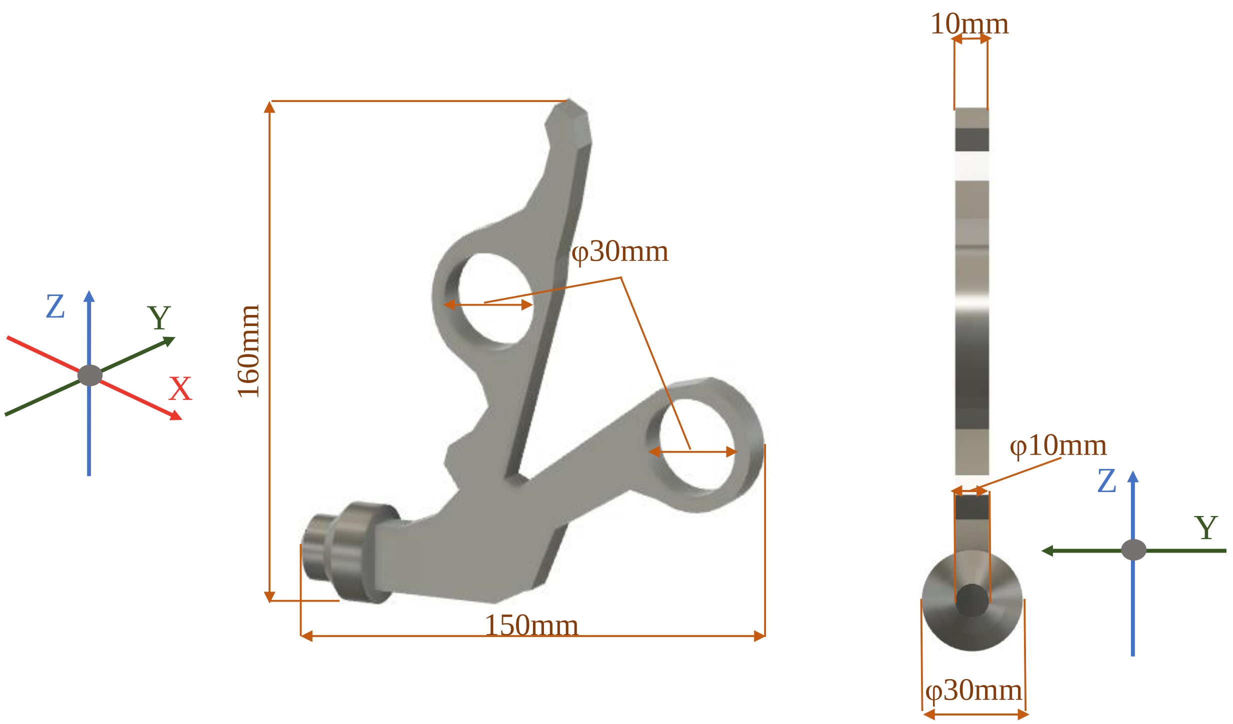
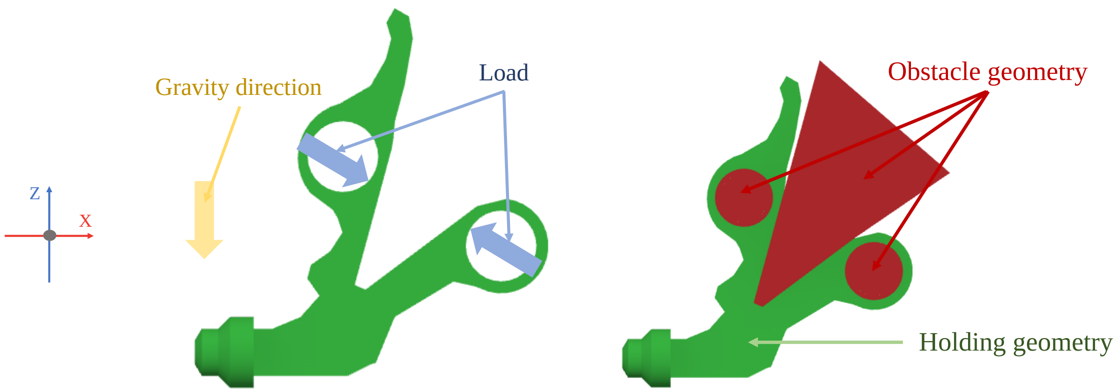


Fig. 3. Set engineering design variables



(a) The set load and gravity direction (b) the specified geometry

Fig. 4. Retention and obstacle geometry set

4. CALCULATION OF MATCHING AMOUNT BY IMAGE PROCESSING

In this study, the change in the shape of the designed device is evaluated quantitatively through comparisons between the matching quantities obtained by image processing. For this, we used Python and OpenCV. Image matching of all the deduced ideas and the base CAD data was performed. The AKAZE method can extract the local features by using a nonlinear and anisotropic scale base [28]. Therefore, we used the AKAZE method for matching. First, the designed image and the two-dimensional image of the idea derived using generative design are photographed. Then, these image data are read. The feature points of these are extracted from the read image data. The error in the feature point of the image of the three-dimensional CAD data based on these extracted feature points was measured. The average value of the error in the measured matching amount was calculated to obtain each matching amount. The lower is the value, the higher is the matching degree. A flowchart of the program is shown in Fig. 5. We show an example of matching in Fig. 6.

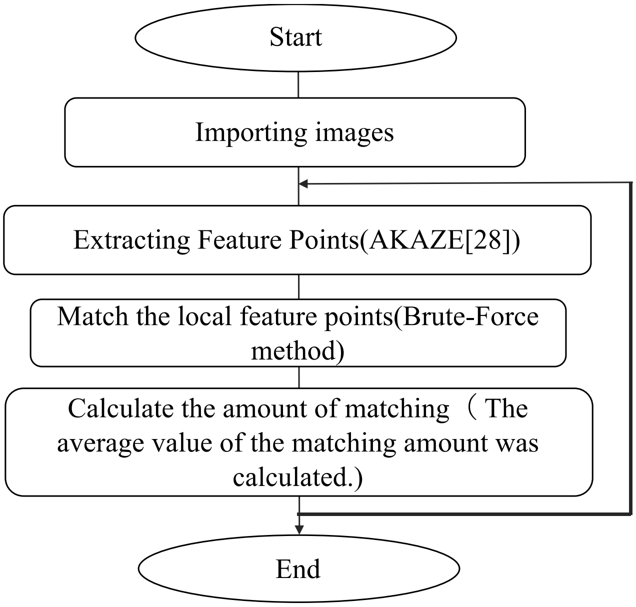


Fig. 5. Flowchart of the calculation of matching amount through image processing

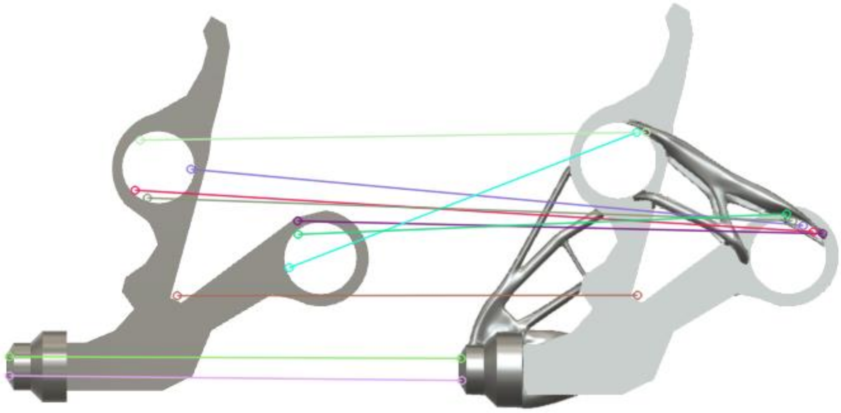


Fig. 6. Feature matching between conventional design and generative idea_1

5. RESULT AND DISCUSSION

The idea derived using generative design is shown in Fig. 7. The engineering parameters are shown in Table 1. Table 2 shows the matching amount obtained by deriving CAD data and generative ideas of conventional forceps, before optimization using image processing. The highest safety factor was obtained for Generative idea_1. Generative idea_1 showed the highest matching amount of 138.36. Therefore, the change in the shape appears to be the largest. The maximum von Mises stress is a scalar value of the stress acting on the object. The maximum von Mises stress shown by Generative idea_1 was 0.2 MPa, which was the lowest among all the ideas. This implies that the stress applied to Generative idea_1 when each load of 5 N was generated from the fingering part was the lowest. Generative idea_2 showed a high matching amount of 126.3; although the variation appeared to be large in this case, the safety factor was 207.73. However, the maximum von Mises stress was 1.2 MPa, which implies that a large stress was generated for the set load. Generative idea_3 and Generative idea_5 had the same engineering parameters. However, their shapes were not the same, and the matching amount was 76.5 for Generative idea_3 and 120.75 for Generative idea_5. Therefore, it can be said that the shape change in Generative idea_5 is larger. From the idea of HCD, it appears to be meaningful to optimize the engineering parameters without substantially changing the shape. Therefore, it is important to quantitatively change not only the engineering parameters but also the shape. Among all the cases, Generative idea_1 appears to be the best from engineering point of view. This idea represents the convergence of multiple ideas in a shorter time by incorporating the evaluation of the change in shape.

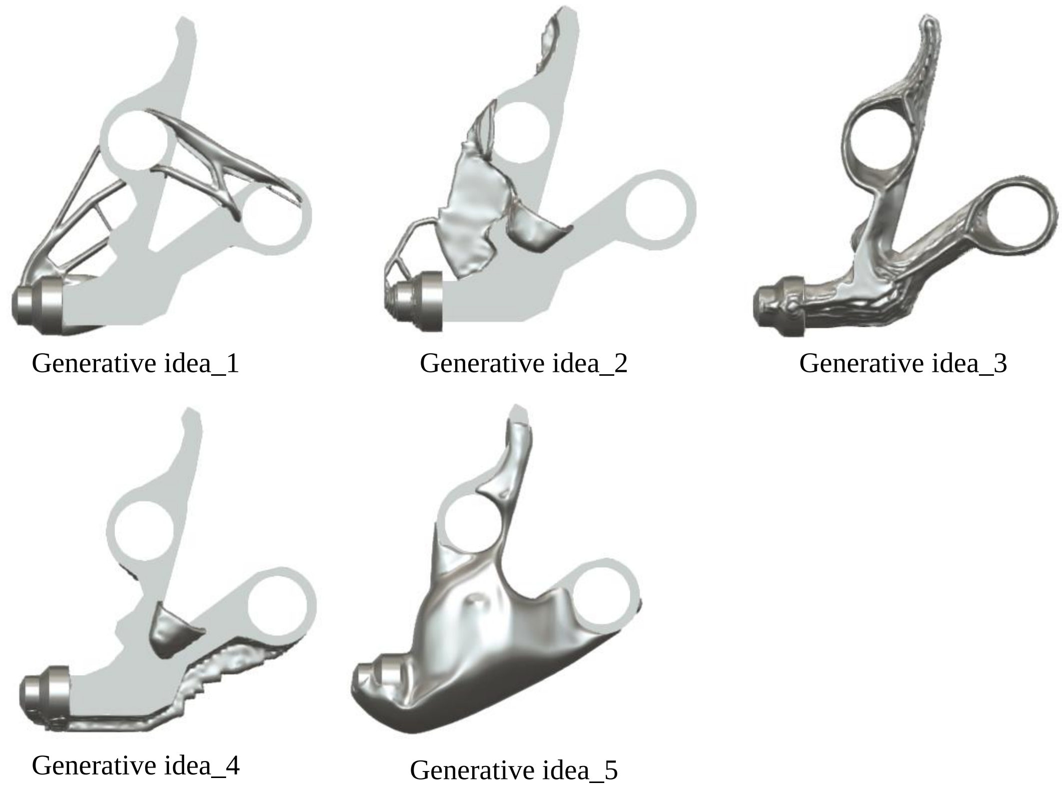


Fig. 7. Idea derived using a generative design between Conventional idea to Generative ideas

Table 1: Engineering parameters of generative ideas

Idea	Safety factor	Maximum von Mises stress (Mpa)	Mass (kg)	Maximum displacement global(mm)	Volume (mm^3)
Generative idea_1	1349.09	0.2	0.18	3.88×10^{-4}	6.75×10^{4}
Generative idea_2	207.73	1.2	0.196	0	7.36×10^{4}
Generative idea_3	178.54	1.3	0.247	0	9.24×10^{4}
Generative idea_4	173.05	1.4	0.187	0.01	7.02×10^{4}
Generative idea_5	178.54	1.3	0.247	0	9.24×10^{4}

Table 2: Matching amount calculated using image processing

Idea	Matching of Feature Quantities between Conventional idea and Generative idea_1
Generative idea_1	138.36
Generative idea_2	126.30
Generative idea_3	76.50
Generative idea_4	121.56
Generative idea_5	120.75

6. CONCLUSION

In this study, a computer-based HCD method for deriving the design plan of a new medical device is proposed, and its efficiency is evaluated based on the divergence and convergence of design thinking, as well as by considering the engineering optimization structure. The feasibility study shows various design example of medical device. In general design discussion, Generative Idea 1 with high safety factor is chosen as the optimum device. However, this is not always the case when considering HCD. If you are thinking mainly about HCD, select generative idea 3 and consider improving the strength by changing the material. We confirmed effectivity of the design proposed method process. In the future, a user test will be performed using a 3D printer.

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