

Article

What Are the Features of Successful Medical Device Start-Ups? Evidence from KOREA

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Abstract: This study analyzes the factors determining the success of medical device start-ups, focusing on the healthcare sector as the starting point of the Fourth Industrial Revolution. The government is also working to establish a business model to revitalize medical device start-ups as a new driving force for the economy. Accordingly, such start-ups based on innovative technologies have been actively developed, but it seems that there is a limit to growth. We employed an analytical hierarchy process to derive an activation strategy for medical device start-ups. A survey was administered to experts in such start-ups, including medical device companies and venture capital firms, prospective start-up entrepreneurs, medical device developers, and professors. A total of 18 responses were obtained for analysis. The results revealed the following priorities for the success of medical device start-ups: technical skills, marketability, entrepreneurial capacity, and funding. In addition, medical device and venture capital firms were divided into separate groups and compared and analyzed. Technical skills are considered a priority for those in the medical industry. However, entrepreneurial skills are a priority for venture capitalists. Based on these results, we suggest measures for the success of medical device start-ups.

Keywords: medical device industry; medical device start-ups; start-ups; success factor; Korea; analytical hierarchy process

1. Introduction

Healthcare is increasingly important in Korea due to the improvement of living standards and an aging population, and the service paradigm in the health and medical sectors is changing from treatment to prevention. Accordingly, the focus is shifting to personal day-to-day care and customized services. Moreover, with the advent of the Fourth Industrial Revolution, there is a surge in the number of medical device start-ups that use the Internet of Things, cloud computing, big data, artificial intelligence, mobiles, and wearable robots [1].

The medical device industry is rapidly transforming into a convergence of state-of-the-art information and communication technologies (ICT) and healthcare. In addition, countries facing excessive medical expenses due to an aging population are attempting to reduce the burden of medical expenses through policy support for the medical device industry centered on healthcare. Medical devices are made of various products, and they are becoming more complex and diversified with the advance in technology. In addition, start-ups based on innovative technologies are being actively advanced by the development of new-technology medical devices using IT/BT (information technology/biotechnology) fusion technology. Global medical device companies have established incubation centers or venture capital to foster start-ups and to promote innovation. However, Korean

medical device companies are mostly small, and the market for such devices has not yet become international; thus, growth is limited. Since existing companies are very small, start-ups have not been activated because of limited investment. It is difficult for new medical devices to enter the market due to the regulatory system. Medical devices can have a direct impact on people's lives, and the licensing system is complex. To launch new medical devices, the device must be approved by the Ministry of Food and Drug Safety (MRDS). New medical technology is evaluated by the National Evidence-based Healthcare Collaborating Agency (NECA). Benefits are evaluated by the Health Insurance Review & Assessment Service. This process takes up to 390 days, and the government has stated that it would shorten this to 80 days, but no full-scale implementation has yet taken place. Therefore, medical start-ups must be invested in the licensing system for a long time, but it is difficult to prepare the regulatory system due to the lack of professional labor. In addition, it is difficult to compete with existing companies because it is a challenge to acquire distribution networks even if they enter the market with permission to produce medical devices. Other difficulties such as clinical or R&D costs, patent application, and registration also exist.

Start-ups are companies that start businesses based on cutting-edge technology. Since the mid-2000s, start-ups have become more important in the global economy and the business environment is changing accordingly. To survive in a rapidly changing business environment, start-ups need the capacity for sustainable growth as well as competence in the market [2,3]. Interest in start-ups has increased due to the global economic recession and rising unemployment. Start-ups with the right diversity and flexibility can create a base industry and promote economic growth through competition and innovation [4]. The number of successful start-ups is on the rise due to the start-up wave, but the reality is that most companies fail. Changes in the domestic and overseas business environment caused by the global financial crisis have led to fierce competition among global companies to take the initiative, thereby causing serious damage to start-ups. The journey from idea and commercialization is complicated and 90 percent of start-up companies struggle to enter the market. Unless they establish core strategies tailored to the rapidly changing market conditions and respond accordingly, it can be difficult for start-ups to enter the market upon their initial attempt.

With the recent growth of the healthcare sector influenced by the advent of the Fourth Industrial Revolution, medical device start-ups are seeing growth in wearable devices as their main product. Medical devices in the healthcare field enable early diagnosis of disease and can be used extensively, from simple healthcare to treatment of serious diseases. Thus, innovative medical devices developed by medical device start-ups will enable personalized healthcare, which will help bolster the public's continued health. Accordingly, the government is also extending its support to provide a basis for start-up growth, but there seems to be a limit to the success of medical device start-ups. Medical expenses continue to increase with age and the use of advanced medical devices helps reduce these expenses by improving patient health. In particular, the medical device industry has been selected by the government as a major industry to secure innovative growth engines and aims to expand its future growth engine through the development of medical device start-ups. That is, the medical device industry's development will bring about economic benefits, resulting in the continued improvement of people's health and the securing of medical expenses [5,6]. Start-ups must build a sustainable business model that can prosper over time. The medical device industry is intertwined with complex stakeholders and needs to interact with understanding stakeholders. Therefore, deriving the key factors of each stakeholder for the initial growth of medical device start-ups will lead to their sustainable growth, which will aid Korea's economic development [7,8]. In this study, we will seek to derive an activation strategy for medical device start-ups based on a priority analysis using the analytical hierarchy process (AHP), with experts as targets, to determine the success factors for medical device start-ups [4]. The success of such start-ups through these measures will result in the promotion of medical device start-ups based on innovative technologies, which will lead to the development of the domestic medical device industry.

2. Literature Review

2.1. The Start-Up Business in the New Market

Start-ups are companies that develop new products and services to create new markets in uncertain environments. They are also defined as new businesses started by entrepreneurs that combine ideas and resources. If these conditions are met, the company is considered a start-up regardless of its size or shape. Thus, a company is defined as a start-up if it combines new ideas and advanced technologies to create new markets and business opportunities. In Korea, start-ups and venture capital firms are close to each other in concept, but there are differences between the two. First, in terms of business activities, venture firms are new companies of whom high growth is expected because they have a systematic organizational structure and a major focus on research and development. By contrast, start-ups operate in smaller sizes around a common project aiming at high risk and high returns, based on innovative ideas or advanced technology, while focusing on commercialization. From a legal standpoint, venture capital firms are those that are provided with policy support as they meet the conditions set out in the Special Measures for the Growth of Venture Businesses Act. Start-ups, however, receive investment and support from venture capitalists or angel investors, and there are no legal requirements [2].

Start-ups create new businesses in highly competitive environments and galvanize the national economy. However, to commercialize their ideas, start-ups must allocate funds to their products based on their growth potential. Without market analysis and experience, it is difficult to operate reliably because the market is uncertain, and start-ups are a new form of business. Hence, for start-ups, it is important to identify marketability, users, competitors, and suppliers based on innovative products [9]. In Silicon Valley, US, there are over 298,800 angel investors available to make the necessary investments in the development and success of start-up products. Korea is expanding its investment in ICT services and biotechnology, but there are only 3984 angel investors in the country. In the US, investment by venture companies is strengthening regarding start-ups, but this is not the case in Korea, which is focused on growth. Therefore, in most countries other than the US, start-ups fail in the initial phase of market entry. Hence, long-term strategy and support are needed. Korea began supporting start-ups in 2013 with a government policy called Creating Jobs by Revitalizing Investment in Start-ups. The government is also encouraging start-ups with a 2018 policy for financial support and deregulation. By doing so, the government aims to ease the financial burden of start-ups and create an environment for growth by establishing a cooperative ecosystem among start-ups [3,10].

2.2. Start-Up Businesses in the Medical Device Industry

One characteristic of medical devices is that they use interdisciplinary technologies such as clinical medicine, electrics, electronics, mechanics, material, and optics. Recently, the medical device market has been expanding into the new convergence sector in connection with the Fourth Industrial Revolution, and it is seeing greater growth with the development of digital healthcare, u-health, wearable medical devices, and so on. As medical devices directly and indirectly affect people's promotion of health and their securing of health rights, regulation and government approval are needed. Hence, the government is regulating the manufacture of medical devices, the safety rules for clinical tests, as well as the distribution and sale of such devices. In addition, as the main demand for medical devices comes from hospitals that are conservative regarding the use of existing devices because of safety and reliability issues, the industry has a high barrier to entry [11–13].

The medical device industry is a promising sector that will create new jobs and secure new growth engines as the medical paradigm shifts to one that is focused on healthcare [14]. In particular, as consumer demands for medical services are increasing rapidly, a new market is being created through convergence of and integration with new technologies such as BT, ICT, and Nano Technology (NT). Medical device start-ups are actively developing wearable devices that collect and manage personal biometric information, medical mobile consultation services, information services for medical

institutions and pharmacies, and personalized healthcare services. Such start-ups have been on the rise in recent years, but more than half fail in the first one to three years of business [15].

The medical device industry requires much time and a large amount of investment before research results are commercialized. Uncertainties regarding success are also very high. In Korea, researchers that want to found a start-up have to look for support programs or investors. There is almost no systematic support system or policy in Korea that can connect the demand for start-up companies in the medical device industry with actual start-ups and make them successful. The medical device industry requires the development and assessment of clinical ideas, connecting with hospitals in the process of technological commercialization, and supporting government licensing regulations. Thus, we need a start-up support service that includes all of these aspects [16].

2.3. Success Factors of Start-Up Businesses

For a start-up to succeed, technology-based infrastructure must be in place for the entrepreneur to utilize. It must also secure key resources such as manpower, technology, and finance [17]. If we analyze previous studies on the success factors of start-ups, Stuart [18] claims that the following are very likely to be successful: companies in markets with low entry barriers and high expected growth, products with innovative technologies, entrepreneurs with strategic marketing skills, experience, and a wide network, and organizations where free communication is possible. Chorev [19] also claims that the following are core success factors for high-tech start-ups: entrepreneurs skilled at market analysis and management, strategies to achieve a competitive advantage, marketing capabilities to identify customer needs, products wanted by the market, organizations that have expertise, financing through venture capital, and external environment for maintaining competence. Nam [20] argues that entrepreneurial competences such as entrepreneurs' level of education, experience in start-ups, and preparedness for start-ups; economic features such as financial resources and start-up investment; and circumstantial features such as government policy and market environment lead to success. Start-up ecosystems are created with start-up growth, recovery, and reinvestment. However, most start-ups do not achieve results in the early stages. Entrepreneurial competence plays a key role in the start-up phase and requires entrepreneurial commercialization, such as finding ideas and opportunities for the business, and building a complete business model. In the early stage of the start-up, network competence is crucial, and cooperation with external companies and corporate resources such as knowledge and technology should be utilized. That is, the start-up preparation phase should have a foundation to support entrepreneurship and commercialization capabilities, and in the early stage, it should be supported by the relevant agency to reduce the likelihood of failure.

Since start-ups are based on new technology and face challenges in the journey from idea to commercialization, they find it difficult to enter the market successfully. According to government statistics for 2016 on the success and failure of companies, the 3-year survival rate of start-ups is 39.1%; it seems difficult for them to stay afloat [2]. Sandberg and Hoffer [21] developed an ERI model, believing that the performance of start-ups is related to the structure of resources and industries as well as the characteristics of entrepreneurs. Thus, in the ERI model, the founders, resources, and the industrial environment influence the performance of a start-up. In particular, the performance of start-ups is influenced by the characteristics of entrepreneurs as well as the company's structure and strategy [21]. Han [22] developed the ERIS model by adding a strategic factor to the ERI model. The ERIS model indicates that the performance of start-ups consists of the interaction between entrepreneurs, resources, industrial environments, and strategic factors. Entrepreneurs need to use their capabilities to manage risks and build management systems in the process of commercializing start-ups. Resources are an important factor in start-up success. The source of competitive advantage for a product or service depends on the level of resources held by the company. In the case of start-ups, they should be able to mobilize resources that contribute to creating capabilities that are difficult to imitate. The industrial environment can be viewed in terms of industrial growth rate, market size, and competition intensity since the industrial structure determines the intensity of competition and

the profitability of the industry. In establishing strategies, the entrepreneur can identify whether the product will create a competitive advantage and whether such an advantage will be sustainable [22]. The ERIS model is shown in Figure 1.

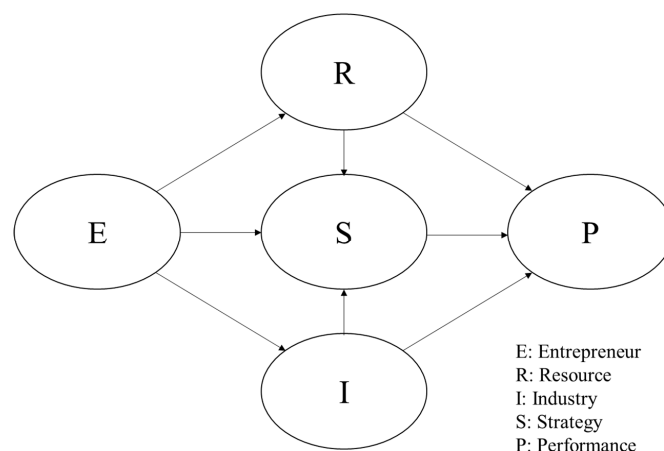


Figure 1. ERIS Model [18].

2.4. Research Purpose

The research purpose of this study is twofold.

First, we wish to derive the priority of medical device start-up success factors. This will help medical device start-ups that lack experience and resources to enter the market smoothly, and create new businesses in a highly competitive environment to galvanize the national economy.

Second, based on these priorities, we will present strategies for activating medical device start-ups that contribute to continuous health promotion. The sustainable operation of medical device start-ups will realize the public value possessed by the medical device, enhance the safety of the public, and reduce the medical burden of the patient.

3. Method

3.1. Analytic Hierarchy Process

An AHP analysis was conducted to derive the success factors of medical device start-ups. The AHP method, developed by Saaty [23], is a method for ranking various factors and distinguishing the important ones. It views the problem to be addressed as a structure consisting of several hierarchies, analyzes them, and decides their relative priority. The AHP is useful for solving complex problems and is primarily used to solve unstructured problems in areas such as politics, economics, society, and management [24]. The AHP method derives the factors that make up the decision-making hierarchy by conducting pairwise comparison on a 9-point scale. If the evaluator's consistency ratio (CR) is less than 0.1, it is considered logical and reliable [16,25].

If the consistency ratio is less than 10%, the pairwise comparison matrix is consistent. If the CR value is less than 0.1, the pairwise comparison is considered to have a reasonable consistency [26–30].

An AHP analysis enables decision-making through the integration of qualitative and quantitative factors, and it is possible to measure or prioritize relative importance even with the participation of only very few experts. It is useful because it can be used both publicly and privately. On the other hand, it is not easy to recruit experts who can participate, and if the logic consistency is not secured, the research results become meaningless. In addition, there is a limitation in that the number of layers that can be measured is limited, and logical consistency decreases when the number of measurement elements increases [31,32].

Park and Kim (2011) conducted AHP analysis of 10 medical industry experts in the Wonju Medical Device Cluster to present a credit evaluation model for medical industry venture firms [33]. Lee (2018)

conducted AHP analysis of 18 medical device industry experts to elucidate the key strategies and direction of the medical device industry [12]. Dhochak and Sharma (2016) used the AHP method to prioritize the factors that influence the investment decisions of venture capitalists. AHP analysis was conducted on 20 venture capital experts. The major factors influencing investment decisions were entrepreneurial characteristics, profitability, and market size [34]. Vanhala and Kasurinen (2014) used AHP analysis to rank the key elements of the business model of computer game start-ups. To this end, a survey of nine experts on computer games were interviewed and the key factors were human capital, marketing, and partners [35]. AHP analysis is applied not only to the medical device industry but also to the research for establishing the start-ups business model and is used to derive the relative importance of evaluation items in various fields. When we examine previous studies using AHP analysis, we can obtain valid results even when at least 10 experts participate. In particular, the higher the consistency among experts, the smaller the magnitude that is not related to the internal validity and reliability. Therefore, the sample number of this study is similar to that of the previous study, meaning that at least the minimum value is secured, and the consistency ratio of each factor is within 0.1, which is considered to be logical consistency [36–38].

3.2. Research Framework and Variables

Kim's [3] Critical Success Factors of a Design Start-up Business was used as the main criteria for the success of medical device start-ups. The AHP analysis was conducted based on entrepreneurship, innovation, technology, and capital environment as success factors for design venture capital firms; the results indicated that continuous investment and commercialization of ideas are important for the success of design start-ups. In addition, entrepreneurial capacity is also important to maintain the technological and capital environment. Frank [39] argued that ICT start-ups require critical growth factors of capital size and marketable technology to succeed. Based on these, the following were derived as success factors for medical device start-ups: entrepreneurial skills, technical skills, marketability, and funds. The definition of each factor is as follows. Entrepreneurial skills are defined as the entrepreneurial experience, education, skills, and knowledge needed to successfully lead medical device start-ups, and ability to communicate with the outside world. Technical skills are defined as technology and products that can make a medical device start-up successful. Marketability is defined as the market orientation of medical device start-ups with high professionalism. Finally, funds are defined as the ability of medical device start-ups to generate profits in the medical device market.

First, according to Tutar [40], a company's strategic market orientation and aggressive innovation orientation, as subcategories of entrepreneurs' capabilities, play an important role in business performance, and corporate culture has an impact on organizational performance. Based on these, corporate culture, as a comprehensive concept of innovation and market orientation, was derived. In addition, network utilization was derived based on Tur-Porcar's [41] argument that building relationships between people and the environment is important for the sustainable development of businesses. Diamonto [42] argues that the founder's career, expertise, and experience enhance ability to cope with new technologies or the environment when doing business. Since the medical device industry is heavily influenced by regulations, competitive advantage can be achieved through the manager's experience in starting businesses and market analysis skills. Founders who have experience in medical device start-ups can have a positive impact on start-up success due to the interaction of product innovation and the ability to utilize market information. Gelderen [43] found that, in terms of success and risk factors, entrepreneurial competence, organizational culture, and corporate surroundings influence the success of venture companies in the pre-start-up phase. Accordingly, start-up experience, market analysis skills, organizational culture, and network utilization were derived as subcategories of entrepreneurial competences. Second, with regard to the subcategory of technological capacities, Lee [2] identified research and development, innovative technology, and patent holding as factors that determine early market advance of medical devices in a study of the success factors in the initial success of a start-up. Sohn [44] states that in the case of latecomers

like Korea, an increase in R&D investment influences the financial performance of a company. He also argues that improving employees' expertise is a way to strengthen corporate capabilities. In particular, the medical device industry is dependent on capital and technology and it takes three to five years for a product to be developed and manufactured, resulting in a long payback period. In addition, as individual products have small markets and a short product cycle, continuous investment in R&D is necessary. Based on these arguments, the following were factors derived: technology innovativeness, R&D facilities and infrastructure, patent retention, and securement of a professional workforce. Third, as a subcategory of marketability, Chesbrough [45] identified the business model as more important than original ideas or R&D for new technology. He noted that if significant financial resources are invested to develop a product that is found to be unmarketable or is delivered to customers through the wrong channel, then the company's profit will be poor. Hyytinen [46] asks does innovativeness reduce start-up survival rates? For the entrepreneurial enterprise to survive, market performance products should have profitability. Furthermore, product competitiveness may help maintain start-up companies lacking capital. Korea's medical device market has a very weak competitive structure compared to the US, Europe, and Japan, where global companies are located. Therefore, for a medical device start-up to be successful, profitability should be created based on product competitiveness. In addition, it is necessary to increase the market size of products by using marketing skills to create a new distribution channel of the medical device market. Based on this, the following factors were derived: the product's market size, product competitiveness, product profitability, and marketing and sales skills. Fourth, as a subcategory of finance, Kohler [47] argues that investment of capital, improved reliability through strategic partnerships, and distribution network support for increasing market accessibility are being implemented to revitalize start-up companies. Park [33] developed an evaluation model for medical venture businesses using the AHP, that author presents a credit rating model for medical venture firms. The top indicators of financial factors are profitability, fundraising ability, and safety. The top indicators of nonfinancial factors are technical, business, and reliability. In addition, securing the capital of venture companies is crucial for securing initial capital, since it can help achieve stable management. Medical device start-ups that are based on innovative technologies require a lot of capital because they need to demonstrate the safety and effectiveness of technology through clinical trials. In addition, due to the nature of the medical device industry, it takes about three to five years from the development to the production of products, and hence, the long payback period, which requires funding capacity. Based on these, the following factors were derived: initial capital, funding capacity, available funds, and potential profit growth. The main factors for the AHP analysis are shown in Figure 2, and the selection criteria of each factor are shown in Table 1.

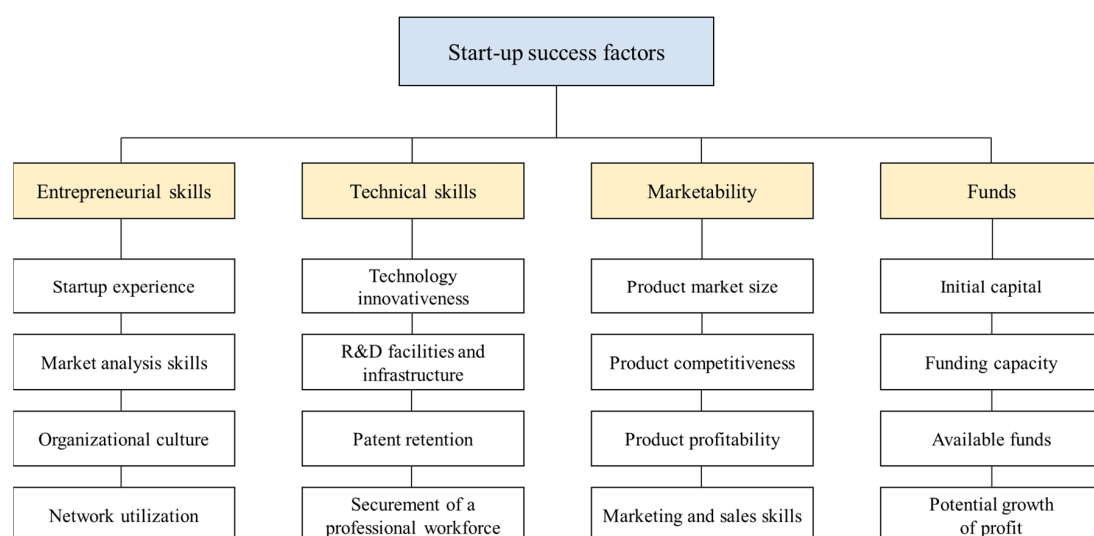


Figure 2. Research framework.

Table 1. Evaluation items and criteria for medical device start-up success.

Area	Item	Selection Criteria	Related References
Entrepreneurial skills	Start-up experience	Founder's career, academic background, expertise	[3,40–43]
	Market analysis skills	Market-based business model	
	Organizational culture	Flexible corporate culture and innovation orientation	
	Network utilization	Cooperation with industry stakeholders	
Technical skills	Technology innovativeness	Originality of new technology	[2,3,44]
	R&D facilities and infrastructure	Facilities and infrastructure for R & D	
	Patent retention	Efforts for intellectual property and technology patents	
	Securement of a professional workforce	Secure workforce for R & D	
Marketability	Product's market size	Market formation status of products	[3,45,46]
	Product competitiveness	Competitiveness of products	
	Product profitability	Market competition situation and profit prospect	
	Marketing and sales skills	Market expansion through marketing	
Funds	Initial capital	Financial stability using venture capital	[3,33,47]
	Funding capacity	Financing for business expansion	
	Available funds	Availability of corporate funds	
	Potential growth of profit	Profit-making ability through product selling	

3.3. Research Process

A previous study that analyzed start-ups' success factors was reviewed to conduct the AHP analysis. Major issues were derived based on opinions of experts from medical device and venture capital firms. First, we selected the main factors and defined each factor through the analysis of previous research that derived start-up success factors. Next, we selected three medical and entrepreneurial venture capital experts and examined whether the extracted factors influenced the success of medical device start-ups. This was done from 24 September 2018 to 3 October 2018, and a consensus was reached on the criteria for success in medical device start-ups. Finally, a questionnaire survey was prepared using literature reviews and brainstorming each of the factors identified by the experts. The survey focused on experts in medical device start-ups, including medical device companies and venture capital firms, prospective start-up founders, medical device developers, and professors. In the case of medical device companies, surveys were conducted mainly on entrepreneurs working in these companies or start-ups. In the case of medical device start-ups, there is often no distinction between management and employees in small-sized companies. Venture capital was targeted at companies with experience in investing in start-up medical devices. For start-up candidates and medical device developers, medical devices were developed to target those who were developing medical devices or who were developing medical devices with the goal of starting their own businesses. Professors and experts selected people working on promoting the medical device industry as research subjects. A total of 30 questionnaires were distributed through the selected research targets (Table A1). A total of 18 valid responses were obtained from an online and offline survey. The survey period was from 29 October 2018 to 19 November 2018.

3.4. Data Collection

The AHP analysis in this study was conducted using DRESS 1.7.00, which is a solution designed for the AHP. A total of 18 valid responses were obtained from medical device start-up experts. The AHP result was judged to be reliable as the CR was less than 0.1. First, demographic characteristics indicate that men account for the majority. In terms of job category, more than half worked in medical device companies and held a diverse range of responsibilities. Professors were divided into other categories because they do not work for a medical device company and do not have any responsibilities (Table 2).

Table 2. Demographic information.

Characteristics		Frequency	Ratio (%)
Gender	Male	14	77.8
	Female	4	22.2
Age (years)	30s	1	5.6
	40s	9	50.0
	50s	7	38.9
	Over 60s	1	5.6
Work experience in the related field	Under 5 years	4	22.2
	5–10 years	2	11.1
	10–20 years	7	38.9
	Over 20 years	5	27.8
Occupation	Medical device company	10	55.6
	Venture capital	2	11.1
	Professor	2	11.1
	Others	4	22.2
Assigned task	Management	6	33.3
	licensing	6	33.3
	Marketing/Sales	1	5.6
	R&D	1	5.6
	Funding and investment	2	11.1
	etc.	2	11.1

4. Results

4.1. Comparing Success Factors

To derive the importance through the AHP analysis, we conducted a pairwise comparison of the top and sub-items and selected their importance and priority. Next, the importance and the priority of the sub-item were obtained through the conducting pairwise comparison of the items, and the importance and priority of the items were selected. Priority was derived based on entrepreneurial skills, technical skills, marketability, and funds, which are the main criteria for success factors in medical device start-ups. The following results were obtained: technical skills (0.38), marketability (0.29), entrepreneurial skills (0.22), and funds (0.11). Based on this, it can be said that to be successful, it is necessary for start-ups to commercialize a marketable medical device based on innovative technology.

Next, priorities were derived based on subcategories of success factors. The priorities for the subcategory of entrepreneurial skills were market analysis skills (0.33), network utilization (0.30), entrepreneurship experience (0.26), and organizational culture (0.11). Priorities in the subcategory of technical skills were securement of a professional workforce (0.44), technological innovativeness (0.27), patent retention (0.15), and R&D facilities and infrastructure (0.13). Priorities in the subcategory of marketability were marketing and sales skills (0.39), product competitiveness (0.32), product profitability (0.18), and product market size (0.11). Finally, priorities in the subcategory of funds were revenue growth potential (0.34), available capital (0.30), funding capacity (0.25), and initial capital (0.11). The results are shown below (Table 3).

Table 3. Analysis of medical device start-up success factors.

Top Item	Factor Weights		Subitem	Factor Weights		
	Importance	Priority		Importance	Priority	CR
Entrepreneurial skills	0.22	3	Start-up experience	0.26	3	0.03
			Market analysis skills	0.33	1	
			Organizational culture	0.11	4	
			Network utilization	0.30	2	
Technical skills	0.38	1	Technology innovativeness	0.27	2	0.02
			R&D facilities and infrastructure	0.13	4	
			Patent retention	0.15	3	
			Securement of a professional workforce	0.44	1	
Marketability	0.29	2	Product's market size	0.11	4	0.03
			Product competitiveness	0.32	2	
			Product profitability	0.18	3	
			Marketing and sales skills	0.39	1	
Funds	0.11	4	Initial capital	0.11	4	0.05
			Funding capacity	0.25	3	
			Available funds	0.30	2	
			Potential growth of profit	0.34	1	
Total	1.0			4.0		

4.2. Comparative Analysis of Major Factors by Job

The major criteria for success factors were determined separately for employees in medical device companies and those in venture capital firms, which were then compared and analyzed. Therefore, we excluded professors from the analysis because they are not directly engaged or do not invest in medical device companies. In the case of those working in the medical device industry, the success factors of start-up companies were technical skills (0.45), marketability (0.30), entrepreneurial skills (0.15), and funds (0.09). For venture capital firms, however, it was entrepreneurial skills (0.34), technical skills (0.29), marketability (0.24), and funds (0.13). Medical device start-ups are increasingly focusing on healthcare. Healthcare is a convergence industry to which ICT-based technologies are mainly applied. Since, in the case of medical device start-ups, competitive advantage must be gained through ICT convergence by securing technology, technical skill was seen as a key success factor. On the other hand, experience and expertise play a leading role in commercialization based on innovation. Since experience with start-ups predicts a company's financial performance and improves its business performance, venture capital firms that raise funds view entrepreneurial skills as the key factor in the success of medical device start-ups [48] (Table 4).

Table 4. Analysis of key factors.

Top Item	Weights of Factors					
	Medical Device Company			Venture Capital Firm		
	Importance	Priority	CR	Importance	Priority	CR
Entrepreneurial skills	0.15	3	0.03	0.34	1	0.08
Technical skills	0.45	1		0.29	2	
Marketability	0.30	2		0.24	3	
Funds	0.09	4		0.13	4	
Total	1.0			1.0		

4.3. Comparative Analysis of Start-Up Success Factors by Job

Subcategories of success factors for medical device start-ups were divided into those for medical device companies and those for venture capital firms. For the former group, the priorities in the subcategories for entrepreneurial skills were network utilization (0.37), market analysis skills (0.35), entrepreneurship experience (0.21), and organizational culture (0.07). In the case of technical skills,

the following were identified: securing experts (0.48), technology innovativeness (0.27), patent retention (0.13), and R&D facilities and infrastructure (0.12). The priorities for marketability were arranged as follows: marketing and sales skills (0.37), product competitiveness (0.36), product profitability (0.17), and product market size (0.10). Finally, in the case of funds, profit growth potential (0.35), funding capacity (0.30), available capital (0.24), and initial capital (0.10) were identified as priorities. Next, for venture capital firms, entrepreneurship experience (0.31), market analysis skills (0.28), network utilization (0.22), and organizational culture (0.19) were identified as priorities in the subcategory of entrepreneurial skills. In the case of technical skills, the following priorities were identified: securing experts (0.41), technology innovativeness (0.28), patent retention (0.18), and R&D facilities and infrastructure (0.14). The priorities for marketability were marketing and sales skills (0.40), product competitiveness (0.27), product profitability (0.18), and product market size (0.14). Finally, in the case of funds, profit growth potential (0.31), funding capacity (0.31), available capital (0.26), and initial capital (0.12) were identified as priorities.

Both groups (medical device companies and venture capital firms) showed agreement on the following subcategories: technical skills, marketability, and funds; however, their view of entrepreneurial skills as a priority for the success of medical device start-ups differed. Medical device companies considered network utilization a priority among the subcategories of entrepreneurial skills. This appears to be because the ecosystem of medical devices consists of a variety of stakeholders, and experts in each field must work together to meet the needs of stakeholders for new products to enter the market quickly. Venture capital firms, in contrast, considered entrepreneurship experience a priority among the subcategories of entrepreneurial capacities. This seems to be because venture capital firms consider the future potential of the company they are investing in, and the expertise and experience of the entrepreneur play a key role in their decision to invest funds [49] (Table 5).

Table 5. Analysis of medical device start-up success factors.

Top Item	Subitem	Weights of Factor			
		Medical Device Company		Venture Capital Firm	
		Importance	Priority	Importance	Priority
Entrepreneurial skills	Start-up experience	0.21	3	0.31	1
	Market analysis skills	0.35	2	0.28	2
	Organizational culture	0.07	4	0.19	4
	Network utilization	0.37	1	0.22	3
Technical skills	Technology innovativeness	0.27	2	0.28	2
	R&D facilities and infrastructure	0.12	4	0.14	4
	Patent retention	0.13	3	0.18	3
	Securement of a professional workforce	0.48	1	0.41	1
Marketability	Product's market size	0.10	4	0.14	4
	Product competitiveness	0.36	2	0.27	2
	Product Profitability	0.17	3	0.18	3
	Marketing and sales skills	0.37	1	0.40	1
Funds	Initial capital	0.10	4	0.12	4
	Funding capacity	0.24	3	0.26	3
	Available funds	0.30	2	0.31	1
	Potential growth of profit	0.35	1	0.31	1
Total		4.0		4.0	

5. Discussion

As of 2017, Korea's medical device market was worth 6.2 trillion won, accounting for 1.7 percent of the world market and ranking ninth globally. However, since imports account for 63.8 percent, the market competitiveness of Korean products is considered low [50]. As the medical device industry has a high value-added rate and a job creation effect, the activation of medical device start-ups based on innovative technologies is expected to lead to job creation. In this study, an AHP analysis

was conducted to derive the success factors of medical device start-ups. The results indicated that the main criteria for the success factors were technical skills, marketability, entrepreneurial skills, and funds. Priorities in the subcategories of the major criteria were market analysis skills, network utilization, entrepreneurship experience, and organizational culture. In the case of marketability, marketing and sales skills, product competitiveness, product profitability, and product market size were identified as priorities. Market analysis skills, network utilization, entrepreneurship experience, and organizational culture were identified as priorities for entrepreneurial skills. For funds, profit growth potential, available capital, funding capacity, and initial capital were identified. Based on these results, we propose the following measures for the success of medical device start-ups:

First, there must be a professional workforce for developing innovative technology. A start-up is a company based on new ideas and technologies. Securing innovative technologies therefore creates a constant competitive advantage. Since medical devices converge with other fields, and because this leads to increased competition in the industry, they need to be better equipped than competitors in other fields. To do so, they need to maintain a competitive edge through technical development by securing an expert workforce. The increasing demand for improved quality of medical devices is increasing the number of medical device start-ups that combine ideas and IT technologies. However, the steady growth of such start-ups is proving to be a challenge due to the lack of experts in medical device R&D, licensing, quality management, and clinical testing. Medical device start-ups need to have products that are more refined than those in other industries. They can succeed in commercialization only when funding and licensing are available and when they understand the needs of medical staff, who are their major customers. It is essential to plan for marketability assessments, clinical tests, licenses, and salaries. In this process, securing skilled professionals with expertise in each field is essential. To this end, field-oriented workforce development should be carried out in the medical device industry by introducing graduate schools geared toward the medical device industry. Currently, a graduate school that specializes in the medical device industry is operating in Korea to impart interdisciplinary knowledge of convergence and work experience to mid-level managers. However, a degree program is needed to train high-quality human resources by balancing learning, industry, and employment. Accordingly, training core leaders in the medical device industry through a specialized graduate school is expected to revitalize medical device start-ups.

Second, we need to expand the marketability of products with marketing that identifies customer needs. Byun (2017) conducted a weighted analysis of the key elements of strategies for each phase of medical device commercialization and found that users, hospitals and buyers, pricing factors, and product differentiation strategies during the commercialization phase were highly weighted. He also states that when selecting products, they should be chosen not based on entrepreneurs' preferences but on the needs of the market and stakeholders [51]. Since medical devices take a long time from technology development to clinical testing, licensing, insurance registration, and distribution, they require a sustained strategy to enter the market. Furthermore, since ideas alone are insufficient for start-up success, it is necessary to accurately identify major customers and needs during the R&D process. The primary consumer of medical devices is the hospital or doctor. Therefore, it is important to know who the product users are, whether the product is helping to treat patients, and if there is a demand. Whether the product has better technical capacities than existing products should also be considered [52]. Safety and reliability are considered first because medical devices directly affect people's health and well-being, which is why market consumers tend to continue to use popular products. There is a high preference for global corporate products that remain competitive, and this leads to high barriers to entry. In addition, price elasticity is low, and awareness of the product and brand power are very important. Thus, when entering the market, medical device start-ups should develop strategies that consider the purchase history, price, and willingness to purchase existing products existing products for their target customers.

Third, the company should enhance its entrepreneurial skills to commercialize the product through market analysis. Unlike the ecosystem of general start-ups, there are a large number of

stakeholders in the ecosystem of medical device start-ups, such as regulators, the government, businesses, patients, hospitals, and venture capital firms. Thus, medical device start-ups require a streamlined process for managing stakeholders during the initial market entry phase. For medical devices to enter the market, they need to undergo procedures such as approval screening by the Ministry of Food and Drug Safety and registering for insurance at the Health Insurance Review and Assessment Service. Therefore, it is essential for medical device start-ups to perform market analyses such as analysis of similar products, status of use, and life cycle. They also need to go obtain approval from the Ministry of Food and Drug Safety, and determine, when registering for insurance, whether they are subject to assessment for new medical technology. To enter the market, medical device start-ups should include strategies for market analysis, licensing, and salary. Accordingly, if medical device start-ups are to enter the market quickly, entrepreneurs must have expertise in the entire life cycle of medical devices. Currently, the medical device comprehensive support center supports early start-up companies. However, it is composed of a one-time consultation focusing on regulation and is not particularly effective. Therefore, we need to ascertain consultation outcomes and provide practical support that is linked to the relevant department's approval process for market entry.

In addition, to enhance entrepreneurial skills, educational courses on the medical device industry are needed. Currently, the National Institute of Medical Device Safety provides practical skill-reinforcement courses. However, as these courses are offered only twice a year, it is necessary to extend the training period. By extending these courses, we will be able to reinforce entrepreneurial skills and increase the success rate of medical device start-ups. Advances in medical device start-ups based on innovative technologies will play a positive role in creating jobs and corporate structures in Korea. In particular, since medical device start-ups need connections with hospitals and support related to government licensing regulations when conceiving and assessing clinical ideas and commercializing, we need a comprehensive start-up support service. To this end, we need to build a medical device start-up platform linking start-up companies with government and regulatory agencies. The active market entry of medical device start-ups based on innovative technologies will lead to the advancement of medical technology and will ultimately improve people's health.

6. Conclusions

This study derived the success factors of medical device start-ups through an AHP analysis. These findings are likely to help medical device start-ups that have difficulty entering the market. Medical devices are heavily regulated given their potential impacts on human health/life. It is also difficult to launch start-ups if policy support is not provided. Therefore, based on the aforementioned discussion, the following policy efforts are necessary. First, a graduate school for the medical device industry should be introduced to secure skilled professionals. The global health market is growing 5.2 percent annually, from 10 trillion dollars in 2017 to an estimated 12.3 trillion dollars in 2021. In addition, the number of jobs in the health industry is expected to increase 3.5 percent to 860,000, including an increase of 2800 in the medical device sector. However, Korean medical device start-ups, which are small in size compared to those in other developed countries, lack the capacity to invest in private R&D, and the institutional basis for promoting new industry fusion is weak. As a result, it is difficult to secure skilled professionals. Therefore, with the introduction of a graduate school for the medical device industry, it is expected that the professionalization of the Korean medical device start-up business and demand for labor will be achieved by fostering pre-emptive and customized medical device specialists. The introduction of the graduate school will contribute to rapid market growth by strengthening the site-centered human resource development function by providing advanced and diversified programs.

Second, support for the development of hospital-enterprise-linked medical devices technology should be expanded to increase marketability. If hospitals, which are a major consumer of medical devices, establish a cooperative system in which clinicians and consultants participate in the development of medical devices, the reliability of medical device start-up products will be enhanced.

Since such products are newly developed medical equipment, the scientific and clinical grounds are insufficient and the use rate in Korean medical institutions is low. Therefore, if the ideas and clinical experience of a hospital are linked to the research and development of a company, a medical device that meets customer needs will be developed. This will ensure marketability and reliability of medical device start-up products. Third, it is necessary to conduct intensive consulting for companies to commercialize medical device products. To this end, it should strengthen initial medical device start-up support in cooperation with the Bio-health Innovation Start-up Center. It is necessary to conduct basic training for the medical device industry by holding a briefing session for start-ups, and to concentrate consultation on practical details after deriving the difficulties faced by start-ups.

The limitations of this study are as follows: In the case of medical device companies, no distinction has been made between the employees of existing companies and start-ups. Medical device companies comprise various types, including those that began as start-ups and succeeded, and foreign medical device companies distributing global medical device products. Therefore, the success factors of medical device start-ups will be different according to the characteristics of medical device companies. In future research, it is necessary to classify and analyze the employees of medical device companies. In addition, the size of the sample as a whole is small, and job distribution of respondents is focused on the employees of medical device companies. Thus, it will be possible to make more objective conclusions in future research if we enlarge the sample size and job distribution is appropriately distributed and analyzed.

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Appendix A

Table A1. Questionnaire Sample. Here are five areas on the key factors for medical device start-up success. Please mark (✓) to indicate their degree of importance.

Item (A)	A Is Important								1	B Is Important								Item (B)
	9	8	7	6	5	4	3	2		2	3	4	5	6	7	8	9	
Entrepreneurial skills																		Technical skills
Entrepreneurial skills																		Marketability
Entrepreneurial skills																		Funds
Technical skills																		Marketability
Technical skills																		Funds
Marketability																		Funds

Note: 1: equal, 3: low importance, 5: important, 7: very important, 9: extremely important.

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