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Original Article

Success Factors in the Tissue Engineering Industry, an Analysis of the Market in Iran

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Abstract

Introduction: Tissue engineering is a field with enormous potential to revolutionize human treatment and medical practices. Despite this potential, the penetration of tissue-engineered products has not met expectations. Identifying the critical success factors is a good starting point to address this issue and find effective solutions. This study attempts to identify and quantify the critical success factors for the tissue engineering industry, and to determine which of these factors have the most significant impact on creating value for customers.

Materials and Methods: The results of the current study were obtained using mixed methods to collect data from customers and experts, mapping data into a network structure, conducting pairwise comparison surveys, and using the Analytic Network Process (ANP) to prioritize identified factors. Finally, the critical success factors were extracted based on their relative significance.

Results: We found out that manufacturing and R&D as well as management are the most critical activities whose high performance is essential for conquering the market. The results also suggest that expert feedback, cost management, overall product quality, brand, as well as credit and reimbursement plans are the critical success factors of the tissue engineering industry.

Conclusions: The outcome of this study suggests that in order to succeed in the tissue engineering industry, organizations must closely focus on expert feedback, overall product quality, brand image, and the availability of credit or reimbursement plans. They should also adjust their costs and, consequently, their prices in comparison to alternative products.

Keywords: Tissue Engineering, Regenerative Medicine, Critical Success Factors, Commercialization, Quantitative Analyses, Value Network

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Introduction

Over many centuries, people have dreamed of an era when it is possible to repair, replace, or regenerate tissues or organs. Despite how appealing it may seem, such practices have always been limited to the human imagination. However, the advancement of technology and medical science in the last couple of decades has opened up a whole new avenue to the realization of that dream; tissue engineering (TE).

This innovative field seems to be quite promising as it aims to remove some of the traditional limitations of medical science. Nowadays, by recognizing the vast potential of this emerging field, a large number of scientists, engineers, and clinicians are cooperating to address patients' unmet needs, leading to a year-by-year growth in tissue engineering global market value.[1-3] Additionally, based on previous studies and several market trends, it is predicted that the field of TE will continue to grow for the years to come, and it will consequently create numerous significant opportunities for various branches of medicine.[4,5]

Despite the potential benefits of tissue-engineered products (TEPs), their widespread use is limited because of various challenges. Physicians tend to avoid using them, while investors are hesitant to fund the development of new products due to concerns about high development costs, complex regulatory procedures, limited target populations, potential risks associated with their use, and the absence of well-developed reimbursement plans. These challenges have acted as significant barriers to the widespread adoption of TEPs.[6-9]

To overcome these problems, it is important to identify the root causes of the challenges, develop a plan to address them, and execute that plan effectively. However, in real-world situations where capital, labor, and time are scarce, organizations need to allocate their resources toward the most critical problems, which involves identifying critical success factors (CSFs). In other words, for an efficient allocation of resources, selection of the right course of action and successful fulfillment of goals and objectives, concentrating on key areas that are crucial to delivering success is highly recommended and is a good starting point to finding proper solutions.[10,11]

One effective approach to identifying CSFs is to adopt a customer-centric perspective. Placing customers at the center of a business and understanding their needs is essential for creating value, especially in fields like TE, where products often fail to meet the economic break-even point.[12,13] It is thus highly recommended that researchers and investigators analyze the market and identify customer preferences even before developing initial concepts. O'Donnell et al. similarly reasoned that the "bench to human application" possesses many hurdles. In order to successfully avoid them, one should implement the "bedside to bench and back again" approach allowing researchers to concentrate on customer needs and preferences. Such a procedure would improve the quality of decision-making and therefore increase the probability of success.[6]

The purpose of this study is to identify the CSFs for the tissue engineering industry, which can benefit various players in the field. However, the real value added by the research lies in quantifying the magnitude of those CSFs. That is, determining which factor is more important for creating value for customers. By doing so, businesses can allocate their resources and investments more efficiently to focus on the areas that have the most significant impact on the value creation process. This strategic approach can help businesses stand out from their competitors and gain a competitive edge in the market.

Materials and Methods

Phase One: Understanding the Problem and Defining the Conceptual Framework

Our goal is to identify and quantify the critical success factors for the tissue engineering industry, and to determine which of these factors have the most significant impact on creating value for customers. In order to achieve this, first we need to define value and its relationship with critical success factors.

"Economic value is created when a producer combines resources such as labor, capital, raw materials, and purchased components to make a product whose perceived benefit exceeds the cost incurred in making the product. The economic value created is thus the difference between the perceived benefit and cost".[14]

Therefore, a producer can create economic value by combining various resources, activities, and features, which we will refer to as "*value-generation factors*." These factors are the drivers that enable a company to create value and can be classified into two categories: threshold features and critical success factors. Threshold features represent the minimum requirements a company needs to meet to remain competitive, while critical success factors are the key drivers that distinguish a company from its competitors and enable it to create superior value for customers.[12]

Phase Two: Choosing an Analytical Approach

After reviewing a handful of techniques and based on the structure of the conceptual framework shown in Figure 1, we concluded that the Analytic Network Process (ANP) is an appropriate option for measuring the relative significance of each value-generation factor.

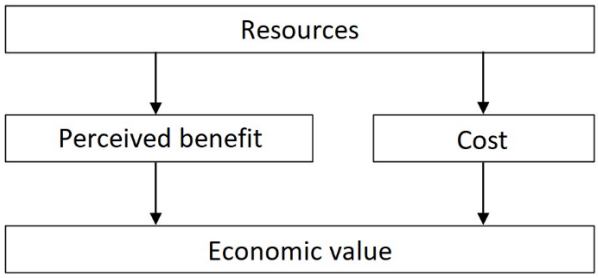

Figure 1. Conceptual Model. This graph tells us that a change in the resource configuration leads to a change in the economic value created by a firm. Optimizing resources or how they interact can increase the perceived benefit or reduce the cost and eventually enhance a firm chance of success in the marketplace.

Phase Three: Data Requirements

In this phase, we determined the kind of data needed to solve the problem based on the analytical approach chosen in the previous phase. We decided to use both customer and expert points of view to identify and prioritize the value-generation factors.

Phase Four: Data Collection-Part One

As shown in Table 1, we used mixed methods to collect the required data. The reasons behind this decision were "Researchers engaging in mixed methods can establish a more complete understanding of an issue" and "Taking a non-purist, or compatibilist or mixed position allows researchers to mix and match design components that offer the best chance of answering their specific research questions".[15,16]

Table 1. Data collection

Target group	Method	Data Type	Section	Purpose
	Document Review	Secondary - Qualitative	2.4	Identifying the value-generation factors in the TE industry
Experts	Semi-structured interview	Primary - Qualitative	2.4	Identifying the value-generation factors in the TE industry
	Pairwise Comparison Surveys	Primary - Quantitative	2.6	Measuring the relative significance of identified value-generation factors
	Five-point Likert scale Questionnaire	Primary - Quantitative	2.8	Evaluating the results
Customers	Semi-structured interview	Primary - Qualitative	2.4	Identifying benefit drivers in the TE industry
	Pairwise Comparison Surveys	Primary - Quantitative	2.6	Measuring the relative significance of identified benefit drivers

The phase four began with a complete review of the related literature on tissue engineering. This step helped us accurately choose the items we were going to discuss in the interview section. After that, two independent groups were selected using the purposive sampling technique; a group of customers (n = 5) and a group of experts (n = 6), both "have the knowledge and practical experience with the matter".[17] The customer group included Iranian physicians and scientists who had employed tissue-engineered products in their practices. In the meantime, the experts were intentionally selected from top executives, management, and marketing teams in Iran who also were familiar with the regulations and approval procedures in the biotechnology sector. As the starting point of our primary data collection, we interviewed both experts and customers to gather information about the value-generation factors in the TE industry.

Phase Five: Data Wrangling-Mapping Data into a Network Structure

The collected data, however, was unstructured and could not be used in its primary form. We needed it to be adjusted in a way that could be easily inserted into the conceptual framework introduced earlier. To resolve this issue and in order to give a meaningful structure to the collected data, we mapped it into four separate yet interconnected layers. As shown in Table 2, Layer 1 as the parent and Layer 2 as the sub-category of the benefit drivers are those features valued by customers and directly determine the price that a customer is willing to pay if there is only a single source of supply. They are essentially the proxy of the perceived benefits in our model. Layer 3 and Layer 4, on the other hand, are those activities and resources that give an organization the ability to deliver the given benefit drivers to the customers and thus are the causes of value creation in the TE industry. Eventually, by inserting the structured data into the conceptual framework, the Value Network shown in Figure 2 has been established.

Phase Six: Data Collection-Part Two

Two pairwise comparison surveys were conducted. The first one focused on measuring the relative significance of benefit drivers shown in Table 2 based on customer perspective. The second survey, on the other hand, was administered to the expert group to measure the relative significance of all value-generation factors demonstrated in both Table 2 and Table 3. By combining the opinions of the customer and expert groups, we tried to address the assorted concerns of all parties involved in the various stages of both production and commercialization, such as regulators, since the expert group included people familiar with the regulations and approval procedures.

Phase Seven: Data Analysis-Prioritization of the Identified Factors

In this phase, using the ANP method, we tried to calculate the relative significance of each factor identified in previous steps. First, by entering the gathered data into pairwise comparison matrices followed by synthesizing the comparisons for the identical nodes, we aimed to estimate the local priority vectors and the consistency ratios. Second, to calculate each element's global priority, the unweighted, weighted, and limit super-matrix were developed, respectively. Finally, the results shown in Figure 3 and Figure 4 were obtained by normalizing values in the given matrix.

Phase Eight: Evaluation

On the one hand, the reliability of the data was measured using consistency ratios estimated earlier. According to Saaty, a CR value of 0.05 or less for a 3-by-3 matrix, 0.08 for a 4-by-4 matrix, and 0.1 for larger matrices are considered to be acceptable.[18] Since the CR values for all matrices were lower than 0.05, we can say that the collected data is consistent and thus reliable.

To measure the validity of the data, a questionnaire was created based on the five-point Likert scale (1 = Strongly disagree to 5 = Strongly agree). With this approach, it is possible to measure the experts' agreement level in both Figure 3 and Figure 4. Accordingly, two One-sample t-tests were conducted to compare the average level of agreement with an acceptable threshold to validate the outcome. The Null

Table 2. Benefit Drivers in the Tissue Engineering Industry

Layer 1	Layer 2
Quality (v_2)	Ease of Installation, Operation, and Maintenance (v_7) Performance and Effectiveness (v_8) Durability (v_9) Aesthetics (v_{10}) Safety (v_{11})
Before Delivery Characteristics (v_3)	Process of Ordering (v_{12}) Speed of Delivery (v_{13}) Credits and Reimbursement (v_{14})
After Delivery Characteristics (v_4)	Complementors (v_{15}) Customer Training and Consulting (v_{16}) Warranties and Maintenance Contracts (v_{17})
Intangible Features (v_5)	Brand (v_{18}) Reputation (v_{19}) Expert Opinions (v_{20})

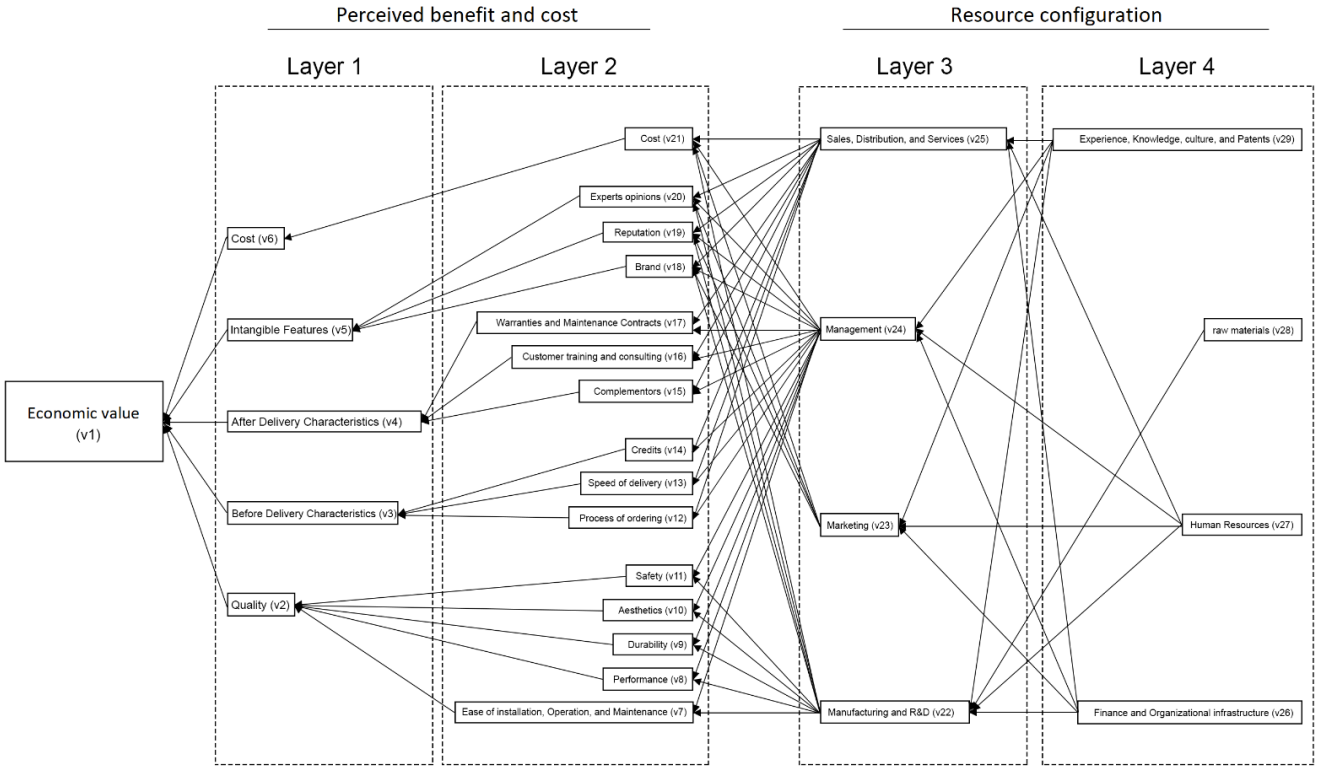

Figure 2. Value Network for the Tissue Engineering Industry (based on the conceptual framework).

Table 3. Resources and Activities Possessed by the TE Organizations

Layer 3 (Activities)	Layer 4 (Resources)
Manufacturing and R&D (v_{22})	Finance and Organizational Infrastructure (v_{26})
Marketing (v_{23})	Human Resources (v_{27})
Management (v_{24})	Raw Materials (v_{28})
Sales, Distribution, and Services (v_{25})	Experience, Knowledge, Culture, and Patents (v_{29})

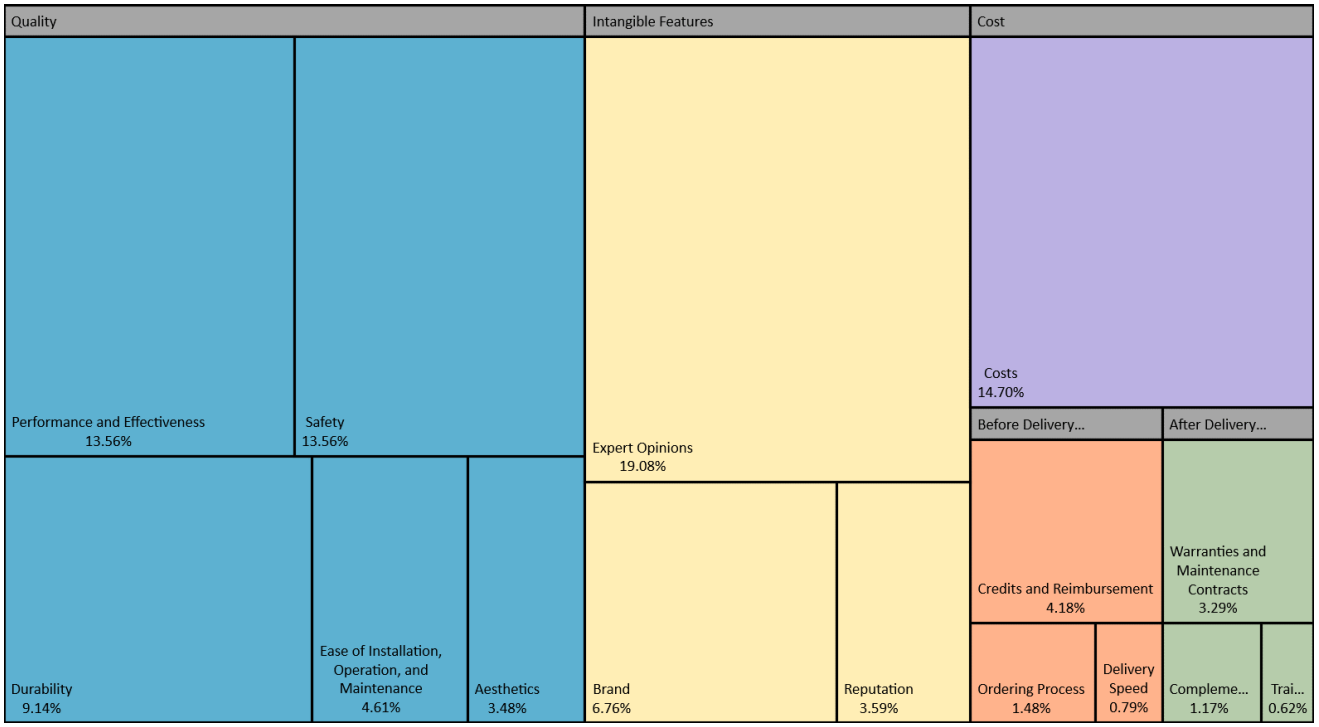

Figure 3. Relative Significance of Features Determining the Levels of Value Creation in the TE Industry.

and alternative hypotheses can be stated as follows:

$$\begin{cases} H_0: the\ average\ level\ of\ agreement\ \leq 3 \\ H_a: the\ average\ level\ of\ agreement\ > 3 \end{cases} \quad \alpha = 0.05 \quad \text{(Equation 1)}$$

Considering the P-values demonstrated in Table 4, which are less than α = 0.05, the null hypotheses are rejected. Therefore, we can say that the results of the two Figures are valid. However, looking at the values, one can say that the agreement level on the results of Figure 4 is somewhat lower than the agreement level on the results of Figure 3. After reanalyzing the information gathered from the interview section, we think this might be due to the relatively low position of the marketing in Figure 4.

Phase Nine: Extraction of Critical Success Factors (CSFs)

Although each value-generation factor shown in Figure 3 and Figure 4 has its own unique impact on the success of a TEP, some factors demand more profound attention since they possess higher relative significance. To extract them accurately, we can select factors with a relative significance higher than the mean in the confidence level of 95%. The critical success factors are shown in Table 5.

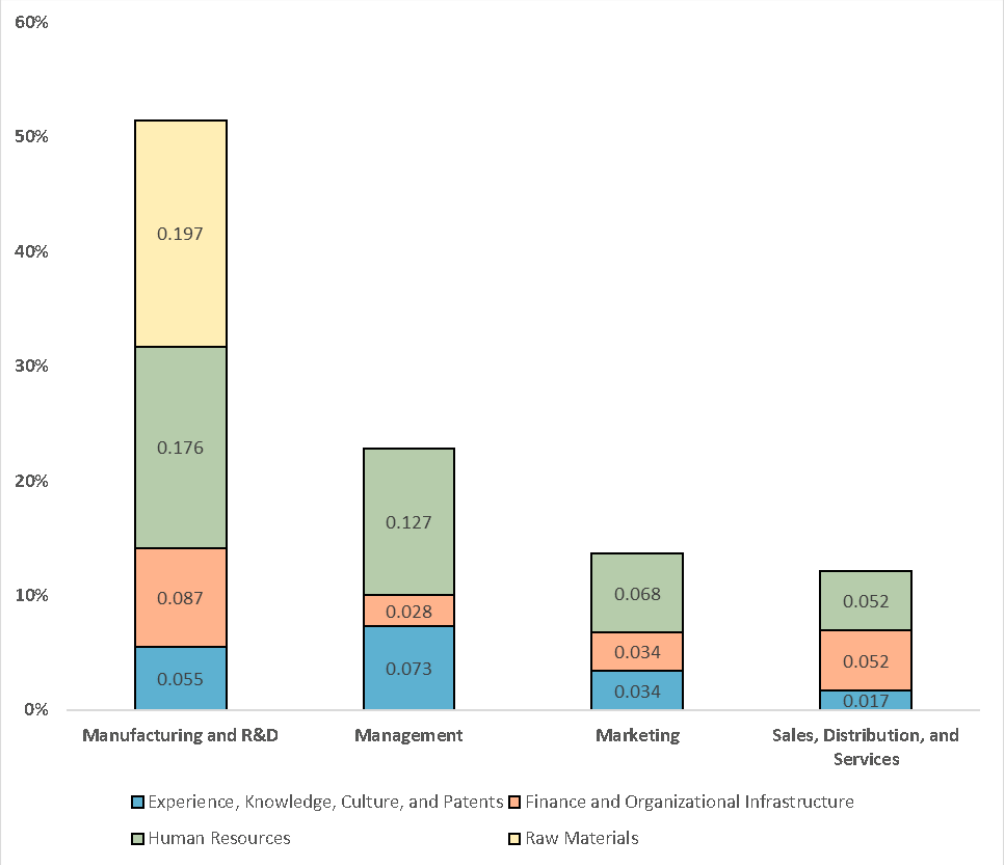

Figure 4. Relative Significance of Resources and Activities in the TE Industry.

Table 4. Results of the One-sample t-tests for Measuring the Validity of the Outcome

Figure	Mean	Variance	df	t-statistic	t-critical (one-tail)	P-value (one-tail)	Mean difference
3	4	0.4	5	3.873	2.015	0.006	1
4	3.5	0.3	5	2.236	2.015	0.038	0.5

Table 5. Critical Success Factors of the TE Industry (ordered based on their RS)

	Critical success factor
Features	I. expert opinions, II. costs, III. performance and effectiveness, IV. safety, V. durability, VI. brand, VII. ease of installation, operation, and maintenance (ease of use), VIII. credits and reimbursement
Activities	I. manufacturing and R&D, II. management

Results

Perceived Benefit and Cost

The chart illustrated in Figure 3 compares the relative significance (RS) of characteristics that determine the levels of value creation in the tissue engineering industry. While each feature or characteristic in the chart makes its own unique contribution to the creation of a successful TEP, some of them demand closer attention since they possess

higher levels of RS. Overall, it is clear that quality, intangible features, and cost have the greatest impact on the value-creation process. The more attention they receive, the more chances of success there are.

Looking at the information in more detail, we can see that expert opinions, costs, performance and effectiveness, safety, durability, and brand by holding nearly four-fifths of the total RS, respectively, are the most important features in the TE industry. If a product is planned to achieve success in this field, producers must put these characteristics at the center of their attention and, by refining them try to achieve higher standards than their rivals.

The result signifies that expert opinions, as the most important feature in the value creation process (with 19% RS), have a notable role in the acceptance of a TEP and, thus, its success. The opinions of physicians, scientists, researchers, and other experts in this field, or their attitude toward a specific TEP could dramatically change the product fate in the market. By being the second most significant characteristic and having roughly 15% RS, associated costs also heavily influence the value-creation process in this field. It means that effective financial planning and cost management is an essential skill in this field. Likewise, performance and effectiveness, safety, and durability, as the subsets of quality, possess 14%, 14%, and 10% of the total RS respectively. It is noteworthy that the overall relative significance of quality is higher than any other group in the chart, implying that TEP customers value the quality of the products more than anything. Besides, having excellent quality will facilitate the approval procedures run by regulators. Finally, the sixth place of the brand among the fifteen features of the chart could imply that possessing a well-known image among the public, experts, and physicians will help producers have a commercially successful product in the market.

Meanwhile, there are other characteristics that are not as significant as the ones discussed earlier; they are called threshold features or minimum requirements. That means they are needed for an organization to achieve parity with rivals in the market, yet they are not the sources of competitive advantage and cannot establish superiority. To be able to clearly distinguish threshold features from critical success factors, the Table 5 was created containing both critical features and activities.

Activities and Resources

Similar to Figure 3, the chart illustrated in Figure 4 also contains information about the relative significance of value-generation factors in the TE industry. However, Figure 4 concentrates on activities and resources needed to create value. In fact, using these resources and activities, organizations are able to create the fifteen features discussed earlier. From an overall perspective, it is evident that manufacturing and R&D (referred to as manufacturing for simplicity) as well as management hold the first and second place, respectively when it comes to the most important activities in the TE industry.

Holding the first place, manufacturing with nearly 50% RS signifies that this activity has the biggest influence on the value creation process. It also means that the features demonstrated in Figure 3 are more affected by manufacturing than any other activity in Figure 4. Therefore, in order to achieve a competitive advantage, executives and managers must pay exceptional attention to their manufacturing systems. Following this, we can see that management, as the second most important activity in the TE industry and having almost 25% RS, also plays an essential role when it comes to being successful in this field. It is noteworthy that these activities together possess around 75% of the total RS, meaning they need closer attention than any other activity in the chart. Meanwhile, we should know that each activity alone, no matter how important it is, is insufficient for the success of a product in this field. One should consider those activities together as a whole, yet prioritized as demonstrated in Figure 4. Although marketing as well as sales, distribution and services have notable roles in the creation of an economic value, they are not as significant as the first two, and they can be called threshold activities.

Examining the information in more detail, it becomes noticeable that all four activities demonstrated in Figure 4 heavily rely on human resources. About one-third of the manufacturing's performance-cost ratio and nearly half of each remaining activity's performance-cost ratio are directly affected by human resources. This signifies that tissue engineering, as a labor-centric field, is highly dependent on various features of its workforce, such as knowledge and experience. As a result, companies with a more skilled workforce certainly have higher chances of conquering the market.

Discussion

Our study highlights the importance of several critical features in the TE industry that have a strong impact on customer attraction and ultimately the economic value of TEPs. These features include expert feedback, overall quality, brand perception, as well as credit and reimbursement plans.

Recommendations from other experts play a crucial role in shaping the perception and decision-making process of physicians and scientists (customers for short) in the TE industry. Producers should be aware of this influence and strive to gain positive feedback from experts to improve their products' market performance. The study also emphasizes the importance of product quality, which aligns with the findings of O'Donnell et al. The evaluation of potential risks by physicians poses a significant barrier to TEP adoption. Therefore, producers should prioritize refining product

characteristics such as performance and effectiveness, safety, as well as ability to fit into the procedures of the operating room in order to create higher economic value and boost customer confidence.[6] Brand perception is another critical factor that can sway customer decisions. Finally, the availability of credit and reimbursement plans for TEPs can increase their attractiveness to customers. We recommend that organizations, especially new entrants, focus on developing products that will be eligible for such support. By addressing these factors, producers in the TE industry can improve their chances of success, create higher economic value, and contribute to the overall growth and advancement of the tissue engineering field.

Our findings also demonstrate that having firm control over the cost structure can boost a company's competitive position in this area, as previously mentioned in other studies. Besides, the cost can indirectly influence the customer decision-making process by changing the price, and thus plays a crucial role in the successful end of a product. As with the Dermagraft, it is believed that the non-competitive price is one of the reasons shattered the high expectation set for this skin substitute. Therefore, TEPs must have reasonable pricing in comparison to their competitors.[6,19,20]

Pangarkar et al. similarly stated that effective financial planning and cost management could have saved Advanced Tissue Science, Inc. from its tragic end.[21] Likewise, O'Donnell et al. as well as Davies et al. showed that one of the major barriers to the widespread adoption of TEPs is the cost incurred in making those products.

According to the results, the two most important activities in the TE industry are manufacturing and management. These two could determine whether a company succeeds or fails by impacting every single essential feature in Figure 3. An organization with an efficient and well-designed manufacturing system has greater control over the cost and perceived benefit, so it is easier to compete in a competitive environment. Furthermore, management decisions and strategies influence almost every activity or process in organizations, and thus every single feature such as brand or product performance. Many internal problems and issues can be easily addressed by simply making the correct management decisions and strategies.

When it comes to manufacturing related activities, Davies et al. stated the most significant barrier to the widespread adoption of cell therapies is manufacturing-related issues. If products are planned to achieve success in this field, various issues, and on top of them manufacturing-related problems, should be addressed.[8] Martin, Smith, and Wendt also think that the reason behind the slow penetration of TEPs into the marketplace stems from production procedures. They claim that bioreactor-based systems can be used to leverage cell-based grafts as therapeutic solutions. Such an approach not only could reduce the cost in the long run, but also enhances the overall quality of the final product.[22]

Our study suggests that producers should devote a greater proportion of their capital, labor, and time to improving manufacturing and management processes. We believe that appropriate management decisions and strategies, as well as efficient and effective manufacturing systems, will address many internal problems, such as scale-up or safety-related issues, unfavorable price-performance ratios, or a lack of well-developed value propositions. However, if the performance-cost ratio of an activity is already satisfactory, the company should allocate its assets to improve the performance-cost ratio of other activities.

The outcome of this study makes a unique contribution to the current literature on tissue engineering and health economics by conducting a quantitative analysis using a combination of both customer and expert perspectives. In addition, due to the strategic nature of our findings, researchers, managers, or even executives could benefit from the results. For instance, it is possible to deploy the findings as a starting point to design a comprehensive, detailed roadmap. Numerous studies, like those conducted by O'Donnell et al. (2019), Davies et al. (2017), and Martin, Smith, and Wendt (2009), suggest that in order to deal with external and internal problems, one must create a roadmap to guide employees from the initial concepts to the widespread roll-out of the products.[6,8,22] With such a paradigm, companies can tailor their activities to market needs and choose the smoothest way to achieve their objectives.

At the end, the study is primarily limited due to the small number of respondents and participants. We collected the majority of our quantitative data using pairwise comparison surveys, which helped us increase the accuracy level. However, there is a disadvantage to conducting such a survey: it requires many comparisons, demanding significantly more time to complete the surveys. Consequently, we were forced to abandon many of our initial data collection targets on both the customer and expert sides. As a result, we highly advise future research to strike a balance between the accuracy and the number of respondents. Furthermore, our assessment is a short-term evaluation of the TE industry, which means that dynamic aspects of the competitive environment, such as changes in customer preferences, cannot be revealed in a single appraisal.

Conclusion

Back in 1998, when Advanced Tissue Science, Inc. first introduced the Dermagraft, no one could imagine that the company would end up liquidated in just five years.[21] What could have been possibly done to avoid such a loss? Or, how to be successful in the tissue engineering industry?

To prevent such losses and achieve success in the tissue engineering industry, organizations must closely focus on expert feedback, overall product quality, brand image, and

the availability of credit or reimbursement plans. These factors significantly contribute to creating economic value by shaping customer preferences. Companies should also adjust their costs and, consequently, their prices in comparison to alternative products. Furthermore, optimizing manufacturing and R&D processes, strengthening management, and investing in human resources are essential for driving success in the TE industry. In essence, for efficient resource allocation, choosing the right course of action, and successfully accomplishing goals and objectives, it is highly recommended to concentrate on key areas that drive success. In the case of tissue engineering, these crucial areas are illustrated in Table 5.

Authors' Contributions

All authors contributed equally to this study.

Conflict of Interest Disclosures

The authors declare that they have no conflicts of interest.

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