



## Iran's Leap into the Future; an Exploration of Tissue Engineering Companies: Review Article

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### Abstract

**Background:** This review represents the first comprehensive compilation of data on Iranian commercial, service, and research entities in the field of tissue engineering up to 2024.

**Methods:** Through an extensive search of official websites, 56 companies were identified: 29 commercial enterprises, 17 service providers, and 10 research institutions. The majority (64%) of these companies are headquartered in Tehran, with many established post-2004.

**Results:** Biomaterials account for half of the product portfolio, with 38% of ongoing research focused on this area. Although cell-based products currently make up only 12% of offerings, they are the subject of 38% of current research, indicating significant potential for future growth.

**Conclusion:** This study provides a detailed overview of the development and future prospects of Iran's tissue engineering sector. The key conclusion emphasizes the need for an expanded focus on cell-based therapies and the establishment of stronger regulatory frameworks to facilitate the commercialization of innovative products. The review identifies key research gaps and proposes directions for future study, utilizing a descriptive methodology with in-depth data analysis and theoretical discussion.

**Keywords:** Tissue engineering; Commercial; Service; Research; Company

## Introduction

Tissue engineering is a multidisciplinary field that integrates principles from various scientific domains to repair or replace damaged tissues and organs (1, 2). Since its introduction in 1993, it has marked a transformative era in medical science. Rapid advancements in stem cell research, bio-

materials, and 3D bioprinting have expanded the possibilities for treating complex medical conditions (3-5). Recent studies have demonstrated the application of tissue engineering in regenerating complex organs such as the liver and heart, pushing the boundaries of personalized medicine (6,



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7). This manuscript aimed to provide a comprehensive review of the advancements made by Iranian companies in the field of tissue engineering. Despite the significant progress in this area, few studies have extensively documented the contributions of Iranian companies (8). This paper seeks to address this gap and offer new insights into the current discourse on tissue engineering by enhancing the existing literature on its clinical and industrial applications (9-12).

Iran has a long-standing history of medical science, dating back to 3,000 BC (13). Artificial body parts were in use as early as 5,000 years ago. This rich historical foundation has influenced the development of modern tissue engineering in Iran, paralleling progress in other pioneering nations. The first scientific publication on cartilage tissue engineering in Iran was published in 2000 (14-16). Since then, Iranian companies have made notable contributions to global innovations, particularly in the fields of biomaterials and stem cell research. Recent global studies have recognized Iranian research centers and companies for integrating advanced technologies such as electrospinning and nanomaterials into their product development (17-19). These innovations align with global trends that emphasize tissue scaffolds and bioactive materials to enhance cellular growth and regeneration (20-22).

The increasing interest in tissue engineering among Iranian researchers has spurred the growth of commercial, service, and research companies in this field. Companies like ChitoTech and Treetta have developed products that meet international standards and are recognized across the Middle East and beyond. Tissue Regeneration Corporation, established in 2004, has emerged as a leading manufacturer of bioimplants for bone, skin, tendons, and heart valves. Fanavaran Nanoomeghyas (FNM) specializes in industrial nanofiber production lines, electrospinning equipment, filters, and masks. Royan Stem Cell Technology has achieved notable success in stem cell therapy, particularly in the treatment of skin and cartilage disorders (23-26). The international recognition of these companies and their products reflects Iran's growing promi-

nence in the global tissue engineering sector. Recent collaborations, particularly in stem cell banking and scaffold manufacturing, have positioned Iranian companies to contribute to global clinical trials and research initiatives (17-19).

This study provides a focused examination of 56 Iranian companies operating in the field of tissue engineering, including commercial, service, and research entities (20-22, 27-30). By situating this analysis within the context of global advancements, the study demonstrates how Iran's tissue engineering sector can further align with international trends in biomaterial innovation, personalized medicine, and regulatory compliance for clinical applications. It complements global and regional studies, offering a detailed and country-specific perspective on advancements in the field.

## **Materials and Methods**

### *Compilation of Company List*

We compiled a list of Iranian companies involved in tissue engineering through a systematic internet search conducted in Persian. We used search terms such as "company + tissue engineering," "company + stem cells," and "company + cell." In addition, we set up daily Google Alerts for these terms to capture ongoing developments in real-time. This approach was chosen because it effectively reflects the scope of tissue engineering activities in Iran, while the use of Google Alerts provided a dynamic way to track new information. Alternative methods, such as relying solely on a centralized industry database, were considered but rejected due to the absence of a comprehensive database in Iran.

### *Inclusion Criteria*

- Companies producing scaffold products for clinical, research, or industrial use, using tissue engineering techniques.
- Companies manufacturing cellular products, including normal/stem cells or autologous/allogeneic/xenogeneic cells.
- Companies producing biomaterials and growth factors for clinical, research, or industrial use.

- Companies manufacturing laboratory materials and equipment related to tissue engineering for clinical, research, or industrial use.
- Companies providing services related to tissue engineering, such as scaffold construction, cell banking, and in vivo or in vitro studies.
- Companies engaged in tissue engineering research, even if they have not yet produced a product.

### ***Exclusion Criteria***

- Companies solely engaged in importing and selling materials and equipment related to tissue engineering for clinical, research, or industrial use.
- Companies manufacturing cosmetics, hygiene products, or therapeutic items unrelated to tissue engineering, such as creams and antiseptic solutions.
- Companies mentioned in news sources as manufacturers of tissue engineering products, but for which no additional information or company website could be found.

These criteria were designed to ensure the inclusion of companies directly involved in the production and services of tissue engineering, while excluding entities that focus only on distribution or non-relevant products.

### ***Data Collection***

We collected data from the official websites of the identified companies, categorizing the information into several fields: company name, products/services/research areas, international standards, location, founding year, minimum number of employees, and website address (Tables 1-3). If companies provided an English name, we used it; otherwise, we transcribed their Persian names into English. Products were categorized into four groups: biomaterials, cells, equipment, and laboratory materials. Companies operating in multiple categories were listed accordingly.

### ***Product Classification***

Products were classified in Table 1 based on their production methods and materials. For instance, Sina Cell Company uses biomaterials in its Amniosin and Amniodisk products, but both cells

and biomaterials in its Cell-Amniodisk product. As a result, we categorized these products under both the cell and biomaterial categories. Additionally, products derived from synthetic or biological materials, including growth factors, were categorized as biomaterials. We also identified the types of commercialized cells (autologous, allogeneic, and xenogeneic) based on available website information. However, we were unable to locate detailed information on the specific purposes for which these cells are used or the centers employing them.

### ***Company Information***

Initially, consumer sectors within commercial companies were categorized into three segments: clinical, research, and industrial. However, due to difficulties in precisely defining these sectors for certain companies, we subdivided them into five categories: clinical, research, clinical/research, clinical/industrial, and research/industrial (Table 1). We recorded company headquarters' locations and the minimum number of employees (MNE), as exact employee numbers were often unavailable on company or official websites. MNEs for certain companies, such as the Stem Cell and Regenerative Medicine Institute (SCRAM), Royan ATMP-TDC, Fanavaran Nano Meghyas (FNM), and Kian Immune Cells, were estimated based on their organizational charts, with each listed position representing at least one individual. For research companies without a website, we provided an alternative official source with relevant information.

### ***Limitations***

Several limitations affected data collection for Iranian tissue engineering companies. We were unable to obtain information on company expenditures, spending, or other details from official sources. Additionally, there was a lack of information regarding the research phases of the companies (Table 3). The accuracy of the data was sometimes unclear due to the absence of mandatory requirements for companies to update or complete their websites. To mitigate these gaps, we reached out to companies via the con-

tact emails listed on their websites, but no responses were received. Despite multiple revisions and cross-checks of the available data across various sources, there remains a small margin of error. Iranian companies provide more comprehensive information, such as products, employee numbers, and financial details. Additionally, we encourage the Iranian government to enforce regulations requiring companies to disclose accurate information. Although direct surveys were considered, low response rates made this approach infeasible.

### Statistical Analysis

A chi-square test was used with a significance level of 0.05 to determine any significant associations or dependencies among these variables.

### Results

Our research identified 52 companies operating in the commercial, service, and research sectors. Among them, three companies (Abtinteb Fannavar, Histogentex Mana, and NanoFannavar Khavar) operate across both commercial and service sectors, while one company (Kian Im-

mune Cell) functions in both the service and research sectors. Since these companies span multiple categories, we listed them separately in each relevant table, ultimately analyzing a total of 56 companies.

Table 1 presents 29 commercial companies offering tissue engineering products that met all inclusion criteria. These companies primarily focus on biomaterials (62%) and equipment (32.4%), with a smaller emphasis on cells (11.8%) and laboratory materials (2.9%). Most of these companies cater to the clinical sector, underscoring the field's application in healthcare. Noteworthy companies, such as Alborz Tissue Science and Tissue Regeneration Corporation, have achieved international standards, including GMP and ISO certifications, reflecting their commitment to quality and global competitiveness. The table includes the company name, product type (biomaterials, cells, equipment, and laboratory materials), consumer sector (clinical, research, clinical/research, clinical/industrial, research/industrial), acquired certifications, location, founding year, employee count, and website information.

**Table 1:** Commercial companies in the field of tissue engineering

| Row | Company Name                    | Category      | Consumer sector      | Standards                                                 | Minimum number of employees | Company website                                                       |
|-----|---------------------------------|---------------|----------------------|-----------------------------------------------------------|-----------------------------|-----------------------------------------------------------------------|
| 1   | Abtinteb Fannavar               | Equipment     | Research             | Unfound                                                   | 2                           | <a href="http://abtinteb.ir">http://abtinteb.ir</a>                   |
| 2   | Alborz Tissue Science           | Biomaterials  | Clinical             | American Association of Tissue Banks (AATB)<br>GMP<br>GTP | 7                           | <a href="https://ats-bio.com">https://ats-bio.com</a>                 |
| 3   | Anacell                         | Lab materials | Research             | Unfound                                                   | 3                           | <a href="https://www.anacelltec.com/">https://www.anacelltec.com/</a> |
| 4   | Arad Nano Alvand                | Biomaterials  | Clinical             | Unfound                                                   | Unfound                     | <a href="https://nivasha.ir">https://nivasha.ir</a>                   |
| 5   | Asapharma                       | Biomaterials  | Clinical             | Unfound                                                   | Unfound                     | <a href="http://asapharma.ir">http://asapharma.ir</a>                 |
| 6   | Asian Nanostructures Technology | Equipment     | Research/ Industrial | Unfound                                                   | Unfound                     | <a href="http://anstco.co/">http://anstco.co/</a>                     |
| 7   | Atlas Saze Arya                 | Equipment     | Research/ Industrial | Unfound                                                   | 5                           | <a href="http://www.anstco.com">www.anstco.com</a>                    |
| 8   | Azma Cell Aria                  | Equipment     | Research/ Clinical   | Unfound                                                   | Unfound                     | <a href="https://azmacell.com/">https://azmacell.com/</a>             |
| 9   | Borna Biopharma                 | Biomaterials  | Clinical             | Unfound                                                   | Unfound                     | <a href="http://bornabiopharma.com">http://bornabiopharma.com</a>     |
| 10  | Cell Tech Pharmed               | Cells         | Clinical             | ISO 9001<br>ISO 10015<br>GMP                              | Unfound                     | <a href="http://celltech.ir">http://celltech.ir</a>                   |

Table 1: Continued ...

|    |                                    |                            |                      |                                                                                                                    |         |                                                                                                        |
|----|------------------------------------|----------------------------|----------------------|--------------------------------------------------------------------------------------------------------------------|---------|--------------------------------------------------------------------------------------------------------|
| 11 | Chitotech                          | Biomaterials               | Clinical             | ISO 14001<br>ISO 13485<br>GMP<br>CE                                                                                | Unfound | <a href="https://chitotech.com">https://chitotech.com</a>                                              |
| 12 | Fanavaran Nano<br>Meghyas          | Equipment/<br>Biomaterials | Research/ Clinical   | VTT<br>DMT<br>CE<br>ISO 9001<br>ISO 10002<br>ISO 14001<br>ISO 45001<br>ISO 13485                                   | 40      | <a href="http://fnm.ir">http://fnm.ir</a>                                                              |
| 13 | Fanavarn Sepid<br>Jamegan          | Equipment                  | Research             | ISO 9001<br>ISO 13485<br>GMP                                                                                       | 6       | <a href="https://3medgroup.com/">https://3medgroup.com/</a>                                            |
| 14 | Histogentex Mana                   | Biomaterials               | Research/ Clinical   | Unfound                                                                                                            | 3       | <a href="https://histogentex.com">https://histogentex.com</a>                                          |
| 15 | Iranian Tissue Prod-<br>uct        | Biomaterials               | Clinical             | ISO 13485<br>AATB                                                                                                  | Unfound | <a href="https://www.regen.ir">https://www.regen.ir</a>                                                |
| 16 | Nanoazma                           | Equipment                  | Research/ Industrial | Unfound                                                                                                            | Unfound | <a href="http://nanoazma.com">http://nanoazma.com</a>                                                  |
| 17 | Nofanavaran Setareh<br>Bartar Asia | Equipment                  | Research             | Unfound                                                                                                            | 2       | <a href="https://sooba3d.com">https://sooba3d.com</a>                                                  |
| 18 | Nanofanavaran<br>Khavar            | Biomaterials               | Industrial /Clinical | ISO 9001<br>ISO 1004                                                                                               | 2       | <a href="http://nanokhavar.com/">http://nanokhavar.com/</a>                                            |
| 19 | Nanotar Pak                        | Biomaterials               | Industrial /Clinical | ISO 13485<br>Nelson Labs                                                                                           | Unfound | <a href="https://masknano.com/">https://masknano.com/</a>                                              |
| 20 | Nanoxin                            | Biomaterials               | Industrial /Clinical | ISO 13485<br>Nelson Labs                                                                                           | Unfound | <a href="https://nanoxinco.com/">https://nanoxinco.com/</a>                                            |
| 21 | Omid Afarinan                      | Equipment/<br>Biomaterials | Research/ Clinical   | Unfound                                                                                                            | Unfound | <a href="https://3d-bio.ir">https://3d-bio.ir</a>                                                      |
| 22 | Pishgaman Saze<br>Nano Zist        | Equipment                  | Research             | Unfound                                                                                                            | Unfound | <a href="https://gamaprinter.com">https://gamaprinter.com</a>                                          |
| 23 | Royan Stem Cell<br>Technology      | Cells/ Bio-<br>materials   | Clinical             | ISO 9001<br>ISO 13485<br>ISO 14001<br>OHSAS 18001<br>ISO 14971<br>ISO 14644<br>ISO 10993<br>ISO 10002<br>ISO 10004 | Unfound | <a href="https://www.rsct.ir">https://www.rsct.ir</a>                                                  |
| 24 | SABZ Biomedicals                   | Cells/ Bio-<br>materials   | Clinical/ Research   | ISO 9001                                                                                                           | 4       | <a href="http://www.sabzbiomedicals.com">http://www.sabzbiomedicals.com</a>                            |
| 25 | Sina Cell                          | Cells/ Bio-<br>materials   | Research/ Clinical   | GMP                                                                                                                | Unfound | <a href="https://www.sinacellco.com">https://www.sinacellco.com</a>                                    |
| 26 | Teb Gostar Trita                   | Equipment                  | Research             | Unfound                                                                                                            | Unfound | <a href="http://www.TreataCompany.com">www.TreataCompany.com</a>                                       |
| 27 | Tissue Regeneration<br>Corporation | Biomaterials               | Clinical             | FDA QSR<br>ISO 9001<br>ISO 13485<br>ISO 45001<br>ISO 14001                                                         | Unfound | <a href="https://trcir.com">https://trcir.com</a>                                                      |
| 28 | Tosan Tajhiz                       | Biomaterials               | Industrial /Clinical | ISO 9001<br>ISO 13485<br>CE                                                                                        | Unfound | <a href="https://tosantajhiz.com/Index.aspx/lang/1">https://tosantajhiz.com/<br/>Index.aspx/lang/1</a> |
| 29 | Treetta                            | Biomaterials               | Clinical             | FDA QSR<br>ISO 13485<br>GMP                                                                                        | 18      | <a href="https://www.treetta.com">https://www.treetta.com</a>                                          |

Table 2 provides an overview of 17 companies delivering services in tissue engineering. These companies focus primarily on cell-related services (64%), such as cell banking and therapy, while 36% offer equipment-related services. This highlights the prominence of cellular technologies

within the service sector, supporting both clinical and research applications. The table includes service type, product category (equipment or cells), standards, location, founding year, employee count, and website details.

**Table 2:** Service companies in tissue engineering and regenerative fields

| Row | Company Name                                          | Category         | Standards                                              | Location | Founding year | Minimum number of employees | Company website                                                                         |
|-----|-------------------------------------------------------|------------------|--------------------------------------------------------|----------|---------------|-----------------------------|-----------------------------------------------------------------------------------------|
| 1   | Abtinteb Fannavar                                     | Equipment        | Unfound                                                | Tehran   | 2017          | 2                           | <a href="http://abtinteb.ir">http://abtinteb.ir</a>                                     |
| 2   | Academic Center For Education, Culture And Research   | Cells/ Equipment | Unfound                                                | Tehran   | 2012          | 5                           | <a href="http://mci.ac.ir">http://mci.ac.ir</a>                                         |
| 3   | Avicenna Research Institute                           | Cells/ Equipment | Unfound                                                | Tehran   | 2009          | 5                           | <a href="https://www.avicenna.ac.ir">https://www.avicenna.ac.ir</a>                     |
| 4   | Bonbiotech                                            | Cells/ Equipment | ISO 9001<br>ISO 13485                                  | Tehran   | 2004          | Unfound                     | <a href="https://bonbiotech.ir">https://bonbiotech.ir</a>                               |
| 5   | Ferdowsi Nano-Biotechnology                           | Cells            | Unfound                                                | Mashhad  | 2021          | 3                           | <a href="https://ferdowsi-nanobio.ir">https://ferdowsi-nanobio.ir</a>                   |
| 6   | Histogenotech                                         | Cells/ Equipment | Unfound                                                | Tehran   | About 2002    | 4                           | <a href="https://histogene.ir">https://histogene.ir</a>                                 |
| 7   | Histogentex Mana                                      | Cells/ Equipment | Unfound                                                | Yazd     | 2020          | 3                           | <a href="https://histogentex.com">https://histogentex.com</a>                           |
| 8   | Iranian Biological Resource Center                    | Cells            | ISO 9001                                               | Karaj    | 2007          | Unfound                     | <a href="https://www.ibrc.ir/">https://www.ibrc.ir/</a>                                 |
| 9   | Kian Immune Cell                                      | Cells            | Unfound                                                | Tehran   | 2020          | 10                          | <a href="https://kiacell-immune.com/">https://kiacell-immune.com/</a>                   |
| 10  | Nanofanavar Khavar                                    | Equipment        | ISO 9001<br>ISO 1004                                   | Tehran   | 2011          | 2                           | <a href="http://nanokhavar.com/">http://nanokhavar.com/</a>                             |
| 11  | Pasteur Institute Of Iran                             | Cells            | cGMP                                                   | Tehran   | 1920          | Unfound                     | <a href="https://en.pasteur.ac.ir/">https://en.pasteur.ac.ir/</a>                       |
| 12  | Pishgam Paya Zist                                     | Cells/ Equipment | Unfound                                                | Tehran   | 2014          | 5                           | <a href="https://pishgampayazist.com/">https://pishgampayazist.com/</a>                 |
| 13  | Royan ATMP-TDC                                        | Cells            | GMP<br>ISO 9001<br>OHSAS 18001<br>ISO14001<br>ISO17025 | Tehran   | 2018          | 47                          | <a href="https://www.royanatmp.com/">https://www.royanatmp.com/</a>                     |
| 14  | Royan Biotechnology Research Institute                | Cells            | Unfound                                                | Isfahan  | 2004          | 4                           | <a href="http://isfahan.royan.org/StemCellfrm">http://isfahan.royan.org/StemCellfrm</a> |
| 15  | Stem Cell And Regenerative Medicine Institute (Scram) | Cells            | Unfound                                                | Tabriz   | 2010          | 13                          | <a href="http://scarm.ir">http://scarm.ir</a>                                           |
| 16  | Tissuehub                                             | Cells/ Equipment | Unfound                                                | Tehran   | 2020          | 11                          | <a href="https://tissuehubco.com">https://tissuehubco.com</a>                           |
| 17  | Zist Fanavri Shayan Pars                              | Cells            | Unfound                                                | Shiraz   | 2014          | Unfound                     | <a href="https://sadrabiolab.ir">https://sadrabiolab.ir</a>                             |



Table 3 lists ten research companies in tissue engineering, with a balanced focus on biomaterials (38.5%) and cells (38.5%), while equipment research constitutes 23.1%. This distribution reflects a comprehensive approach to advancing

tissue engineering technologies in Iran. The table includes research fields, product categories, standards, location, founding year, employee count, and website details.

**Table 3:** Research companies in the field of tissue engineering

| Row | Company Name                              | Category                | Location | Founding year | Minimum number of employees | Company website                                                       |
|-----|-------------------------------------------|-------------------------|----------|---------------|-----------------------------|-----------------------------------------------------------------------|
| 1   | Azma Pajohan Zist Yakhte                  | Cells/ Equip-ment       | Shiraz   | 2014          | Unfound                     | Unfound                                                               |
| 2   | Kian Immune Cell                          | Cells                   | Tehran   | 2020          | 10                          | <a href="https://kiacell-immune.com/">https://kiacell-immune.com/</a> |
| 3   | Nanozist Polymer Pars                     | Biomaterials            | Tehran   | 2018          | Unfound                     | <a href="http://panotech.ir">http://panotech.ir</a>                   |
| 4   | Razi Pars Azar Bio-technology             | Equipment               | Tabriz   | 2016          | Unfound                     | Unfound                                                               |
| 5   | Rooein Tan Cellul                         | Cells                   | Tehran   | 2017          | 5                           | Unfound                                                               |
| 6   | Sina Tissue Engineering And Re-generation | Cells/ Bio-materials    | Tehran   | 2015          | Unfound                     | <a href="http://www.sterco.org">http://www.sterco.org</a>             |
| 7   | Soufar Darou                              | Biomaterials            | Tabriz   | 2019          | Unfound                     | Unfound                                                               |
| 8   | Toseeye Paydar Mobtakeran Sivan (TPMS)    | Cells/ Bio-materials    | Shiraz   | 2014          | Unfound                     | <a href="http://www.sivancells.ir">http://www.sivancells.ir</a>       |
| 9   | Zist Fanavari Novin Darman Persia Vista   | Cells                   | Shiraz   | 2014          | Unfound                     | Unfound                                                               |
| 10  | Zist Farayand Tajhiz Sehand               | Biomaterials/ Equipment | Tabriz   | 2020          | Unfound                     | Unfound                                                               |

Table 4 further reveals that commercial companies predominantly focus on biomaterial production, while service companies are primarily centered around cell-related services. Research companies exhibit a balanced interest in cells and biomaterials. A significant association ( $P=0.000$ )

between company type and focus area suggests that the company's sector—commercial, service, or research—plays a key role in determining its specialization within tissue engineering, reflecting strategic choices based on market demand and research opportunities.

**Table 4:** Association between company type and product/service/research category

| Variable     |            | Product category (N(%)) |               |               |              | P-value |
|--------------|------------|-------------------------|---------------|---------------|--------------|---------|
|              |            | Biomaterials            | Cells         | Equipment     | Lab material |         |
| Company type | Commercial | 18<br>(52.9%)           | 4<br>(11.8%)  | 11<br>(32.4%) | 1<br>(2.9%)  | 0.000   |
|              | Service    | 0<br>(0.0%)             | 16<br>(64.0%) | 9<br>(36.0%)  | 0<br>(0.0%)  |         |
|              | Research   | 5<br>(38.5%)            | 5<br>(38.5%)  | 3<br>(23.1%)  | 0<br>(0.0%)  |         |

Table 5 shows that 50% of biomaterials are used clinically, emphasizing their crucial role in patient care. Equipment produced by commercial companies is primarily utilized in research (45.5%) and the research/industrial sectors (27.3%), underscoring its importance in advancing scientific knowledge and industrial applications. Laborato-

ry materials, exclusively used for research (100%), reflect their specialized nature. Cell products are evenly split between clinical (50%) and clinical/research (50%) sectors, highlighting their dual function in both therapeutic treatments and ongoing research.

**Table 5:** Association between product category in commercial companies and consumer sector

| Variable         |              | Consumer sector (N(%)) |               |                   |                     |                        | P-value |
|------------------|--------------|------------------------|---------------|-------------------|---------------------|------------------------|---------|
|                  |              | Clinical               | Research      | Clinical/Research | Clinical/Industrial | In-Research/Industrial |         |
| Product category | Biomaterials | 9<br>(50.0%)           | 0<br>(0.0%)   | 5<br>(27.8%)      | 4<br>(22.2%)        | 0<br>(0.0%)            | 0.004   |
|                  | Cells        | 2<br>(50.0%)           | 0<br>(0.0%)   | 2<br>(50.0%)      | 0<br>(0.0%)         | 0<br>(0.0%)            |         |
|                  | Equipment    | 0<br>(0.0%)            | 5<br>(45.5%)  | 3<br>(27.3%)      | 0<br>(0.0%)         | 3<br>(27.3%)           |         |
|                  | Lab material | 0<br>(0.0%)            | 1<br>(100.0%) | 0<br>(0.0%)       | 0<br>(0.0%)         | 0<br>(0.0%)            |         |

Table 6 shows no significant relationship between the founding year of companies and their product/service/research category ( $P>0.05$ ). The focus areas of companies have evolved consist-

ently over time, independent of when they were established, suggesting steady growth in the tissue engineering sector across all categories.

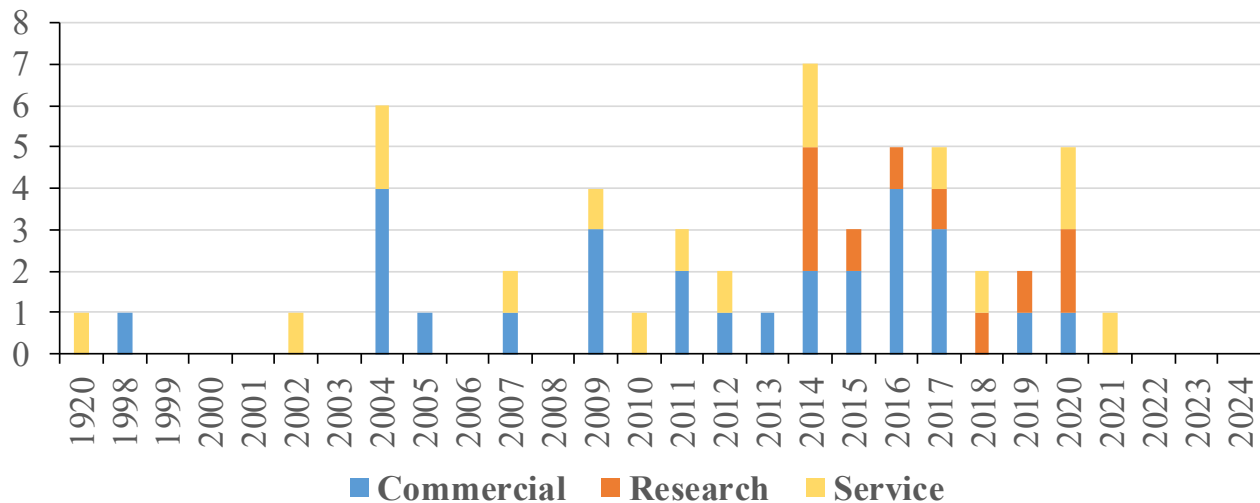
**Table 6:** Association between product/service/research category and founding year in commercial, service, and research companies

| Company type |                   |              | Founding year (n(%)) |              |               |              | P-value |
|--------------|-------------------|--------------|----------------------|--------------|---------------|--------------|---------|
|              |                   |              | Before 2010          | 2011-2016    | After 2016    | Unknown      |         |
| Commercial   | Product category  | Biomaterials | 9<br>(50.0%)         | 7<br>(38.9%) | 1<br>(5.6%)   | 1<br>(5.6%)  | 0.149   |
|              |                   | Cells        | 3<br>(75.0%)         | 1<br>(25.0%) | 0<br>(0.0%)   | 0<br>(0.0%)  |         |
|              |                   | Equipment    | 2<br>(18.2%)         | 4<br>(36.4%) | 3<br>(27.3%)  | 2<br>(18.2%) |         |
|              |                   | Lab material | 0<br>(0.0%)          | 0<br>(0.0%)  | 1<br>(100.0%) | 0<br>(0.0%)  |         |
| Service      | Service category  | Cells        | 7<br>(43.8%)         | 3<br>(18.8%) | 6<br>(37.5%)  | 0<br>(0.0%)  | 0.707   |
|              |                   | Equipment    | 3<br>(33.3%)         | 3<br>(33.3%) | 3<br>(33.3%)  | 0<br>(0.0%)  |         |
| Research     | Research category | Biomaterials | 0<br>(0.0%)          | 2<br>(40.0%) | 3<br>(60.0%)  | 0<br>(0.0%)  | 0.819   |
|              |                   | Cells        | 0<br>(0.0%)          | 3<br>(60.0%) | 2<br>(40.0%)  | 0<br>(0.0%)  |         |
|              |                   | Equipment    | 0<br>(0.0%)          | 1<br>(50.0%) | 1<br>(50.0%)  | 0<br>(0.0%)  |         |



Fig. 1 depicts the growth of tissue engineering companies—commercial, research, and service—from 1920 to 2024. The first service company was established in 1920, with no further companies formed until 1998. The sector began expanding significantly in 2004, with four commercial

and two service companies being registered that year. Since then, tissue engineering companies have been founded almost annually, with research companies entering the field in 2014. However, no new companies were identified between 2021 and 2024.



**Fig. 1:** The number of companies established in the field of tissue engineering from 1920 to 2024

Fig. 2 illustrates the geographical distribution of companies by type. Tehran, the capital of Iran, is home to 36 out of the 52 identified companies, accounting for approximately 64%. Other cities include Tabriz with five companies (9%), Shiraz with four (7%), Isfahan with three (5%), Yazd

with two (3%), and Kish, Qazvin, Shahrood, Zanjan, Mashhad, and Karaj each hosting one company (approximately 2% each). This concentration in Tehran highlights the city's central role in the tissue engineering industry in Iran.



**Fig. 2:** Geographic distribution of commercial, research, and service companies. **A) Commercial companies:** 21 in Tehran (Red), 2 in Isfahan (Green), 1 each in Kish, Gazvin, Tabriz, Shahrood, Yazd, and Zanjan (Orange). **B) Research companies:** 4 in Tehran (Red), 3 each in Shiraz and Tabriz (Green). **C) Service companies:** 11 in Tehran (Red), 1 each in Mashhad, Tabriz, Shiraz, Yazd, Karaj, and Isfahan (Orange)

## Discussion

This study represents the first comprehensive review of commercial, service, and research enterprises within the field of tissue engineering in the Islamic Republic of Iran. Although previous reviews have analyzed scientific publications in this area (17-19), no prior studies have focused on the commercial and research landscape in Iran.

The findings underscore a notable increase in economic activity in tissue engineering, with approximately 50 firms providing products and services related to this sector. Iran's tissue engineering sector is becoming a key component of the healthcare market, particularly in the production of biomaterials and cell-based products, aligning with global trends in tissue engineering. The sector generates annual revenues exceeding \$1.3 billion and has facilitated treatments for over a million patients. In addition, there are 110 companies in the developmental phase, advancing over 55 products through preclinical and FDA-level clinical trials, illustrating the resilience and evolution of the sector following the economic downturn of 2000-2002 (30). However, the lack of public access to financial data limits a comprehensive assessment of the sector's economic impact. While these firms have introduced substantial innovations, a full evaluation of their success remains challenging. Future research should address this by encouraging financial transparency and data-sharing initiatives.

The expansion of research companies, particularly those focused on cell-based therapies, presents significant potential for these treatments to enter clinical trials, contributing to advancements in tissue engineering and fostering international collaboration. About half of the companies have successfully commercialized products, while only 18% are research-focused since 2014. This low percentage suggests an opportunity for growth in research-oriented enterprises. Encouraging such companies to develop commercially viable products could significantly enhance the sector's contributions to healthcare innovation.

Although research companies are actively engaged in the development of cells, biomaterials, and equipment, their products could eventually contribute to commercial ventures. Future research should focus on transforming promising experimental technologies into scalable commercial products. This could involve pilot studies and partnerships with industrial stakeholders to validate the efficacy and scalability of new tissue-engineering innovations.

The report also emphasizes the role of scientific understanding in regulatory decision-making for tissue engineering and regenerative medicine (TE/RM) products (20). Improving the regulatory framework is essential for speeding up product approvals and market entry. Simplifying regulations and providing clearer guidelines for clinical trials and product testing could attract greater investment and promote faster sectoral growth. Addressing gaps in regulatory knowledge would also support the commercialization of new therapies and technologies. A comparative report on the United States' tissue engineering sector (2011-2018) highlights 49 companies and 21 entities in various stages of financial development, collectively generating \$9 billion in 2017 revenue (21). The global trajectory of tissue engineering aligns with the Gartner Hype Cycle, which currently places it in the "enlightenment" phase. This is supported by an increasing number of clinical trials and recent regulatory approvals in both Europe and the U.S. (29). For Iran to maintain pace with global advancements, fostering collaboration between research institutions and commercial enterprises will be crucial. Additionally, establishing an integrated national database to track ongoing clinical trials and product development would enhance transparency. Investors remain willing to invest over \$2 million in tissue engineering companies, but challenges related to regulatory pathways, clinical application translation, and reimbursement structures persist. Investment in this industry has fluctuated over the past decade, with investors targeting a 1-5-year investment horizon before considering exit strategies through mergers and acquisitions (28).

While positive trends in tissue engineering are promising, consistent funding, regulatory clarity, and successful translation of research into commercial products remain key challenges. Investors are ready to commit substantial capital, but they require greater regulatory transparency and predictable timelines for product approvals. Addressing these issues will be vital for scaling Iranian companies to global competitiveness.

Increasing investment in Iran's tissue engineering sector, especially in cell and biomaterial research, could accelerate growth and enable Iranian companies to compete internationally. By 2000, the tissue engineering and stem cell industry had expanded significantly, with over 3,300 permanent workers distributed across 70 companies. A challenging period followed, with a 20% decline in private sector activity and a 90% reduction in capital value. Despite these setbacks, the industry rebounded, surpassing objectives set in the 1990s. Public tissue engineering companies experienced a more than tenfold increase in capital values compared to 2003, with some products entering FDA clinical trials and achieving profitability (27). Iranian companies face similar challenges in scaling operations, and addressing capital shortages will be crucial to sustaining growth. Over the past 25 years, the tissue engineering industry has evolved into the broader field of regenerative medicine, with global private sector activity valued at around \$2.5 billion in 2007 (22).

The tissue engineering sector is experiencing significant expansion, with numerous companies successfully bringing products to market. The intersection of scientific advancements and regulatory decisions is critical to the commercialization process, and addressing gaps in both areas could unlock further growth and innovation. The rising demand for regenerative solutions, as evidenced by global trends, indicates a bright future for the sector (21). Global investors are prepared to support the industry's expansion, despite the hurdles posed by regulatory and translational challenges. These factors suggest that tissue engineering is poised for continued success, with scientific advancements, regulatory improvements,

and financial investment converging to propel the industry forward.

## Conclusion

Ongoing research in cells, biomaterials, and equipment is likely to lead to an increase in tissue-engineering products in the coming years. Iran's strong emphasis on biomaterials positions it to make significant strides in this field. However, expanding efforts in cell-based therapies and clinical applications will be essential for maintaining global competitiveness. While the study provides a detailed analysis of available data, the lack of financial transparency remains a challenge for assessing the sector's economic impact. Policies that encourage financial disclosure will be critical for fostering investor confidence and enabling more accurate market projections. The study also highlights the importance of a streamlined regulatory framework to expedite product approvals. The establishment of a government task force focused on regulatory reform could accelerate the commercialization of tissue-engineering therapies, boosting both domestic and international growth. Future research should focus on overcoming experimental gaps, particularly in scaling technologies for clinical applications. Collaborative efforts between academic institutions and industry leaders will be pivotal in addressing these challenges and ensuring that Iran remains a key player in the global tissue engineering landscape.

## Journalism Ethics considerations

Ethical issues (Including plagiarism, informed consent, misconduct, data fabrication and/or falsification, double publication and/or submission, redundancy, etc.) have been completely observed by the authors.

## Data availability

The datasets generated and/or analyzed during the current study are publicly available.

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## Conflict of interest

The authors declare that there is no conflict of interests.

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