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Advancements of 3D Bioprinting

A market development study

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Abstract

Advancements of 3D Bioprinting – Study on market development

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In most cases new technology emergence does not guarantee overnight success nor is it developed overnight, rather it is a result of industry expertise spanning over several fields of research. 3D bioprinting is an industry that promises revolutionary implications for healthcare and scholars are discussing application areas such as tissue for oncology research, tissue for patient specific drug development and lastly complex organs for implantation. The promises and strides of the industry pose new prospects in healthcare, for instance printing new skin for burn victims & drug development all while being patient specific. The promises of bioprinting are practices that will lead to improved quality of life whether it be in the form of medicine or a new organ. The industry is characterized by fast pace and rapid technological advancements, research has explored these technological advancements and explained them in detail, but information on the market remains scarce. To contribute to filling this gap the thesis explores what the state of the market currently is and what the stage of market development is.

In order to explore how the market has developed and the current state of it a longitudinal case study, in Sweden which is one of the most innovative countries in the world was conducted. Newspaper articles from three news outlets were collected, two of which are Swedens most reputable publishers regarding new technology and business and economic development, the third is an industry specific outlet to biotechnology advancement. This resulted in finding that while the dialog of bioprinting is promising, the degree of readiness remains the same, furthermore it shows that the industry is heavily dependent on external actors to further develop the market and technology. It was also found that there is no shortage in actors spanning across various industries that collaborate with bioprinting firms since not all industries need the full capacity of the technology that is necessary to print complex organ structures. It can be stated that while the bioprinting market is evolving the development of it is in early stages and is far from being established.

Keywords: 3D bioprinting, Market, market developmet, Technology readiness levels,

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Popular scientific summary

3D bioprinting is an emerging technology that can be applied across multiple industries and fields of research. While there is no shortage in both market studies and research directed at 3D bioprinting, combinations of the two are rarely seen. This allows researchers to study a developing industry, which includes both accounting for technology and market activities, thus giving a better understanding of new emerging industry actant behaviors. The scope of how to explore the market can be from the scope of adopting fields as well as strictly 3D bioprinting companies. Opportunities for studying market development for 3D bioprinting are for instance, patient-specific implants, medicine development systems, and regenerative medicine firms, which are all fields that aim to improve quality of life and care.

The industry is often expressed as being highly complex with rapid technological advances forming the industry, which are done with support from industry, academia, and research institutions. One way to address technological development across various fields is through technology readiness levels framework that aims to assess the maturity of technologies in development stages. It is then possible to assess the degree of technological capability across these adopting industries. To assess the development of the industry a content analysis was done through findings across three news outlets in Sweden. Here seven themes were found, and the findings highlight how multidimensional the technology is in terms of application areas. This led to the understanding that the readiness level is defined by industry capability needs as varying areas need distinctive capabilities. Overall, the conclusion is that 3D bioprinting is far from reaching its full potential which is why bioprinting actors deliberately aim towards building strong long-term relationships in order to secure revenue and funding.

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1. Introduction

The following chapter will include, background, problematization, purpose and aims, delimitation, ethical considerations, and disposition.

According to Sleeman et al., (2019) severe life-threatening and life-restrictive diseases prove to be a massive burden on both society and healthcare organisms. As of 2060 it is estimated that 48 million people (47% of global deaths) will be in relation to health-related suffering which is a 87% increase from 2016 (Sleeman et al., 2019). Which begs the question, how can society tackle challenges that the healthcare faces whilst improving the quality of patient care? In recent years, new industries have emerged aiming to address these concerns, with one of them being 3D bioprinting, an industry that promises the production of complex organs, aiding drug development and furthering research in fields such as oncology (Murphy and Atala, 2014). The field has been growing so rapidly that the global market share for bioprinting is expected to be well over 1 billion (USD) by 2025, 30% of which is ascribed from North America (Tong et al., 2021). This growth indicates that the bioprinting sector will expand considerably particularly in medical and dental fields Santoni et al., (2022), which is why studying and understanding the development of the 3D bioprinting market is important. This thesis aims to deliver understanding of market development in the bioprinting industry by reviewing bioprinting literature and addressing the level of technology readiness.

1.1 Background

Additive manufacturing hereby AM as called 3D printing is a heavy contributor to innovation across several fields, such as engineering, manufacturing, and medicine (Murphy and Atala, 2014). 3D printers create three-dimensional objects from digitally organized deposition by consecutively layering material until the object is formed (Murphy, De Coppi and Atala, 2019). AM was first developed in 1980 and is the origin of 3D bioprinting, it is important to note the relationship between the two since bioprinting has relied on the success of conventional 3D printing for investments in the field (Campbell et al., 2018; Combellack, Jessop and Whitaker, 2018; Jovic et al., 2020). Much like AM 3D bioprinting is a layer-by-layer process that uses biomaterial (commonly known as bioink), that enables researchers to print real-life tissue and organs (Murphy and Atala, 2014).

Since the development through AM 3D bioprinting, has had an upswing in attractiveness in clinical applications, mainly healthcare because of the technologies capability to produce complex structures. This allows the technology to create organs that fit the needs of patients on an individual level (Ozbolat, Peng, & Ozbolat, 2016). Market areas for bioprinting include the cosmetics industry, surgical planning, drug development, regenerative medicine, and production of medicine (Murphy, De Coppi and Atala, 2019). However, there are some challenges to be addressed as 3D bioprinting evolves (Murphy, De Coppi and Atala, 2019). One challenge that 3D bioprinting firms need to address is the standardization within its technical domain (actual printers), as the bioprinters need to be specifically designed for one

specific medical task, there is no one printer fits all (Bicudo, Faulkner, & Li, 2021). The deficiency in technical standardization will likely affect market development (Bicudo, Faulkner, & Li, 2021). Another technical difficulty to address is the fact that researchers have only managed to create smaller constructs using bioprinters because the systems and biomaterial structures cannot create vascular networks (Bicudo, Faulkner, & Li, 2021).

The expansion of the bioprinting industry is mainly driven by technological improvements in bioprinters and bioinks, which has driven actors to cultivate and improve their production and distribution capabilities (Tong et al., 2021). To review and analyze the development of these activities on the market we will use the technology readiness level framework. The framework was developed to assess how ready a technology is for usage in projects and in this way, the study will give insights to how developed the industry is (Mankins, 1995).

Aside from technical challenges the industry also faces financial challenges such as influx of investments as a result of exaggerated expectations (Combellack, Jessop and Whitaker, 2018). Because of inflated expectations of bioprinting capabilities several organizations have begun investing in bioprinting technology, with project investments for the entire industry is valued at around $10 billion USD by 2025 (Combellack, Jessop and Whitaker, 2018; Tsao, 2018). However, bioprinting capabilities are still in their developing stages and the market is described as nascent (Ozbolat, Peng, & Ozbolat, 2016). However, the bioprinting industry is rapidly expanding giving a unique opportunity to research the development and maturity of the market. With this expansion bioprinting could become a new standard practice for tissue production in fields such as regenerative medicine, where many printing firms have started commercializing their offerings for example consulting, biomaterial, and printers (Tong et al., 2021). For this report, it is important to understand the market for bioprinting when assessing what the industry of what bioprinting looks like since the literature mainly focuses on the description of the technology regarding processes and biomaterials.

1.2 Problematization

When reviewing existing literature there are a few aspects that have become evident. Firstly, the competitive atmosphere during the 20th century and into the 21st century has become more intense as time has gone on, due to product life cycles shortening as well as increased demand for product variety (Davies et al., 2011). The technological innovations that have been made in todays' society are astounding in many regards, however, these innovations rely on the amalgamation of various actors within the market to further advance these innovations (Reinganum, 1989). 3D bioprinting technology is a blend of several fields and industries, to name a few, manufacturing, life sciences, biology, and biochemistry. The end result is a system that produces living structures through biomaterials either freed-based or in scaffolds through various printing systems and computational processes (Jovic *et al.*, 2020; Bicudo, Faulkner and Li, 2021). However, as the market and its technology are nascent there are indistinct meaning systems, which result in unclear market boundaries, lack of plans and scripts for products as well as insufficient organized logistics to coordinate action (Granqvist, et al., 2013). From this, more personalized innovative product solutions have erupted such as 3D bioprinting, which is

as stated a new market in its infancy but rapidly developing. It is stated that new technology will only succeed if it is accepted by the public, thus there are incentives to clarify bioprinting in a fashion that the public will understand, or the industry risks being dismissed as the technical attributes are hard far too complex. Therefore, it is especially important to account for social aspects (Vijayavenkataraman, et al., 2016).

The advantage of 3D bioprinting is the future technological promises and capabilities, today the technology is described as solving a multitude of problems, with an example being organ shortage solution as well as offering a lower transplant rejection. It also offers personalized medicine for areas such as oncology. This leads to the promise of improved quality of life through several industries such as pharmaceuticals, healthcare, academic, and research institutions (Javaid and Haleem, 2019). The bioprinting market is still in its early stages, with a multitude of investments pouring in, and the technology itself is described as highly complex (Kelly, 2017). Furthermore, literature raises awareness of how technical aspects work, whether it be biomaterials or bioprinters, and subsequently what capabilities are found in theory. Scholars support the notion that bioprinting is an industry with enormous potential and often evaluated the market to be worth over a billion (USD) by mid-2020 (Choudhury, Anand and Naing, 2018; Tsao, 2018; Tong *et al.*, 2021).

While the description of application areas as well as the market trajectory is important, it is just as important to address the gap in the literature which is that very little focus has been on evaluating what/which type of market(s) bioprinting currently serves. An area of research that can address these types of questions and offer insights into development is the market research perspective paired with the technology readiness level perspective. As described by Mankins (1995) technology readiness levels can be seen as a framework to assess the maturity of a technology in its developing stages. The market literature addresses and gives context to market activities and how they can be viewed. When new disruptive innovations are introduced, they can be seen to shift market activities and create entirely new market emergences (Sprong *et al.*, 2021). As mentioned, the literature provides examples of what the technology can accomplish for example printing organs. However, research remains to be done on what markets technology can address in its current stage. To explore this notion there is a to use a framework that captures both market and technology to determine how ready the technology is. Opportunities are still being discussed by scholars, mainly from a technological perspective although it ranges from innovativeness and various industry application areas. To explore this notion there is a to use a framework that captures both market and technology to determine how ready the technology is. Regrettably, little literature addresses what the bioprinting market looks like. However, some studies have focused on mapping actors within the market of 3D bioprinting as seen in (Santoni *et al.*, 2022). But none have addressed market development. Therefore, the research will bridge the gap in the literature by providing an understanding of what the bioprinting market looks like and general market development through the scope of Swedish news outlets.

1.3 Aims & research questions

The aim of this study is to address the gap in the literature by investigating the market development of 3D bioprinting. This entails looking at application areas, TRL and what type of players are active. To address this aim, the following research questions have been constructed:

1. What does the market for the 3D Bioprinting industry look like?
2. What is the stage of market development for the 3D bioprinting technology?

To address these research questions a two-pronged approach is adopted, firstly which relates to both research questions, this thesis addresses this aim by adopting a longitudinal case study approach to better comprehend changes of development within the market over time. In order to establish this understanding, the case will be through the scope of Swedish media outlets, taking a content analysis approach in the treatment of the data. One reason for using a Swedish scope is the acknowledgment of the complexity of investigating industry development from a global scope, this is further expanded upon in Chapter 3. Second, from the theoretical perspective, this thesis supplements what is found in the content analysis through the newspaper articles with existing literature on 3D bioprinting and market development literature. The empirical findings are presented in both quantitative and qualitative fashion, highlighting both the number of occurrences and how this has changed over time, as well as presenting quotes to exemplify the meaning of the occurrence.

1.4 Delimitations

Firstly, the study does not aim to address the technical aspects of 3D bioprinters or biomaterials, rather the study will focus on general market development of the 3D bioprinting industry. However general information regarding bioprinting will be presented although it is not the focus of the study. Second, the time constraints of the study make it unrealistic to try and address market development from a global perspective, which is why a smaller market such as Sweden was chosen. Third, sample size; the sample will not account for the global perspective which is partly because of time constraints but also because the scope of the study would become too comprehensive. The thesis will investigate market development through the scope of Swedish news outlets. Although this approach creates a natural bias as the media outlets are from one country which will be further discussed in limitations.

1.5 Disposition

The first chapter aims at familiarizing the reader with the core subject of the study, as well as presenting purpose & aims, and delimitations. In the second chapter, applicable theories are presented. The main purpose is to present existing research on aspects related to the research questions, such as complex products and systems, technology readiness level, and bioprinting literature.

Chapter 3 is where the methodology is presented, which describes how the study aims at answering the research question.

Chapter 4 presents the empirical findings of the study, mainly interview data as well as reports from newspaper articles. Which is paired with the literature presented in previous sections in Chapter 5. The 5th chapter is made up of a discussion regarding the subject which is based on the analysis.

Conclusions are presented in chapter 6 which are based on analysis and discussion. This is followed by Chapter 7, where recommendations and further research is presented.

2. Theoretical framework

In this chapter relevant frameworks and theories will be presented, these are connected to the study's aims and problematization. The main objective of the chapter is to give the reader understanding of market development, 3D bioprinting, and technology readiness level. The bioprinting literature addresses the first research question of what the market looks like, eg., what type of actors, what application areas, etc. The second stream of literature addresses the second research question, exploring how mature the market is through technology readiness levels.

2.1 Contextualizing Market Development

In recent years there has been a notable upswing in the market research literature that examines market development through social perspectives, this body of literature highlights social constructs that increase the stream of reliable information that actors utilize to lessen market exchange uncertainties (Aldrich & Fiol, 1994; Zuckerman, 1999; Pollock and Rindova, 2003). According to Helgesson & Kjellberg, (2013) markets are sites where actors face the question of value and valuation, meaning an economic exchange that entails efforts to qualify the object that is to be exchanged to value it based on criteria. A broader point of view on market activities is recognizing that policymakers, stakeholders, customers, and suppliers all participate in market practices and influence how it is studied (Viswanathan et al., 2010). When referring to development, the oxford dictionary defines it as a gradual growth over time, something that becomes more advanced or complex or progress when creating something new (*Oxford Advanced American Dictionary*, 2023). Thus, in this study, market development refers to the level of market exchanges between actors. Furthermore in this study, the term 'market development' is used to highlight development in the market rather than development of a market (Sprong *et al.*, 2021).

Various markets are essentially an amalgamation of similar objects or products directed towards individuals or businesses who make valuation decisions, it allows customers to distinguish more easily between objects and products, and take action based on perceived attributes (Bowker & Star, 2000; Granqvist, et al., 2013). As the market grows so does the degree of legitimacy within it, which typically marks the shift from market emergence to maturity, typically related to a prototype of a product or service Navis and Glynn, (2010), this shift can also be seen as gaining investments from other market participants (Granqvist, et al., 2013). It is proven that legitimacy leads to market growth since it inspires other actors to enter the market (Aldrich and Fiol, 1994). Granqvist & Ritvala, (2016) argue that market maturation stems from an increase of legitimacy combined with an upswing in knowledge from new market entrants. Lately this type of maturation has been seen in the food industry with an emergence of plant-based meat firms growing rapidly (Wang *et al.*, 2023). The market has matured due to consumers engagement with the products which allows for more entrants and thus more knowledge to improve further develop the industry (Granqvist, et al., 2013). Firms enter or exit markets because of strategic value, the firms develop new offerings, repositioning the firm, or because the market has

transformed (Granqvist, et al., 2013). Market creation ensues when firms develop new innovations that diverge from the industry, meaning they do not have close replacements, when the product is launched the market is created (Darroch and Miles, 2011). Darroch and Miles, (2011) further argue that by forming a new market the 'market creating innovation' shifts the existing product-market relationship, in market creating contexts the 'innovation' is likely to embody scientific advances and technology resulting in a shift in the technological profile of the industry. Hence, firms that launch the innovation require advanced R&D capabilities such as cutting-edge technology access and skillful workers to operate the technology (Darroch and Miles, 2011).

Market development innovation

Pontikes & Kim, (2017) argue that markets are social constructs where producers and analysts seek to bolster the product or object's value through development. Markets are typically long-lasting largely due to technological transformations, however, they do not always last (Pontikes & Kim, 2017). Sprong *et al.*, (2021) also argue that current markets can experience immense changes, and, in some cases, new markets emerge. For example, the cell phone first represented a portable landline where you could make and take calls while outside of your home, which rapidly transformed to including SMS, emailing, and now essentially being a source of information, or social media deliverance platform, and the cellular phone is now called a smartphone, today, firms that manufacture landlines serve a very narrow market (Pontikes & Hannan, 2014). Another example of when a market has shifted due to innovation can be seen in low-emission automobiles, which emerged as its own market to rival other traditional automobile players in the industry. In this example, low-emission manufacturers faced several challenges in the development such as navigating complex stakeholder networks (e.g., car dealers), health and safety regulations, policymakers, and governments, infrastructure (charging stations), and achieving market legitimacy (Sprong *et al.*, 2021). Hence, manufacturers' market activity/interaction can be seen as reactions to changes in the market environment, as markets are affected by regulations or innovations, which inherently change the actions of managing business operations (Durand, 2006; Kuilman and van Driel, 2013). In conclusion, market development literature highlights the roles of innovation, new technology, and stakeholder interaction.

2.2 3D Bioprinting

Bioprinting entails several intricate processes, including but not limited to computational modeling (software), biomaterial research, biomaterial disposition, and an ensuing maturation of bioprinted products (Leberfinger *et al.*, 2019). Bioprinting uses a digital file as its outline to print the structure layer by layer, in contrast to 3D printing bioprinting uses cells and biomaterials allowing it to make organ and tissue structures which enables living cells to multiply (Mironov, Reis and Derby, 2006). The process of bioprinting can be considered very specialized where biomaterial composition and bioprinting process (software) must be considered when developing constructs (Jamieson *et al.*, 2021). The development of stereolithography in the 80s is seen as the core of modern bioprinting and sparked the

development of far superior printers, bioinks and scaffold materials capable of supporting tissue growth (Chia and Wu, 2015). Today the original expectations of printing have been succeeded with 3D bioprinting being used in both scientific and commercial arenas, examples being, drug supply systems, cosmetics, and printing 3D frameworks to promote tissue growth (Chia and Wu, 2015; Combellack, Jessop and Whitaker, 2018; Jovic *et al.*, 2020). However, the complexity of bioprinting is highlighted in much literature where authors use the timeline for printing fully functioning organs as an example of how far the technology has come (Little and Wallace, 2016). One study by Little and Wallace (2016) claim that the timeline for printing organs such as hearts, kidney and livers are at least a decade away even though it is reported that advancements in the field are being made at a rapid rate.

3D bioprinting can be used to fabricate multifaceted biomedical devices, which is critical in tissue engineering (Seol *et al.*, 2014). Application areas of these devices include, restoration of 3D anatomic defects, reconstruction of organs that have complex 3D microarchitecture such as organs and frameworks for stem cell distinction (Chia and Wu, 2015). One study defines bioprinting as the immediate script of live cells and biomaterials with prearranged layer by layer stacking, using a computer assisted procedure of bioengineered paradigms (Ozbolat, et al., 2016). This has been enabled due to recent research advances that have allowed for 3D printing of bio suitable materials, cells and other supporting components into multifaceted 3D functional living tissue (Murphy and Atala, 2014). Thus, bioprinting provides the potential of creating tailored tissue-engineered structures to address patient illness by offering solid multifaceted organs on demand (Combellack, Jessop and Whitaker, 2018).

The original aims of producing solid 3D polymer models have been succeeded, and today 3D bioprinting is used in a range of scientific and commercial fields such as in drug delivery (Chia and Wu, 2015; Combellack, Jessop and Whitaker, 2018). With this development firms within the bioprinting industry have acknowledged the prospect to supply the health-care sector with patient tailored tissue-engineered structures and the investments are seen in the development and advancement in printer systems and creation of original biomaterials (Chia and Wu, 2015; Combellack, Jessop and Whitaker, 2018). This can be seen in the capabilities of bioprinting today, where several biomaterials and cell types can be produced in close to clinically applicable size, examples of these are cartilage, bone, and skin (Murphy, De Coppi and Atala, 2019).

Bioprinting functions in a multitude of ways as the application and technology dictates what firms use it for (Mironov, Reis and Derby, 2006). There are three fundamental stages of workflow, firstly bioink is selected and prepared to create the ideal fit for the application. Secondly, the bioink is placed correctly in the bioprinter with appropriate printing parameters, then print. Third and last is treating the printed structure in accordance with application need (Lindahl, 2023).

2.2.1 Biomaterial and printing approach

To successfully perform bioprinting there are three essential components, bioink, a suitable bioprinting process and a bioprinter (Leberfinger *et al.*, 2019). Any of the bioprinting processes (extrusion, droplet, and laser-based bioprinting), seen in figure 1, itself or combined can be used for tissue production (Leberfinger *et al.*, 2019).

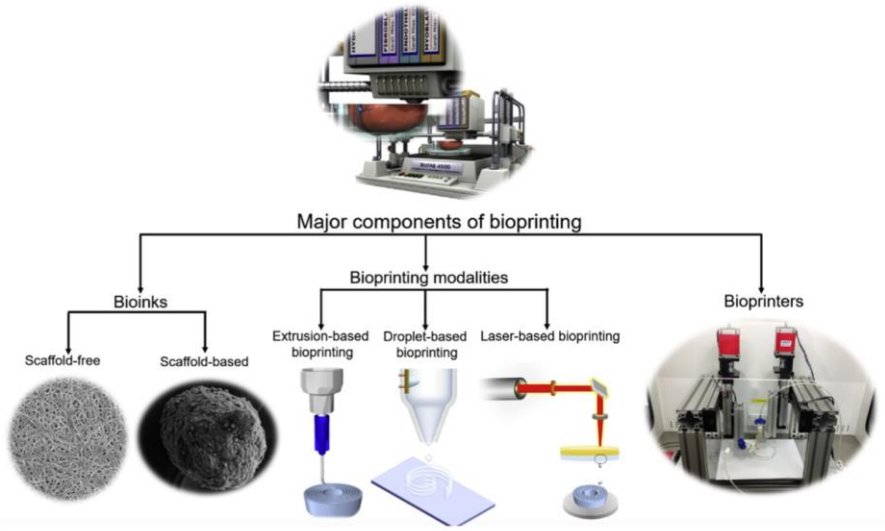

Figure 1 Illustrates the major components of 3D bioprinting presented by (Leberfinger et al.*, 2019).*

Extrusion-based bioprinting hereby EBB is a process where bioink is deposited from a syringe/nozzle-based system that builds onto a platform, the structure that is printed is created based on a CAD design. The design is the foundation for the software so that it can determine the position on the platform where the bioink needs to be extruded, to create the sought-after 3D construct. Extrusion is executed by cylinder-shaped depositions of the biomaterial, which is air-filled or mechanical driven as seen in Figure 1 (Ozbolat and Hospodiuk, 2016).

The vulnerability of the bioink dictates what system is chosen, because the process aims at progressively pushing down the ink without compromising the cells within it. One advantage EBB offers compared to other systems is the printing speed paired with an assortment of bioinks that can be used for the system, both scaffold and scaffold-free can be used (Ozbolat and Hospodiuk, 2016). Furthermore, it offers enhanced structural integrity because it progressively pushes the ink uninterruptedly and is easy to pair with CAD software (Leberfinger *et al.*, 2019).

In contrast to EBB "Droplet-based bioprinting (DBB) manipulates bioink stored in a cartridge to form droplets utilizing gravity, atmospheric pressure, and fluid mechanics, in order to form constructs by controlling fluid properties such as surface tension and viscosity" (Leberfinger et al., 2019). The system stems from conventional paper printing practices and uses 4 varying methods of droplet formations, namely inject, electrohydrodynamic jet, acoustic-droplet-ejection and micro-valve (Leberfinger et al., 2019). With Inkjet being the most popular within bioprinting because of its over-simplified principles of using fluid mechanics, atmospheric

pressure, and gravity to create droplets (Leberfinger et al., 2019). Advantages related to using DBB system from the biomaterial standpoint is its cost efficiency, multi-nozzle capacity, and cell viability (Leberfinger et al., 2019).

Laser-based bioprinting herby LBB prints using a laser pulse that is directed through mirrors on a bioink layer over the substrate. This produces a bubble created by the pressure that is created from the heat, transferring parts of the bioink-stimulating cell-laden droplets to be issued to the substrate (Leberfinger *et al.*, 2019). LBB uses a multi-layer structure and entails two types of processes, namely photopolymerization (stereolithography) and the process of cell transfer, which is laser-induced transfer. The cell transfer process uses the prior mentioned bubble which drives the ink. In contrast, the photopolymerization process uses an ultraviolet laser that cures the hydrogels in a vat (Leberfinger *et al.*, 2019).

According to Leberfinger et al., (2019), the processes offer high cell viability in its initial usage although it is seen to decrease over time. When comparing EBB, DBB, and LBB research finds that LBB is the most complex process as it requires intricate machines and costly controls. The use of a laser also affects the cell viability and material properties, furthermore, the biomaterial needs to be compatible with a multitude of conditions such as mechanics, crosslinking post-printing, and fluids, presenting limitations for the materials (Leberfinger *et al.*, 2019).

Although LBB offers advantages in that it has the highest resolution and precisions of the three processes and can print several materials with worthy cell density giving the prospect of producing multiple cell types (Leberfinger *et al.*, 2019). LBB is the most intricate of the processes which means it is also the most expensive one, it is also unknown what effect the laser has on the cells (Leberfinger *et al.*, 2019).

Hydrogel-based bioinks have several appealing attributes for use as a tissue scaffold, one benefit is that they are biocompatible and typically biodegradable (Gungor-Ozkerim *et al.*, 2018). A majority of hydrogel bioinks have particular cell-binding sites that are sought after for cell attachment, cell spreading, growth, and differentiation (Gungor-Ozkerim *et al.*, 2018). Examples of hydrogel biomaterials are "*alginate, gelatin, collagen, fibrin/fibrinogen, gellan gum, hyaluronic acid (HA), agarose, chitosan, silk, decellularized extracellular matrix (dECM), poly(ethylene glycol) (PEG), and Pluronic,"* (Gungor-Ozkerim *et al.*, P. 917 2018) which all have varying usage.

Scaffold-based methods use biomaterials to produce a short-lasting structure that aims to maintain cell attachment and tissue formation, the approach uses a biomimicry approach where singular components of the structure imitate properties of tissues or organs (Bishop *et al.*, 2017). The scaffold-based printing method is more cost-efficient and scalable because the method requires lower cell density and gives higher resolution in comparison to scaffold-free methods (Ozbolat, 2015). The scaffold-based bioprinting method uses hydrogel-based bioink as well as microcarriers or dECM-based inks, however, the most popular bioink to use is hydrogel (Jamieson *et al.*, 2021). Hydrogel scaffolds have the ability to be manipulated into any shape, size, and form as well as being able to withstand up to a thousand times their dry weight, these

attributes are what make hydrogel so flexible in production and attractive in the eyes of researchers (Jamieson *et al.*, 2021).

In contrast, scaffold-free bioprinting is dependent on tissue independently assembling as it develops, this process relies on the notion that tissue doesn't need a stencil or scaffold because it possesses instinctive mechanisms to create surrounding tissue builds (Jamieson *et al.*, 2021). The scaffold-free approach aims to replicate the embryonic environment and structure development by allowing cells to assemble by themselves (Bishop *et al.*, 2017). This approach in comparison to the scaffold-based approach, is easier on the cells since it avoids using exogenic material, which leads to less toxicity, improved cell viability, and increasing cell to cell interactions as well as reducing the time for maturation post-bioprinting (Jamieson *et al.*, 2021). However drawbacks to the scaffold-free approach include the need for higher cell density which limits printer selection, has low scalability, and has low mechanical reliability since there is no support for the tissue (Ozbolat, 2015).

2.2.2 3D bioprinting market

The 3D bioprinting market is still in the developing stages, however, market and technology forecasts conducted by analysts within leading companies estimate that the market value will be in the tens of billions (Combellack, Jessop and Whitaker, 2018). Its preliminary value is estimated to be achieved by 2027 at $1.8 billion (Combellack, Jessop and Whitaker, 2018; Tsao, 2018). As the bioprinting industry developed reports show that firms focus on different usages, where some firms focus on cellular products and tissue analyses, whereas other firms focus on printer technology and consumables (Jovic *et al.*, 2020).

However, the bioprinting wound market is projected to be valued at $25 billion by 2024 (Elemoso, et al., 2020). Which covers skin grafts, plastic surgery, orthopedic surgery, and field surgery for military or civilians (Elemoso, et al., 2020). In 2014 it was estimated that the skin market for bioprinting would be worth around $1 billion and the market for cartilage was estimated to be worth $130 million by 2024 (Elemoso, et al., 2020). Another emerging market within bioprinting is space experiments, one example is the Swedish company Cellink which has partnered with the company Made in Space. Which is a microgravity manufacturing expert, the partnership aims to explore opportunities for the international space station (Elemoso *et al.*, 2020). Several 3D bioprinting firms have started producing commercially accessible printers, with this it is evident that the bioengineering industry is rapidly developing (Ovsianikov, Yoo and Mironov, 2018).

Market Overview of 3D Bioprinting

As stated previously, the development of the bioprinting market has derived from the success of AM which surpassed its initial market forecast by $1 billion in 2018 (Jovic *et al.*, 2020). Investments and evaluations are propelled by future promises and early presentations of possible applications of the bioprinting tech (Campbell *et al.*, 2018; Tsao, 2018). It is difficult to value companies within the bioprinting industry as they all promise they will be first to

market with tissue printing, which has prodigious revenue potential (Combellack, Jessop and Whitaker, 2018). There have been several market forces that have been driving the global growth rate Jovic *et al.*, (2020), namely production technology progressions and biomaterial innovations with research showing the market share of compound annual growth rate (CAGR) between 15.8% and 20.4% from 2022 to 2030 (*3D Bioprinting Market Trends, Size and Forecast to 2030,* 2023; *3D Bioprinting Market Size & Share Report, 2022 - 2030,* 2023). The forecasted growth is based on emerging and new printing capabilities as well as the expansion of applications that span beyond the medical industry, although the expected growth is the largest in the medical industry (toxicity screening and organ transplants) (Choudhury, et al., 2018). Table 1adopted from Coudhury et al., (2018) describes both bioprinting actors as well as the technology/material they use for their bioprinter. It is seen that EBB (described in the previous chapter) is the most popular mode for existing bioprinters, due to operational simplicity, low maintenance, and set-up costs. The most prevalent biomaterial seen for printing activities is in the form of hydrogel. It is also seen that only a few of the firms offer inkjet printing due to technological challenges (described previously) of achieving high cell densities. As described previously LBB printing promises the highest resolution and cell viability of the different modes is the most uncommon as only one company offers LBB. Proving that cost is a factor that many avoid.

Table 1 Summary of commercially available bioprinters as of 2018 (IPF: Individually Pore Filling; IF: Injection Filling; FDM: Fused Deposition Modelling) (Choudhury, et al., 2018).

Company	Technology & material	Company	Technology & material	Company	Technology & material
3Dynamic Systems	Extrusion	**Cyfuse biomedical**	Kenzan method	**RegenHU**	Extrusion, Inkjet Hydrogel, thermopolymer
Advanced Life Sciences	Extrusion	**Envision TEC**	Extrusion Hydrogel, thermoplastic, ceramic, and metal paste	**Regenovo**	Extrusion
Aether	Extrusion, Droplet jetting, FDM	**GeSiM**	Extrusion, Inkjet, Melt electrospinning	**ROKIT**	Bio-dispenser, FDM
Allevi	Extrusion (hydrogel, Thermoplastics and thermopolymer)	**nScrypt**	Extrusion	**Se3D**	Extrusion
Bio3D Technologies	Extrusion	**Pensees**	Extrusion	**Seraph Robotics**	Piston-driven or pneumatic extrusion, Traditional FDM
CELLINK	Extrusion, Inkjet, and FDM	**REGEMAT 3D**	IPF, IF, FDM	**SunP Biotech**	Extrusion & electromechanical

Exploring the market landscape

The cost of pharmaceutical development is becoming excessively expensive with increasingly strict guidelines on animal testing. This means that pharmaceutical and cosmetic companies are looking for cheaper alternatives for development without conceding results. For bioprinting companies, this proves to be a gap in the market and provides opportunities for firms within the industry. One example is Procter and Gamble, which has banned animal testing on 80% of its products because of legislation (Gordon, 2015). Another gap seen in healthcare is the organ donor waiting lists, such as for dialysis patients who are very costly for the healthcare systems worldwide (Combellack, Jessop and Whitaker, 2018).

Bioprinting has a wide variety of applications that can be used across several industries. First *regenerative medicine* aims to one day produce fully functioning organs that are transplanted in patients. Regenerative medicine is the self-healing process of the human body through the improvement of medicine by healing options possibilities of tissue engineering, meaning creating repair tissues and organs exploitation of cells derived from a patient (Li, 2014). Second *Drug discovery & development*, namely in drug delivery, drug screening, Microarrays and high-throughput screenings, and Absorption, distribution, metabolism, and excretion. In contrast to other options, 3D bioprinted human tissue offers superior spatial controls. Third, *disease control* offers the possibility of molding diseases in vitro so that the disease model is similar to when it's in a human body, with an example being tumor research which often changes quickly (Choudhury, et al., 2018). These application areas of bioprinting have propelled the development of industry processes in recent years. New firms have emerged with aims to exploit the industry, one study finds there are three crucial business models within the bioprinting industry that see new entrants, selling bioprinters, offering contractual bioprinting services, and commencing in partnerships with a party that has a tissue/model of attentiveness (Choudhury, Anand and Naing, 2018).

According to Santoni et al., (2022) Many players are now seeing the value of bioprinting with its widespread application areas and considerable market valuation, in 2014-2015 several new companies entered the bioprinting space with examples spreading from startups, spin-offs and subsidiaries. As the bioprinting market develops it is found that firms for example Cellink, EnvisionTEC, and GesSIM are diverged in their market efforts, which range from printer technology, consumables, or production of cellular products (Jovic *et al.*, 2020). However, even though many studies have studied the potential of bioprinting both by showing market value and by describing technological advances no research has focused on what the market looks like. Reportings show that several firms use bioprinted cartilage, bone, skin, and vessel constructs are used in animal testing, reportings of technology use on humans is sporadic (Jovic *et al.*, 2020). Which begs the questions, what activities are conducted, what current technological capabilities are found in industry and in research. In summary, there is information regarding application areas, technological descriptions and some reportings of technological use, however market development insights remain unexplored.

Furthermore, the bioprinting market faces regulatory issues, challenges and complexities in manufacturing according to a journal article written by (Jovic et al., 2020). Legal aspects of bioprinting are proving to be progressively important as technology is gaining traction across several industries and according to Elemoso et al., (2020), the current laws that govern the industry do not allow actors to mitigate risks related to patients. The laws that govern medicine and medical research does not address the healthcare providers or manufacturers (Elemoso *et al.*, 2020). It is also worth noting that the software and hardware used for bioprinting setup is viewed as medical devices, these fall under the EU MDR framework and will need to be certified before being put to market (Li, 2014). Therefore, this study needs to take regulation into consideration as the scope of the study is to examine what the market looks like and how mature the market is.

Regulatory aspects of bioprinting

This sub-chapter provides an overview of regulatory aspects that concerns bioprinting firms' products and activities. The principle of market regulation is to promote the growth of actors within a framework that permits unbiased and open trade, and it is essential for markets to have such a framework to prevent market collapses (Bailey, 2018). Thus, regulation is considered in the thesis when exploring the market development of the bioprinting industry. As stated bioprinting promises the creation of complex organs based on tissue engineering, however, this creates various different hurdles which are particularly intricate because they related to patients that need new organs to survive (Kelly, 2017). It is the perspective of human health and safety that make regulatory aspects of bioprinting particularly interesting since policymakers are still working on how to classify the outcomes of the systems (Li, 2014), Which is another reason for why regulation is important when studying bioprinting. Furthermore, it is stated that the 3D bioprinting industry will face regulatory challenges for the implantation of tissues and organs since regulatory bodies such as the FDA places the manufacturing methods under the same guidelines as 3D printed medical devices (Murphy, De Coppi and Atala, 2019). In US congress proceedings' the 21st century cures act it is found that:
" Upon request, the FDA must facilitate development and expedite review of regenerative advanced therapies, including cell therapies, therapeutic tissue engineering products, and human cell and tissue products. For a therapy to be eligible, there must be preliminary clinical evidence that the therapy has the potential to address an unmet medical need for a serious condition." (Rep. Bonamici, 2016 sec. 3033).

Thus, to help structure the industry of 3D bioprinting within healthcare the FDA has created guidelines for 3D printer producers (Murphy, De Coppi and Atala, 2019). Within the 'technical Considerations for Additive Manufactured Medical Devices' document it is found that there are a number of regulatory challenges that apply to 3D-bioprinting firms that construct structures with living cells and bio-functioning material (FDA, 2017). The first challenge being that they are fundamentally different from other products paired with having highly complex processes and mechanisms with unknown effects on humans. The second challenge is that tissue structures several components, making it difficult to adhere to regulation definitions (Murphy, De Coppi and Atala, 2019). Slight manufacturing changes could immensely affect

the characteristics of the product due to complexity, which further proves challenging for firms (FDA, 2017). The 3D bioprinting market has had regulatory complexity together with increasing cost. However, with advancements in production technology, biomaterials innovation has given way for new entrants (Jovic *et al.*, 2020).

Since 3D bioprinting is a developing market with high technical features firms operate in uncertainty to when new regulations are imposed from the likes of FDA or EMA, as for regulations for patient matched device PMD, should be in accordance device specific documents (FDA, 2017). For AM PMDs it is a must to include an accompanying healthcare practitioner labeling that addresses, *patient identifier, use* such as surgical guide, and *final design reiteration or form used to manufacture the device* (FDA, 2017). The expiration date for devices or products is decided by imaging date or design finalization, it is also encouraged to include precautions to the label as patients could have had events that impair the performance of the product (FDA, 2017). In summary, countries in the west (EU & US) have no explicit regulatory framework or strategy for bioprinting in countries that drive and develop biofabrication research as well as industry applications (Elemoso *et al.*, 2020). This is further intricate because bioprinting is a never before seen technology in that it combines different techniques from various fields (3D printing, cell biology, and materials science), meaning bioprinting pools challenges from various application areas (Elemoso *et al.*, 2020). Which will be further addressed in the following section.

Challenges and complexities

Seol et al., (2014) claim that whilst traditional tissue engineering methods have proven to be successful in producing several tissue structures clinically, challenges are still a big factor in creating complex compound tissues and organs. Even though tissue engineering has progressed there are challenges that remain which inhibit production of complex structures, such as insufficient scaffold methods that are capable of replicating tissue architecture, accessibility of biomaterial that for tissue production, and methods to provide multiple cell types in a precise fashion (Seol *et al.*, 2014). Choudhury, Anand and Naing., (2018) further argue complex challenges that must be addressed before functioning organs can be produced. Firstly, vascularization to the degree of capillaries: Second, incorporating multiple cell types with precision to create complex structures: third, stable mechanical and structural integrity: fourth, supply structures with nerves: fifth, maturing the printed structure for long-term function (Choudhury, Anand and Naing, 2018). Meanwhile these challenges are undoubtably very complex and difficult to solve, which means those actors who first deliver solutions will gain market advantages. Thus, these challenges will most likely influence the market development.

2.3 Technology readiness level (TRL)

Technology readiness level (TRL) is a system developed by NASA that allows actors to systematically assess the maturity of specific technology and consistently compares the maturity between different technologies (Mankins, 1995). Furthermore TRL is used to assess the maturity of the technology in development phases (Mankins, 1995). The framework of TRL consists of 9 levels of maturity as found in table 2. However, the original TRL framework consisted of seven levels, Mankins later developed two additional layers (Mankins, 2009).

Table 2 Technology readiness levels as seen in EU horizon 2020 program (Héder, 2017).

Technology level	Process	Technology readiness level summary
TRL 1	Research	Basic principles observed
TRL 2	Research	Technology concept formulated
TRL 3	Research	Experimental proof of concept
TRL 4	Development	Component/technology validated in lab
TRL 5	Development	Technology validated relevant environment
TRL 6	Development	Technology demonstrated in relevant environment
TRL 7	Deployment	System prototype demonstration in operations environment
TRL 8	Deployment	System complete and qualified
TRL 9	Deployment	Actual system proof in operations environment

TRL 1 Basic principles observed:

TRL 1 is the lowest degree of the technological scale of maturity (Mankins, 1995), at this level fundamental scientific research is conducted and resulted in reporting observations of basic principles that have been found (Mankins, 2009). The principles are found, but there are no practical applications (Straub, 2015).

Examples of TRL 1 could include research papers of fundamental characteristics of material such as durability as a function for a new plastic, these findings would generally be followed by Research & development organizations on a university level or institutions (Mankins, 2009).

The expense to reach the first level of TRL varies from case to case depending on the discipline of research, to put it in perspective the cost to achieve 'TRL 1' could be a fraction of the systems cost in entirety or it could cost more than the system itself (Mankins, 2009). Furthermore, costs are typically unique which is the reason why it varies across different research disciplines, an example that shows how costs can vary is when discovering new algorithms which involves computer, a couple of researchers and work space, in contrast to biochemistry discoveries that need laboratories with super-computers (Mankins, 2009).

TRL 2 - Technology concept is formulated:

Once fundamental principles have been observed, the following stage of TRL 2 is reached which involves the further development of the technology based on the basic observations found in the previous stage. For instance, when discovering superconductivity in materials, possible applications of the newfound material could be outlined (Mankins, 2009). Essentially potential of the technology has been identified and concept has been tried. The cost for reaching TRL 2 is typically low, usually a fraction of the costs associated to a possible system, although as found in the previous stage costs are unique and vary depending on the research discipline, activities are generally connected to universities and small businesses (Mankins, 2009).

TRL 3 - Experimental proof of concept:

The third level of technology readiness is where active R&D is conducted, it includes analytical studies as well as laboratory-based studies. The former consists of setting the technology in a suitable context, whilst the latter refers to validate the analytical predictions to make sure they are accurate. The research conducted acts as a proof of concept of what has been established in the previous stage (Mankins, 2009). For example, TRL 3 for bioprinting would be achieved when cells are proven in vitro cases (laboratory success), this would mean to print tissue or a body part in a lab, but it is not proven in a suitable environment (Murphy and Atala, 2014). For instance, when cartilage constructs have been created in vitro from the bioprinting process (Murphy and Atala, 2014).

By including both analytical and experimental approaches in TRL 3 to prove the sought-after concept, researcher can choose which approach best suites their studies, some cases can be proven analytically whilst others need physical validation (Mankins, 2009). Costs associated to the third stage of technology development are generally not too high, it is said that the cost is moderate in relation to the system application, although as seen in previous level descriptions costs vary depending on the field of research (Mankins, 2009). In these stages there is often some form of sponsorship (government sponsorship or grants), due to high risks and prolonged lead times (Mankins, 2009).

TRL 4 - Component/technology validated in lab:

Once proof of concept has been established for the central elements, the basic technological functions have to be integrated into the invention in order to validate that the components

function together. Mankins, (2009) further argues that the purpose of TRL 4 is to achieve and prove performance that furthers the concept found. Validation for TRL4 must be planned to best fit the concept that was expressed in previous stages and be aligned with the requirements for the systems applications (Mankins, 2009). Costs associated to TRL 4 are generally moderate, it is estimated to be a modest fraction of the cost for the system application, as previous levels have shown costs are specific to the research discipline and more so to technology needed for the invention. In TRL 4 research activities are generally carried out by R&D institutions or organizations but because of increasing costs it is not unheard of to involve some sort of sponsorship (government grants, or industry investments), however because of decreasing risks and lead times some sort of venture funding is not uncommon (Mankins, 2009). In the case of bioprinting TRL 4 would be includes transitioning from in vitro to in vivo (cells are in natural environment) application, then it is refined and prepared for human trials (Jovic *et al.*, 2020). An example that shoes this transition is when a bioprinter has created bone structures that matured in vitro prior to implantation. Post implantation the structure continues to mature and for similar density as endogenous bone tissue (Murphy and Atala, 2014).

TRL 5 - Technology validated in relevant environment:

During technology readiness level 5 the reliability of the technology being tested is substantially improved, the technology is most likely involved in some form of demonstration in a relevant environment (Mankins, 2009). For TRL 5 the costs are generally related to R&D and are moderate to high, although as in all previous stages' costs are technology specific. The cost is similar but slightly greater than that of TRL 4, once again research is conducted by R&D institutes and are often sponsored (Mankins, 2009). An example of TRL 5 related to bioprinting is initial clinical trials have commenced, although literature that describes clinical trials are scarce, it is found at there are in vitro models (derived from patients) will be treated with chemotherapy drugs to see how they respond (Peking Union Medical College Hospital, 2022).

TRL 6 - Technology demonstrated in relevant environment:

Once TRL 5 has been completed the technology validation progresses significantly increases the reliability of the system (Mankins, 2009). TRL 6 essentially ensures the system is tested in a relevant environment, in relation to bioprinting the relevant environment would be the human body or animal testing. For TRL 6 to be viewed a success the technology must have gone through a successful demonstration in its relevant environment, although not all technologies undergo a demonstration at this level (Mankins, 2009). For TRL 6 the maturity is driven by assuring confidence from management rather than R&D needs (Mankins, 2009). Costs in TRL 6 are often high and are fairly specific to the technology or demonstration that is to be performed, activities performed in this level are only conducted by recognized organizations which practically always include funding from governments, industry investments or venture funding (Mankins, 2009). TRL 6 translated to terms of bioprinting would be second round of clinical trials, where the system proves efficiency and safety (Jovic *et al.*, 2020). In relation to the previous example, the second round of clinical trials (phase 2) would be proven success in

how the tissue responds to the drug treatment, thus the second study ensure safety and efficiency.

TRL 7 - System prototype demonstration in operations environment:

According to Mankins, (1995)Technology readiness level 7 is a crucial step in the maturity of a technology, it requires a definite system prototype validation in an operational environment (in a human as the case with medical device). The prototype should be as close in functionality as the final operational technology as possible. However not all technology systems need to be demonstrated at TRL 7, demonstrations are usually done in high-risk applications (such as medical devices in human body) (Mankins, 2009). The cost of achieving TRL 7 is usually very high and could be comprised of a significant amount of the cost for developing the final system. As previously stated costs are specific to the technology or demonstration that is to be performed, activities performed in this level are only conducted by recognized organizations which practically always include funding from governments, industry investments or venture funding (Mankins, 2009). Using the previous example TRL 7 is where the technology has moved on to the last stage of trials (phase 3), it has proven that the drugs have a safe effect on the tissue model and there is evidence backing it up.

TRL 8 - System complete and qualified:

Mankins (1995;2009) defines all TRL 8 system as being the actual systems for use, for most cases TRL 8 is the proven development of the system and its elements. A TRL 8 system can either be its own product or be integrated into an existing system (Mankins, 2009). An example where the product is integrated to an existing system is seen in the development of a new bioink for a bioprinter system (Jamieson *et al.*, 2021). Another example is a loading and testing a control algorithm for a computer that is belongs to a space system (Mankins, 2009). Costs for TRL 8 are typically very high and in most cases the cost exceeds all previous levels costs by five to ten times (Mankins, 2009). Because of the dramatically increased costs TRL 8 projects are generally conducted by formal project organizations and involves sponsorships from either government, funding from industry, or venture capital funding (Mankins, 2009). In terms of bioprinting TRL 8 is where the products gain regulatory approval and is available to the market.

TRL 9 - Actual system proof in operations environment:

Generally, technology that has been successfully implemented in a operational system will progress to TRL 9, however the concluding stages of resolving minor bugs in the system remain until the system is actually deployed for use (Mankins, 2009). The main difference between TRL 8 and 9 is that 9 entails actual system operations, for instance in the case of building a new space craft, TRL 9 would be an actual mission. The costs connected to reaching TRL 9 are typically high but considerably less than that of TRL 8 (full scale system development) (Mankins, 2009). TRL 9 activities can only be conducted by the end user or formal operations organization (Mankins, 2009). In the case of bioprinting this would be hospitals or clinics

(Thakur *et al.*, 2018). An example of TRL 9 for bioprinting is where the system is on the market, is safe, and functioning but still being monitored.

Understanding technology readiness level is central when attempting to license technology or evaluate the maturity of it for commercialization, TRL provides a standardized way of measuring technology maturity as well as assessing risks associated with implementation (Tzinis, 2021). It is shown in the much of the literature that current bioprinting practices are in the first 4 stages of TRL, in vitro experiments where researchers aim to optimize scaffolds and cell mixtures, as well as bioink and bioprinting methods (Jessop *et al.*, 2017). As the scope of the research is to explore the maturity of market development the TRL stream of literature is deemed appropriate as it addresses the maturity levels of technology (Mankins, 1995). Thus, it is through TRL that we will be able to pinpoint current technological capabilities in terms of market maturity.

Summary

As mentioned there is an abundance in literature describing biomaterial, bioprinters, and processes as seen in (Murphy and Atala, 2014; Ozbolat, 2015; Ozbolat, Peng and Ozbolat, 2016; Combellack, Jessop and Whitaker, 2018; Tsao, 2018; Murphy, De Coppi and Atala, 2019). However, no existing literature has given detailed information regarding what the bioprinting market looks like in terms of application areas, firm activities, or type of actors. Furthermore, current literature addresses that bioprinting is making rapid strides in terms of capabilities, with new application areas reported as well as technological achievements (Jessop *et al.*, 2017; Combellack, Jessop and Whitaker, 2018; Santoni *et al.*, 2022). However, there is no detailed information on technological maturity. Therefore, the scope of this study is to investigate these gaps, emphasis will be on what the market looks like and what the stage of market development is.

3. Methodology

In the following chapter, the methods used in the study are presented, methods that are presented aim to explain how the research question will be answered. The chapter will also include a discussion regarding validity, replication, and reliability. The methodology chapter is where the researcher addresses the research problem, focusing on who, when, what, where, and how the research will be conducted. The chapter does so through the scope of the research questions: RQ 1: What does the market for the 3D Bioprinting industry look like? RQ 2: What is the stage of market development for the 3D bioprinting technology?

3.1 Research Strategy

Generally, research strategy describes the direction of the research that is conducted, this thesis originally took a qualitative research strategy in order to investigate how the 3D bioprinting market has developed. According to Bell, et al., (2019), qualitative research aims to express findings with language as opposed to quantification and includes a description of the phenomena, some form of discovery, exploration, and interpretation. To address these aims the thesis needs to interpret data in depth, Silverman (2006) describes this characteristic to be qualitative in nature. It is also stated by Bell et al., (2019) that qualitative research strategy is suitable when exploring a multifaceted phenomenon. The study takes on a qualitative approach to draw meanings that can provide insights that quantitative data misses to capture (Bryman & Bell, 2011). As this thesis aims to address market development there is a need for supplementary visualization of the data. Thus, to broaden the visualization of findings the thesis adopts a quantitative approach as well. The aim focuses on numerical aspects of collected data, this is when we confirm already established theories through the empirical data found (Bell, et al., 2019). According to Bryman & Bell, (2011), the combination of qualitative and quantitative studies is called a mixed methods approach, which is where both data types are combined. The basis for the mixed methods approach is that the integration of the data will give way to new insights that would have been overlooked otherwise. Generally, this approach will allow us to combine the strengths of qualitative and quantitative approaches while minimizing the limitations when examining the market development for bioprinting. The data is presented both qualitatively and quantitatively, allowing us the triangulate the results found.

Furthermore, to explore the research questions an inductive approach is taken as this method allows us to produce generalizable findings that can be formulated as theoretical conclusions. However, the relationship between theory and research can be seen through three different lenses, deductive, inductive, and abductive studies (Bryman, 2008). An inductive approach inhibits impositions of presumptions because of the relationship between observation and theory (Bell, et al., 2019). The approach for this study is characterized as abductive as the findings and conclusions are both drawn from the data as well as an iterative process from the literature review. For example, in the content analysis and coding, the second theme which concerns TRL is deductive as the criteria for this was found in the literature, meanwhile, other themes and categories were an abductive iterative process

3.2 Research design

Research design delivers structure for data collection and data analysis, the choice of research design suggests what is essential for the report. Research design is created through various dimensions (Creswell, 2009). The dimensions are concluded as, conveying fundamental connections for variables, simplifying big sets of data or groups of individuals, understanding behavior and why that behavior has risen in a social context (Patton, 1990). According to Bell et al. (2019) there are five kinds of research designs, experimental design, cross-sectional, longitudinal design, case study design, and comparative design. Experimental design focuses on scheduling procedures to explore the relationship between two variables (Bell, et al., 2019). Longitudinal design aims at collecting data over an extended time of the same variables (Bryman & Bell, 2011). Case study is a research design which aims to create in depth understanding of a multifaceted subject in real time (Creswell, 2009). A comparative research design engages in studying variation though comparison of cases (Hesse-Biber, 2010).

A case study was deemed optimal for the scope of this thesis as case studies deliver extensive information specific to the research scope. In this study the case is used in association to a specific geographic location and organizations in a confined system or situation. The focus has been on examining the setting of the bioprinting market. Bell et al., (2019) argue that case studies are commonly associated to qualitative research, because of the methods nature to draw in depth analysis of the case. According to Bell et, al., (2019) there are 5 different types of distinctions that can be made, *a critical case* which is when there is clearly defined hypothesis which the case is chosen based on. *A unique case* common in clinical studies, *a revelatory case* when researching a previously inaccessible phenomenon making it a revelation. *a representative case* explores everyday happenings, *and a longitudinal case* which refers to looking at how a situation changes other time (Bell, et al., 2019).

It is vital to make the right distinction when selecting the right case as it should be insightful and representative of the general case population (Bell, et al., 2019). As this study aims to address what the market for bioprinting looks like as well as the stage of maturity for said market, to assess this there is a need to look at the phenomenon over time. In order to draw conclusions, the optimal case study will be of longitudinal character. The selected case will be presented in the chapter below, and it will highlight how and why the case was selected.

3.3 Case study

The case that has been selected is regarding market development of bioprinting in Sweden. The subsection will provide a setting and sampling description and lastly presenting archival sources.

3.3.1 Case selection and setting

The case study explores the market for bioprinting by using Swedish media outlets, the scope of the case is to understand what the market for bioprinting looks like and what stage of maturity the market is in. The bioprinting market is widespread, there is a multitude of actors globally, the companies that create and commercialize bioprinters are nearly on every continent, as of 2022 73,5% are based in Asia, 5,2% in Europe, 1,3% in Oceania, and 20,1% are in North America (Santoni *et al.*, 2022). In Sweden, there are a few noteworthy companies one being Cellink which is publicly traded on NASDAQ (Ahmadi, 2021). The choice to use Sweden, to as a case is further motivated by the innovation mindset in the Swedish culture seen in a report by WIPO, Sweden is among the top three most innovative economies for high income in the world with only USA and Switzerland ranking higher (Dutta *et al.*, 2022). The study will be looking at articles from Swedish news outlets, all organizations that occur will be taken into account. Since the aim is to explore the market development of 3D bioprinting this will be done through Swedish news articles, it is not limited to the Swedish market, but rather the general activities that are found through the scope of Swedish articles. This will mainly concern themes that are discussed in the following chapter. While most of the firms are in Asia the case of Sweden was selected due to the availability of data. Sweden has two major publications that report on business insights as well as on upcoming technologies. Dagens industri is a Swedish financial newspaper that offers business, finance, and analytical news on its webpage (*Dagens industri: Översikt | LinkedIn*, 2023). NyTeknik reports on the latest trends and innovations as well as new companies, furthermore, it is Swedens' largest technology and IT newspaper in terms of monthly readers (Nyteknik, 2023). The third news outlet for the case is Biostock which is a leading digital newspaper that specializes in Nordic life science company developments (BioStock, 2023). More information will be provided in the following chapter. The newspapers were selected based on their reputation and extensive coverage of financial news and analysis of Swedish industries, as the case is on the Swedish market the geographical coverage falls within the scope of the study. The combination of the focuses (business technology, and industry) from the outlets has given extensive information on the current market and how it has developed.

3.3.2 Sampling

The qualitative sampling process often includes selecting a fitting site, such as a geographic location (Bell, et al., 2019). This thesis will focus on Sweden to assess the market development of 3D bioprinting. One deciding factor to look at Sweden is the timeframe and scope of the project as investigating the global development would be too extensive. Furthermore as previously mentioned Sweden is the third most innovative country in the world (Dutta *et al.*,

2022). This means the statements regarding technology and markets by outlets in Sweden could be at the forefront of the industry. The concept of purposive sampling is based on the selection of units such as people, organizations, or documents, that direct reference the research questions (Bell, et al., 2019). Several studies of mass media include specifying the research problem of x in y; however, the choice of what media outlet is right remains (Bryman & Bell, 2011). Will it be newspapers, television, or magazines, and in the case of newspapers will it be tabloids or something else. Another specification is what features to include (Bell, et al., 2019). For this case study, purposive sampling is used as the sampling method for selecting the media outlets. It is a non-probability form of conducting sampling, the objective of purposive sampling is to sample news media outlets in a calculating or strategic way to ensure that the information presented is relevant to the research (Bell, et al., 2019). For this study Dagens industri (DI) was chosen, which is a Swedish business and financial publication and is the largest publication in Scandinavia, however, they are subscription based. It is estimated that DI has 288 000 daily readers (DI, 2020). The second outlet was NyTeknik a Swedish media publication that specializes in new technology and is the largest publication in Sweden with a monthly readership of over one million people, furthermore, it is distributed to all civil engineers that are members of Sveriges ingenjörer making it specific to individuals who may have industry competencies or interest (Ny teknik, 2023). Biostock is one of Scandinavias leading digital news and analyst publications, with the main readership being investors, firm representatives, and organizations within biotechnology, MedTech, diagnostics, and drug development (BioStock, 2023).

This sampling approach does not allow for generalizations (Bryman, 2008). Sampling can be conducted in several ways; in this study, the choice of purposive sampling is justified by two criteria. The first criteria are whether there is a need for generalization, and the second criteria are if the research questions call for specific sources of information (Bell, et al., 2019). Firstly, the selection of media outlet does not call for generalization, secondly the research does call for specific sources of information. In this study participants for the media outlets were identified based on their reputation within journalism and by public perception, they were also selected based on industry expertise and in the case of Dagens industri their business analytics, as well as monthly readership. Thus, media outlets were chosen in a strategic manner since they were selected based on their ability to contribute with relevant knowledge to the research questions (Bell, et al., 2019).

As for the decision of sample dates, this is dictated by the occurrence of a phenomena Bell, et al., (2019), with the first ever bioprinter being developed in 2009 by Organovo, and since their emergence other actors have followed such as Swedish Cellink (Przychodniak, 2019). Since the emergence of Organovo the industry has seen multiple market entrants, mainly in 2014/2015 (Santoni *et al.*, 2022). The emergence of new actors and developing technology is the main reason for the time span choice when exploring the emergence of technology from 2010 and onwards to present day March 2023. Newspapers were chosen because they report about business development, analyze business development, report on market activities, technological advances, challenges and issues that reflect market development, furthermore articles are read by the public as well as companies within the industries. One issue that

qualitative research often faces it to establish an adequate sample size, how many individuals or articles should one collect (Bryman & Bell, 2011). In this research the sample size was determined by the number of articles presented in each of the media outlets, which came to a total of 49.

3.4 Data collection

When data is being collected it can be from two scopes, quantitative or qualitative, the former focuses on data that is numerical and the latter focuses on data sources that provide a deeper context (Bryman and Bell, 2011). Generally, data is collected through six types of foundations when adopting a case study such as this thesis documentation, archival records, interviews, direct observations, participant observations, and physical objects. (Bryman, Bell and Harley, 2022).

Documentation refers to materials such as emails, company documents, reports, or news articles. The pros of documentation data collection are stability and the wide variety of topics that can be addressed through these methods. However, in some cases, the drawbacks can be availability or access to data when utilizing company documents (Bryman, Bell and Harley, 2022). This thesis adopts the documentation method of collecting data through new paper articles in order to conduct a content analysis of the found material, this is an approach that previous scholars have adopted when researching market development eg., (Navis and Glynn, 2010; Granqvist and Ritvala, 2016). The study has made use of articles across three different media outlets Dagens industri, Nyteknik, and Biostock, the coverage of the news outlets is business, commerce, and technology development, with a focus they are Scandinavian news publishers. Most newspapers are subscription based, which was the case for NyTeknik and Dagens industri, whereas Biostock was open to the public. Fortunately, we had subscriptions to the news outlets that required this, furthermore, articles can be found through Uppsala Library service Retriever research. the thesis buzzwords such as Bio* Bioprinting* AM* 3DP* Biotech* Bioprinter* 3Dskrivare* Bioskrivare* Biomaterial* when searching for the articles. The time period for the search was 2010- March 2023, which captures when buzz first started regarding bioprinting, the emergence of businesses, and how the market has developed over time. Using these keywords 49 articles that referred to 3D bioprinting were found, these are presented in Appendix A. The newspaper data allowed us to meticulously identify market development discourse and audiences, and to discover key vocal points of actor activities over the time span. This was key in order to examine the market development of 3D bioprinting.

3.5 Data analysis

It is stated by *Säfsten & Gustavsson*, (2019) that the data analysis depends on the research aims & research question(s). This thesis aims to address the Swedish market development of 3D bioprinting through the research questions RQ 1: What does the market for the 3D Bioprinting industry look like? RQ 2: What is the stage of market development for the 3D bioprinting technology?

Based on this the thesis could opt for either a thematic analysis or a content analysis. A thematic analysis is when themes are derived from qualitive data such as transcripts or field notes (Bryman & Bell, 2011). A content analysis is a popular method when examining something shown by mass media such as news papers (Bell, et al., 2019). Based on this and what has been presented in previous subchapters, content analysis is required to address the studies aims.

3.5.1 Content Analysis

Content Analysis is a process frequently used for studying communication by mass media and is defined as "*Content analysis is a research technique for the objective, systematic and quantitative description of the manifest content of the communication*. (Berelson 1952: 18)" (Bryman & Bell, 2011, P. 289). Content analysis is often used when examining the text, speeches, images, or video, although the approach can also be used using mass media (Bryman & Bell, 2011). The content analysis was conducted in order to explore what the market for bioprinting looks like and what the stage of market development is, through line-by-line coding which is then categorized and lastly allocated into themes, which will be presented and analyzed in upcoming chapters. The advantages of content analysis are transparency as coding schemes and categories can be replicated fairly easy (Bryman and Bell, 2011). This thesis takes shape as a longitudinal case study; thus, the focus is on how the 3D market development has changed over time. Content analysis is a useful method as it allows for analysis with relative ease due to changes in emphasis being examined. Content analysis is also un-reactive since there are no participants that can influence that research or be harmed in an ethical sense (Bryman and Bell, 2011). However, the content analysis is only as good as the documents being analyzed, it is also extremely difficult to formulate coding manuals that do not include any sort of interpretation. Furthermore, there is a risk of invalid inferences being made from the data.

This thesis takes a mixed methods approach to document analysis, which is similar to what has been described in previous chapters. According to Altheide (1996), the main emphasis is related to discovery and description through underlying meanings and patterns, this is an interpretive approach. However, the mixed methods approach is incorporated as the findings are presented from both a numerical perspective as well as a qualitative one. This strengthens the trends interpreted in the data as it is also accounted for in a numerical sense (Altheide 1996). For example, the study assumes that there is a specific media content per outlet, one example is the number of times young people see violence on tv and also the context of what has been shown. In terms of this thesis both the times market activities occur and in what context it occurs are accounted for.

The first stage in the content analysis was collecting all of the material, some articles were in Swedish and some were in English, the articles in Swedish were translated accordingly. When all the articles had been collected, they were placed in a Word document for further treatment. The second stage of the content analysis process was to meticulously read all the articles examining them for similarities. This was done by commenting on similarities. It was through this process that codes emerged from the text which referred to the indications, and similarities in occurrences. For this thesis, an indication refers to implicit sentences or remarks that show

something is happening or an opinion. Similarities simply refer to when sentences were alike but not the exact same. This is where we began coding the data, codes were established by phrases and distinct words that were found in the articles. An example is when an article mentions bioprinters, instead of commenting on each specific bioprinter by name they were given a phrase. Codes were assigned an ID and an abbreviation on the outlet they were found in. The initial round of coding was then categorized by a term that represented them. Thus, the codes are categorized based on similar topics established. When initial codes had been established, they were placed in categories, also called sub-themes. Again, using the same example, the category for all mentioned bioprinters would then go in the category "bioprinter" Another example is looking at the type of activity, in the articles an example of code would be a phrase such as 'distribution deals are made in China'. The category for market activity would then be 'distribution' and the theme is type of activity. The process ensures that categories were named and derived in a representative way from the data and helped in understanding underlying meanings and frequency of words in a systematic approach (Bell, et al., 2019). To ensure that the process was as systematic as possible both a coding schedule and coding manual were constructed (Bryman & Bell, 2011).

In the final stage of the coding process these categories gave way for themes that represent them in a meaningful way, these themes were thought out in relation to the scope of the research and the research questions. In total 7 themes were found to represent the data, however as some of the codes have multiple meanings and refer to more than one category, in such cases the code was duplicated leading to a higher degree of code than total articles N=49 these are presented in appendix A. The themes as well as the categories are presented in the following chapter. A benefit of the content analysis procedure is it allows for replication since the data used is often archived and readily available to other researchers who are wanting to conduct a study on the same subject (Bell, et al., 2019). The entire process was done inductively, meaning the codes, categories, and themes were identified and based on the available data.

3.6 Data quality

The data quality in this study has been evaluated by determining validity, transferability, credibility, dependability, and conformability (Bryman & Bell, 2011). Validity treats the integrity of the conclusions made in the research, there are five main sorts of validity, measurement, internal, external, and ecological (Hesse-Biber, 2010; Bell, et al., 2019; Bryman & Bell, 2011). The review of the data quality contributed to the fact that general conclusions could be drawn in a more credible way. As the research progressed, both supervisors, opponents via Uppsala University and colleagues from the additive manufacturing for the Life sciences competence center have contributed to ensuring the general quality of the thesis work.

3.6.1 Validity

Validity in qualitative research essentially means that the researcher assures the accuracy of findings through certain procedures (Creswell, 2009). Thus, the degree of validity establishes the integrity of the conclusions (Bell, et al., 2019). Although there are some threats to validity

which are both internal and external, internal threats to validity concern procedures, treatment of data, and experience of interviewees that affect the researchers' analysis capabilities (Creswell, 2009). External threats to validity occur when researchers draw invalid inferences from the sample data, which is a concern when adopting the content analysis method (Creswell, 2009). Transferability parallels external validity in that it considers the degree of qualitative research that can be used in different contexts (Bell, et al., 2019). When conducting case studies, it is important to address external validity and generalizability concerns as findings in single case studies cannot be applied to other cases, thus it is vital to ensure external validity by clearly defining between different types of case studies as was done previously in this chapter (Bryman & Bell, 2011). For this research transferability is a limitation since the research is quite niched, however, the research can still be used in similar fields and or emerging, that are characterized as having a high degree of technical aspects. The study also provides a framework that future research can replicate. Although to ensure transferability the author uses a thick case description as recommended by (Bell, et al., 2019).

To ensure external validity and mitigate the risk of drawing invalid inferences the coding process was conducted on separate occasions and then proofread. According to Bell, et al., (2019) credibility parallels internal validity, which treats the query of how data has been evaluated and that it has been done candidly. Since this study uses news outlets as its primary data the internal validity cannot be measured to the same extent as with interviews since the time restraints make it unrealistic to conduct respondent checks for all authors of the 49 articles. Another method to ensure credibility is through member validation as Bell, et al., (2019) describes. In this study member validation is conducted through multiple peer reviews and multiple reviews by the subject reader and supervisor. Which is done by being transparent in showing the coding process.

3.6.2 Reliability

Dependability parallels reliability in the qualitative context, it refers to the trustworthiness of the work and does so by implementing an audit type of approach. The approach refers to documenting all steps in the research process from formulation of research questions to analysis of data, for peers to audit (Bell, et al., 2019). As stated, this research is audited multiple times, by peers, the subject reader, and the supervisor. Furthermore, the dependability of the coding was ensured by a code-recode method, to ensure that errors that occur while coding are minimized, the author had a gestation period between coding sessions and then compared the codes in search of discrepancies. When conducting qualitative research, the author may take steps in mitigating the bias by conformability which parallels objectivity, although efforts seldom eliminate all bias as it is impossible to be completely objective in qualitative research (Bell, et al., 2019). In this research the author tries to mitigate bias by displaying data and empirical findings as they are presented to them, as well as adhering to peer reviews. The peer reviews are conducted by colleagues who are part of the additive manufacturing for the Life Sciences (AMA4Life).

3.7 Limitations

A major limitation in the study is that newspaper articles are the main source of data. This poses as a limitation since newspaper articles may be biased or not completely accurate in describing a phenomenon, furthermore, newspaper articles may be sponsored to write about certain subjects or told by editors what can and cannot be included. Furthermore, they may be influenced politically or by other factors. Another limitation of using newspapers the sample might not be representative of the entire population, which would affect the validity of the findings. Additionally, when using content analysis as done in this study, the coding phase imposes limitations on the sample size as well as the author being alone when coding, increasing the risk of bias. These limitations are addressed in earlier chapters in the methodology chapter. As this thesis only uses data from news outlets based in Sweden there is a natural bias in the data collected. However, if the thesis was to include news outlets from other countries this would impose greater consequences than only looking at Sweden. One issue would be the comparison through a longitudinal perspective as is central to addressing the aims and research questions of this study.

4. Empirical findings

This chapter consists of a general description of the themes produced through the content analysis from the articles found across three different news outlets that are shown in figures throughout the chapter.

4.1 Themes Derived from Code

After coding through an inductive approach as described in the methods chapter, we identified several categories in the data across three media outlets (seen to the right in Table 3), that became seven main themes for investigating RQ, *What does the market for the 3D Bioprinting industry look like? And RQ 2 What is the stage of market development for the 3D bioprinting technology?*

First, the codes were established, often in the form of a phrase or sentence relating to the text from this the categories were developed through common words or phrases found in the data which led to theme development as described in the methods chapter. The themes will be presented and analyzed to investigate the market development, themes and categories are seen in Table 3 below.

Table 3 Themes and categories derived from data

Themes	**Categories**
Use of technology	Research & development Animal testing Human testing Drug development Preclinical trial Biomeat
Development of TRL	As stated in TRL framework
Type of actor	Biotech University Institute Cosmetics Pharmaceutical Other
Type of technology	Biomaterial Implant Bioprinting Body part other
Customer by industry	Research and development University Pharmaceutical Clinics
Type of activity	Partnership Collaboration Sale CRO (contract research organization)
Region of actors	USA Canada EU China Other (Australia, Japan, New Zeeland)

4.2 Overview of Articles

In figure 2 the author has found that across the span of 2010-2023, there were a total of 49 article, with the first being published in 2016. The data shows that Nyteknik was the outlet reporting most regarding bioprinting in the early years publishing a total of nine articles, it is also apparent that articles published by Nyteknik diminish over the years and haven't been reported on bioprinting since 2020. Biostock who also published the articles in 2016 show an increase in interest regarding bioprinting with an increase in articles in 2020 and 2021, however no articles in 2022 and then regaining publishing in 2023. Dagens industri has published articles steadily from 2017 and on to 2023, however this publisher shows peak interest from 2019 to 2022. Overall, the most interest was shown in 2021 with a total of 12 articles even though not all publishers published articles that year. The number of articles posted show an upswing in interest in 2016 and between 2019-2021. To investigate further the identified themes will dive deeper into technology development and other factors that can give insight to market development over the years.

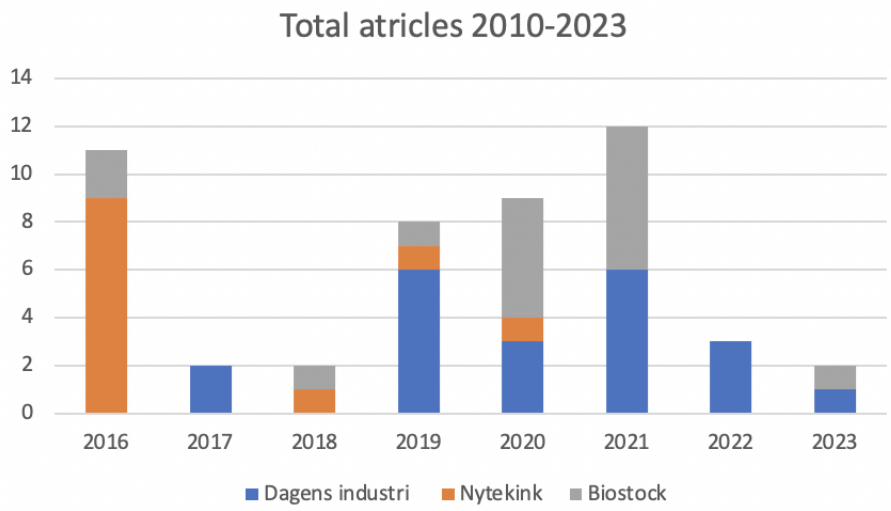

Figure 2 Illustrates the total articles found across three news outlets from 2010-2023

4.3 Overview of content analysis themes

This chapter presents findings from all 49 articles presented in the previous section. The data is presented in the form of figures and are analyzed in combination with presentation. In order to assess what the market looks like, and market development 7 themes were identified through the content analysis which were presented previously.

4.3.1 Use of technology

The theme use of technology consists of six categories, *Research & Development, Animal testing, Human testing, Drug development, Preclinical trial, and Biomeat* which refers to what the technology is being used for. The categories were created based on similar occurrences or indications in the articles. The focus of this theme is to explore how technology use has been described over the course of the given time span. Looking at Figure 3 we see that Research & Development is the most used term when the use of technology has been indicated or discussed. This is the case for all three news outlets with above 20 occurrences in specific years. Looking at Biostock Research & Development is most prevalent in recent years being mentioned most in 2020 and 2021. Looking at the development of technology use occurrences we can see that there are reportings of preclinical trials, however, these are indications for future capabilities.

The data shows that there was little interest in reporting technology use in Biostock before 2020 which is interesting since technological reportings are seen in the other news outlets in the years leading up to 2020. Research & Development in Dagens industri was most mentioned regardless of year but peaked in 2019 which is interesting since the media outlet published the same number of articles in 2019 and 2021. Furthermore, it is interesting when comparing to Biostock which only had four occurrences compared to Dagens industri with 27 occurrences. This poses the question of what the focus of these two articles was and why they shifted. Dagens Industri also mentioned cases of human testing in both 2017 and 2022, and a couple of occurrences regarding the technology being used for drug development. As for the animal testing that was mentioned, it is stated that bioprinting is far from replacing animal testing but new findings in the community is resulting in a minimized need for animal testing (Biostock, 2021/07/01).

Looking at the occurrences in Nyteknik the majority of all occurrences are in 2016 which is the year the outlet published the most articles apart from Research & Development Nyteknik reported on cases of human testing, animal testing, and Biomeat. In a translated quote regarding animal testing shows "*Parts of a rat skull have been operated on a rat with good results, this includes bone muscles. Long-term studies have commenced*"(Nyteknik, 2016/02/17). Indicating that bioprinting is making strides with its technology as early as 2016, however, even though the quote states animal testing it is still denoted that the technology is used for research. The occurrence of Biomeat is interesting, KFC has of 2020 tried to launch a Biomeat nugget in one of its stores in Russia (Edgren, 2020), however, there is no more mention of Biomeat since Nyteknik has not published articles since 2020. The following quote below emphasizes technology usages *"By using cells from humans, rabbits, rats, and mice, the researchers have*

so far produced bones, cartilage and skeletal muscles" (Nyteknik, 2016/02/17). Here it is implied that the cells will be used for tissue-engineering and regenerative medicine to create user-specific constructs. As previously seen this quote can be seen as both animal testing and research and development.

Years with gaps and category discussion

There are some years where there are gaps in the data, for instance nothing was mentioned in 2022 in the case of Biostock since the outlet did not publish any articles, however, Biostock has published in 2023 with no mention of technology use. In contrast to Dagens industri & Nyteknik, Biostock has more categories seen in the theme, although technology being used towards research and development is most prevalent. One reason could be that Biostock is an industry-specific outlet and are more thorough in their technology reportings, while Dagens industri and Nyteknik are directed toward the public.

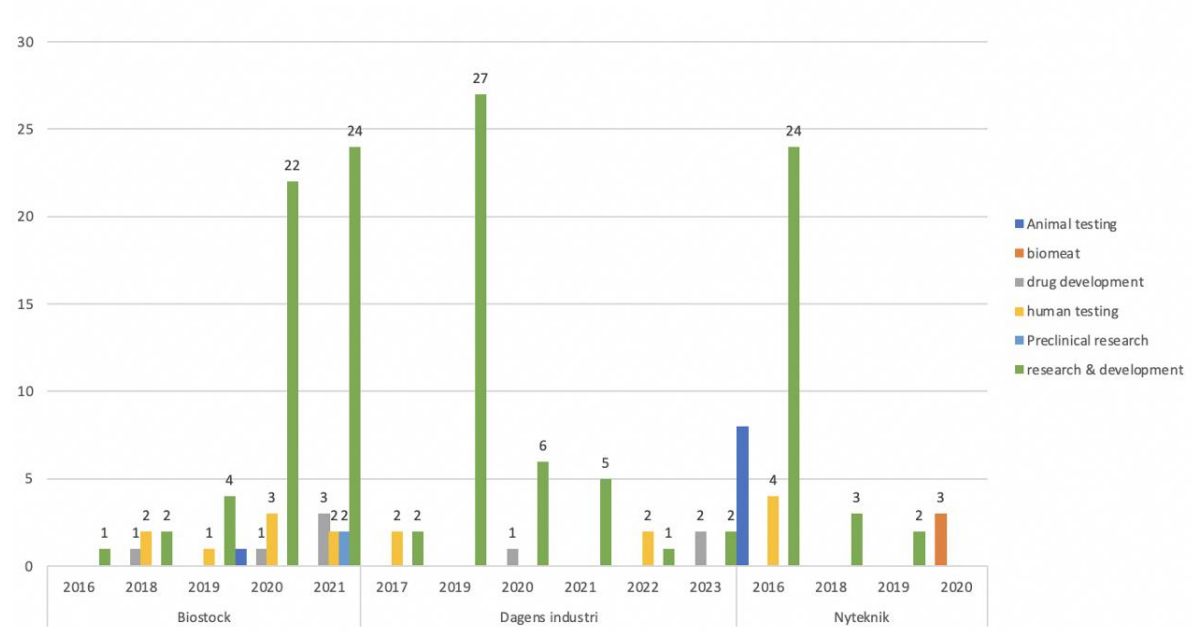

Figure 3 Illustrates the use of technology by year and news outlet on the horizontal axis and the amount of occurrence on the vertical axis

4.3.2 Development of TRL

The theme TRL development consists of nine categories derived from the TRL framework, which refers to how mature the technology is based on criteria in each stage. The categories were created based on similar occurrences or indications in the articles. The stages were then put into the context of bioprinting to help assess the level that was reported in the data. The reasoning for the levels of technology readiness was judged based on what the articles stated the technology was capable of and how far it had progressed in certain aspects. For example, findings show TRL 8 system complete and qualified, this is not representative of bioprinting rather it refers to one area of usage seen in Nyteknik; *"Now the chain is developing a way to 3d-print its bestseller from chicken cells. The chicken nuggets of the future will be tasted at a*

restaurant already this autumn." (Nyteknik, 2020/07/20). The system is complete and qualified for that specific use. However, given the scope is industry related in that it is one of many application areas, in the case of this quote the application area is fast-food.

One quote found that bioprinting has multiple application areas, although the stage of readiness is low, specifically in the first stage basic principles observed "We *are still only at the beginning, and its utility will most probably penetrate many new and upcoming fields. One such field is that of personalized or stratified medicine, which focusing on tailored solutions for individuals or groups*" (Biostock, 2020/12/21). Different application areas have different capability needs and TRL will vary depending on the application area. Furthermore, findings presented in Figure 4 show that across the three news outlets, TRL 3 experimental proof of concept is the most mentioned, however looking at the outlets separately it is seen that Dagens industri differs in that TRL 1 basic principles observed is most mentioned with TRL 3 coming in second. However, there are some occurrences of higher TRLs mentioned one being described as; "*The breakthrough in transplanting a 3D printed ear happened the other week at a clinic in San Antonio, Texas. The patient was the first of eleven people in a clinical study of the disease microtia, where the outer ear is deformed at birth, to receive a new 3D-printed ear*" (Dagens industri, 2022/06/17). This quote is an example of clinical transition from TRL 4 to 5 where the technology was first completed in vitro and later in vivo. Again, TRL 3 is most mentioned for Biostock which experimental proof of concept (TRL 3) shown in the quote below, the article doesn't directly address that the technology has reached the level of experimental proof of concept. However, the quote shows that bioprinting has shown enough capabilities to use the technology in drug development; *"Last week, the company announced that it has entered into an agreement with a major pharmaceutical player to use Biopixlar to create bioprinted heart tissue for safety pharmacology studies."* (Biostock, 2021/09/29). The technology will be used for pharmaceutical studies by aiding the research through printed heart tissue. Which is why the category proof of concept was given.

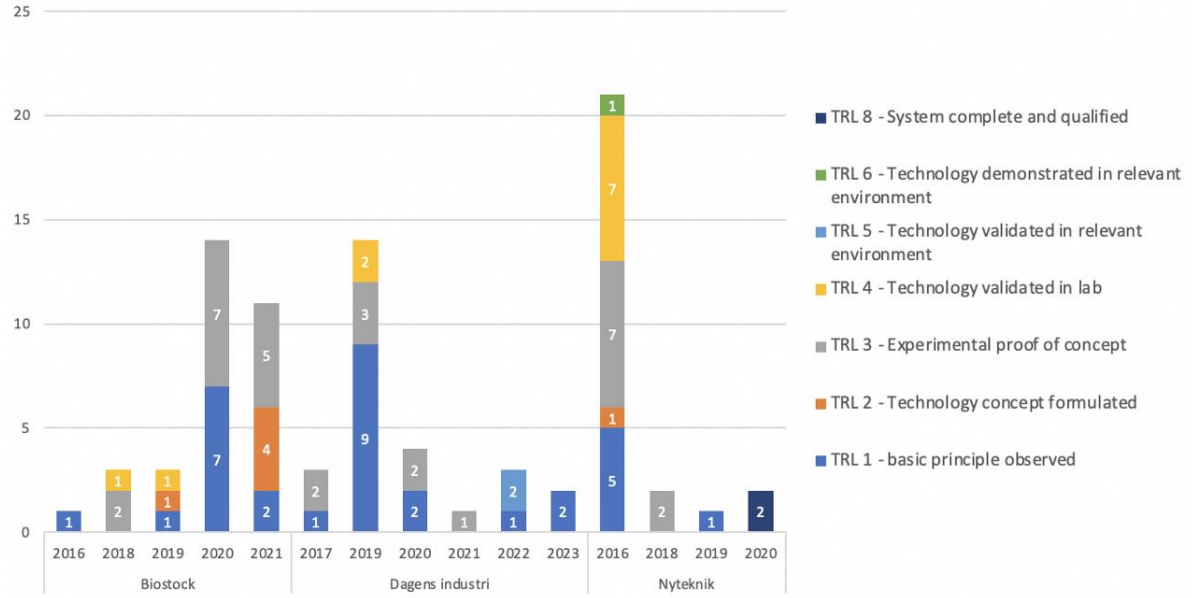

Figure 4 Illustrates the development of TRL by year and outlet on the horizontal axis and the amount of occurrence on the vertical axis

The development for TRL shown in Nyteknik show most occurrences in 2016, experimental proof of concept being the most prevalent again, with basic principles observed second. An example of TRL 3 in Nyteknik; *"That's why researchers at Dresden University of Technology have been working on a method to 3D print human tissue in space"*(Nyteknik, 2019/06/30). Technology demonstrated in relevant environment stems from the quote seen below, where the bioprinter has proven to print skin for cosmetics customers to use instead of animals. They also mention other customers such as number of universities in contrast to industry customers. The technology is still heavily used for R&D even though it has shown to be used in industry; *"Among the customers are around 20 universities worldwide as well as around ten in industry. This includes cosmetics companies that want to use the printer and ink with skin cells to print human skin for animal-free testing."*(Nyteknik, 2016/10/26).

Another example where bioprinters have exhibited basic principles observed is with single but small body parts such as ear and jaw. This seems to be a significant finding; however, it cannot be classified higher in readiness level since there is no indication of studies being made on the ear or jaw nor is it evident that it is demonstrated through experimentation. It was simply stated that there was a case where this was printed; *"To show how customized parts could be used for facial reconstruction, the researchers have, among other things, printed a piece of a human jaw as well as an outer ear*"(Nyteknik, 2016/02/17).

Summary

The findings across the three news outlets indicate that the TRL development is increasing with new areas of use, however looking at overall findings and quotes the technology is far from being fully complete. The degree of TRL is still low mainly between levels 1-3 with some cases of exception, furthermore, the exception of TRL 8 is not related to healthcare. It is evident that there are certain areas where the degree of TRL is increasing, these areas have less complex printing requirements, and three have been no reports on actual organs.

4.3.3 Type of actors

The theme type of actors consists of six categories, *Biotech, University, Institute, Cosmetic, Pharmaceutical, and clinics* which refer to actors that are involved in bioprinting activities over the period. Figure 5 shows that biotech firms are the most mentioned actors across all news outlets, in general, the mentions of biotech actors increase over time, except for Nyteknik where there is a decline in mentions with only one mention outside of 2016. Out of the three outlets, Biostock is the outlet that has laid the most emphasis on actors in general, there is a disproportionate in coverage across the three outlets even though Biostock published on third of the total articles. In Dagens industri Biotech actors are consistently mentioned across the period with a peak in 2021, whilst the occurrence of biotech firms' universities mentioned increased over time.

Furthermore, in 2023 it is found that biotech firms and pharmaceutical firms are mentioned the same number of times in Dagens industri, these occurrences also increase over time across all three news outlets. An example of the context can be seen in; "*The partnership gives Novo Nordic access to Aspect biosystems expertise and technology for development of cell therapy*"(Dagens inudstri, 2023/04/12). The quote gives clarity as to the context of how pharmaceutical firms and biotech firms work together. In contrast, looking at how university actors are mentioned in 2019; *"CELLINK announced a collaboration with Umeå University and GE Healthcare to develop bioprinted skin grafts to improve quality of life for burn patients"(Dagens industri, 2019/11/04)*. The two quotes are similar since both quotes name the actors directly by name, name the focus of the activity as, and what is hoped to be accomplished. Furthermore, both quotes focus on research in some aspect, the only difference is the industry of the actor.

Summary

As seen over the three outlets in figure 3 the main actors through the six categories are biotech firms, the occurrence of biotech firms seems to increase with time, except for the case of Nyteknik. It is also seen Biostock occurrences for actors are more diverse in comparison to the other outlets. In 2023 it is seen that pharmaceutical actors are mentioned the same number of times as biotech firms, although when looking closer at the quotes this is because of collaboration and partnership activities. Correspondingly universities are also mentioned in the context of collaboration engagement. For example, in the 2019 quote that highlights Umeå

University and GE. In conclusion, there is a wide variety of actor occurrences that increases and is diversified over time.

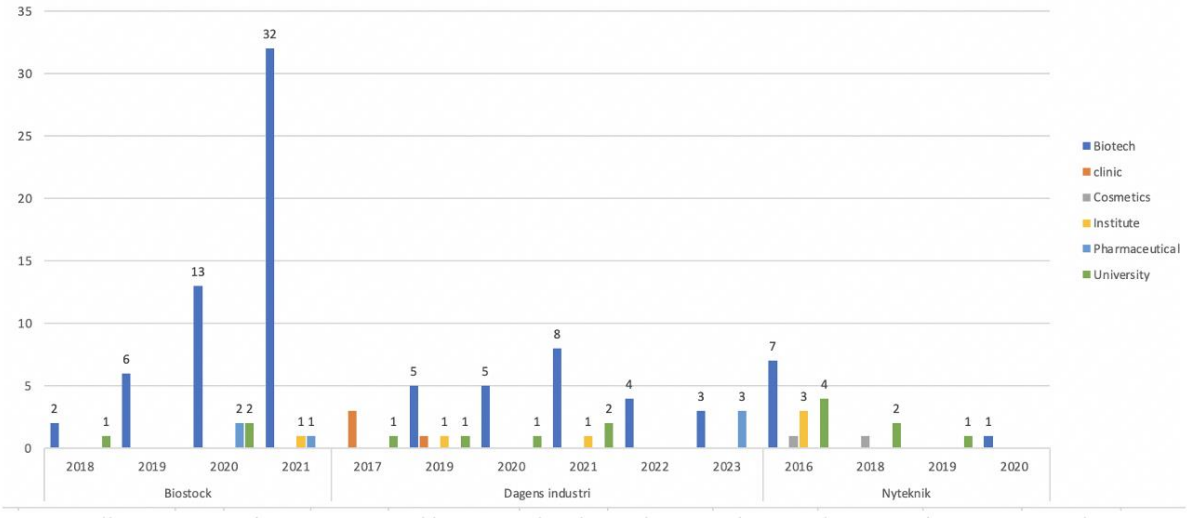

Figure 5 Illustrates the type of actors mentioned by year and outlet on the horizontal axis and amount of occurrence on the vertical axis

4.3.4 Type of technology

The theme type of technology consists of 7 categories, *Biomaterial, Bioprinting, Body part, bioprinting process, drug development, Implant or other (bioprinting instruments such as microchip)*. In Figure 6 findings for Dagens industri show that type of technology described decreases with time, in all categories throughout the time span, taking a closer look at quotes from 2019;*"In a new publication, a research team from Rensselaer Polytechnic Institute successfully bioprinted a living skin model complete with blood vessels using CELLINK's BIO X" (Dagens industri, 2019/11/04).* The quote clearly states the context of the technology and what it is used for, however since it is not clear that the skin has been implanted the category is body part. Whilst findings from Biostock show that the occurrence of bioprinting technologies increase drastically from 2018 and onwards. In 2018 there is a reporting of body parts being printing, a groundbreaking event for researchers and the industry. However as seen in the quote below it was not done by a clinic or healthcare professional, it was researchers at a British university who achieved the feat; *"Researchers at Newcastle University have bioprinted human corneas for the first time."* (Hilding, 2018). It was later shown that there were indications that researchers would be able to mass produce corneas in the near future (Biostock, 2018/06/05). Again, the technology has managed to print something, but it is not implanted which is why it is categorized as body part. The findings from Nyteknik are mainly from 2016 since the outlet hasn't published many articles since then, however occurrences are mainly concerning bioprinting technology with a few observations focusing on biomaterial and the printing process. One of the statements regarding bioprinting refers to the time for cartilage to grow, emphasizing the capabilities of bioprinters although also inferring those expectations should

not be too high;*" It takes time, it's about months. For cartilage, it takes at least 28 days before the first component is produced. Consider that it takes nine months for a fetus to develop. But the 3d printer does not create life"(Nyteknik, 2016/02/18).*

In this quote from 2016 researcher Atala explains how bioprinting has overcome previous experience challenges in order to print more complex structures. The category for the quote is bioprinting and is an example of where bioprinting is mentioned as a type of technology but does not address implants, body parts or other activities;*" Now, researcher Anthony Atala at the Wake Forest Institute for Regenerative Medicine in North Carolina reports that they managed to overcome the problem by using a proprietary 3d printer to print cells together with a degradable biopolymer in a structure with microchannels. The polymer provides mechanical stability while the tissue matures in the body."*(Nyteknik, 2016/02/17). Other mentions in 2016 indicate the importance of biomaterials to the bioprinting process and identify biomaterial as an enabler for future research*;" Human skin that replaces animal testing. It is one of the markets for a Swedish 3d printer that uses ink with living cells." (Nyteknik, 2016/03/31).* In 2018 the narrative had slightly changed from 2016, focus on the type of technology is still bioprinting, however the dialog is much more specific in what the technology does; "*CTIBiotech is working on printing patient-specific cancer tumors that can then be used in the development process to produce new drugs that would work for the patient's own tumor*" (Biostock, 2018/06/05). The quote shows a specific interest in communicating prospects of what the use of technology can achieve.

In 2019 the focus still hasn't shifted, largely there are dialogs on printing human tissue in the scope of furthering research; *"That is why researchers at the Dresden University of Technology have been working on a method to 3d print human tissue in space."* (Nyteknik, 2019/06/30). Even though the type of technology remains the same, the sift is seen in where the technology is being used. Furthermore, findings in 2020 show that the capabilities of bioprinters and the industry, in general, are targeted at researchers and other institutions. The quote shows that bioprinters are making strides in the quality of the tissues produced; *"The biotechnology company specializes in developing technology that enables researchers to create detailed in vitro organ and tissue models with greater biological relevance than today's available methods."* (Biostock, 2020/09/02). As the focus is on methods and the printing itself the category bioprinting process was deemed appropriate. This supports the point that type technology of bioprinting is used for research, this continues through 2020, 2021, and 2022.

Seen in 2020 "*Although the systems to replace in vitro studies are in their infancy, and there is still a long way to go before animal testing for scientific purposes can be replaced on a large scale, companies such as Fluicell's innovative technology, e.g., 3-D bioprinting, bring us closer to a more sustainable R&D environment*." (Biostock, 2020/09/02*).* The dialog is slightly different in that it is more transparent in the capabilities of bioprinting; however, a similar conclusion can be drawn in that communication focuses on future capabilities and possible achievements, and the focus is still on bioprinting research & development although from a slightly differing scope.

Seen in 2021, where it is reported that scientific strides have been made in printing tissue with technology being used for more complex structures and having wider application areas than previously reported within drug development; "*The goal is to focus on developing drugs for advanced therapy (ATMP) based on transplantable microtissues, thereby targeting important disease areas such as type 1 diabetes, heart failure or age-related macular degeneration (AMD).*" (Biostock, 2021/07/01). In three years of development the occurrences have shifted slightly from communicating capabilities to presenting goals and how this is to be achieved. Seen in 2022 it was reported in relation to bioprinting that the technology had made a huge breakthrough in being able to print a body part; *"Last week, two American companies, United Therapeutics and 3D Systems, also came out and said that the first 3D-printed lung is expected to be tested in clinical studies in a maximum of five years."*(Dagens industri, 2022/06/17*)*. However, there is no mention of the functionality or size of the lung.

Summary

In general, bioprinting occurs the most out of all the categories, there is an increase in occurrence when looking at Biostock whilst this is not the case for the other news outlets. Overall, the occurrences for the type of technology decrease with time, even showing fewer categories than in earlier years. Throughout the timespan, the focus is heavily on research and development or further scientific understanding regardless of what the type of technology is. However, it is seen that bioprinting capabilities have made strides through this scope and are able to create more complex structures as seen in quotes from later years. There is a shift in the dialog, at first occurrences focused on communicating future capabilities which later became communicating goals.

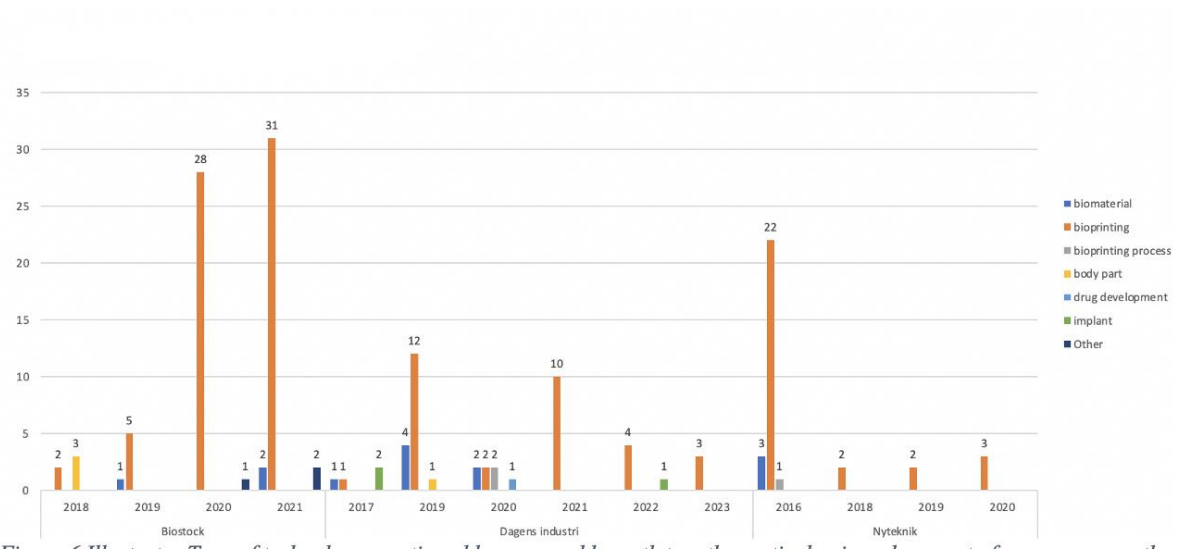

Figure 6 Illustrates Type of technology mentioned by year and by outlet on the horizontal axis and the amount of occurrence on the vertical axis

4.3.5 Customer by Industry

For this theme there are 8 category differentiators namely *Research & development, Biotech, Clinics, Cosmetics, Drug development, regenerative medicine, Fast food, Universities, pharmaceutical companies, bioprinting firms and other*. The category other includes space companies. The focus for this theme is to explore what type of customers have been mentioned the most within the market and if the occurrence of customers of the industry has evolved over the time span of 2010 to March 2023. Looking at the findings in Figure 7 in general shows that occurrences of customers increase overall although peaking in 2020 and 2021. However, this is not the case when looking at the news outlets separately. Both Dagens Industri and Nyteknik show decreases in the occurrences concerning customers by industry over the time period. Although the occurrence varies, the findings are conclusive in that actors in Research & development are the main customers of biotech firms. In Biostock the occurrence of customers even increases with time which is not the case with the other two outlets. Furthermore, articles posted in earlier years in Biostock tended to focus more on universities rather than research & development. Findings in Nyteknik show the most diverse results with multiple categories present, in contrast to Biostock focus shifted towards the cosmetics industry, Biotech, and fast food.

In Dagens industri we also see a shift in focus, here the emphasis is placed on the regenerative medicine industry and pharmaceutics firms as the main customers;*" The business now encompasses four areas, regenerative medicine, which means that organs and tissues can be regenerated after damage, multiomics, which deals with the sequencing of various diseases, cell line development for the production of biological drugs and diagnostics"* (Dagens Industri, 2022/06/17). This quote shows the diversity of bioprinting technology and refers to several categories but mainly regenerative medicine.

The data in figure 7 shows 2016 was a big year in the bioprinting industry with many reports of customers; *"Among the customers are around 20 universities worldwide as well as around ten in industry. This includes cosmetics companies that want to use the printer and ink with skin cells to print human skin for animal-free testing.*"(Nyteknik, 2016/03/31). Once again, the industry shows the diversity and was categorized as both university and cosmetics. The quote from Nyteknik describes how bioprinting interest is increasing and furthermore, the quote includes cosmetics firms that underline one application area of bioprinting, which is printing human skin to minimize animal testing.

A similar quote was presented in 2018 that shows how bioprinting that universities are still the main customers of bioprinting, however the bioprinting industry is evolving with more industries taking notice to technological benefits which is further shown as early 2018; *"Within 12 months, the company has been able to commercialize products in more than 40 countries and sold to more than hundreds of prestigious labs around the world, such as Harvard, MIT, Princeton and the FDA"*(Biostock, 2018/06/05). Here the dialog is intensified with an

underlining of commercialization, however it only describes universities which is why it was categorized as such. The main development is that regulatory bodies are now adopting the technology. The customer development is further shown in reportings that firms network consists of multiple pharma companies and research institutions. Indicating that the goal for the firm is to further research of bioprinting. One occurrence showing firms deliberately perusing specific market, namely the pharmaceutical industry by developing specific technological capabilities that complement the industry; *"CTIBiotech works with printing out patient-specific cancer tumors that can then be used in the development process to produce new drugs that would work for the patient's own tumor. CTIBiotech has a very good network of pharma companies and research institutions working in this field*." (Biostock, 2018/06/05). The quote was subsequently categorized as pharmaceutical customer since this was the main focus.

Summary

Overall, the findings shown in figure 7 show that there is an increase in occurrences regarding bioprinting customers, peaking in 2020 and 21. Although after looking at the findings from the three news outlets separately it is seen that occurrences in both Nyteknik and Dagens industri decrease. The primary customers are universities and cosmetics firms although more customers, such as fast-food companies are emerging due to increase application areas. The general focus in Dagens industri is on regenerative medicine and pharmaceutical firms, in contrast the focus in Nyteknik is on bioprinting customers. One quote specified that the technology is being commercialized globally, naming several prestigious institutions. Overall, the network of bioprinting firms seem to focus on universities, pharmaceutics and cosmetics.

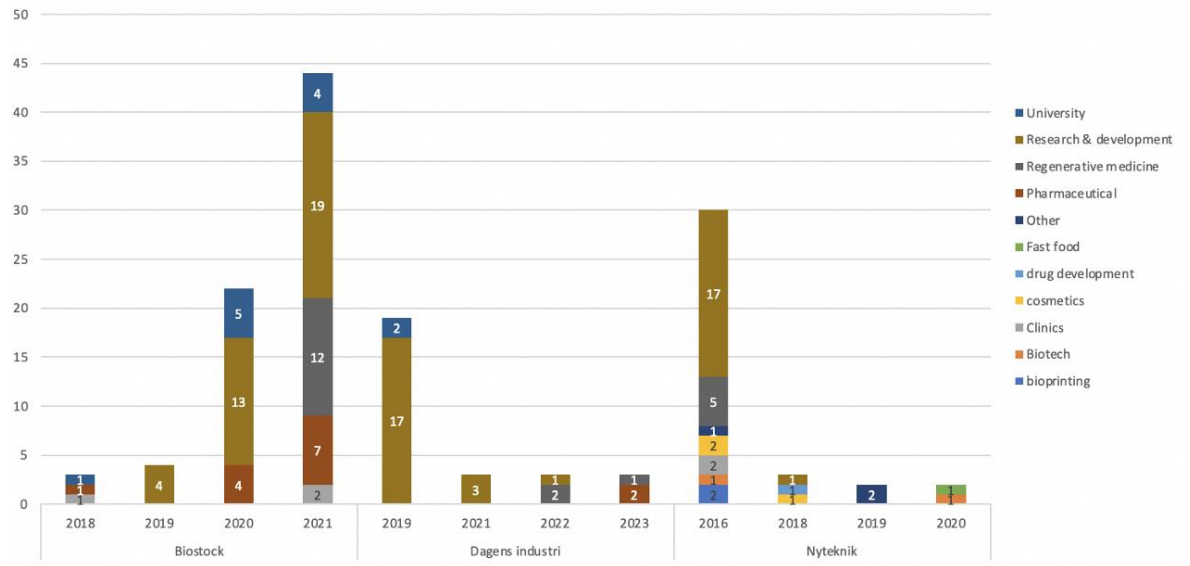

Figure 7 Illustrates customer by industry by year and outlet on the horizontal axis and amount of occurrence on the vertical axis

4.3.6 Type of market activity mentioned

The theme type of market activity consists of 5 categories, *Collaboration, partnership, distribution, contract research organization (CRO), and sale*. The focus for this theme is to explore what type of activity has been mentioned and to see how occurrences of market activity has changed over the years.

The overall findings in figure 8 shows a general upswing in interest in reporting on market activity, 2019, 2020 and 2021 is where amount of occurrences peak. Interestingly there are no occurrences in 2022. Sales is most prevalent across all three outlets, however 2 out 3 media outlets show a trend of mentioning collaborations, partnership and CRO activities. Findings from Dagens industri regarding market activity show most of the focus is on collaborations and partnerships with only three occurrences of sales during the time span; *"This project is conducted in collaboration with Hahn-Schickard and the Department of Microsystems Engineering ("IMTEK") at the University of Freiburg."*(Dagens industri, 2020/04/29). The quote highlights the nature of the bioprinting market between firms as being collaborative and was categorized accordingly. The collaboration allows firms with different expertise to combine knowledge and improve the practices of the industry. In 2023 focus has shifted from what has been accomplished in isolated events for bioprinters to a biotech firm commencing a collaboration with a pharmaceutical company; *"On Wednesday, the Danish pharmaceutical giant Novo Nordisk begins a new collaboration for bioprinting with the Canadian biotechnology company Aspect Biosystems."* (Dagens industri, 2023/04/12). There are also reportings on accelerator programs between bioprinting firms, the collaboration aims to further their capabilities as well as plans to optimize and refine the complex nature of bioprinting to make it more user friendly; *"CELLINK today announced that it has joined Dassault Systèmes' 3DEXPERIENCE Lab global accelerator program, with the aim to optimize the complex bioprinting process and provide a unique and intuitive 3D design experience for its bioprinting users across geographies"* (Dagens indistri, 2020/02/20). Notably the collaboration is for bioprinting research. Market activity mentioned in Biostock is most diversified across the three outlets, the main categories are CRO, sale, distribution, collaboration and partnership, the data shows an upswing in interest from 2020 and 2021, prior to these years there was little focus on market activities overall.

The quote below communicates positive notes of a collaboration between the biotech firm and healthcare/pharmaceutical company Roche. It demonstrates the relationship between the two firms has been longstanding, successful, trustworthy and effective; *"We look forward to carrying out another collaborative project together with Roche. Our collaboration stretches back to the development of Biozone 6 and we have thereby built a good and reliable relationship"*(Biostock, 2021/09/29). Making it clear that bioprinting firms value long lasting relationships. Another example of where the focus is on biotech firms' commitment to collaboration and fostering relationships in the research community; *"The company is also very committed to creating a robust collaboration within the research community around the work of developing new technology and methods to replace animal testing for research*

purposes."(Biostock, 2020/09/02). The aim of the collaboration is to develop new technology and processes that could in the long term replace animal testing, the quote insinuates engagement in the research community will foster innovation and development of the technology. Furthermore, it is seen that biotech firms opt for distribution deals when it comes to sales of their products, the aim is to strengthen their sales channels giving them a holistic market approach by not only focusing on specific markets such as the EU but given them greater global reach and thus expansion opportunities. It is also stated that the firm launches a CRO service to which diversifies their revenue stream; *"in March, 16 months after the launch of the 3D bioprinter Biopixlar, which has led to both new distribution agreements, increased sales and the initiation of CRO services*"(Biostock, 2021/07/01). The quote below highlights the firm's intent to establishing partnerships with Research & Development actors. The partnership aims to facilitate two things, collaborate with regenerative medicine firms and second to assist in drug development within the industry; "*In conjunction with this, we will also focus on establishing partnerships with important R&D players, either towards regenerative medicine or for drug development purposes"* (Biostock, 2021/07/01). Consequently, this was categorized as a partnership activity.

Market activity mentioned in Nyteknik shows only occurrence of Collaboration and sales with the bulk of findings displayed in 2016, however there is a shift of focus from sales to collaborations as time passes. It is stated by a biotech firm that while they are new to market they know their target audience, which is researchers, the following quote which was categorized as sale since it indicates sales activities; *"We have entered the market very quickly and find that it is easy for researchers to adopt our platform"*(Nyteknik, 2016/10/26). It is also highlighted that the customers are mainly universities, and the next biggest customer base is cosmetics firms. The firms bioink technology suggests a rare solution for printing human skin, which is mainly why cosmetics firms want to purchase the technology as this eliminates the need for animal testing. The universities are likely using the technology for R&D, investigating what the bioink and bioprinter is capable of, mainly by printing tissue aimed at serving the regenerative medicine market and for drug testing seen in the following quote categorized as sales; *"Among the customers are around 20 universities worldwide as well as around ten in industry. This includes cosmetics companies that want to use the printer and ink with skin cells to print human skin for animal-free testing*."(Nyteknik, 2016/03/31).

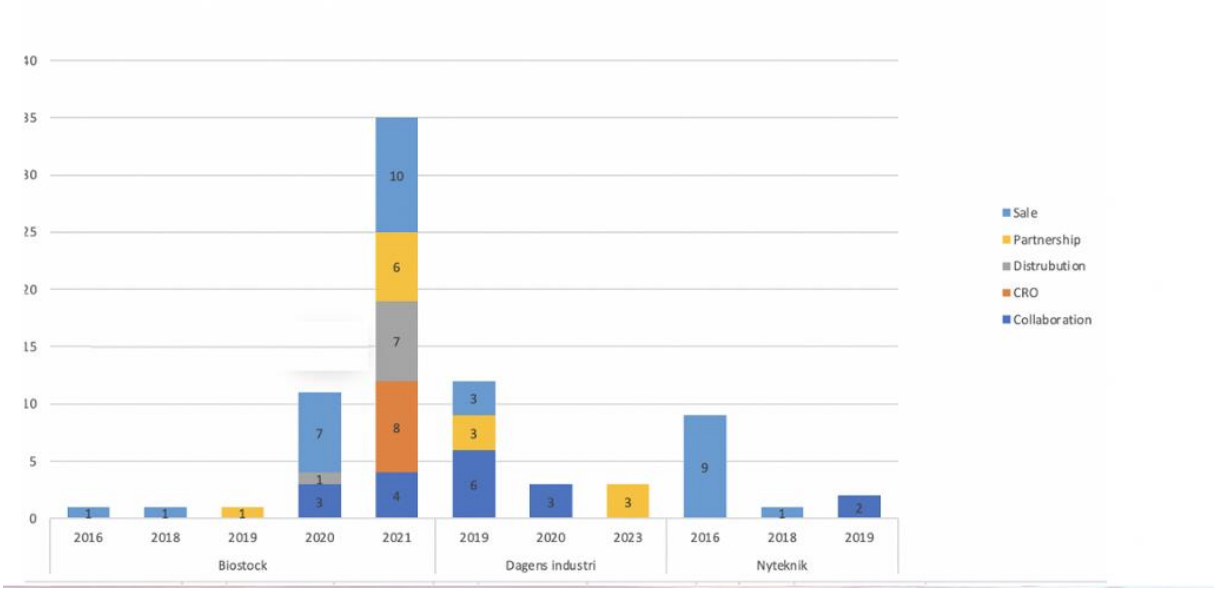

Figure 8 Illustrates market activity by year and outlet on the horizontal axis and amount of occurrence on the vertical axis

Summary

The data shows that there is growing interest in bioprinting market activities with occurrences steadily increasing from 2019 and onward. Between the 5 categories occurrences for sales being mentioned the most. Furthermore, it is seen that firms value a global reach rather than single markets by entering in distribution deals. Collaborations, partnership and CRO activities are all frequently seen throughout the timespan. Dagens industri highlight collaboration activities the most while Biostock show more diversity in occurrences. Furthermore, quotes often highlight the importance of long-term relationships when collaborations are initiated. Lastly, Nyteknik emphasizes collaborations as time progresses. Overall, the technology is being used for research activities, whether it be towards medical, cosmetical or drug development purposes.

4.3.7 Region of actors

The theme regions of actors simply refer to illustrating what regions of actors are mentioned, here there were 3 main regions identified, USA, Canada, Europe (Sweden, France, Germany, etc) and China. There were other regions observed (Australia, New Zeeland & Japan) although not to the degree of having their own category, thus these actors are referred to as other. The focus for this theme is to explore the regions of actors in order to understand the general market development of actors. The results of figure 9 are somewhat similar, the majority of occurrences are EU, and USA with a couple of actors mentioned in china and other. The difference in the three figures is when the actors are mentioned, which would be explained by publishing date as seen in figure 9, it is also worth noting that significance of an actor's region seemed to be more relevant from 2019 and onwards.

In the two quotes presented the direct region isn't mentioned, however it is implied as the readers are given context earlier, aspect biosystems is a Canadian bioprinting company and is

seen in the bar chart for Dagens industri. *"Aspect Biosystems is a biotechnology company focused on bioprinting tissues for the treatment of chronic diseases."*(Dagens industri, 2023/04/12). 3D biosystems is a Russian bioprinting firm and was categorized as other since this was an isolated occurrence; *"The technology to create the world's first artificial chicken nugget has been developed by the company 3D Bioprinting Solutions"* (Nyteknik, 2020/07/20).

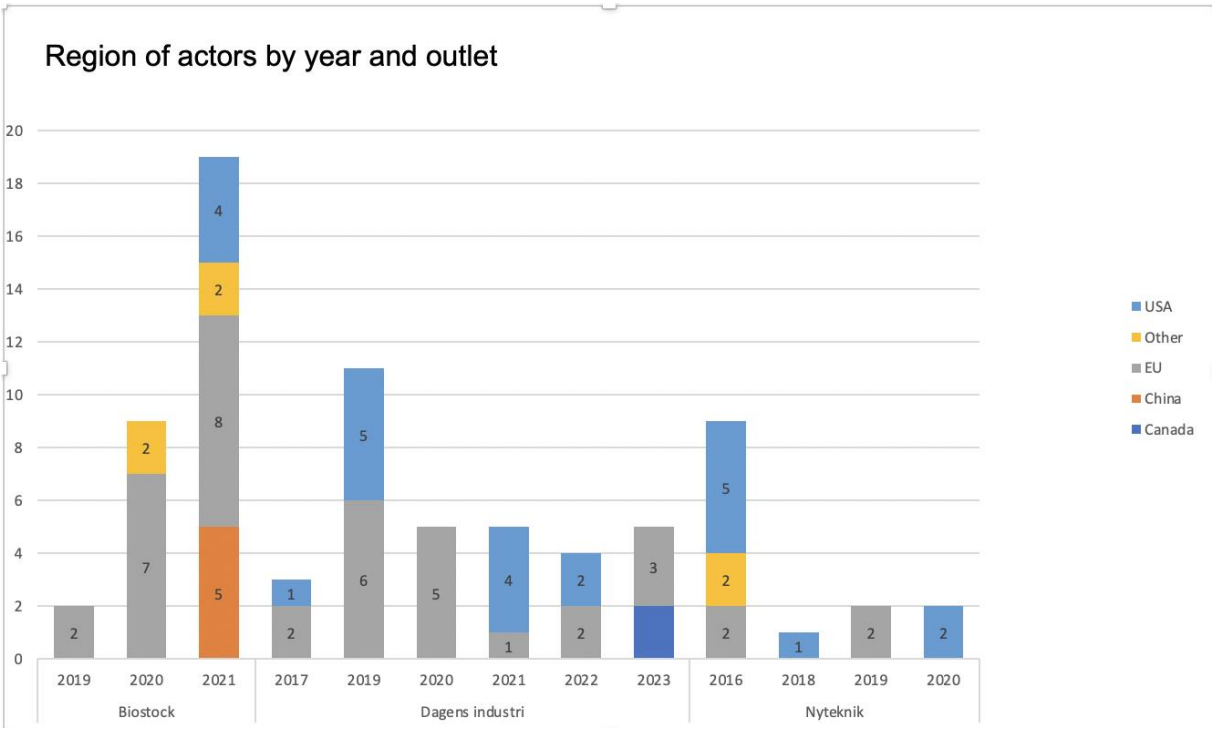

Figure 9 Illustrates the region of actors mentioned by year and outlet on the horizontal axis and amount of occurrence on the vertical axis

Summary

Overall, the region of actors is indirectly mentioned, and it is most common when it is in relation to company names with the bulk of occurrences seen in the EU and USA. The majority of occurrences stem from Dagens industri with Biostock coming in close second, the former having a evenly distributed whilst the former showing a distinct increase as years pass.

5. Discussion

The following chapter contains a discussion of the empirical findings through the literature presented in the study.

5.1 Chapter overview

Here we aim to contextualize the findings from the previous chapter through discussion supplemented by literature found in Chapter 2. The research questions aim to address the general market development of bioprinting through these themes see Chapter 4, something that current literature has not addressed. The literature presented in Chapter 2 concern market development, bioprinting, and Technology readiness level. Consequently, the two research questions that have guided the research are

1. What does the market for the 3D Bioprinting industry look like?
2. What is the stage of market development for the 3D bioprinting technology?

5.1.2 Bioprinting market

The first research question in this study aims to address what various activities were mentioned regarding bioprinting, in order to determine the state of the current bioprinting market. The use of technology has progressively increased through the years, findings show that the technology being described is used for more and more complex applications as the time-span progresses. This isn't reflected in the figures as they only indicate that the technology is used for research and development. As stated application areas for bioprinting include the cosmetics industry, surgical planning, drug research, and the production of medicine (Murphy, De Coppi and Atala, 2019). The occurrence of what the type of technology is used for in contrast to bioprinting literature is inconclusive as the literature regarding the subject is mainly focused on explaining how the technology works whilst news outlets report on what type of technology and what it does within the application areas. In some cases, it was found that literature and articles aligned where research indicates that research advances have been made which has allowed 3D bioprinting to excel in creating living tissue (Murphy and Atala, 2014). In the three news outlets' articles stated that bioprinting technology is used for printing living tissue to cure illnesses with patient-specific 'products' through research and development. This is in line with research that also states bioprinting creates custom-made tissue structures that meet patient needs in regard to their specific illnesses (Combellack, Jessop and Whitaker, 2018). Other examples from the literature that has also been mentioned in the findings are application areas, such as the reconstruction of organs, stem cell distinction, and restoration of anatomic defects (Chia and Wu, 2015). Elemoso et al., (2020) estimate that the wound market will be worth a whopping $1Billion by 2024, in contrast, news outlets have reported on the success and hopefulness in printing functional skin to be implanted but no indication of the estimated value. Rather occurrences of printing skin have been reported as major advances in the industry. Thus, the

estimated value of the wound market is not seen in this thesis empirical findings. On the one hand one reason could be that the market is so underdeveloped that news outlets focus on 'substantial' progression such as printing more complex body parts. Current bioprinting literature rarely accounts for what type of actors are currently in the bioprinting market, therefore it remains unclear from a scholarly perspective what actors are currently driving the technological development. Looking back at Figure 5, unsurprisingly we see that it is mainly biotech firms that drive the market themselves. This is seen in sales activities where firms deliberately lower the quality of printers to increase sales, which will ultimately drive the sales of biomaterials. As a result, it is seen in recent years that actors within various industries are now engaging, such as universities and some pharmaceutical firms. The projects that biotech firms conduct tend to have several actors such as firms, producers, users, regulatory bodies, and universities. All of these are present in the empirical findings in Figures 2-9. According to Darroch & Miles (2011), market development innovation embodies scientific advances through meticulous R&D leading to an industry (market) shift in the existing industry. Bioprinting is seen to enter several industries, offering never-before-seen solutions such as the ability to print skin when developing new cosmetics, eliminating the need for animal testing. Thus, enabling the cosmetics industry to navigate around the newly imposed regulations on animal testing. Furthermore, in the case of drug development where bioprinting allows researchers to print patient-specific tissue in order to assess how a patient would react.

In conclusion, the current bioprinting market is developing with emerging application areas and interest for various actors. However, most of the biotech firms' market activity is based on research and development, consequently, each of the actors is perusing technological advancement through these activities to gain a competitive advantage.

5.1.3 Diverse markets

As seen in chapter 4 both in figure 8 & 7 bioprinting serves diverse markets that use the technology for various needs. The focus when exploring the type of activity was to clarify what activities have developed during the data period and whether categorical occurrences have seen an increase or decrease. As seen in both figures 7 & 8, the bioprinting firms focus heavily on research and development, through collaboration activities, partnerships and CRO activities. All of these are consistent throughout the figure 7. CRO activities are where bioprinting firms have created an additional branch to their operation that addresses CRO activities with customers. It is found that when firms launch their innovative products that are market-creators, it needs very advanced R&D capabilities as well as workers that know how to operate the systems (Darroch and Miles, 2011). The current bioprinting industry is heavily invested in furthering its capabilities through every means necessary and all indications when consulting literature points to the market being at the very early stages of development (Sprong *et al.*, 2021). In 2015 and 2018 it was stated that bioprinting had exceeded its expectations and was being used in multiple fields of research and commercial fields such as drug development (Chia and Wu, 2015; Combellack, Jessop and Whitaker, 2018). In the empirical data regarding customers by industry we found that this is an accurate claim and that the industry has gone beyond the commercial use stated, with customers in the ranging from cosmetics firms, fast-

food and even clinics being stated as a customer. The assertion of bioprinting being used in multiple fields of research is also accurate seeing as customers are also universities, regenerative medicine, and institutions. It was made clear in the findings that cosmetics companies use bioprinting in efforts to replace animal testing due to regulations in the EU regulation. The occurrence of cosmetic customers has increased over the time span which indicates that bioprinting is developing and has the possibility to serve multiple markets, many of which were not mentioned in bioprinting literature. However, the literature states that bioprinting capabilities are still in the developing stages and the bioprinting market is described as nascent but growing at a rapid rate (Ozbolat, Peng and Ozbolat, 2016). One reason for the rapid development could be that Bioprinting firms specifically target industries where regulation is somewhat lax in comparison to what was described in Chapter 2.2. This could be one reason why the empirical findings show results that are not yet documented in the recent scientific literature for example with regenerative medicine customers shown in the data, can be explained by the fact that bioprinting has shown great promise because of tissue printing capabilities and advancement in printing precision (Bicudo, Faulkner, & Li, 2021). Although there have been developments in the precision of printers it is noticeable that there is a connection between price and precision. One reason could be various market strategies by bioprinting firms, as some are seen to develop highly advanced systems and others have lowered their price points in order to increase sales. The lower-end systems typically use EBB systems while more advanced systems use microfluidic single-cell systems. The market development of the former system aims to generate revenue from bioink sales, the printer is thus an enabler of these activities.

5.1.4 Technology readiness level

As discussed in the literature review TRL assess the maturity of the technology in development phases through nine levels (Mankins, 1995). Across three news outlets seven out of the nine levels were mentioned. Occurrences mainly concern research and development.
What was found is that many basic principles were observed which is supported by literature, which explains how technology is developed (Ozbolat, Peng and Ozbolat, 2016). There were some occurrences where bioprinting showed high levels of TRL, however, these cases don't reflect the entire systems capability, as seen in the case of KFC where biomeat was mass produced. Therefore, the system is working in an operational environment; however, the system is not capable of operating at full capacity in clinics, in fact there was no occurrence of technology in clinics referring to products to patients, only research and development at clinics. The development of TRL and how it is described has evolved over the years as seen in the data but the technology is still in the very early stages of readiness, another factor is of course regulation which is mentioned in both bioprinting literature that one challenge is several structure components for tissue production make it hard to follow regulation(Murphy, De Coppi and Atala, 2019). Which is also mentioned in the empirical findings. It is not uncommon for scientific publications to discuss cartilage, bone or skin as seen in several examples (Chia and Wu, 2015; Bishop *et al.*, 2017; Combellack, Jessop and Whitaker, 2018). Likewise, it is not uncommon for biomaterials to be mentioned in (Ozbolat, 2015; Ozbolat and Hospodiuk, 2016; Ovsianikov, Khademhosseini and Mironov, 2018). However, as in previous cases, these

publications cover the technical aspects of the technology whereas it is mentioned in a different context in the newspaper articles. The development of the type of technology has been steady over the years as all three outlets cover bioprinting in general and report specific types when there have been breakthroughs with the technology. Overall, the TRL for bioprinting is steady between levels 1- 4, Researchers face the challenge of; a) creating more complex systems overall and b) shifting capabilities from in vitro to in vivo. Although it was seen in the data that outer ears had been implanted on patients, when looking at this through TRL it still wouldn't be higher levels of the scale since there have not been any clinical studies on the technology.

6. Conclusion

Exploring the development of any market is a challenge, the bioprinting market is no exception and groundbreaking advances are being made every year that passes with this newly developed technology. However, as the industry continues to progress so does the body of literature supplement it, which discusses new technological findings. Nevertheless, literature addressing what the market looks like and furthermore what the degree of stage of development the technology delivers is scarce. Therefore, this thesis aims to contribute to the literature by exploring the current stage of the market and development of it. The research did so through a longitudinal case study. Empirical findings were based on newspaper articles spanning from 2010 to March 2023, it was through data derived from articles where predominant categories regarding market development were established. These later came to develop themes presented in the empirics. Through the identification of these 7 themes, the study promotes understanding of the bioprinting market and its development.

In relation to the first 2 findings discussed in chapter 5 which relates to the first research question, it was established that bioprinting has the capability of serving multiple industries, some of them needing requiring vastly different technology. The bioprinting market relies heavily on Research & development at this point, although the data indicate that more and more industries are making the leap in adopting the technology. Furthermore, research & development is not always in relation to universities or institutes, there were examples of industry actors conducting their own research toward their own goals, even though bioprinting is still in its infancy. The most dissimilar and successful use of bioprinting is in the fast-food industry. Regulatory aspects may work in favor of bioprinting as animal testing is being banned across Europe, which allows bioprinting firms to market the systems. A major finding is that bioprinting firms have shifted market efforts from only selling to offering research services alongside the bioprinters & biomaterials, through collaborations, partnerships & CROs. In conclusion, the bioprinting market is progressing and evolving mainly through research & development actors, although other actors are emerging. Market development is driven by bioprinting firms building long-term relationships through research & development, thus furthering bioprinting capabilities.

Regarding the third finding discussed in Chapter 5, which relates to the second research question. It was found that while the dialog toward bioprinting is positive with articles mainly reporting on advances. The stage of market development has not changed, which is based on the TRL findings in Chapter 4. Although at this stage in market development bioprinting technology does offer many opportunities, again spanning several industries. At the current stage, bioprinting firms find it important to help clients recognize the value, which based on research question 1 is done through collaboration, partnerships, and even CRO branches as the awareness of bioprinting potential is vital in adopting the technology at this stage in market development.

In conclusion, the bioprinting market is heavily dependent on Research & development in terms of market development and whilst the bioprinting market is still in the early stages of development firms from several industries are adopting the technology. Interestingly research & development activities are not limited to universities or institutes, it is also conducted across the industries that are adopting bioprinting in their respective fields. Existing literature estimates the market value of bioprinting to be in the billions, however, it should be noted that this is a global estimation, including powerhouses like Japan, China, and the US. Although there were no occurrences where Swedish news outlets disclosed market value the investigation of activities, actors, advances, collaboration, and more indicate that the market valuation claims and prognosis are correct. One element that speaks to this is the rapid growth of biotechnology firms, where Swedish Cellink reported an employee growth of 1000 plus individuals. Another element is the emergence of new entrants seeking to adopt the technology, mainly cosmetics and pharmaceutical companies. Although the findings in this thesis show that bioprinting is generally used for R&D, they do support the enormous potential of bioprinting as well as the current market valuations. Furthermore, the empirical findings show positive advancement within the industry while the market development stage based on TRL remains the same. Thus, the market is developing although it is in various fields other than printing complex organs. Bioprinting firms aim to advance the stage of market development through long-term relationships built on research & development.

7. Future research and self-reflection

The master thesis has been a special learning experience, as a student makes you aware of time management and planning on a different level than coursework. The thesis also provokes new thoughts, and new methods and gave me a new outlook on research is conducted. One thought has been with me throughout the thesis, don't overextend yourself, keep it within the scope of the research. However, this is a challenge when news ideas form along the way, these ideas will be presented in the form of future research recommendations. First, data collection, which is the main limitation of this study. Most firms within the industry emerged within the last 7 years and are very protective of their systems. Thus, if the strategy is to conduct a qualitative study using interviews as the data source, make sure you have the participants signed up as soon as you start working as there is a risk the data collection methods will fall through. This would be a major improvement to this study. Furthermore, this study emphasized market development it was limited, and the subject could be further explored and explained by adopting a more technological scope in regard to research. Thus, the connection to the market and technology would be strengthened. Additionally, future research could benefit from combining findings in order to map out trends seen over the years, this would contextualize the growth of the industry over time which would be interesting to investigate. Last, the literature used could be expanded by using both TRL and market readiness level (MRL), thus the study would include the scope of how ready bioprinting systems are to be commercialized. Lastly, this study as stated early on intends to contribute to what current bioprinting literature has paid scarce attention to, the bioprinting market from an activities point of view. Hopefully, this study will serve as a building block for other studies that seek to explore the market of bioprinting.

Implications for society

The implications of the findings from a societal perspective are mainly providing insight and understanding to a rapidly advancing field. As stated in the introduction the healthcare industry faces major challenges for life-restrictive diseases as well as patient care because of the growing population. Bioprinting promises a solution to both challenges through forming on-demand patient-specific organ, tissue, and drug development. For some, it might be hard to understand the implications of bioprinting and what stage the market currently is in, which this thesis provides answers to by investigating the market development and technology readiness. Healthcare is one of the most important sectors of our infrastructure, as well as one of the most profitable, therefore the social implication is to educate the public regarding developments. Although the findings in this thesis does not touch on what implementing bioprinting would have on the healthcare sector it is an important aspect to consider with the promises presented by current literature. Implementation of bioprinting would undoubtedly raise ethical questions from a patient perspective.

Implications for practice

Bioprinting poses many beneficial implications for practicing firms, first industry professionals will gain insights to the industry by reading the thesis. Conclusions show that the technology is advancing and those firms that are looking for new solutions to ongoing trends or regulations. Firstly, from a sustainability perspective, findings in this thesis show KFC taking a step towards Biomeat which can give way for new entrants in the fast-food industry looking for meat or plant alternatives. Furthermore, in the long term, this may pose an alternative to the meat industry as a whole and possibly contribute to cutting emissions as a result. Secondly, long-term implications for clinics are organ transplants with reduced risk of organ repulsion. Subsequently, the organ market would no longer be as prominent. Bioprinter adopters in the cosmetics industry will no longer need to test their products on animals and would hopefully get better results on how the products interact with human skin. Resulting in superior products for their consumers.

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9. Appendices

9.1 Appendix A – Newspaper outlets and articles

News outlet	Article title	Date published	ID
Dagens Industri	CELLINK to partner with Made In Space to advance bioprinting technology in space	16 december 2019	1
Dagens Industri	Svenska 3D-printare jublar över transplanterat öra	17 June 2022	2
Dagens Industri	Novo Nordisk i nytt bioprinting-samarbete	12 April 2023	3
Dagens Industri	Bioprinting advanced skin architecture complete with blood vessels using CELLINK technology	4 November 2019	4
Dagens Industri	Bicos vd i första rapporten efter kollapsen: ”Känner större tilltro än någonsin”	24 August 2022	5
Dagens Industri	CELLINK joins Dassault Systèmes' 3DEXPERIENCE Lab global accelerator program	20 February 2020	6
Dagens Industri	Bico köper amerikanskt för 6 miljoner dollar	6 May 2022	7
Dagens Industri	CELLINK launches new bioinks to further strengthen the company's bioink portfolio	21 November 2019	8
Dagens Industri	2cureX German subsidiary receives a grant contribution to support the activities towards automation of the IndiTreat® test	29 April 2020	9
Dagens Industri	Cellinks aggressiva köpstrategi fortsätter: ”Tittar på flertalet bolag”	29 June 2021	10
Dagens Industri	Kursrusaren Cellink byter namn	7 July 2021	11
Dagens Industri	Cellink förvärvar tyska Nanoscribe	19 May 2021	12
Dagens Industri	Cellink köper amerikanskt bolag för 62 miljoner	20 May 2021	13

Dagens Industri	CELLINK har fått bidrag för att utveckla nya vävnader som efterliknar organ in vitro som kan appliceras inom läkemedelsutveckling och testning för njursjukdomar.	4 March 2020	14
Dagens Industri	Cellink förvärvar amerikanskt bolag för 580 miljoner	10 March 2021	15
Dagens Industri	Karolinska Institute study shows CELLINK's I-DOT liquid-handling system can enable genetic cancer diagnostic research	22 October 2019	16
Dagens Industri	CELLINK signs agreement to expand its production area	23 December 2019	17
Dagens Industri	CELLINK's BIO X wins The Chicago Athenaeum's prestigious GOOD DESIGN Award	19 December 2019	18
Dagens Industri	Cellink tog Chalmers biobläck till börsen	14 mars 2017	19
Dagens Industri	Tillväxtraketen rusade på börsen: ”Vi har en superaggressiv förvärvsagenda”	26 January 2021	20
Dagens Industri	De skriver ut mänsklig vävnad	14 March 2017	21
Nyteknik	Svenska experten: "3d-skrivaren skapar inte liv"	18 February 2016	22
Nyteknik	Hud och ben kan 3d-printas i rymden	30 June 2019	23
Nyteknik	Cellink vill skriva ut mänskliga reservdelar	3 December 2018	24
Nyteknik	Hud-skrivarens nästa steg: bli enklare	26 October 2016	25
Nyteknik	Hyllade biotech-startupen Cellink kliver in på börsen	30 September 2016	26
Nyteknik	Sug efter 3d-skrivare för hud	31 March 2016	27
Nyteknik	3d-skrivare för hud ersätter djurförsök	21 March 2016	28
Nyteknik	Hårdare krav efter KI-skandalen	14 March 2016	29
Nyteknik	Organ direkt ur skrivaren tog hem 33-platsen i Göteborg	29 February 2016	30
Nyteknik	Svenska experten: Bioskrivare ett steg närmare kliniken	23 February 2016	31
Nyteknik	3d-skrivare för ”levande” mänskliga reservdelar	17 February 2016	32
Nyteknik	Då ska KFC presentera sin 3d-printade ”slaktfria” nugget	20 July 2020	33
Biostock	VD-intervju: CELLINKs teknologi bakom bioprintade mänskliga hornhinnor	5 june 2018	34
Biostock	Fluicell ingår avtal med big pharma för 3-D-bioprintingprojekt	29 September 2021	35
Biostock	Fluicell at the forefront of 3D bioprinting	20 March, 2020	36
Biostock	Fluicell ska tillgodose behovet av nya experimentella modeller	2 September 2020	37

Biostock	Fluicell utnyttjar mikrofluidik för att bli ledande inom biomedicin	21 December 2020	38
Biostock	Säljteamet – en nyckelkomponent i Fluicells tillväxt	15 April 2021	39
Biostock	2021 innebär en början på en ny era för Fluicell	1 July 2021	40
Biostock	PHI äntrar lovande forskningsfält	12 October 2021	41
Biostock	Fluicells Q1-rapport indikerar fortsatt expansion	18 May 2020	42
Biostock	Fluicell gör avtryck inom neurovetenskapen	11 November 2020	43
Biostock	2020 – ett år av tillväxt och expansion för Fluicell	26 January 2021	44
Biostock	Fluicell satsar på regenerativ medicin	18 May 2021	45
Biostock	Analys pekar på ljusare tider för bioteknik	8 march 2023	46
Biostock	Stort intresse för nytt biobläckbolag på First North	3 November 2016	47
Biostock	Börsnykomling rusar vidare på informationsläcka	15 November 2016	48
Biostock	Cellink dubbelt prisat	16 October 2019	49