Executive Summary

Science has given us the opportunity to understand biological systems in a more sophisticated manner, developing intricate biomaterial structures to support transplanted body tissues. The complexity of human bodies provides many unanswered questions, questions the Warwick iGEM team are interested in finding solutions for. We are using our understanding of biomaterials and current 3D Printers, to create a new product providing methods in order to build bodily accepting repair structures. Current bio 3D printers are using inefficient methods, such as material deposition, to fabricate products. In order to solve this, we are implementing our ideologies parallel, to create an improved cost effective method to generate biocompatible scaffoldings for implants.

In order to obtain productive efficiency, we aim to reduce our production costs by implementing a lean manufacturing system. Lean manufacturing will minimise the waste, thus, helping cut down costs and implementing the savings in further product improvement (through R&D). Using JIT, an optimal solution, we are able to produce goods as a response to demand.

There will be minimal waste and no need to hold stock. In relation to our product, we aim to reduce production costs by thoroughly understanding the flaws within the field of 3D bioprinting. Previously, we have studied the leading competitors within the market as well as conducted research on a wide range of potential stakeholders. We have gained inspiration and knowledge from great, current firms- thus, using this to our advantage to improve our product.

As explained later on in the page, our interest in entering the low cost bioprinting market gap has allowed us to cultivate our understanding of current engineering affairs. We strongly believe that we will be able to produce and create goods that can be used as medical aid for low income areas, adding to our philosophy of essentially, helping others, through to heights of natural sciences and engineering.

Market Understanding

The global medical implant market is predicted to grow to $1 16.3 billion by 2022 at a rate of 7.1% compound annual growth rate (CAGR), due to a growing healthcare sector, technological advances and an ageing population. Within the medical implant market some of the most attractive product sectors for investment are for orthopaedic and dental implants, due to high market growth rate and an attractive niche market. The dental implant market is predicted to grow to $12.32 billion by 2021, at a CAGR of 7.2%, due additionally to the increase in disposable income and cosmetic dentistry. The largest share of this market is for titanium implants, due to their high strength, durability and biocompatibility. Europe is the leading global market for dental implants and Asia Pacific is the fastest growth market for dental implants.

It is predicted that by the end of 2021 the global medical device coatings market will grow to $1 1.8billion at a CAGR of 7.8%, due to lenient government regulations, improved healthcare access, increased awareness of disease spread in hospitals and an increase in growth of epidemic diseases. The medical device coatings market includes the modification of the surface of devices, equipment and implants. These modifications help reduce wear and tear, the development of microbes and infections, friction between devices and tissue and improvement of Osseo integration of medical implants. Anti microbial coatings are the dominant market segment and the fastest growing segment is hydrophilic coatings. General surgery, orthopedics and cardiovascular applications dominate the market, with cardiovascular applications been the fastest growing due to the increase in pace makers and implants.

North America is the dominant region in the market and Europe is the second most dominate. The highest grow this in the Asia pacific region, which is driving growth. An increase in health awareness and in the population age in Latin America is increasing demand. From this we decided to create a product aimed at certain sectors such as the dental coatings market, which would allow for expansion into the coatings market for other medical devices such as cardiovascular and orthopedics. The product is aimed at the European market initially with the aim of expanding into the Asia pacific region. As the market is dominated by anti—microbial coatings, the product has been altered to improve the microbial resistance and reduce the likelihood of infection, which is a current problem within the dental implants industry.

Market Competitors: Direct

Within the bio 3D printer market, the most prominent technique used is ink jet printing. This method has a high xyz resolution of typically 5um (u = micro) similar to our printer. These cost significantly more for professional models, within the $10,000 to $100,000 range for the EnvisionTEC bioplotter and over $15,000 for the Ourobotics model. A simple DIY model is available, which can obtain similar resolution and cost as our own design. Bio inkjet printer shave a fast printing speed, at 1-10,000 droplets per second, similar to the high fabrication speeds of projection stereo—lithographic printers, such as our own. For implants where the fabricated part is small and resolution is high, the printing process is very fast but if large parts are required this will be a more time-consuming process. For this reason, the possibilities for expansion into larger commercial parts is currently infeasible. The EnvisionTEC printers all use UV light while instead our 3D printer uses visible light as this isn't damaging to cell DNA, increasing the range of cells we are able to use for current, and more importantly, future research.

EnvisonTEC is the most prominent competitor within the light based 3D printing market, having started in 1999 with the first patent. They have developed their range to include four families of light activated 3D printers as well as expanding into the inkjet printer market. The four light activated 3D printer families available are the desktop, which has lower xy resolution (82x105um) than our own and a price of over $10,000; the Perfunctory, which has a resolution down to 19um but a significant price tag; the CDLM, which reaches resolutions of 39.8urn for jewelery but with a high price; and the SSP, which is a relatively new patent and is priced over $40,000.

The competitor 3D printers have larger print beds for high resolutions compared to our method, which limits the commercial applications of our 3D printer, but as the market we are targeting is dental implants the small print bed size is currently not a necessary consideration. In the future for further expansion the printer bed would have to be increased but this has a damaging effect on the printer resolution, reducing the resolution to our competitors that use lower resolution. We are currently restricted to one material that needs to be altered before printing which limits the product applications compared to our competitors that have a range of materials available, however, as we are dealing with a niche market- we will be able to focus on perfecting the certain areas. Our philosophy is working on creating a 3D printer that does not need to build on large scales, therefore, this helps reduce our cost overall.

This one material we are using right now may limit our ability to expand into different markets such as pharmacology and the fashion industry. However, if to create a small object/ surface coating- a £30,000 printer is needed, then customers will need another option. Our method creates a smaller, cheaper way of creating small parts which will be enough for a firm in need of implant coatings.

Market Competitors: Indirect

The main material competitors for our coating would be titanium and Hydroxyapatite (HA), which are both porous with good Osseo integration, fast recovery rates, high bone fixation and reduced pain compared to other implant coating materials. These offer long-term improvements to overall implant performance compared to alternative coatings due to the good Osseo integration and the level of bone in growth.

In a recent study the combination of these materials and silver was used to create a nano-coating that inhibited bacterial growth and reduced the formation of bacterial biofilms on the surface by 97.5%. The formation of biofilms on the surface of dental implants is a significant problem that leads to peri-implantitis, which affects the soft and hard tissue surrounding dental implants.

An alternative method of inhibiting bacterial growth is by applying an antimicrobial coating, of antibiotics or chlorhexidine, in addition to other coatings but this is only effective in the short term. Our 3D printed coating offers good Osseo integration, on the scale of titanium and hydroxyapatite, due to the micrometre wide holes introduced to the material using our stereo-lithographic printer, as well as incorporating antibacterial properties making it suitable for dental applications.

Profits

Possible market size = number of hip transplant per year in the UK, it is possible to consider international markets, but at this point we will only think about local opportunities. There are ~160,000 case per year in England and Wales it is not logical to assume that most case require a coating, this is a developed technique and the coating we provide is an extra rather than a necessity. So we take 5% of the total number of surgeries instead, that is 8000 cases.

Materials needed = 20cm^2 x number of operations + margin of error and wastage, the area accounts for wastage. Each cm^2 will be charged £10, every case will vary so a general estimation was used.

Gross income = charge for one operation x number of operations year.

This will give us a rough income per year, the gross income give 27.4% return in the first year, this should increase after the first year as more hospitals will know about this product we provide.

Cost

Location for mass production – working with other 3D bio printing companies that is already established will help to reduce cost.

Wages - how many people will we need to function, plus supervisors, judging from the average income data we will be looking at around £600000 a year. From 3 material scientist, 7 lab assistants, 3 chemist, 3 quality control, 3 medical information specialist and 1 clinical trials specialist.

Equipment and maintenance – cost of each 3d printer, in large scale we will need to count cost for each compartment, e.g. projector, moving arms… or buy readymade industrial printers and adjust them, which can cost 200,000 USD each. We need to keep the printers sterilised, machines that can sterilise equipment with electrical components is necessary. Chlorine Dioxide Gas Sterilizer is one of the choice, they cost around £2000 each.

Environmental charges and waste processing – the cost was estimated using the Environmental permitting charges scheme document from the UK government's website.

Raw materials – cost of cell culture, medium used etc.

Packaging and shipping –a 10cm x 10cm box will be used for each craft, cost ~£5 each, we will transport them in insulated boxes that cost around £ 20 each, the total cost is dependent on how much is needed.

Costs

Equipment	**Cost (GBP £)**
3d Printer	50000
Gas Sterilizer	6000
Incubator	36350
Flasks	140
Measuring equipment	450
Total	92940

Fixed cost	**Cost (GBP £)**
Labour	600000
Supervision	95000
Maintenance	6240
Taxes & Insurance	3100
Environmental charges	21770
General overhead	250000
Total	976110

Variable cost	**Cost (GBP £)**
Raw materials	30000
Packaging & Transport	16000
Consumables	60600
Total	106600
Total production cost	1175650

Profits

Factors	**Value (GBP £)**
Charge for coating	200
Revenue	8000
Gross income	1600000
Gross profit	322350

27.4% return if total cost is £1175650