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USABILITY OF ADDITIVE MANUFACTURING IN THE FIELD MEDICAL SYSTEM

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TIIVISTELMÄ

LUT University

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LUT Kemiantekniikka

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Lisäävän valmistusmenetelmän käytettävyys kenttälääkintäjärjestelmässä

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Diplomityön tavoitteena oli selvittää lisäävän valmistusmenetelmän käytettävyyttä osana Puolustusvoimien kenttälääkintäjärjestelmää. Perinteiset lääkintämateriaalien toimitusketjut ovat pitkiä ja muodostuvat useista toimijoista. Moniportainen toimitusketju sisältävää riskejä ja epävarmuustekijöitä, jotka heikentävät materiaalista huoltovarmuutta. Lisäävän valmistusmenetelmän nopea kehittyminen mahdollistaa uusien lääkinnällisten sovellusten tuottamisen. Tuotteiden valmistus paikallisesti biopohjaisista raaka-aineista lyhentää toimitusketjua ja sisältää perinteistä toimitusketjua vähemmän riskejä. Biopohjaisten tulostusmateriaalien käyttö vähentää haitallisia päästöjä ja on ympäristöystävällisempi ratkaisu kuin fossiiliset tulostusmateriaalit. Lisäävä valmistus mahdollistaa keskeisimpien lääkintämateriaalien valmistamisen yksittäiselle sotilaalle, sekä lääkintäryhmille. Suunnittelussa voidaan paremmin huomioida erilaisten käyttöolosuhteiden asettamat vaatimukset ja tuotteet voidaan helposti muokata vaadittuihin olosuhteisiin. Lisäksi kokonaiskustannukset ovat merkittävästi pienemmät kuin perinteisellä valmistusmenetelmällä tuotetuilla vastaavilla tuotteilla. 3D-biotulostus mahdollistaa lääkinnällisten mallien tulostuksen ja malleja voidaan hyödyntää hoitotoimenpiteiden opettelussa, joka vähentää tarvetta käyttää koe-eläimiä koulutuksessa.

ABSTRACT

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Usability of additive manufacturing in the field medical system

Master's Thesis
95 pages, 35 figures, 4 tables
Examiners: Associate professor Eveliina Repo, D.Sc. (Tech)
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Keywords: Additive manufacturing, 3D printing, biomaterials, field medical system, supply chain, logistics, supply security

The aim of this thesis was to find a medical solution from the field of additive manufacturing which can be used to support the Finnish Defence Force's field medical system. Recent wars in the world have pointed out many problems in combat casualty care: long medical material supply chains contain several risks and unreliabilities, which reduces supply chain security. Additive manufacturing is a fast-developing field and new medical applications are created continually. Local production with biobased raw materials shortens and reduces risks in the medical materials supply chain. Production with biobased raw materials is a more environmentally friendly solution compared to fossil-based raw materials. It is possible to produce medical products for individual soldier and medical groups with lower overall costs compared to those produced conventionally. The average profiles of injuries diverges from injury profiles in normal conditions, and 3D bioprinting offers possibilities to print medical models which can be used to support training in field medical measures, which reduces the need for using animals for training purposes.

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ABBREVIATIONS

Advanced materials	New materials and modifications to existing materials to obtain superior performance in one or more characteristics that are critical for the application under consideration
Biomaterials	Substance that has been engineered to interact with biological systems for a medical purpose
Biobased materials	Material intentionally made from substances derived from living (or once-living) organisms
CASEVAC	Casualty Evacuation: care occurs while the casualty is being transported off the battlefield to a medical treatment facility
MEDEVAC	Medical Evacuation, efficient movement and en route care provided by medical personnel to wounded being evacuated from a battlefield
Triage	Process of determining the priority of patients to reach efficient treatment within sufficient resources
CNC	Computer Numerical Control
AM	Additive Manufacturing
3DP	Three-Dimensional Printing
STL (File Format)	Standard Triangle Language
CT	Computerised Tomography
MDCT	Multiple Detector Computerised Tomography
MRI	Magnetic Resonance Imaging

DCR	Damage Control Resuscitation
DCR	Damage Control Surgery
WHO	World Health Organization
UN	United Nations

1 INTRODUCTION

The Finnish Defence Force's Logistics Command has responsibility for the operational capability of troops, systems, and material availability. This Master's thesis is part of the Logistic Command additive manufacturing and 3D-printing research activities in the fields of medicine and logistics.

The Geneva Conventions (International agreement) are rules that aim to protect people (soldiers and civilians) in armed conflicts. These rules of war aim to protect people who are not (or no longer) taking part in hostilities, including sick and wounded members of the armed forces in the field or at sea, civilians, and prisoners of war. (The Geneva Conventions 1-4)

> "Officers and soldiers and other persons officially attached to the armed forces who are wounded or sick shall be respected and protected in all circumstances; they shall be treated with humanity and cared for medically, without distinction of nationality, by the belligerent in whose power they may be.
> Nevertheless, the belligerent who is compelled to abandon wounded or sick to the enemy, shall, as far as military exigencies permit, leave with them a portion of his medical personnel and material to help with their treatment." (Convention for the Amelioration of the Condition of the Wounded and Sick in Armies in the Field, Chapter 1. Art 1.)

There have been several wars around the world in recent decades. Even though warfare and tactics have changed, still there are similar problems related to combat casualty care which have always existed. Will and skill are the key aspects of reducing these problems, but the goal cannot be reached without the needed materials being located in the right place at the right time.

1.1 Background

Technological improvements in the field of additive manufacturing (AM), also known as 3D-printing (3DP), have taken huge steps forward in last few years. Additive manufacturing offers new way to make products with benefits that cannot be created by conventional manufacturing methods. Computer Numerical Control (CNC) milling technology has been one of the largest production methods since the 1950s, and has a wide range of applicability in different fields of technology such as industrial and commercial equipment, machines, and engines, etc. CNC technology is still a reliable and cost-effective production method. However, when AM technology matures, it can be seen to have benefits which may disrupt the existing balance and also has impacts on for industrial and military architecture.

Technological development has been key in leading changes in warfare tactics and is also the driving force for increasing dependence on materials. This relevance can be seen when defence forces define areas where advanced materials can be used as an optional alternative for existing materials or when identifying new application areas. It is standard nowadays for militaries to undertake the planning of material requirements to ensure such materials are available for production purposes. Defence research and development organisations are using different materials in the development process at the same time as the non-military sector is researching and developing materials and it is important to be aware of both. (Lele 2019, 80-81.)

3D-printed medical applications are expanding rapidly, and this has an impact on the armed forces health domain. Military medical teams could use 3D-printing technologies for personalised medical products such as prosthetic limbs, heart valves, other prosthetics, hearing aids and organ replacements. The civilian medical domain uses AM-based techniques for diagnostic and equipment handling processes which can also be useful in military medical purposes. (Lele 2019, 106.)

Increasing awareness of the global problems caused by petro-chemical based material production and its negative impacts to environment has motivated the scientific community to find new environmentally friendly raw material sources. Huge problems with petroleum-derived plastics are one driving force to develop renewable and carbon-neutral materials which can be used to cut emissions. (Calvo-Flores *et al*. 2015.)

War-conflicted countries need to increase the attention they pay to health care systems because conflicts cause a shortage of healthcare workers, lack of medical goods and treatment delays. In many conflict situations, hospitals, ambulances, and other health care infrastructure are specifically targeted. Burning and looting clinics and hospitals and attacks on patients and medical workers have been reported from countries such as:

- Democratic Republic of the Congo
- Iraq
- Afghanistan
- Mali
- Syria
- South Sudan
- Sudan
- Yemen (Ramadurai and Bhatia 2019, 17)

Also, the passage of ambulances and medical supplies has been routinely limited in Central African Republic, Mali, Occupied Palestinian Territory, Syria, and South Sudan. An example of violating international law in Syria can be seen in Figure 1, where attacks to health care facilities caused 814 medical persons to be killed from 2011 to 2017. In addition, siege areas rarely managed to have the medicines and surgical supplies they needed, which are a highly important part of casualty care. (Ramadurai and Bhatia 2019, 17.)

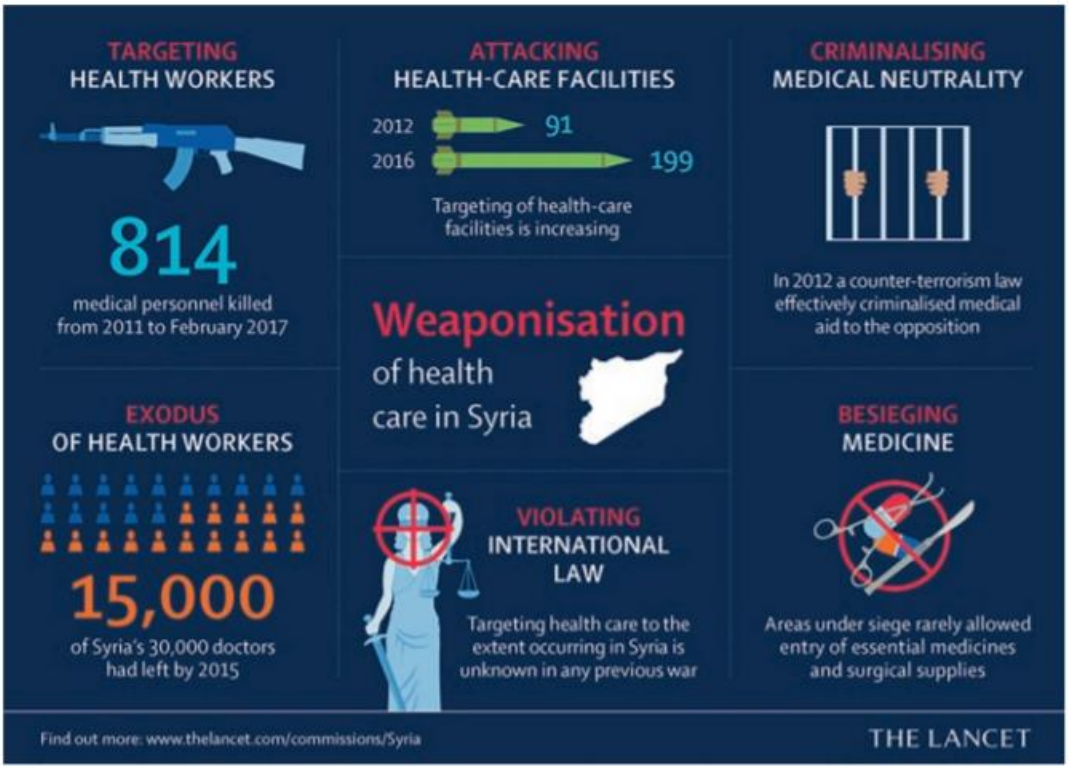


Figure 1. Health care in Syria infographic (Fouad et al. 2017)

As can be implied from Figure 1, self-sufficiency in material production is one of the key aspects which give time and possibilities to operate in different scales of siege areas. Siege areas can be formed by opponents' tactical solutions, but there can also be a lack of global health care material availability due to strong demand. Other fields of logistics are mainly struggling with how to get materials through the supply chain in battlefield conditions or in siege areas, but medical problems also come from working out how to evacuate casualties out from these conditions. When casualties cannot be evacuated out of the mentioned areas to better medical facilities, the care chain lengthens and becomes congested, which reduces casualties' survival possibilities.

1.2 Method, goal and delimitations

Increasing number of documents related to “additive manufacturing”, “3D-printing” and “3D- bioprinting” from Scopus can be seen in figure 2. More than 35,000 documents can be found with these search words between years 2010 to 2019.

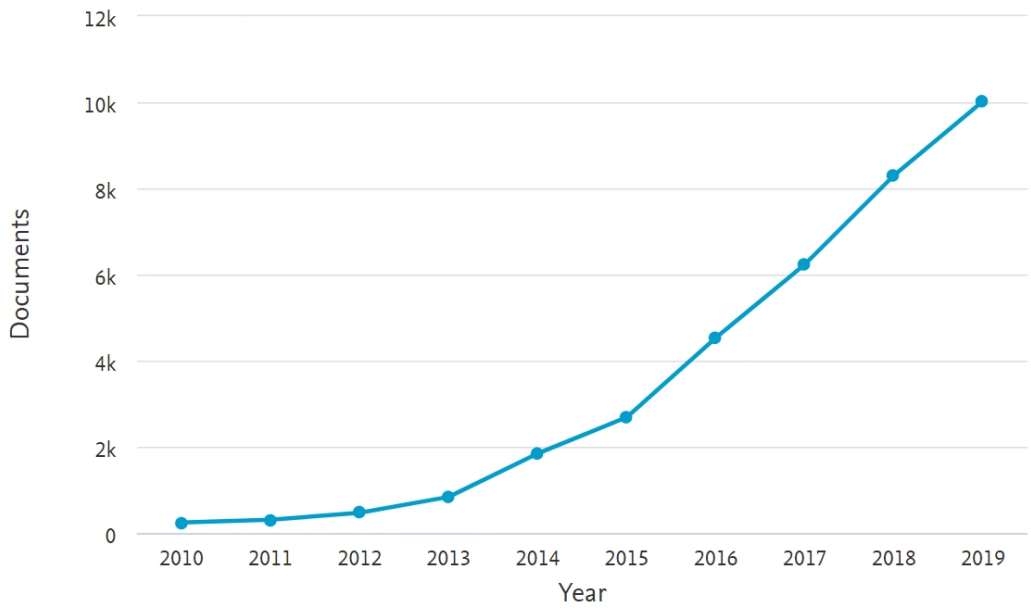


Figure 2 Documents by year from Scopus. Documents related to {Additive manufacturing}, {3D- printing} or {3D- bioprinting} between 2010 to 2019.

The aim for this study is to find useful AM applications and solutions from civilian medical systems which can be used in the frame of military medical systems. The main target is to improve current field medical systems used in defence forces and reach a better chance for injured soldiers to stay alive through evacuation chains. However, this study is not medical research, but focuses on already existing additive manufacturing medical applications which are already used in the civilian medical sector. There are many differences between defence forces’ field medical systems and civilian hospitals (to mention a few: infrastructure, risks, materials and know-how, etc.) which means that not all existing AM medical applications are useful or possible to use in the field.

Moreover, the main target and purpose of each medical level is different, but they will support others in the best conditions. This thesis produces a concept where applicable AM application are fitted to CASEVAC and MEDEVAC chains.

The framework of this thesis can be seen in figure 3, where the conventional field medical system is described by different (phase 1-4) levels of medical services, which have different purposes in the whole chain. The phases and their purposes are described in more detail in section 6.

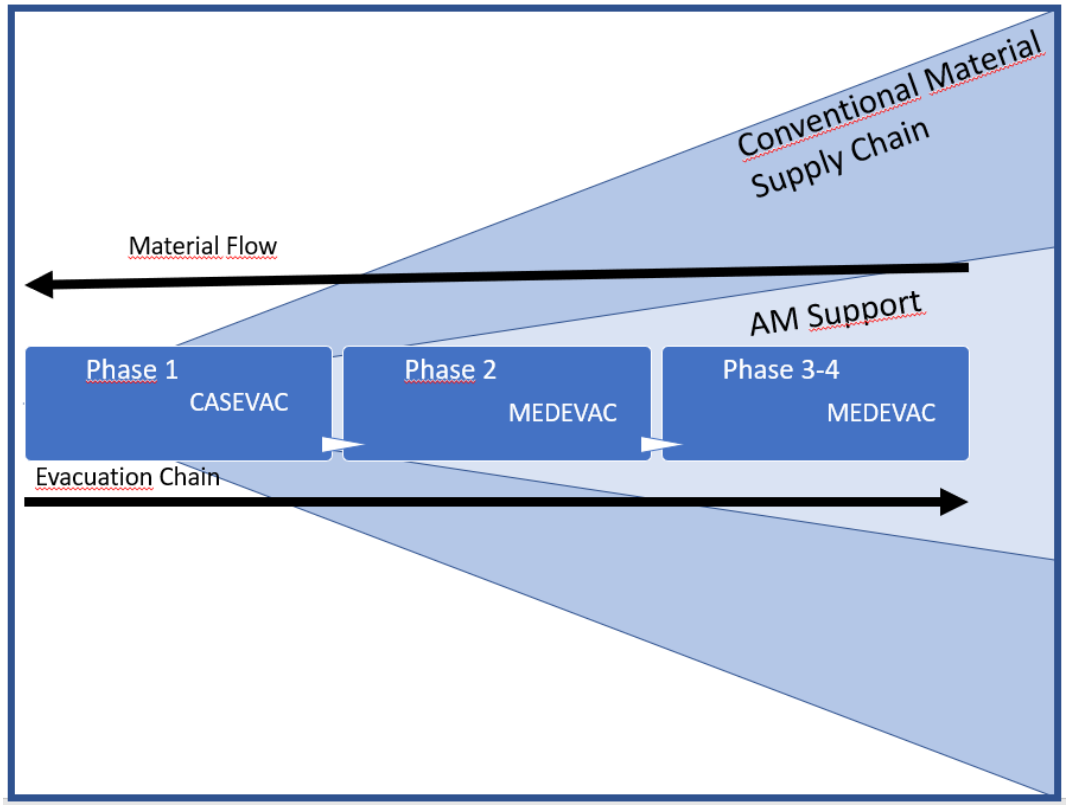


Figure 3. Frame and delimitations. Phase 1. is the first stage of injury, where life-saving first aid can be started. Phase 2 starts damage control resuscitation. Phase 3- 4 starts damage control surgery and is the interface of military and civilian medical infrastructure. The level of treatment increases with the level of phase number. The focus of this thesis is on the defence forces' field medical system, including casualty evacuation and medical evacuation, but the civilian hospital level is not part of this thesis. Medical materials chains and evacuation chains are important to keep the phases in operational conditions. The main task of this whole system is to get injured soldiers alive through the evacuation chain and finally to civilian hospital-level treatment.

1.3 Research questions

Three main questions are defined for this study:

1. Which additive manufacturing applications can be used to support the field medical system?
2. What are the benefits of the AM supply chain?
3. What are the impacts of AM on supply chain security?

2 ADDITIVE MANUFACTURING

In the last 30 years additive manufacturing has grown, and several application areas have been founded. Nowadays, 44% of AM applications are used the rapid prototyping (models, etc.) and the rest are used to produce real parts (directly and indirectly). (Diegel *et al*. 2020,7.) Additive manufacturing technologies have huge potential for producing many kinds of objects and has several benefits compared to conventional manufacturing processes, however there is quite limited amount manufacturers and end users who make use of it. There are several books, journals, and publications available, but general agreement on the reason for the mentioned limited use is lack of deep knowledge and skills around this technology. (Pei *et al.* 2019)

2.1 What is additive manufacturing?

The basic meaning of Additive Manufacturing (referred to as AM) can be described by a model which is first planned with Computer-Aided Design System (CAD) and can be produced directly without separate process planning. Before the technical committee reached consensus on the standard naming for this kind of manufacturing technology, the prior name was rapid prototyping (RP). However, RP is used mainly when a prototype is made quickly for commercial needs or representation, and the used term Additive Manufacturing describes more widely this kind of manufacturing process. The evolution in the terminology and industrial interest of AM can be seen in Figure 4. (Gibson *et al.* 2015, 1-3)

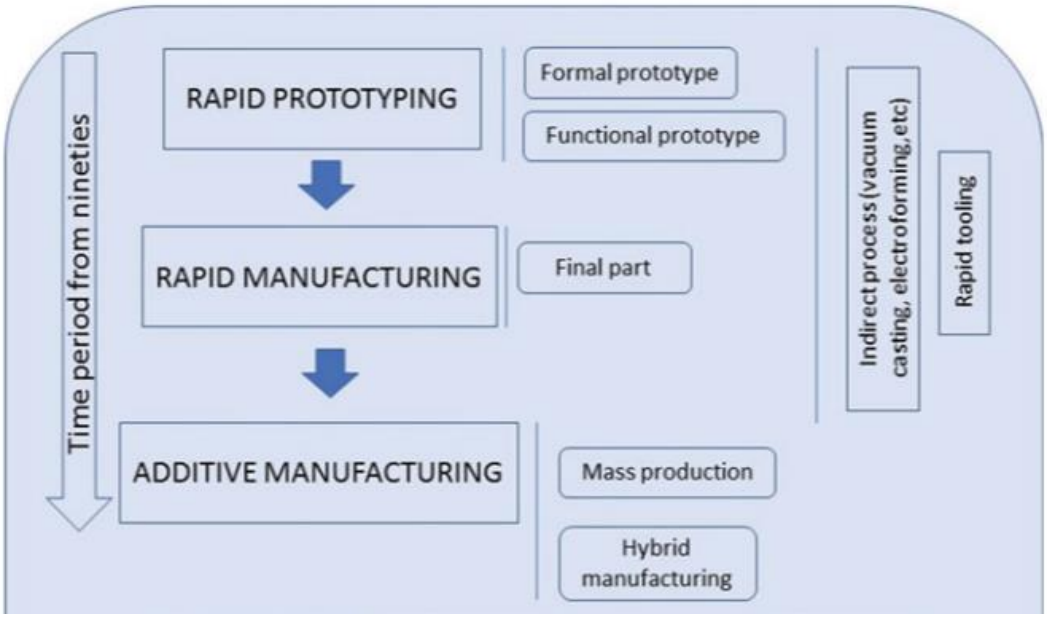


Figure 4. Evolution of AM and industrial interests (Pei *et al.* 2019)

The manufacturing process of AM is based on layer-by-layer printing. It is planned on computer and a ready model is sliced before printing. Different production methods are used for many purposes, but all are based on material adding to produce the planned part. One keyway to reach a match with the original model is to print thin layers, as thinner layers mean that the product will be closer its original model. Another important aspect which defines the end product quality is the printing material and how the layers are bonded. The printing method and material will also determine the time that is needed to create the final product. (Gibson *et al.* 2015, 1-3.)

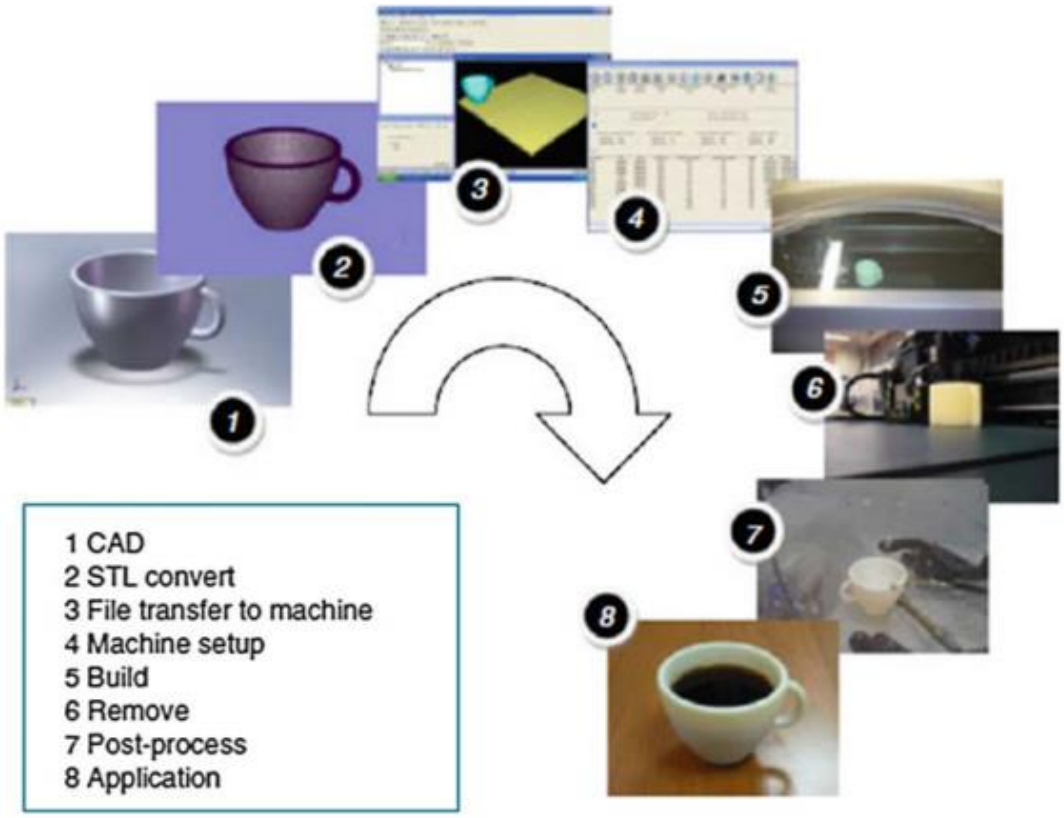


Figure 5. Process steps from CAD model to ready part. (Gibson *et al*. 2015, 5)

The additive manufacturing process can be described by eight steps, from planning to the ready physical part, and the process steps can be seen in Figure 5. The first step in AM is always to produce a digital model which can be made with different CAD software: the important outcome is to produce a surface representation. It can be a new model defined with CAD software or an already existing part which is reverse-engineered by scanning, and the digital model can be modified if needed. The second step is to convert the planned CAD model into STL format, which is the standard format in almost every AM machine: most CAD software can convert the output. In step three, the produced STL file needs to be transferred to the AM machine. During this step, the file can also be optimised to the desired size, position, and orientation. Step four is AM machine setup, where production parameters can be defined; this includes the layer thickness and timing, etc. Step five is building the part, where a digital part turns into a physical object, and this is mainly an automated process. The building process runs automatically, but the supervisor needs to ensure that materials, power, etc., do not run out. Step six is removing the built part from the AM

machine. At this point is important to wait until the part has cooled down sufficiently. Step seven is post-processing: some parts needs to be cleaned after removing it from the AM machine and also support elements need to be removed at this point. Step eight is application: depending on what the part is planned to be used for it can be ready at this point or it can be painted, etc., if needed. Some parts can be assembled with others if the final product is formed from several parts. (Gibson *et al.* 2015, 4-6.)

One challenge in conventional manufacturing technologies is inefficient processes, which produce a large amount of waste materials; the material efficiency of AM technology is much better and can solve many questions of sustainability in manufacturing processes. The benefits of AM production as a highly customisable, efficient, and sustainable process gives huge potential to use it for medical applications. AM provides better surgical access and delivery which can save human lives in the short and long term. (Bhatia and Ramadurai 2017, 23.)

AM has advantages which give possibilities to produce objects that cannot be produced by other manufacturing technologies. For example, with AM it is possible to produce intricate and complex structures. Other advantages of AM include product customisation, production time and cost-effectiveness. Production can be based on demand requirements, which minimises the need to invest in and maintain warehouses, as only the needed products will be produced. (Lele 2019, 103.) Different AM techniques can be seen in Figure 6.

Photopolymerisation systems are based on energy delivery for curtain areas to cure wanted regions or parts. Materials such as liquids, radiation-curable resins or photopolymers can be used for photopolymerisation processes. Reactions for photopolymers are produced mainly with the UV range of wavelengths but there are also systems for the visible light range. Radiation is used to produce a reaction which makes solid materials. (Gibson *et al*. 2015, 55, 63.)
Photopolymerisation advantages: resolution, accuracy, surface finishing, fabrication speed, various materials can be used. Disadvantages: support and post-processing needs. (Lee *et al*. 2017.)

Material extrusion systems are based on materials which are extruded through a nozzle to specific areas to produce the object. The system requires the used materials to be in a semisolid state which enables the material to pass through the nozzle and then it needs to solidify and bond with already extruded materials. (Gibson *et al*. 2015, 147.) Material Extrusion advantages: low cost, wide scale of materials, multi-function and simple customisation possibilities. Disadvantages: fabrication time, low precision, cannot produce sharp external corners, anisotropic structure of printed object. (Lee *et al.* 2017.) Powder bed fusion systems use a container which is filled with powder and an energy source (usually a scanning laser or electron beam) which is selectively directed to specific areas. The energy source combines powder particles to produce the wanted object in the powder container. (Gibson et al. 2015, 107.) Powder bed fusion advantages: polymer powders do not need support, materials can be recycled (polymers and metals), various printing materials can be used, accuracy and resolution is good for metals. Disadvantages: machines are expensive, surface finishing for polymers is rough, quite a slow build rate, mainly for small and medium sized parts only. (Lee *et al.* 2017.)

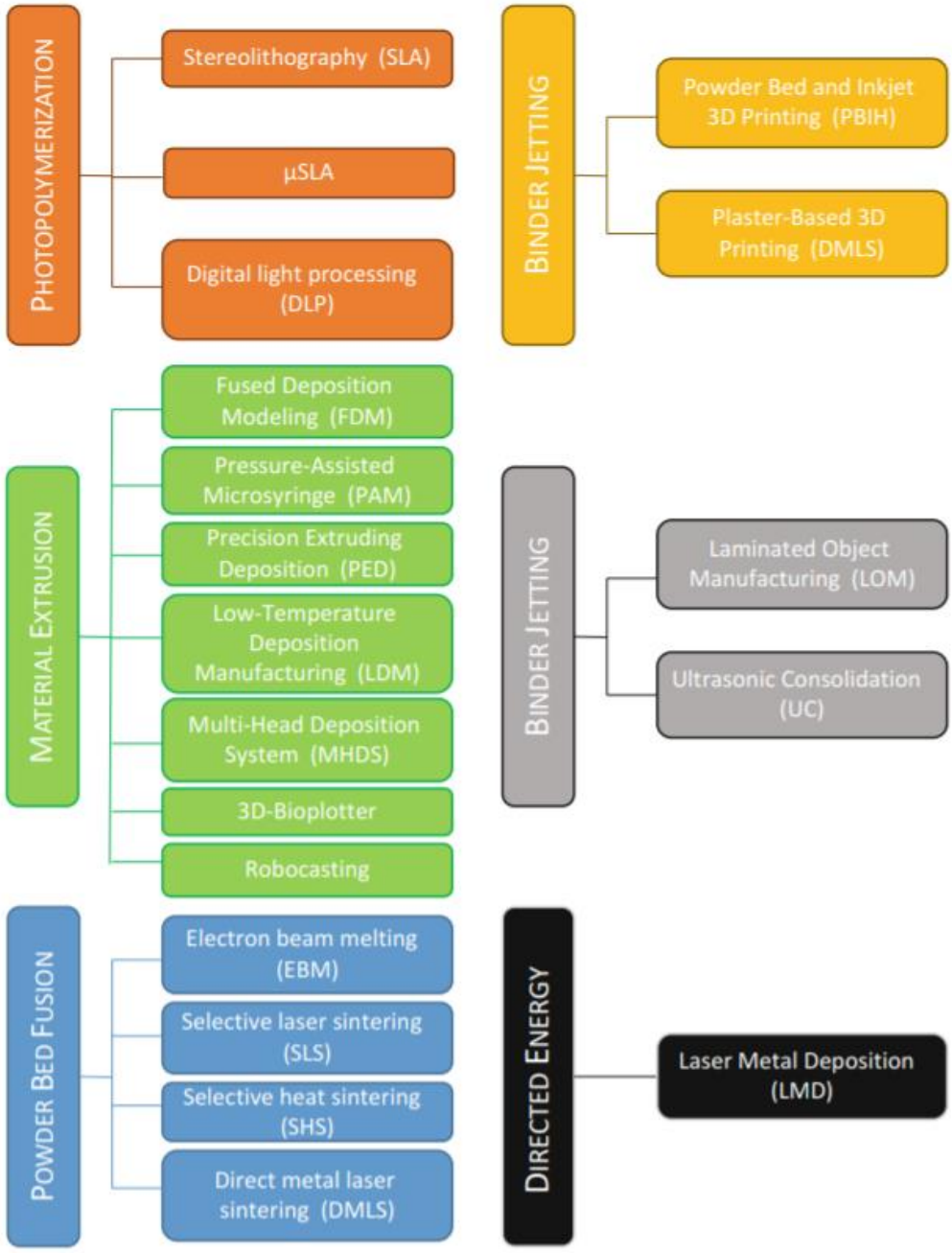


Figure 6. AM techniques for 3D- printing. (Ovsianikov *et al.* 2018)

Binder jetting uses powder and a binder to produce an object in the powder container. The binder is usually added by droplets which combine powder particles when a new layer is produced. (Gibson et al. 2015, 205.) Binder jetting advantages: wide-scale potential materials, possible to create ceramic moulds for metal casting, automatic support structures, low imaging-specific energy. Disadvantages: rough and grainy finishing, low strength, post-processing is needed. (Lee *et al.* 2017.) Directed energy deposition systems use materials

(usually powder or wire) which can be melted in the focused region using directed energy. (Gibson et al. 2015) Direct energy deposition advantages: deposition and utilisation are high, can be used to produce large metal components, repair and add-on features. Disadvantages: complexity for low parts, surface finishing and resolution, accuracy, limited materials can be used. (Lee *et al*. 2017.)

2.2 AM and medical applications

Medical applications have been developed alongside AM technology since it started to be used. The reason for this can be seen from the basic benefits that AM gives for customised products, which are important for medical applications. AM is a digitally driven technology and 3D CAD makes it possible: when 3D CAD was developed, CT (Computerised Tomography) was also developed alongside 3D representation. CT is based on the X-ray technique, where the sensors move in 3D space; this makes it possible to take multiple pictures and combine them into one 3D image. This technology is commonly used to make pictures of human bones from different angles: matter density is the key in this technology, as bones are denser than the surrounding matter which makes it possible to choose picture parameters. This technology can also be used to create images of soft tissues and not only bones, and it is mainly used in clinics for this. This technology was first used mainly for diagnosis purposes but nowadays the development of AM is the main reason for CT being used in CAD/CAM systems. The medical data of individuals is always unique, and AM gives many benefits for solving medical problems. AM is used in many different categories of medical applications. (Gibson *et al.* 2015, 455-456.)

The CT data set can be modified with transfer functions to visualise the wanted parts from the data. An example of volume ray casting can be seen in Figure 7. (Ovsianikov *et al.* 2018.)

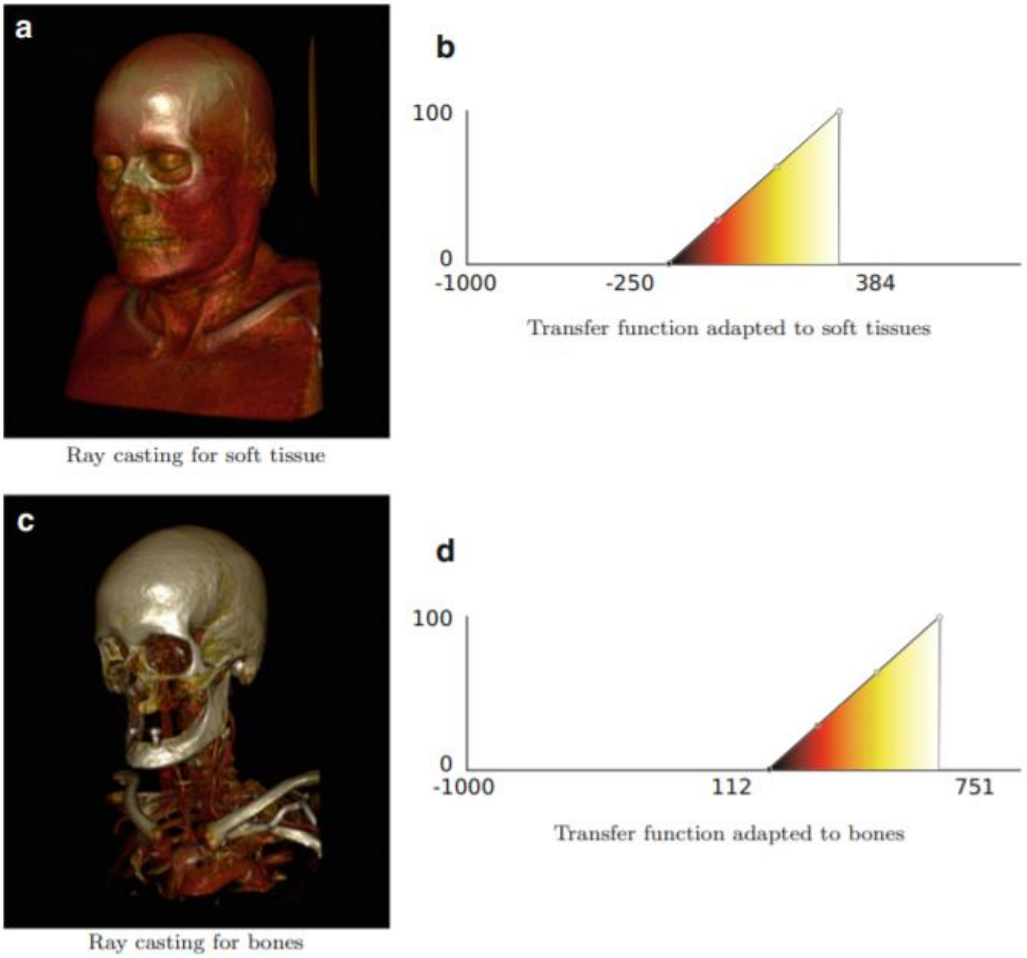


Figure 7. Modified transfer function for ray casting, (a) adapted for soft tissues and (c) adapted for bone structure. (Ovsianikov *et al*. 2018.)

2.2.1 Surgical and diagnostic aids

In the field of medical devices, additive manufacturing has been used for diagnostic purposes since AM technologies have existed. Surgeons' operating procedures inside the human body are carried out by their senses of touch and vision. Models that they can see and touch from different angles help them to do their work better. AM is used to make complex models for surgeons to gain a better understanding of surgical procedures, this helps them to plan better and also reduces surgery time in complex cases. MRI (Magnetic Resonance Imaging) data is commonly used for soft tissue imaging but can be also used for complex vascular models. Soft tissue models are used mainly for visualisations, but do not fit very well for practising surgery. Models of bony tissues are rather produced

from CT data because they are more similar to real bone and can respond similarly in cutting operations. (Gibson *et al.* 2015, 457.)

Early experience and training are very important factors for success in surgeons' operations. Surgeons use 2D medical imaging techniques such as MRI and CT to plan surgical processes, but often 2D images or 2D virtual images cannot give the best information which is needed to get the best possible understanding of anatomically complex structures. Reversible and sectioned layers provided by virtual 3D reconstruction methods give much more information and this is proven to be a more useful method to visualise complex structures. Still there are differences between real anatomical structures and virtual 3D images, so to reduce these limitations, 3D-printing is now used to make real physical models for preoperative planning and surgical simulation purposes. Surgeons can use 3D-printed surgical models for training on new techniques and also to prepare for complex operations; this reduces the need for cadavers or animal models for practising. CT and MRI data can be used to print 3D models of patient organs or tissues and these recreated models can be used to simulate realistic surgical procedures. (Ganguli *et al*. 2018.) An example of visualisation with 3D-printed models for surgical planning and training can be seen in Figure 8.

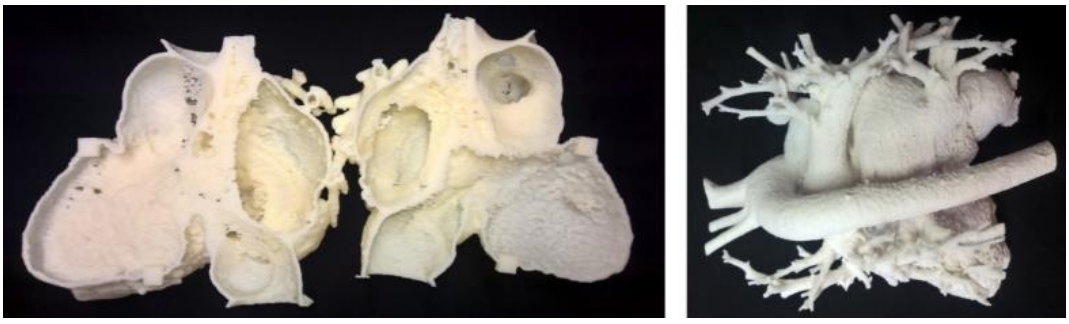


Figure 8. 3D-printed medical models. Left side, model of hollow heart produced by material extrusion and right side solid heart produced by binder jetting. (Salmi. 2016)

2.2.2 Prosthetics development

The main early problem in producing 3D-printed prosthetics were that they were low-resolution CT-data-based 3D models. The models looked anatomically correct but did not correlate very well with the actual patient. However, the development of AM technology has made it possible to produce models with much better accuracy, and modification options are better nowadays with CAD software. A bone replacement model can be seen in Figure 9. (Gibson *et al.* 2015, 458-460.)

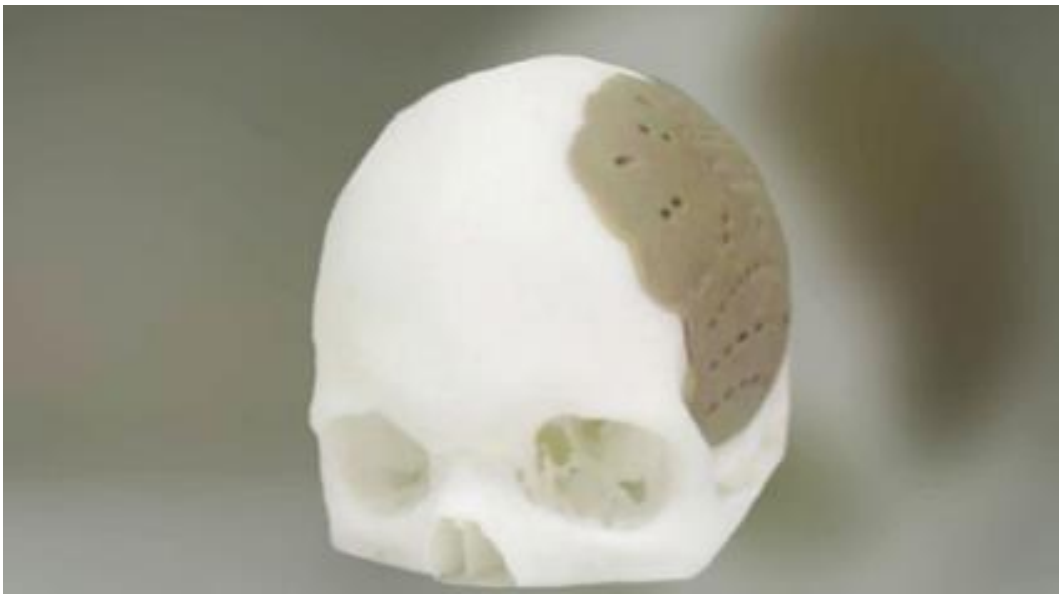


Figure 9. Customised 3D-printed cranium replacement printed from polymers using powder bed fusion. (Kumar *et al.* 2019, 183).

Digital models can include fixtures for orientation, guidance for tooling and attachment points to bone. Many prosthetics components have a range of sizes to fit the standard population, which makes it hard to achieve precise fitting for patients. When prosthetics components can be produced more uniquely and based on the individual data of patients, there can be fewer problems in rehabilitation and less corrective surgery needed. (Gibson *et al.* 2015, 458-460.)

2.2.3 Tissue engineering and organ printing

The AM technique has the potential to produce body parts for humans, where living cells, proteins and other materials are used to assist the formation of tissue structures. An example can be seen in Figure 10. Tissue engineering and organ printing is an active research area, but it will take time to reach ready practical applications. There are many 3D cell printers available which can produce cells layer-wise; however these are mainly used for experimental purposes. (Gibson *et al*. 2015, 460.) Bone tissue production is a widely studied area, where the main target is to fabricate patient-specific tissues with high anatomical correlation. Heart failure is a devastating disease which has increased interest in studies where 3D-bioprinting techniques are used for cardiac tissue fabrication. Conventional tissue engineering techniques have not succeeded in producing indistinguishable tissues in the field of cartilage tissue engineering, but 3D-bioprinting has shown its better potential in this area. Damaged heart valves do not possess regeneration capability so these need to be replaced with prosthetic counterparts: a few studies are trying to fabricate them using 3D-bioprinting techniques. Even though the liver has high regenerative properties, failures of highly drug toxicity sensitive liver tissues have increased the need to produce bioprinted liver tissues for organ transplantation. Lung tissue printing is a new field which has only few studies, however it has been shown that the tightness of bioprinted versions is better than manually pipetted versions. The nervous system can be damaged by disease, age or injury, which has initiated studies on 3D-bioprinted neural tissues, and some bioprinting nerve grafts concepts have been done. Limited studies on bioprinting pancreas tissues are being done: even though pancreatic cells hardly survive in vitro, there is demonstration of tissue strands for bioprinting purposes. Skin tissue has been printed but there are still problems with biofabrication of skin substitutes. To reach better success in scaling up tissue and organ printing, it is important to be able to print vascular tissues, and there are many studies ongoing in this field. There are also studies to print composite tissues with hybrid constructs by using a multi-head nozzle, for example printing of muscle-tendon units. (Ozbolat *et al.* 2016.)

Figure 10. 3D-printed ear cartilage from hydrogel seeded calf cells with silver nanoparticle antenna, printed with material extrusion. (Kumar *et al*. 2019, 183).

2.3 Design process of 3D-printed Objects

The first step to producing a physical 3D-printed object is data acquisition of the desired object. Data can be in the form of a new design using CAD or models can be based on datasets from CT, MRI, ultrasound, or rotational angiography procedures, for example. A virtual model is produced, segmented, and improvised with CAD and turned into an STL file which can be printed with a 3D- printer. The planned digital model's accuracy has impacts on the accuracy of the final 3D-printed object MDCT (Multiple Detector Computerised Tomography) images give ease of post-processing and good resolution, so MDCT is a commonly used modality. (Ganguli *et al*. 2018.)

AM is used for biomodelling for better surgical plan and diagnostic purposes. Models, surgical simulations, and surgical guides can be produced from patients' CT or MRI data, which helps surgeons, teams, and support staff to plan the whole surgical process. (Niaki and Nonino 2018, 43.) Other techniques such as laser-scanning, ultrasound and positron emission tomography are used to produce data for individual patients (Javaid and Haleem 2017).

Figure 11 shows a workflow example for planning and production of adapted or novel surgical instrument production. With conventional methods, the stainless steel surgical instruments that are produced cannot be 3D-printed without model adaptation, this is based on the 3D-printed materials' properties: their strength properties need to be improved with better modelling. Testing and surgeons' feedback are important for success in surgical instrument production: when the instrument materials' properties have been improved by optimising the outfit, it still needs to be approved by surgeons so it can be used for the desired purposes. (George *et al*. 2016).

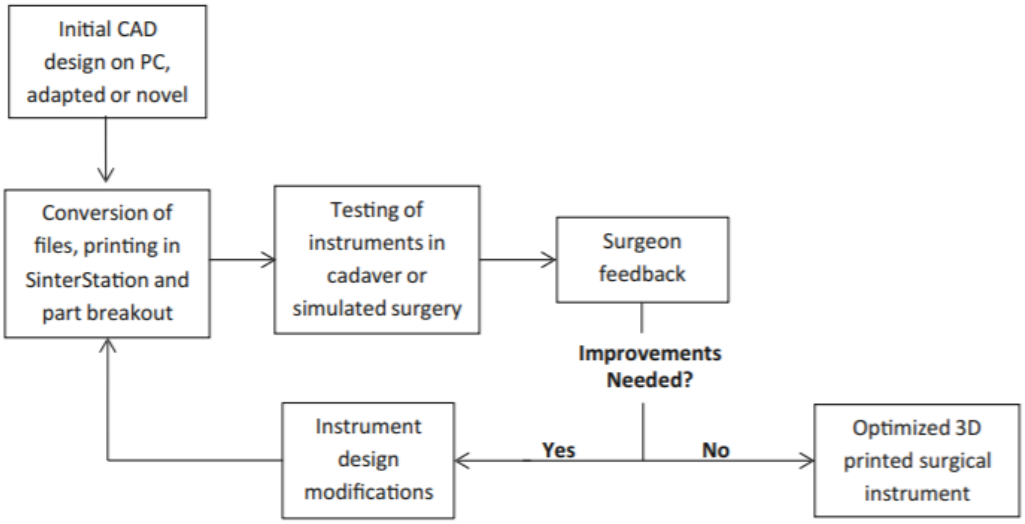


Figure 11. Example of design cycle for surgical instruments production (George *et al.* 2016).

Topology optimisation makes it possible to generate models which are not intuitive to the designer. The shape of the model is defined by the best structural performance, where it is planned to use and what properties the model needs to have. (Sigmund and Maute 2013.) Topology optimisation provides possibilities to reduce objects' weight, which also means less material is needed to produce them. Usually this means that the object's wall thickness is reduced, which is only possible while the needed strength properties are high enough. An object's weight, strength and rigidity properties can be improved with topology optimisation. A topologically optimised object can be seen in Figure 12. These benefits have impacts on object usability and transportation requirements. (Campana *et al.* 2017, 153.) Topology optimisation has existed for a long time,

but conventional manufacturing processes cannot take full advantage of it. Topology optimisation is highly suitable for use with AM. (Diegel *et al.* 2020.)

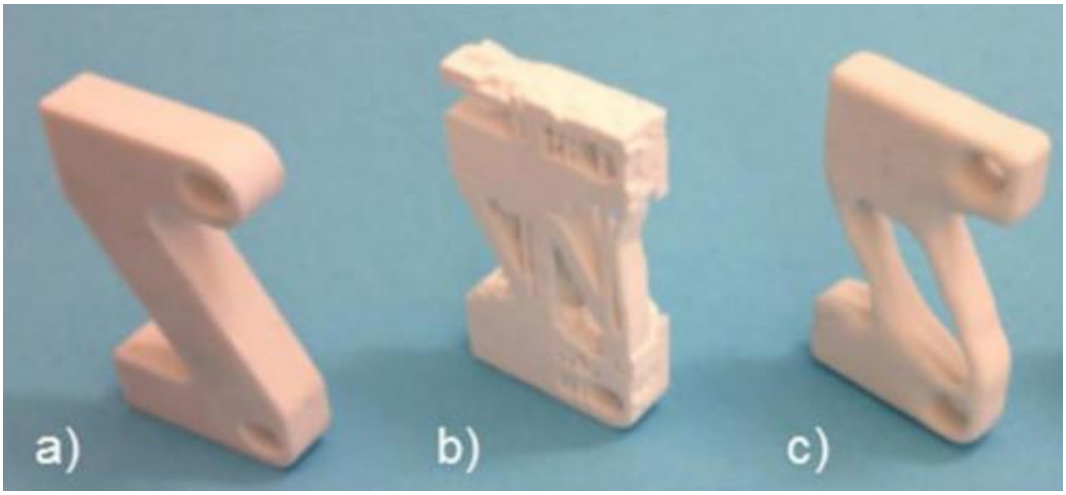


Figure 12. Topological optimisation, a) original object from CAD model, b) topology optimised object, c) final smoothed object (modified from Campana *et al.* 2017).

Example of process steps in topology optimisation (Campana *et al.* 2017, 154):

1. Product specification (list of requirements)
    - Requirements
    - Construction space
    - Boundary conditions

2. CAD system (STEP format)
    - Design of component

3. Topology optimisation (Native format)
    - Optimisation of topology for designed component

4. Surface smoothing (STL format)
    - Repairing and smoothing

5. Data processing
    - Slicing and positioning

2.4 3D-printing risks and ethical issues

Safety regulations are mainly instigated to protect centralised manufacturing technologies and there are not many regulations for additive manufacturing and 3D-printing techniques.
The conventional manufacturing process has test protocols and certificates where products are tested to ensure they reach the required quality standards. Factories produce identical copies in certain centralised locations and products are copies from original models. The conventional production safety model may not answer additive manufacturing's quality needs: even the same CAD model can have a huge variation in quality when 3D-printing happens with different 3D- printers. Quality control would be possible if 3D- printers were in centrally locations, but, for example, home users are difficult to control. One option to decrease this problem might be regulating software instead of physical objects. There are several online platforms where design plans can be shared, and there is not much control in that area, which makes it free to share or sell unsafe plans all over the world. However, there has not been much success in other fields that have tried to control online information, for example pirating of music and films, etc. Uncontrolled online platforms are sharing models which can be planned by someone who has enough understanding of engineering or someone who has not. (Neely. 2015, 1-4.)

Safety is one issue, but there are also challenges with intellectual property and plagiarism.
AM technology is challenging for today's plagiarism rules, and value-added networks may replace conventional supply chains. Nowadays 3D- printers are very cheap, which has increased the need for protection against plagiarism. Trade associations and technology lawyers are warning of upcoming dangers from the 3D-printing and medical technology sector. It is important to produce security mechanisms and digital licence management for the transfer of digital design data, otherwise there will be huge problems with customs control and intellectual property, product liability and warranties. (Holland *et al.* 2017, 1.) There are two main ways to recreate an object using a 3D- printer: you need a CAD file which

can be 3D-printed, and if you use a protected file rather than a legal one, it will be illegal. Another way to produce 3D-prited object is using of scanner where the desired object is scanned and turned into a digital model which can be 3D-printed. (Neely. 2015, 8-9.)

The rising field of 3D- bioprinting has issues of ethics, policies, regulation, and social acceptance. Bioprinting uses stem cells for raw material to produce artificial tissues and organs, and there can be seen cross-disciplinary (engineering, medical, biological, environmental) ethical issues. There is a need for developing bioprinting ethics, which would cover the different technologies from raw materials, bioprinting and manufacturing techniques to the end use of cells. (Vijayavenkataraman *et al.* 2016.)

3 3D- BIOPRINTING

3D -bioprinting is having a significant impact on medical sciences and has been growing worldwide in recent years. This technique enables the production of living cells and biomaterials which can be used in various application areas. (Ozbolat *et al.* 2016, 1.) Clinically biomaterials are used for several purposes to repair damaged parts of the human body such as:

- Bone cement
- Bone plates
- Dental implants
- Joint replacement
- Artificial ligaments and tendons
- Blood vessel prostheses
- Contact lenses
- Heart valves
- Skin adhesives
- Artificial tissues
- Breast implants
- Cardiovascular tubes (Tripathi and Melo 2017, 118)

3.1 What is 3D- bioprinting?

3D biofabrication technology can be used to construct complex living tissues and artificial organs with high printing resolution and high correlation to native tissue structure (Tripathi and Melo. 2017, 229). The development of 3D- bioprinting has been influenced by biology, biomaterials science, mechanical engineering, mathematical modelling and computer sciences. The research directions of 3D-bioprinting are evolving rapidly, which can be seen from the many books and

article publications related to this field. (Ovsianikov *et al.* 2018.) 3D- bioprinting is a technique where computer-aided bioengineered data is printed layer-by-layer from living cells and biomaterials. The 3D- bioprinting process has broad applications, because with this technology cells, proteins, DNA and drug particles can be set exactly, which gives huge potential to produce tissues, tissue models and organs. (Ozbolat *et al.* 2016, 1.)

The 3D- bioprinting process can be presented as six steps, as seen in Figure 13: imaging, design approach, material selection, cell selection, bioprinting and application (Murphy and Atala 2014). It is a quite new and fast-developing technology, which has three fundamental goals:

- Biomimicry: the purpose is to create similar tissues and organs to those found in the human body. The shape, framework and microenvironment need to be replicated.
- Creation of tissue building blocks: structural and functional units of whole tissue, self-governed assembly of cell spheres and restructure by native design, high quality reproduction of tissues assembled into functional tissue.
- Self-assembly: Own capability to produce own components and biological microarchitecture and applications. (Kumar *et al* 2019, 196.)

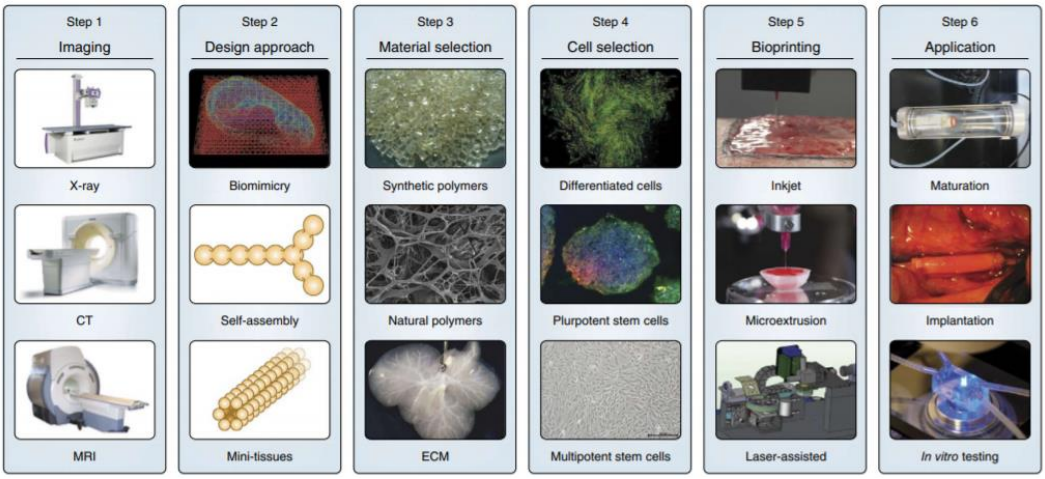


Figure 13. 3D- bioprinting process from imaging to ready application (Murphy and Atala 2014).

3.2 Biomaterials

Several types of biomaterials can be used for many applications and purposes in the human body, and the chosen material type depends on the use purpose. Biomaterials need to undergo critical surface adjustment to reach the desired degree of tolerance, as contact with tissues and organs can cause allergenic or toxic reactions. The best possible biomaterial can be defined as having the following features: biocompatible, biofuctional, bioactive, bioinert and sterile. Biocompatibility means the organism is accepted by the body and is admitted as part of the whole, giving no signs of harmful effects. It comprehends different material properties such as biofunctonality properties, toxicity, tissue and blood compatibility. Biofunctionality is the usability of the material for the planned functions: the material needs to keep its chemical and mechanical features for the required time. Metals for example can cause harmful effects to the body if corrosion occurs. Biomaterials can be characterised by the response of the body into different categories: bioactive, bioinert, biotolerable and biodegradable. Bioactive materials can produce chemical bonds with the bone tissues which is important to connect the implanted material and bone tissues. Unlike bioactive materials, bioinert materials cannot produce chemical reactions with tissues. Bioinert materials release a minimal amount (or none) of components and fibrous housing is minimal. Biotolerable materials can be tolerated by the body, and the implanted material formulates a layer of chemical compounds and ions. This produced layer keeps the implanted material separate from the host tissues. Biodegradable materials will degrade when in contact with the human body for a certain time. When a biomaterial fulfils all the other requirements, it also needs to be sterilisable, and impurities and microorganisms must be eliminated before the material is suitable to be used as an implant. (Dos Santos *et al*. 2017, 5-7.)

The biomaterials used currently include:

- Ceramics
- Metals
- Alloys

- Glasses
- Polymers
- Composites (Tripathi and Melo 2017, 118)

3.3 3D-bioprinting techniques

3D- bioprinting research and commercial application currently use more than 40 different techniques. Inkjet printing, extrusion printing, light-assisted printing and stereolithography are the main techniques used for 3D- bioprinting. Specific requirements for 3D-printed products are: pore size, structure, geometries, porosity and pore interconnectivity. Nowadays organ donor shortage is one main reason for the development of 3D- bioprinting techniques, which can reduce the numbers of people dying while waiting for suitable organ transplantation. 3D-bioprinting is a combination of CAD and tissue engineering, which can produce a combination of multiple cell types and components, also mimicking the microarchitecture of the tissue. Personalised artificial organs are produced from patients' autologous cells, and here the main research areas are: skin, cartilage, bone, aortic valve, vascular trees and kidneys. However, 3D- bioprinting is at an immature stage and has challenges such as high-resolution cell deposition, but it has the potential to reduce the organ shortage in the future. (Tripathi and Melo 2017, 230-231.)

3.3.1 Inkjet printing

Inkjet technology is divided into two main categories, Drop-on-Demand and Continuous. A chart of inkjet printing technology can be seen in Figure 15. Drop-on-Demand was developed to decrease the disadvantages of continuous printers, such as drop charging and unreliability problems. (Ovsianikov and Mironov. 2018, 284-285.)

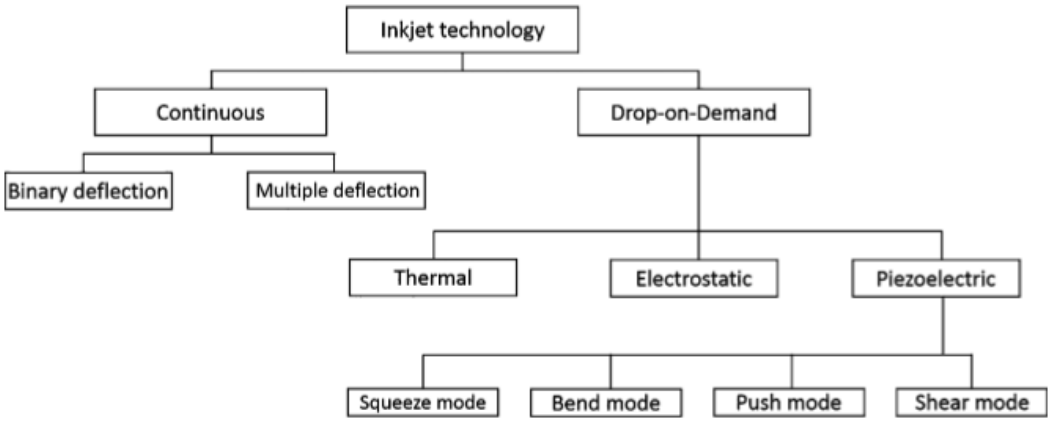


Figure 14. Inkjet technology is divided into different techniques, where the main groups are continuous and drop-on-demand printing technology (Ovsianikov and Mironov 2018).

At first, inkjet printers were used for 2D-printing in the 1970s, because of technical limitations. 2D Inkjet printers were upgraded to 3D- printers in 1992 by adding an x-axis to printers. The development of inkjet printers has produced four different types of printers, thermal, piezoelectric, acoustic and electrostatic. Thermal and piezoelectric inkjet printers are the main techniques used for 3D-bioprinting purposes. When using inkjet printers for tissue engineering, hydrogels or pre-polymer solutions are always used for printing material with or without their cells encapsulated. Fast fabrication and low cost are the main reasons for inkjet printers being used for a wide scale of areas and purposes. Thermal inkjet printing produces ink drops with localised heating up to 300 C: the ink drops are ejected from nozzles and produce 3D cell-laden constructs. The piezoelectric inkjet printing technique produces pressure with changing voltage, which extrude lead ink out of the nozzle. (Tripathi and Melo 2017, 230-231.)

3.3.2 Extrusion printing

Extrusion printing can be described as modified inkjet printing, when inkjet printing uses low viscosity bioink, and with extrusion printing raw materials can be of various viscosities. Extrusion printing is based on the use of a pneumatic and mechanical screw plunger to generate continuous force. Printing materials

with high viscosity such as cells cell-laded hydrogels and other high viscosity biomaterials can be printed with extrusion printers. There are two different dispenser systems: pneumatic micro nozzles and screw-based nozzles. Pneumatic micro nozzles use compressed gases, which makes it possible to print a wide scale of viscous materials, while the screw-based nozzle system has more problems with highly viscous materials. Extrusion printing and the bioplotting technique started in 2000, and this technique makes it possible to use continuous filaments. Bioplotting is based on mechanical and pneumatic systems, which makes it possible to operate in ambient or physiological temperatures. Still, bioplotting techniques need improvement because there are challenges with printing flexibility. However, many extrusion printers have multiple printer heads, which makes it possible to print several bioinks at the same time. The areas of benefit which make extrusion printers widely used are the control of shapes, pores, porosity, and cell distribution. (Tripathi and Melo 2017, 231-233.)

3.3.3 Laser-assisted printing

Modified laser direct write and laser-induced forward transfer techniques are the basic techniques, and laser-assisted printing has developed from these. Biomaterial laser-assisted printing uses mainly the method of photo polymerisation, where a wide range of cells can be printed. A pulsar laser source, laser focusing tool, film of laser energy adsorbing metallic ribbon and receiving substrate are the main parts of laser-assisted printers. The basic mechanism of laser-assisted printers is quite similar to that of conventional typeprinters. There are no nozzles in this system, which cuts the challenges of other printer types where nozzle clogging is a problem. The system has two layers, the upper is an energy adsorbing layer and the bottom layer of this system consists of a liquid biological material: when the laser pulse is focused on the upper layer, this produces droplets from the liquid which is ejected onto the substrate. It is possible to print pico to nano scale structures with laser-assisted printing but compared to other printing techniques it is quite a slow and costly system. Printing materials can be hydrogels, ceramics, cells, and cell-encapsulating materials. (Tripathi and Melo 2017, 233-234.)

3.3.4 Stereolithography

Liquid photo-sensitive polymers are selectively solidified with ultraviolet rays in this technique which is quite similar to laser-assisted printing. The main factor for the final quality of stereolithography printed products are the computer design of the planned structure and the curing kinetics. First, a stereolithography file needs to be produced from CT or MRI techniques and the designed structure is sliced into thin layers. The stereolithography technique has high resolution and accuracy, so can use various materials such as curable acrylics and epoxies. (Tripathi and Melo 2017, 234.)

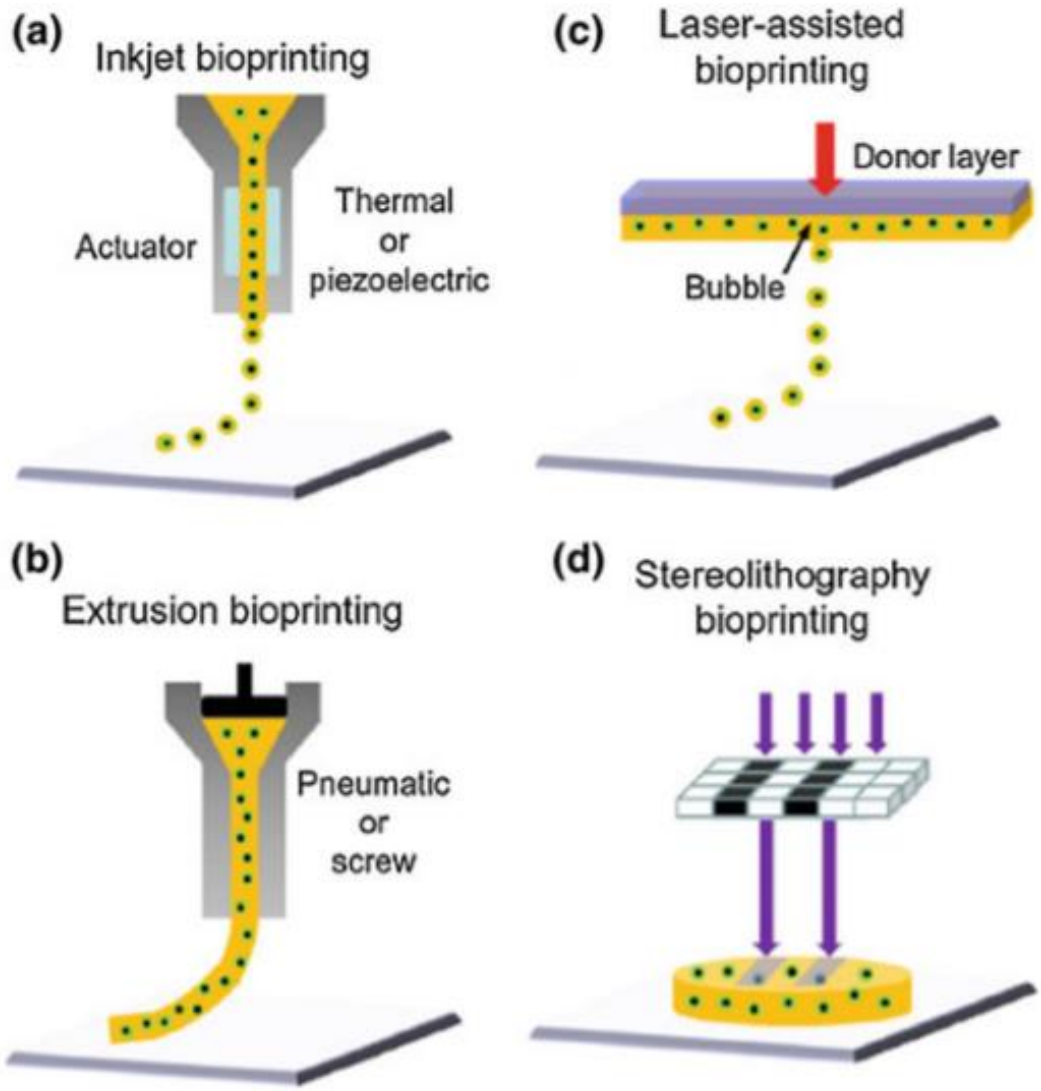


Figure 15. Basic of inkjet printing techniques. All of these techniques can be used for biomedical and tissue engineering. Cell viability is the priority when choosing which technique is used for different purposes. (Mandrycky et al. 2017.)

4 MATERIALS AND APPLICATIONS

A wide scale of materials can be used in additive manufacturing and new material types and combinations are studied all the time. Material development increases AM applications which can be used for medical purposes. Applications can produce totally new products because of the benefits of AM or they can replace already existing products which are conventionally produced by other manufacturing techniques.

4.1 Ceramics

Ceramics' benefits are high resistance for strength, wear and heat, which is the reason to use them for medical devices. Hydroxyapatite and tricalcium phosphate are used for substituting the hard tissues of the human body, but other types of ceramics are also used. Low fracture and notch toughness are disadvantages of ceramics, and so they are not used when there is concentrated stress from large and frequent loads. There are three groups of ceramics:

- bioinert ceramics (no reaction with human tissue)
- bioactive ceramics (integrate with bone)
- biodegradable ceramics (absorbs in human tissue) (Setsuhara *et al.* 2019, 376)

Orthopaedic surgery uses medical devices where ceramics materials are used, such as artificial joints, bone extending agents, fixators, artificial tendons, and ligaments. Otolaryngology uses ceramic materials for artificial auditory ossicles. Dentistry uses ceramics materials for dental implants (fixtures and abutments), periodontal pocket fillers, dental cement powder, dental porcelain, crowns (bridge) and artificial teeth. (Setsuhara *et al*. 2019, 377.)

Ceramic materials do not fuse together by applying heat, which means that individual ceramic powders cannot be 3D- printed like thermoplastics and metals. Only a few commercial 3D-printing systems can be used to print ceramic objects. (Eckel *et al.* 2016.)

4.2 Metals and alloys

A wide range of metals are used as biomedical materials and are a very important raw material in the medical field. Metallic materials which generally consist of metal bonds have advantages when used as biomaterials: high strength, easy to work with, large fracture toughness, elasticity, and stiffness and electroconductivity. In some cases, metals are seen as unfavourable for biomaterials, because heavy metals have historical impacts on humans and the environment. However, since there has been improvements in safety aspects, corrosion resistance and mechanical durability, metals have had a wide scale of medical uses. Metals used for biomedical purposes must be corrosion resistant. Use of ceramics and polymers are replacing some medical devices which were previously made from metals, because metals typically have poor biofunctions. However, metals still have benefit areas, for example 70% of all implant devices are produced from metals, because of their high strength, toughness, and durability, as these properties are hard to find from other materials. (Setsuhara *et al.* 2019, 374.)

Materials such as cobalt, chrome and titanium alloys offer biocompatibility and strength properties which are needed for medical devices. AM with metals are used for medical and dental applications such as dental crowns and dental bridges. AM techniques like direct metal laser sintering and electron beam melting are used to produce metal medical devices and implants for human use. Metal 3D-printing is used for direct medical purposes, because of rapid and personalised production but also for secondary medical purposes, for example drill guides and fixtures, etc. (Milewski, 2017,14-15.)

As mentioned before, metals are mainly artificial and have no biofunctions, and surface treatments are needed when metals are used as a biomaterial. With surface treatment it is possible to change the surface composition, structure, and morphology, keeping the metal's properties intact. Surface treatment can be done with dry or wet processes and the process improves tissue compatibility. (Setsuhara *et al.* 2019, 380.)

Orthopaedic surgery uses medical devices with metals such as, spinal fixation, bone fixation, artificial joints and spinal spacers.
Cardiovascular medicine and surgery use metals for implant-type artificial hearts, pacemakers, artificial valves, stents, guide wires, embolisation wires and clips.
Otolaryngology uses metals for artificial inner ears and artificial eardrums.
Dentistry uses metals for fillings, inlays, crowns, thermosetting resin facial crowns, soldering, dental implants, orthodontic wire, magnetic attachments, and treatment devices.
General surgery uses metals for the needles of syringes, scalpels, catheters, and staples. (Setsuhara *et al.* 2019, 375.)

4.3 Glasses

Originally bioactive glasses were named because of their capability to bond with living bone, and the reason for this chemical reaction was the ion exchange mechanism. Recently it has been found that the same reaction can also be done with soft tissues such as in peripheral nerve repair and wound healing. Different bioglasses have traditionally been produced by the melt-quenching route, which needs high temperature (over 1500 Celsius), which reduces its bioactive properties. Avoiding this problem led to the development of gel derived glasses, which have shown promising possibilities to be used with AM techniques. There are possible applications for bioactive synthetic bone substitutes and bone healing support. (Baino and Fiume 2020.)

4.4 Polymers

Polymers have a high degree of flexibility, light weight and plasticity which are reasons why polymers are used widely for medical devices. Polymer materials are known for their biocompatibility and biofunctionality because they exist in the human body. Still, 90% of medical polymers are used outside the human body and less than 10% inside. Low strength properties and low sterilisation potential (low thermal resistance) are reasons for polymers' limited usability under large loads. Crystallisation and fragmentation decrease polymers' molecular weight when they are used long term. When polymers are used inside the human body, a decrease of local pH is seen, and polymers degrade because of enzymes, infections and inflammations. (Setsuhara *et al.* 2019, 377-378.)

Orthopaedic surgery uses polymers for artificial ligaments, bone substitutes, artificial hip and knee joints, artificial knuckles, spinal cages and spacers, bone cement and hernia patches. Plastic surgery uses polymers for artificial skin, artificial breasts, facial prostheses and nose prostheses. Internal medicine and urology use polymers for blood purification membranes, ascites filtration membranes, haemodialysis circuits and artificial kidneys. Cardiovascular medicine and surgery use polymers for artificial hearts, artificial valves, pacemaker electric wires, vascular grafts, balloon catheters, stent grafts, heart patches, cardiopulmonary bypass circuits and pericardial sheets. Otolaryngology uses polymers for artificial pinnas. Respiratory medicine uses polymers for artificial lungs. Ophthalmology uses polymers for contact lenses, intraocular lenses, and haptics. Dentistry uses polymers for denture bases, artificial teeth, and fillers. Surgery uses polymers for artificial levers, membrane oxygenators and artificial oesophaguses. General surgery uses polymers for disposal supplies, sutures, catheters, nonwoven fabrics, haemostatic materials, synechia preventives, wound dressings, adhesives and emboluses. Other clinical uses for polymers are in transfusion sets, infusion bags and drug-eluting carriers. (Setsuhara *et al.* 2019, 378-379.)

Nowadays environmental and sustainability issues have increased needs to produce goods from renewable resources. Biobased polymers are derived from organic biomass, such as cellulose, wheat and sugar beet, etc., and the process can be seen in Figure 16. Biobased polymers derived from mentioned sources include:

- polynucleotides
- polyamides
- polysaccharides
- polyoxoesters
- polythioesters
- polyhydrides
- polyisoprenoides
- polyphenols (Bhatia and Ramadurai. 2017, 40-41)

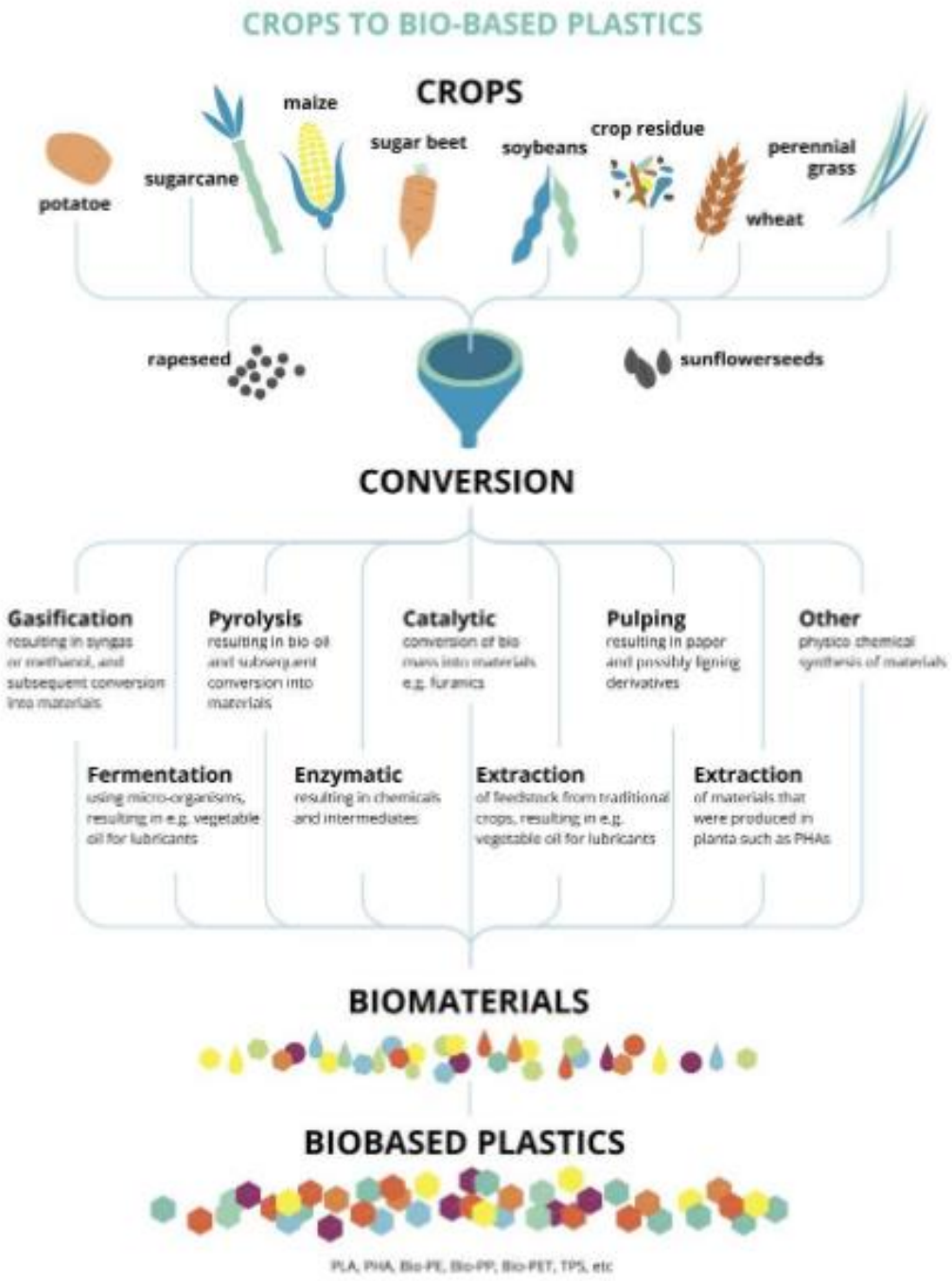


Figure 16. Production chains to produce biobased plastics from crops (Wijk and Wijk 2015).

Biobased polymers can be used to produce bioplastics, which is more sustainable compared to conventional petroleum-based plastic productions. Biobased plastics can be produced with the same material properties as petroleum-based material, which has increased usability in the fields of medicine, biomedical engineering, and polymer chemistry. Different crops can be used to extract sugars, starches, oils, and lignocelluloses. Using biomass conversion techniques such as

gasification, pyrolysis, catalytic conversion, pulping, fermentation and enzymatic conversion, crops can be converted into different kinds of biobased bulk chemicals. Starch and sugars can be converted into glucose by hydrolytic cracking and after the fermentation process it is possible to produce polylactic acid (PLA) and polyhydroxy alkanoate (PHA). Sugar can be also used as a raw material to produce bio-polyethylene (bio-PE), biopolypropylene (bio-PP) and biopolyvinyl chloride (bio-PVC). To be able to use biobased plastics in AM processes, the polymer type must be thermoplastic: the heated polymer must be pliable and return to solid when cooling. (Bhatia and Ramadurai. 2017, 40-41.)

Biobased plastics are always produced from renewable sources, but biobased plastics can be found in two different categories: biodegradable and non-biodegradable polymers (Wijk and Wijk. 2015, 46).

With regard to the processing properties of biobased plastics:

Derivatives can be processed at 190- 240 Celsius temperatures and can be used with:

- Injection moulding
- Sheet extrusion
- Fibre extrusion

Cellulose derivatives' mechanical properties and thermal resistance are good and they have a shiny transparent appearance. However, there can be thermal degradation problems. (Wijk and Wijk. 2015, 46.)

Starch-based plastics can be processed at 120-180 Celsius temperatures and can be used with:

- 3D- printing
- Film blowing
- Injection moulding

- Sheet extrusion
- Foam extrusion

Starch-based plastics' mechanical properties are good and they have excellent gas barrier properties, their biodegradable properties are fast and they are anti-static. However, starch-based plastics are dependent on humidity and are not completely transparent. (Wijk and Wijk. 2015, 46.)

PLA (Polylactic acid) can be processed at 170- 210 Celsius temperatures and can be used with:

- 3D- printing
- Film extrusion
- Thermo-forming
- Blow moulding
- Injection moulding
- Fibre extrusion

Polylactic acid is transparent and has good mechanical properties. However, it is only suitable for industrial compostables and is sensitive to water; it also has a low melt strength when processed. (Wijk and Wijk. 2015, 46.)

PLA is an excellent material for biomedical applications because of its bioresorbability and biocompatibility. PLA is derived from biobased and renewable sources, where the products of degradation H_2O and CO_2 are not toxic or carcinogenic, when used in the human body. PLA is approved for medical device applications by the European regulatory authorities and the US FDA. (Xiao *et al.* 2012.)

PLA belongs to the polyhydroxy acids and is the most important biobased plastic. Materials such as starch, sugar and biogenic waste can be used for raw materials to produce PLA. Several microorganisms can also be used in the fermentation process to produce lactic acids. (Endres et al. 2016.) PLA bioplastic can replace polyethylene, polystyrene or polyethylene terephthalate and worldwide over 90%

of PLA is produced by the glucose fermentation process. (Murillo et al. 2016.) The lactic acid polymerisation reaction from L-lactic acid to dilactide and final polylactides can be seen in Figure 17.

PLA is a biodegradable and recyclable thermoplastic polyester resin which has led to expanding application areas and its biocompatibility has increased its use for biomedical applications (Vas 2018, 81).

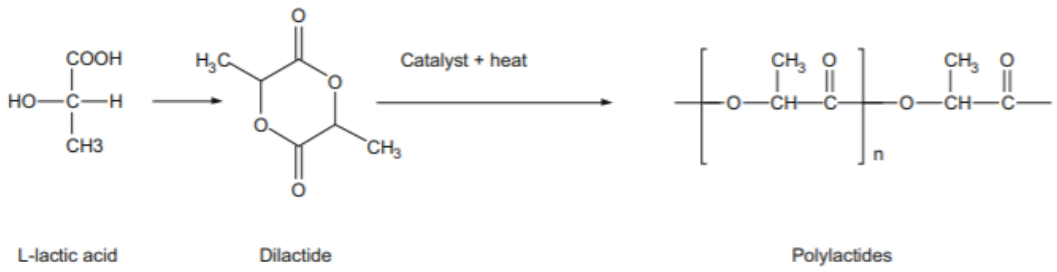


Figure 17. Polymerisation reaction from lactic acid to polylactides (Endres and Siebert-Raths 2011).

The PLA production process can be seen in Figure 18, giving the fundamental process steps to produce PLA with fermentative production (Wagemann and Tippkötter 2019, 450). Lactic acid can be processed with direct polymerisation; however, the process is more efficient if lactic acid is first converted to pre-polymer with a low molecular weight and then depolymerised to the lactide.

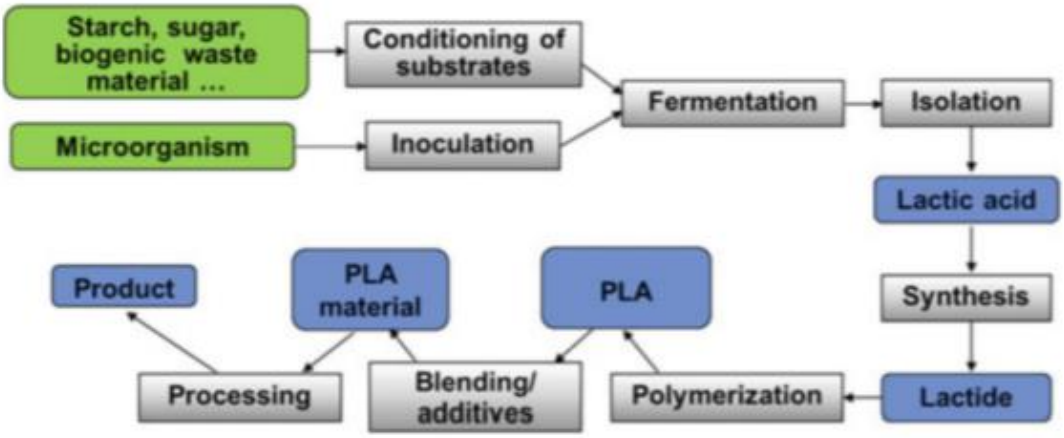


Figure 18. PLA production process (Endres and Siebert-Raths 2011).

Amount of sugar cane or sugar beet to produce 1 t of PLA:

1. Sugar cane 11.31 t or sugar beet 9.19 t
2. Sugar 1.47 t for fermentation
3. Lactic acid 1.25 t for dehydration
4. Lactide 1 t for polymerisation
5. End product PLA 1 t

Amount of potato or wheat or corn to produce 1 t of PLA:

1. Potato 9.26 t or wheat 3.54 t or corn 0.37 t
2. Starch 1.67 t for hydrolysis
3. Glucose 1.47 t for fermentation
4. Lactic acid 1.25 t for dehydration
5. Lactide 1 t for polymerisation
6. End product PLA 1 t (Endres et al. 2016)

4.5 Composites

Biocomposites are materials where at least one of the constituents is derived from biological material. Most biocomposites are produced from synthetic polymer reinforced by fibres. (Filgueira *et al*. 2018.) The main advantages of natural fibres are:

- Easy availability
- Low cost
- Bio-degradability
- Renewability
- Recyclability
- Low density

- Acceptable specific strength and stiffness
- Reduced tool wear
- Non- abrasiveness
- Ease of manufacture
- Light weight
- Non-toxic nature (Jawaid *et al*. 2017, 31)

Reinforcing fibres are embedded in the composite matrix which forms the discontinuous or the dispersed phase of the composite. This reinforcement carries load and stress because of its improved stiffness and strength. It also protects the composite against environmental and chemical contact. (Duigou *et al*. 2016.)

5 SUPPLY CHAIN

The digital transformation has led to several changes in business and personal life in recent decades, and the growth of data and automatised data monitoring systems has decreased needs for human data handling, although algorithms are still made by humans. Nowadays, almost all operational processes are in contact with digitalisation, which has also changed supply chain and logistics process handling. Better safety and security in supply chains may have started from increased data transparency and has caused a smaller risk of fraud in complex chains. Nowadays supply chains are heterogeneous, but still every stakeholder has the same goal where information security can be verified and logistics processes are uninterrupted. To reach this logistics and supply chain goal in tactical and operational level, conventional data analytic techniques are supported with artificial intelligence. (Zijm *et al*. 2019, 17-18.) The new industrial revolution (Digital manufacturing, Industry 4.0) can be seen as a game-changer which is changing the future of manufacturing processes, and AM will definitely be a part of it. (Fawcett and Waller. 2014)

5.1 Supply chain management

The supply chain includes all operations needed such as raw materials, component manufacturing and final production, also including materials handling and storage systems. The supply chain can be seen in Figure 19. A closed loop supply chain includes return flows of materials and components for re-use purposes. End-to-end supply chains need joint operations between several organisations and companies which operate in different places. Logistics is materials and product storage, transportation in the supply chain. Including material and information flows to and from warehouses and materials handling (internal and external). (Zijm *et al.* 2019, 33-37.)

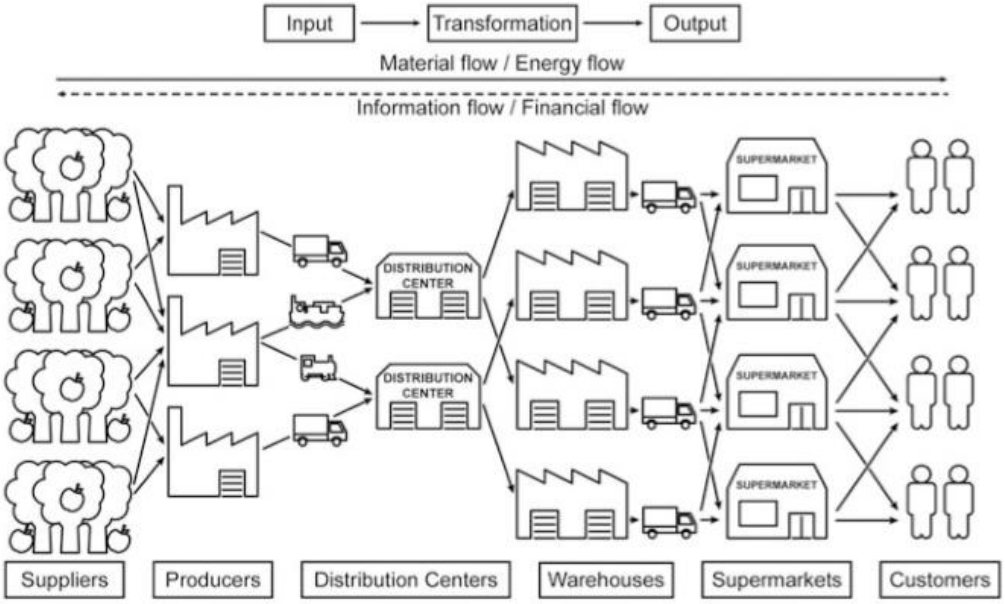
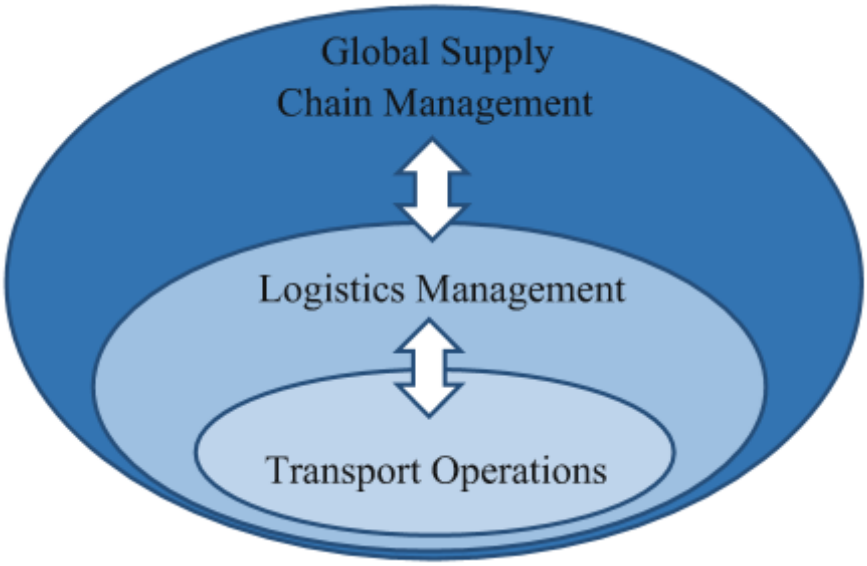


Figure 19. Supply chain from suppliers to customers (Ivanov *et al.* 2019).

The main objectives that logistics planning should take into account are:

- Right goods
- Right quantity
- Right quality
- Right time
- Right cost
- Right sustainable impacts (Zijm *et al.* 2019, 33-37)

Supply chain management levels can be seen in Figure 20, which takes into account all of the planning and management of supply chain operations. It includes the coordination and collaboration of different levels of providers and companies but also customers. Logistics management is one part of supply chain management which plans, implements, and controls the forward/reverse flows of materials, products, and information. (Zijm *et al*. 2019, 33-34.)



Picture 20. Supply chain, logistics and transportation at different hierarchy levels (Zijm *et al.* 2019, 34).

Logistics has been mainly associated with the business field, but recent years have shown that humanitarian logistics and disaster management have become more and more important, from causes such as:

- Natural disasters
- Political conflicts
- Terrorism
- Maritime piracy
- Economic crises
- Destruction of information systems
- Transport infrastructure failures (Ivanov *et al.* 2019, 28)

Political conflict and natural disaster-based humanitarian and disaster logistics has been very challenging. Goods (type and amount) needed for destroyed environments are mainly unknown and have complex parameters, also when/where disaster starts and actual shipment locations has shown to be very challenging to predict. Worldwide there are over 500 different kinds of catastrophes each year. The UN Humanitarian Response Depots have developed a

concept for worldwide emergency supplies, and the target is to cut reaction times when disasters occur. The UN's five hubs can be seen in Figure 21, in Ghana, UAE, Malaysia, Panama and Italy, with food, water, medical kits, shelter items and IT equipment stored in these locations. Logistics speed and efficiency is key to reaching an efficient emergency aid response, and these factors have a direct impact on how many lives can be saved from disasters. (Ivanov *et al*. 2019, 28.)

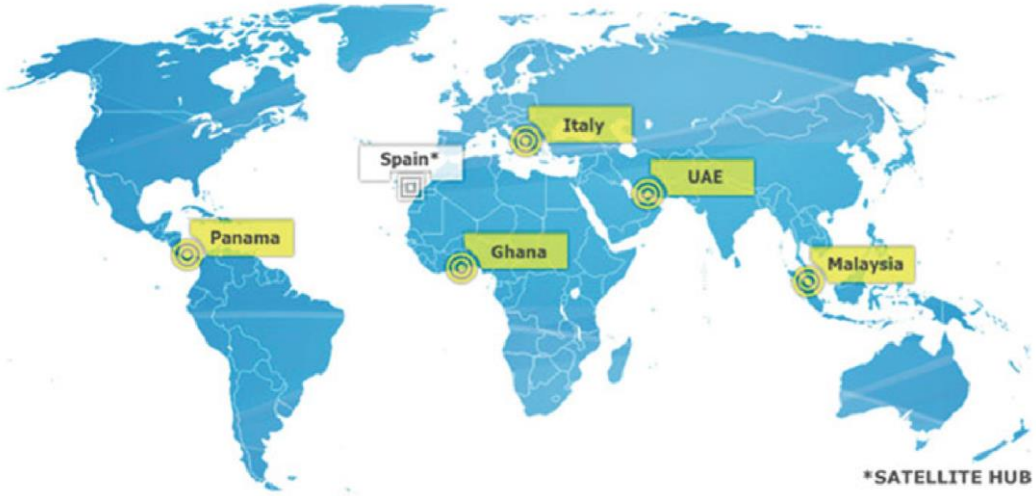


Figure 21. UN medical hubs locations (Ivanov *et al.* 2019, 29).

Disaster response occurs mainly at three levels, which can be seen in Figure 22:

- Local
- National
- International (Vitoriano *et al*. 2013, 4)

The local response can start immediately when needed and coordinates search and rescue activities. If international humanitarian organisations are already based in the disaster area, they can take part in the local response, which has happened in some earthquake cases. When the magnitude of the disaster is too great for local response, the national system will be activated. National systems can usually support the local response with basic items such as medicines, water, food, and shelter, and also with logistics support. When the national system cannot produce enough capacity, the national government makes a request to activate the international system to fulfil the needed capacity. (Vitoriano *et al.* 2013, 3.)

Figure 22. Disaster response from local to international level (Vitoriano *et al*. 2013).

5.2 AM supply chain

Supply Chain Structure: usually, conventional manufacturing or assembly processes can start when all of the needed components are available, when these functional components can be integrated into AM process; this will reduce synchronisation needs. AM reduces the corresponding supply relations and multi-level process planning, which will reduce overall risks and costs.

Supply Chain Inventories: the AM process enables the consolidation of functions and final products can be produced directly from raw materials; this reduces the need for downstream stocks. Conventional customisation is often achieved with modular product designs, where high inventories are needed to get different components which are needed for final products. AM is based on strong digitalisation where products are customised digitally and only the final part is printed to a physical object: this reduces raw material needs compared to subtractive manufacturing techniques.

Decentralised Manufacturing and Transport Times: AM production facilities can be quite modest, which supports decentralised manufacturing, even more so in situations where component stocks are limited. AM production can be closer to customers which reduces physical distribution and transportation needs and also total times. Of course, raw materials need to be supplied to decentralised production locations, but this is mainly bulk transport of limited basic materials. A

growing group of AM service providers offer their printing capacity which can be used on demand and in remote locations.
Component Lead Times: the conventional assembly process orders most of the needed components from external suppliers or they may have capacity to produce components independently. However, conventional manufacturing produces components in batches because of efficiency, but this increases lead times and inventories. In many cases, it is possible to reduce overall lead times in the supply chain by using AM.
Customer Responsiveness: for conventional manufacturing to have the potential to reach short customer response times it needs generally high inventories such as final products, modules or components. Otherwise, lower stocks mean longer waiting times for customers. AM provides production flexibility, altered to setup or speed. The required responsiveness of AM mainly needs investments in raw material stocks. (Zijm *et al*. 2019, 521.)

One driving force which has a huge impact on the fast improvements of AM techniques is its capability to answer to today's sustainability development requirements such as reducing the use of non-renewable raw materials, low carbon emissions and waste production, which has direct impacts on environmental protection and associated taxes. Other reasons for this development are because AM technologies reduce operational costs, which impacts material import and export flows in the long term because there is no need for centralised production in a certain location. (Niaki and Nonino 2018, 72.)

The international medical device supply chain can be seen in Figure 23. The medical supply chain is often vulnerable to:

- Long lead times
- High transport costs
- Large carbon foot print
- International tariffs and import taxes
- Limited supply and market penetration (Bhatia. Ramadurai. 2017, 101)

Figure 23. Conventional medical device supply chain (Engel 2014).

With AM techniques it is possible to redefine the medical device supply chain and medical devices can be produced where needed by 3D- printing. The option to use AM techniques for surgical instrument production is cost-effective because of on-demand production, less need for transportation, less need for storage capacity and low customs costs. The initial input capital which is needed to fabricate surgical toolkits will be recovered immediately when production runs, and this will be net-positive in the short and long term. The direct source allocation and domestic manufacturing process of AM are benefits which can increase 3D-printed medical device market penetration. The traditional supply chain uses mainly major ports and cities for delivery, but these are commonly limited to the immediate surrounding areas. With AM it is possible to increase access to critical medical supplies in much wider areas. AM can also reduce delivery delays and other uncertainties of materials supply. When products can be manufactured on site and at the points where products will be used, it reduces the problematics of conventional supply chains, where it can take months to get wanted products. Remote clinics struggle with medical device supply and there is potential for damage, this means that medical teams have to travel with required instruments or

use alternative tools. (Bhatia and Ramadurai. 2017, 101.) The AM-based supply chain can be seen in Figure 24.

Figure 24. AM-based medical device supply chain (Engel 2014).

AM can be used to reduce risks in conventional supply chains. Supply chains can be simplified by production reshoring, products can be simplified and production can be on-demand where needed. The supply chain can have less continuity risks because suppliers and sites can be mainly removed which reduces the needs to identify risks of single suppliers in the whole chain. Brand and compliance risks can be smaller because unmonitored geographically remote subtier suppliers can be removed, reducing production waste. Eviscerating capacity risks can be minimised because on-demand production reduces inventory or safety stock. Security risks of the physical supply chain can be mainly eliminated by the digital supply chain. The cyber risks of a supply chain change position because the simplified supply chains shifts upstream risks to downstream risks. (Campana *et al.* 2017, 283.)

5.3 Biobased industry and biorefineries in Finland

Raw materials are an important part of the supply chain: when raw material sources, production and product end user are at a short distance there will be lower transportation costs and emissions. Sustainability and use of renewable raw material sources are highlighted in today's world and will increase in the future, and the use of biobased raw materials provides possibilities to reduce needs for conventional fossil-based sources.

Plant biomass's properties, great heterogeneity and complex chemical structures provides a wide scale of end products with the use of different biomass types such as starch, lignocellulosic, oleaginous, and saccharide biomasses (Vaz 2018, 2).

The use of biobased materials not only cuts long raw material chains but also provides more environmentally friendly solutions compared to petrochemical-based raw material chains. Biobased industry market segments are evolving quickly in fields such as:

- Various applications of polymers and materials
- Chemical commodities
- Pharmaceuticals
- Cosmetics
- Hygiene products
- Fine chemicals and specialties
- Fuels and energy (Vas 2018, 4)

Figure 25 provides a map of the bioindustry in Finland. These biobased industries are working in several areas and provide different biobased products such as in pulp and paper mills, biomethane plants, starch and sugar plants, chemicals, timber, liquid biofuels, composites, and fibres. (European Commission. Joint Research Centre 2020.)

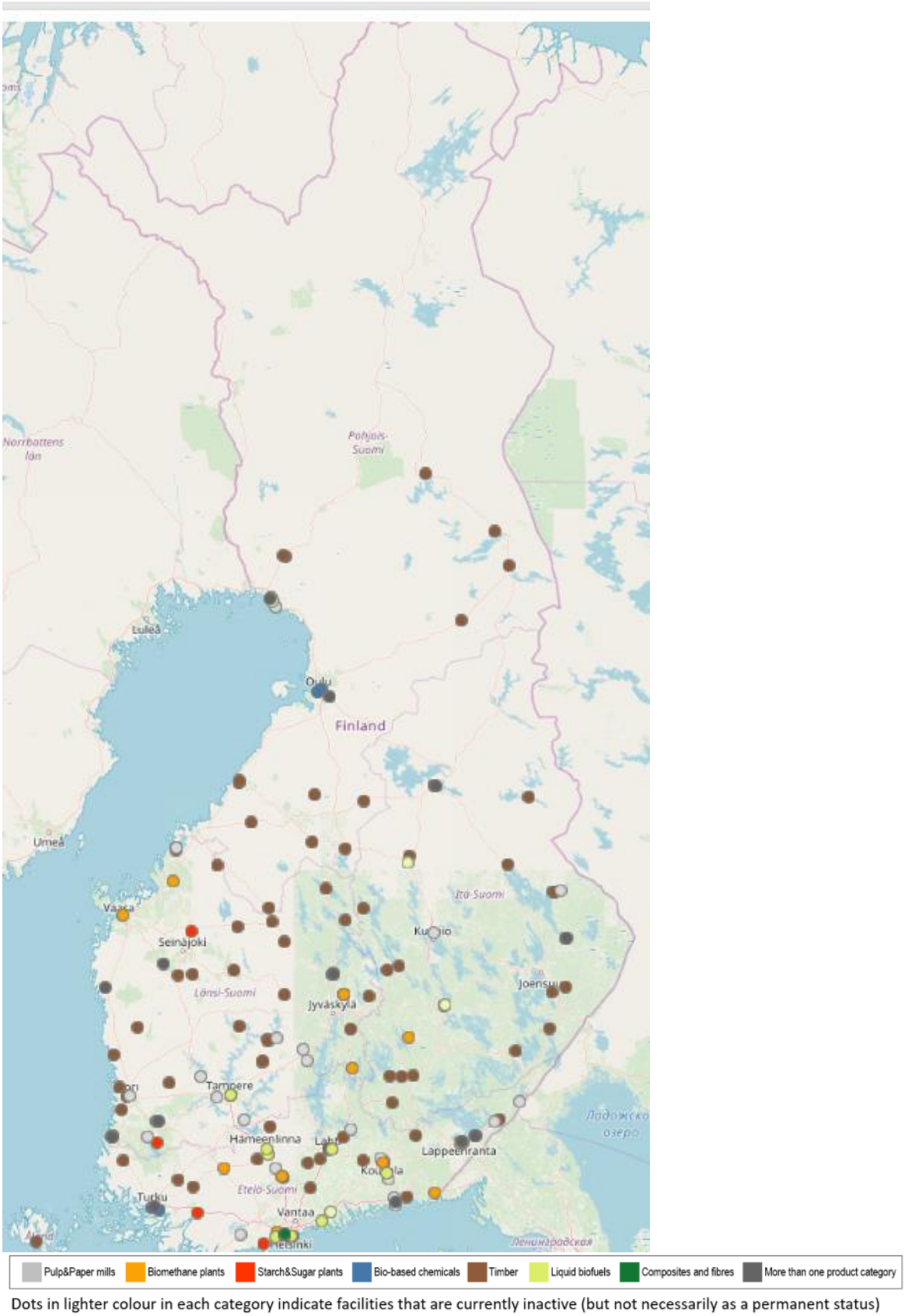


Figure 25. Biobased industry plants, including biorefineries in Finland (European Commission, Joint Research Centre 2020).

6 THE FIELD MEDICAL SYSTEM

The field medical system is a chain of several actors which starts from soldiers' self first aid and continues through the evacuation chain to an evacuation hospital. The target is to evacuate injured soldiers rapidly to the next level of treatment. First aid measures increase through the evacuation chain, and the final level is the evacuation hospital. Combat care facilities needs to be flexible and fast-moving systems, and the ability to adapt for different tactical frameworks is essential. (Jokela 2014.)

6.1 Background and critical measures

Approximately 90% of combat-related deaths happen before the casualty reaches medical treatment facilities. Deaths are tried to reduce by improved all combatants' casualty care training and material development so that injured soldiers would reach treatment facilities (Kotwal et al. 2011). The challenging part of the field medical system is the first measures after injury, because this usually happens under opposing forces' lethal implications and priority one needs to be the execution of the combat mission. The basic requirements for combat casualty care are summarised as 10-1-2. Immediate life-saving first aid measures needs to be started within 10 minutes after wounding. Damage control resuscitation by medical personnel needs to be started within one hour after wounding. Damage control surgery needs to be started within two hours after wounding. (Tien *et al*. 2015.)

Combat casualty care does not start at the hospital, it starts at the point of injury and it must continue until the injured soldier reaches the needed level of treatment. The first phase of care has a huge effect on the chain of survival for injured soldiers: it has been suggested that 25% of deaths on the battlefield could

be avoided with better casualty care. Improving combat casualty care can be significantly more challenging than hospital-based care, because of military medical structural challenges. (Mabry and Delorenzo, 2014.) Factors which affect prehospital care in the combat environment include:

- Temperature and weather extremes
- Visual limitations in night operations
- Combat and logistical related delays in evacuations and treatments
- Dispensing of specialised medical care providers
- Medical equipment supply chain
- Opposing forces with lethal implications (Kotwal *et al.* 2011)

The US Military distribution of wounds by body region from World War II to Operation Iraqi Freedom and Operation Enduring Freedom, can be seen in Figure 26. The data show that more than half of wounds are related to extremities. Head and neck region wounds have increased significantly and thoracic wounds have decreased significantly. (Owens *et al.* 2008.)

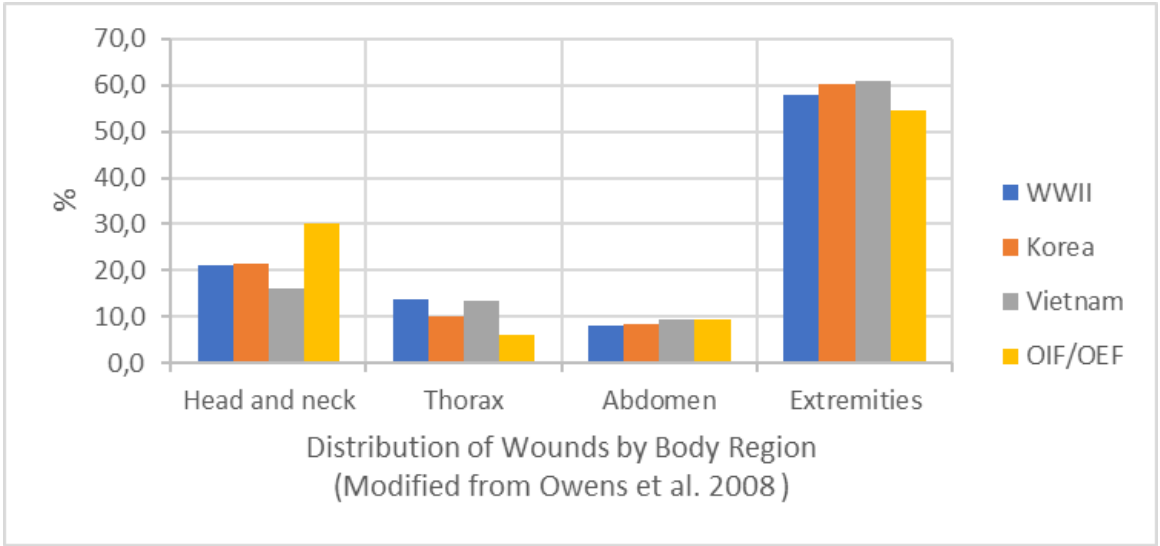


Figure 26. US Military combat wound percentages from WWII to OIF/OEF (modified from Owens *et al.* 2008).

In 1998, the US 75th Ranger Regiment made complete integration of TCCC (Tactical Combat Casualty Care), which included training for all assigned personnel. The results from the wars in Afghanistan (continuous combat for 8.5 years) and Iraq (continuous combat for 7 years) in 2001- 2010, were 419 casualties from the 75th Ranger Regiment, US Army Special Operations Command. The regiment's numbers were 10.7% KIA (killed in action) and 1.7% DOW (died of wounds), which are lower than the figures for the overall US military population of KIA 16.4% and DOW 5.8%. Nonmedical personnel in the phases of Care Under Fire and Tactical Field Care used overall 42% (37/89) of all the tourniquets used. (Kotwal *et al.* 2011.)

In World War II, many soldiers suffered amputations because tourniquets were used too tightly or too long. The use of tourniquets was re-evaluated in modern battlefield casualty studies in wars such as Vietnam, Somalia, Iraq and Afghanistan, and two major issues were found. One was an increase in the percentage of limb injuries, because of better body armour which reduced abdominal injuries. The other was higher capacity to evaluate the reasons for death of individuals who died on the battlefield. Studies have shown that the reason for 10% of deaths in Vietnam and Somalia was extremity wound bleeding, and if tourniquets were used, the death percentage would be smaller. (Gooch, 2019,118-119.)

Different kinds of tourniquets have been used to control excessive haemorrhaging in the battlefield since the days of the Roman Empire. The technical definition of a tourniquet is any device which can be used to prevent blood flowing through vessels. A properly used tourniquet can be an extremely effective way to control wound haemorrhage. (Gooch 2019,117.) The development of better tourniquets with consistent and effective training for all combatants and medical personnel improves control of major haemorrhage (Wartman, 2015).

6.2 First aid for all combatants

TCCC is emergency first aid measures in every soldier's training. The purpose of TCCC is to improve the possibilities for critically injured soldiers to survive to the next phase of care. A soldier needs to have skills to help themself and their team mates. The tactical combat casualty cABC rules can be seen in Table 1 (Finnish Defence Forces 2017, 230).

Table 1. cABC rules in combat casualty care (modified from Finnish Defence Forces. 2017).

Tactical combat casualty care cABC rules
c= catastropical bleeding Life-threatening limb haemorrhage - Examine limbs in case of possible life-threatening haemorrhages - Treat haemorrhages with a tourniquet or other available means
A= Airways - Verify that airways are open - Ensure that they stay open
B= Breathing - Chesk if breathing is normal - Treat possible injuries that endanger breathing
C= Circulation - Check for other possible bleeding - Stop bleeding - Place emergency blanket against the skin, under the clothes of the injured person to support circulation
Make preparations for immediate evacuation

Combat first aid: Major haemorrhage needs to be stopped. Usually this can be done with pressure, a tourniquet and also with haemostatic agent in wound packing. The airway recovery position needs to be maintained. Medics need to be assisted if required. (Kotwal *et al.* 2011.) The basic management plan for care under fire can be seen in Table 2.

Table 2. Care under fire and cABC rules (modified from Finnish Defence Forces 2017).

Basic Management Plan for Care Under Fire
1. Return fire and take cover
2. Let the soldiers closest to you know that you have been injured
3. Use a tourniquet to stop intense bleeding from a limb
4. Continue combat until the situation has passed
5. If you feel you are about to lose consciousness, turn yourself on your side to ensure that your airways stay open
6. If you are unable to move or take cover, try to let the soldiers closest to you know that you are alive by moving e.g. your hand
Each soldiers medical kit includes: - Tourniquet - First field dressing - Emergency blanket - Atropine injection syringe - Clasification/ treatment card

6.3 Measures of medical personnel

DCR (Damage Control Resuscitation) is a concept is used for the early coagulopathy of trauma, used for casualties who may die from an uncorrected state of shock. The fundamental tenets of DCR are:

- Arresting surgical haemorrhage
- Containing gastrointestinal spillage
- Inserting surgical sponges
- Applying a temporary abdominal closure (Ball, 2013)

DCR is early care used for severely and multiply injured casualties. It aims to keep casualties alive and avoid risks that would make their situations worse by controlling the lethal triad of hypothermia, coagulopathy and acidosis or excessively stimulating the immune-inflammatory system. DCR is an overall approach to casualty care which has evolved from DCS (Damage Control Surgery). It aims to restore physiological stability with early blood products, decrease haemorrhage and restore blood volume. (Giannoudi and Harwood 2016.)

The focus of DCS is on critical measures which are required to save life and limb and increase a patient's physiological stabilisation (Giannoudi and Harwood 2016). Ballistic injuries have effects beyond the wound area so primary and secondary surveys are important to get a general impression of the wounded person. Essential steps in the early phase of resuscitation are antibiotics, prophylaxis against tetanus and blood stabilising agents. Recovery possibilities for an injured limb are mainly determined by the success of early stage operations. (Birch *et al.* 2015.)

Contamination is a considerable risk factor in war wounds, because of direct open wounds to muscles and blood vessels. High-velocity bullets and explosive missiles cause shock-waves which produce damage surrounding the penetrating injury area. Combat wounds are more likely to be contaminated with dirt, uniform material and soil. (Jacoby 2008.)

The management principles of combat casualties are:

1. The possibility that large number of casualties will arrive simultaneously and with multiple injuries
2. Mobility requirements of different level medical units because of the tactical situation
3. Difficult conditions with lack of material, supplies, equipment and weak facilities for diagnostics and monitoring
4. Wide scale of high-energy-based injuries and burns
5. Hostile and hard environment, with different temperature conditions and lack of sterility
6. Continuous need for evacuation to next phase care facility
7. Factors such as morale, fatigue and fear
8. Patients ca not be under full control all the time (Rao and Singh. 2016)

7 CONCEPT

This section divides the field medical system into four phases. Phases can be seen in table 3.

The Phase 1 framework is life-saving first aid measures at the platoon (or equal) level, where about 30 personnel are operating.

The Phase 2 framework is company level (or equal) <300 personnel, where damage control resuscitation can be started by the medical group and medical officers.

The Phase 3 framework is battlegroup level (or equal) <2500 personnel, where damage control surgery can be started by medical groups and surgeons.

The Phase 4 framework is the logistical support level between the armed forces and evacuation hospitals, where damage control surgery continues and casualties are evacuated to civilian hospital-level care.

Table 3. Critical elements of the Field Medical System

PHASE 1 Personnel<30	PHASE 2 Personnel<300	PHASE 3 Personnel<2500	PHASE 4 Logistic support
Life Saving First Aid within 10 min -Nonmedic response 1 in 10 personnel -Medics 1 in 30 personnel Critical material - Tourniquets - Pressure bandages	Damage Control Resuscitation within 1 hour Evacuation to PHASE 3 -Medical group including medical officers Critical material: - Medical instruments - Tourniquets - Pressure bandages	Triage Damage Control Surgery within 2 hours Evacuation to PHASE 4 -Medical groups including medical officers and surgeons Critical material: - Surgical instruments - Medical instruments - Tourniquets - Pressure bandages	Triage Damage Control Surgery continues -Evacuation support -Evacuation hospital -Medical groups including medical officers and surgeons
Evacuation Chain →			Material Supply Chain →
←			←

7.1 Phase 1

Many things (tactics, shields, equipment, environment, etc.) that affect war injuries have changed in recent decades, but still more than half of war injuries are related to the extremities. This has led to the basic rule that every soldier should have a tourniquet available and before action they should be trained to use it for themselves and also on other personnel. This gives a better chance for the wounded soldier to survive to the next phase of care.

The main causes of death that could be prevented are:

1. Massive limb haemorrhage
2. Loss of airways
3. Pneumothorax (pressure in the lung cavity) (Finish Defence Forces 2017, 231)

The Finnish Defence Forces' wartime reserve is 280 000 soldiers (Finnish Prime Minister's Office 2020). The price of conventionally produced tourniquets is about 30 € each, which means overall 8.4 M€ if the full reserve was activated. The price of a 3D-printed tourniquet is less than 10 €, with overall costs of 2.8 M€.

Annually approximately 21 000 conscripts perform military service in the Finnish Defence Forces. Training is a very important part of every soldier's casualty care, including applying a tourniquet to yourself and other soldiers. Tourniquets are mainly disposable products and when they are used in training, they lose features which are needed in real cases. When every conscript uses a new tourniquet in their military service, it costs annually more than 600 000 € with conventional tourniquet prices. The cost of 3D-printed tourniquets is 30% of conventional ones. There are also other needs for tourniquets such as reserve repetition exercises, peacekeeping missions, etc. The annual need for tourniquets is more than the conscripts service needs. However, for training purposes it is possible to use the same tourniquet several times, but it still has impacts on its features.

In crises involving several countries, there will be problems with the medical devices supply chain. In addition, it can be impossible for medical devices and equipment supply to enter some areas. When tourniquets can be printed locally and with local raw materials this will give a faster and more reliable supply chain than the supply chain between countries, especially in cases where several countries are involved in the same conflict.

Phase one includes only self first aid, nonmedic first response and medics, and the main task is to stop massive bleeding and prepare for casualty evacuation to the next phase. Materials needs to be simple to use without a long training time. As mentioned above, more than half of war injuries in recent wars have been to extremities, and an efficient way to stop limb bleeding is the tourniquet. Several different field tourniquets are available but almost all unite with a simple structure which can be used for upper and lower limbs.

Conventional field tourniquets have problems stopping massive bleeding from limbs (*Taylor et al*. 2010). Patients with tourniquets were evaluated in a Baghdad combat support hospital and only 53% (164 of 309) of bleeding limbs were stopped by one tourniquet: adding a second or more tourniquets side-by-side on the same limb improved overall effectiveness to 87% (270 of 309) (Kragh *et al.* 2008).

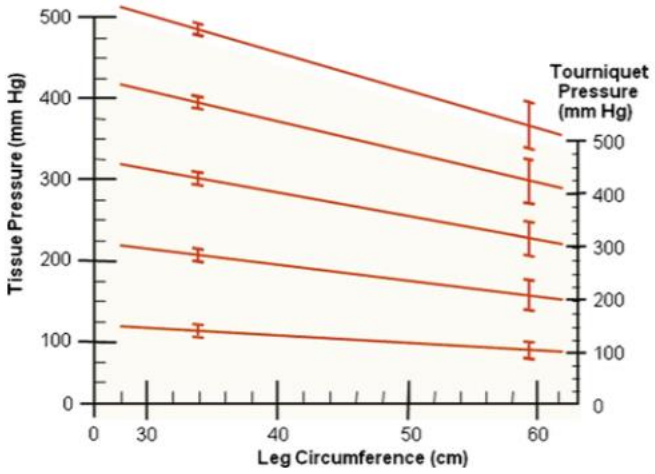


Figure 27. Leg circumference versus tissue pressure (Gooch 2019).

The effect of limb circumference on the tourniquet-tissue pressure ratio can be seen in figure 27 (Gooch 2019, 123). Conventionally produced tourniquets are

mainly planned and sized for warm conditions, where less clothes are needed. Massive bleeding needs to be stopped as soon as possible, so there is no time to remove clothes in the battlefield. This will also increase hypothermic problems for injured soldiers if clothes needs to be removed before the tourniquet can be put on. 3D-printed tourniquets can be planned and sized precisely so there is potential to produce tourniquets with better properties in Arctic or other different conditions.

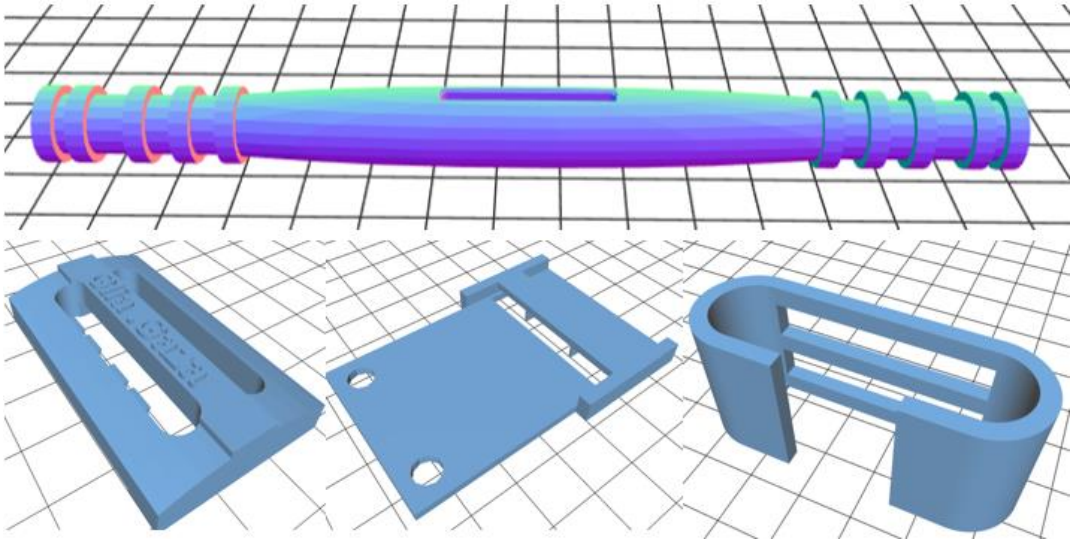


Figure 28. STL files of 3D-printable tourniquet parts (open source Glia tourniquet by github.com).

Figure 28 shows an example of the STL files of the open source Glia tourniquet, which was used in field trials in the Gaza protests in 2018 (Loubani 2018). The pressure region difference with narrow and wide belt tourniquets can be seen in Figure 29.

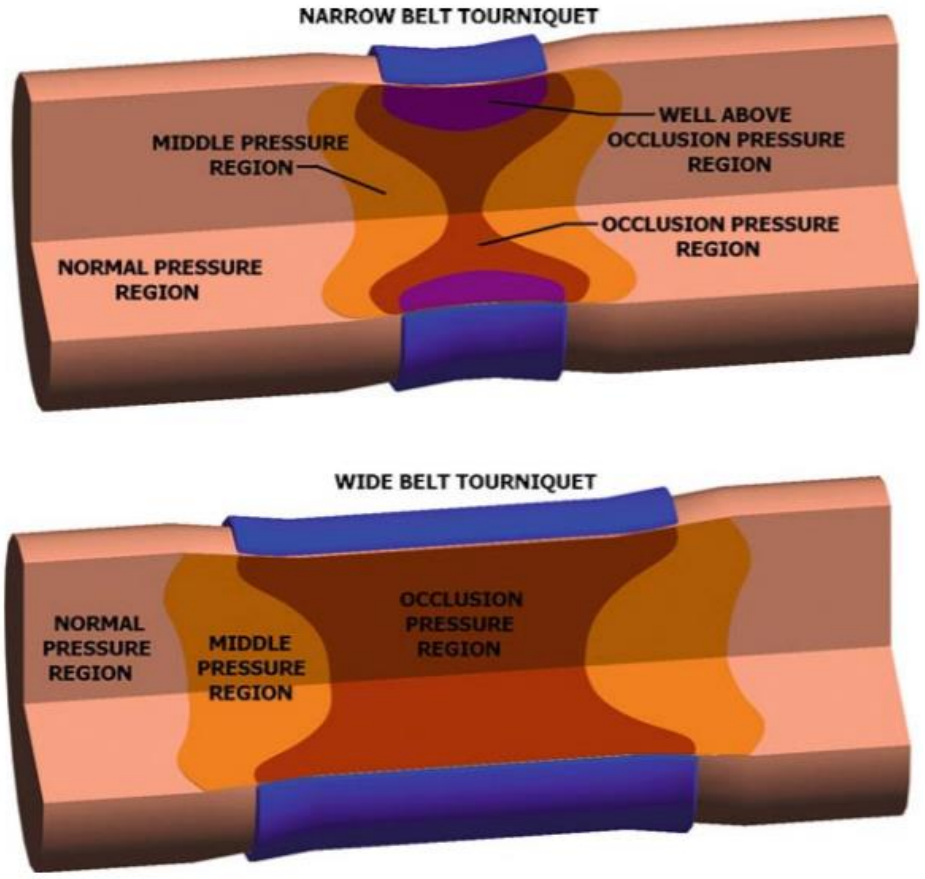


Figure 29. Difference of pressure effects between narrow and wide belt tourniquets (Gooch 2010, 118).

Field tourniquets must apply enough pressure to stop arterial bleeding, however tourniquets have often damaged limbs, because they are placed too tight and above the systolic pressure. When the tourniquet gives enough pressure to stop only the venous flow it may increase blood loss from an arterial wound. (Gooch 2019, 120.) Tourniquets are very important life-saving tools in battlefield care, however there are problems with field tourniquets. Field tourniquets needs to be small, light, robust and fit for different environments, but these features challenges material properties. In some mid-thigh level cases there have been several tourniquets used for one limb and still active bleeding happens. Another problem has been with strength properties, where mechanisms have snapped when tourniquets were tightened to stop bleeding. (Taylor *et al*. 2010.) A ready 3D-printed tourniquet can be seen in Figure 30.

Figure 30. Example of ready 3D-printed tourniquet, printed with photopolymerization (Permission to reprint from Cgtrader).

7.2 Phase 2

This section shows some basic medical instruments which are already used in conventionally produced forms in Phase 2. These instruments have been turned into digital form and 3D-printed in different studies. Phase 2 also has also needs for Phase 1 devices to be able to improve first aid that was given in Phase 1.

Phase 2 is the first level where a professional medical group with medical officers starts damage control resuscitation. When the casualty reaches Phase 2, they are called patients until the end of the evacuation chain. The target in Phase 1 is to prepare evacuation to Phase 2 within 1 hour after life-saving first aid has been done in the area where the casualty was injured. When the casualty is evacuated to Phase 2, the medical group can start DCR. A wider scale of materials and instruments are needed in this phase. Usually the physical distance between Phase 1 and 2 is lower than the distance between Phase 2 and 3. Before the patient can be evacuated to Phase 3, their condition needs to be stabilised so well that it is possible to evacuate them for longer distances.

Medical groups need to work rapidly, making only necessary life or limb-saving measures to the patient and preparing evacuation to the next phase. The medical group needs materials to support first aid measures taken in Phase 1 and basic instruments to start DCR. In figure 31. can be seen 3D-printed basic instruments which are needed in this phase, such as:

- Scalpel handle
- Haemostats
- Needle drivers
- Forceps

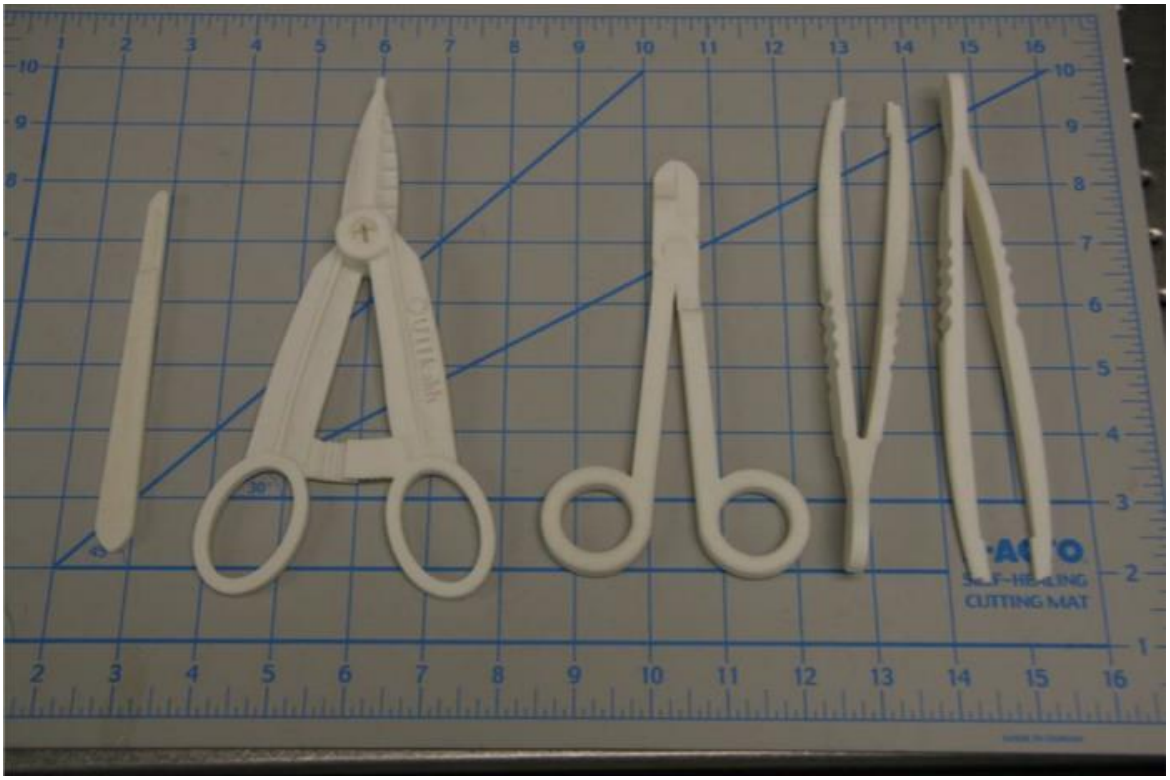


Figure 31. 3D- printed basic medical instruments from polyamide, printed with powder bed fusion (George *et al.* 2016).

Example of 3D-printed basic medical instruments which have been modified from conventionally produced instruments can be seen in Figure 31. Printing the needle drivers from two parts can be challenging because of 3D- printers' tolerance. The

axis model has to be tight so the force distribution can be equal and tip crossing can be eliminated. George *et al.* 2016 planned and produced needle drivers from three parts to eliminate these problems. Needle driver planned from three different parts can be seen in figure 32.

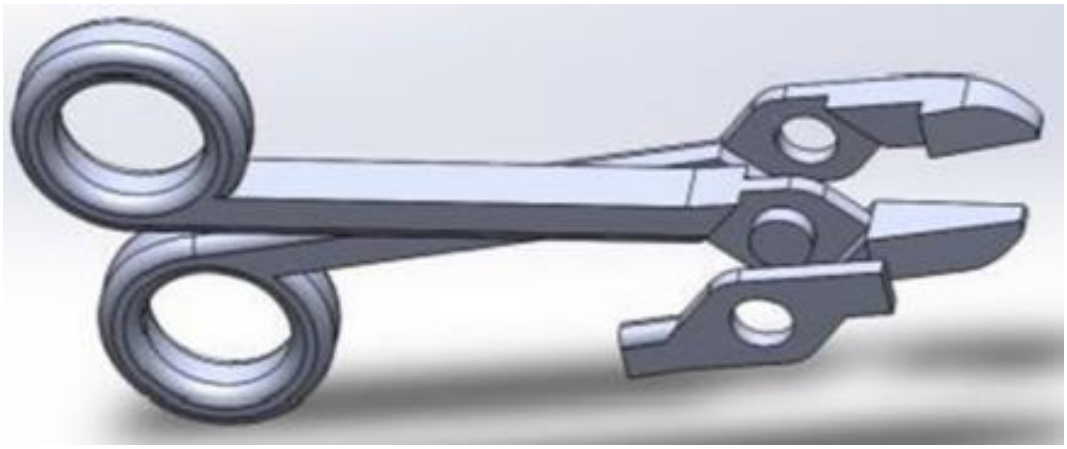


Figure 32. Modelling needle drivers from three parts to avoid axis problems (George *et al.* 2016).

There have also been similar problems with haemostats because of the hinge, which was reduced by having a large bearing surface and central locking to improve holding the arms together. The scalpel handle blade attachment was not robust enough and its strength properties were modified to improve its properties, so it could be used like a standard stainless-steel scalpel handle. The forceps were modified to improve the gripping surface and resting positions and stiffness properties were improved. (George *et al*. 2016.)

When conventional produced instruments are turned into digital form to be 3D-printed, several modifications can be needed. This development needs to be done with cooperation between the designer and medical professionals, so the instrument’s usability can be tested and accepted after its appearance has changed.

7.3 Phase 3

Phase 3 is the first phase where DCS can be started and wider scales of instruments and materials are needed. There are also similar needs to those shown in Phase 1 and 2. The first surgeons can be found in Phase 3.

The WHO's and other surgical studies have defined surgical instruments to provide a wide scale of surgical care which can be used in several critical surgical interventions. (Bhatia and Ramadurai. 2017) An example of conventional surgical kit and 3D-printed surgical kit can be seen in Figure 33 and the approximate price differences can be seen in Table 4.

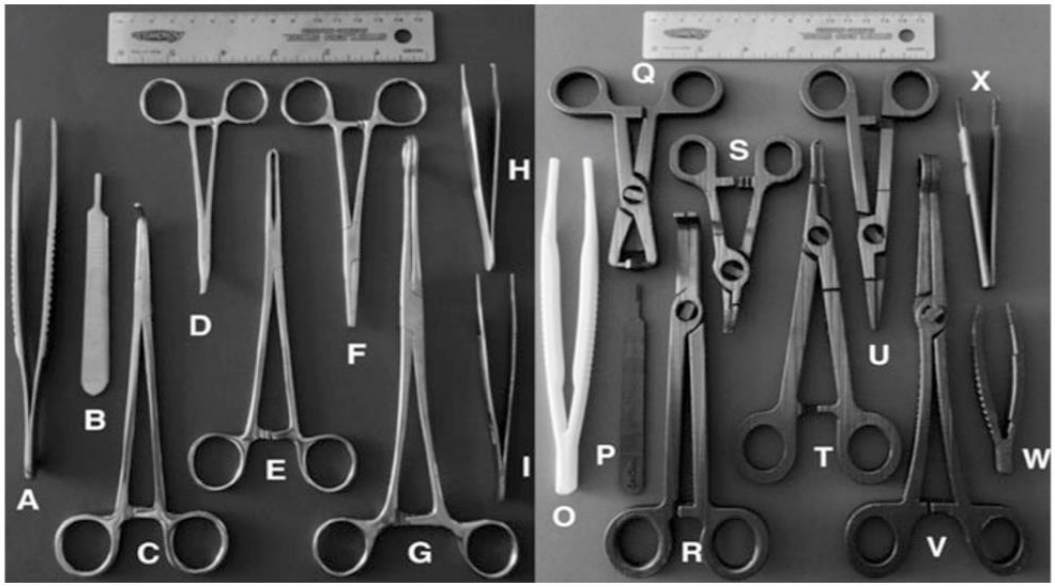


Figure 33. Left: conventionally produced stainless steel surgical instruments. Right: 3D-printed surgical instruments from acrylonitrile butadiene styrene with material extrusion. (Bhatia and Ramadurai 2017, 65).

A, O: Debakey tissue forceps

B, P: Scalpel handle

C, R: Right angle clamp

D, S: Curved haemostat

E, T: Allis tissue clamp

F: Straight haemostat

G, V: Sponge clamp

H, X: Adson toothed forceps

I: Smooth forceps

Q: Towel clamp

Table 4. Comparison of 3D-printed PLA instruments and conventionally produced stainless steel instruments (modified from Bhatia and Ramadurai 2017).

Surgical instrument	Approximate price of conventional stainless-steel instrument (€)	Approximate price of 3D-printed PLA instrument (€)
Adson toothed forceps	34.25	0.32
Allis tissue clamp	35.8	0.31
Army-Navy retractor	21.37	0.36
Debakey tissue forceps	130.53	0.18
Kelly haemostat	142.03	0.46
Needle driver	30.29	0.46
Pennington clamp	48.18	0.68
Scalpel handle	25.03	0.14
Senn retractor	19.12	0.18
Smooth tissue forceps	33.02	0.18
Sponge clamp	80.89	0.5
Tenaculum	78.33	0.68
Umbilical cord clamp	3.19	0.31
Vascular clamp	389.26	0.23
Total kit cost	1071.29	5.01

Army-Navy surgical retractors are used for several procedures with retraction of shallow incisions. The Army-Navy surgical retractor has been made from PLA which can be used in a combat zone. (Chen *et al.* 2019.) Figure 34 shows a 3D-

printed Army-Navy surgical retractor which weighed 16 g and was printed in 90 minutes. The printed instrument's tangential force tolerance was 13.6 kg. The printing cost for one instrument was 0.42 €. (Rankin *et al.* 2014.)

Figure 34. 3D-printed Army-Navy surgical retractor from Polylactic acid with material extrusion. (Rankin *et al.* 2014).

The Army-Navy surgical retractor's primary purpose is retraction and improving visibility in surgical operations. The model in Figure 34 was modified to improve its strength properties. (Rankin *et al*. 2016.) 3D-printed Army-Navy retractors made from PLA are cheaper, lighter weight and space-efficient compared to conventional stainless steel-based ones, with the same surgical retraction capabilities. (Chen *et al*. 2019.)

7.4 Phase 4

Phase 4 contains different operators between battlegroups and civil evacuation hospitals, including the same medical elements as in Phase 1 to 3. Phase 4 is also the material supply chain interface between civilian industry and military groups. Phase 4 can be used for evacuation support and material support, and field emergency care centres can be used in this phase to ensure there is enough prehospital medical capacity before evacuation hospital-level care.

Conventional material transportation to hostile areas can be risky and transportation needs to be protected. There have been situations in recent wars where medical material support and casualty evacuations from hostile areas have been blocked. The operating model can be seen in Figure 35. There are two different situations, where transportation and evacuation can be implemented and where the battle area is under siege and both chains are blocked.

After medical elements have been found, the conventional field medical system can operate as planned. Materials can be supplemented from the next phase while evacuating casualties or patients. The field medical system can operate as long as material flow and evacuations can be made without barriers or own losses. Field medical facilities can be prepared to operate for longer times without support by estimating different conditions and loss profiles. Based on supply estimations, medical groups can have additional materials if available, however there are still problems with the evacuation chain if patients cannot be evacuated to the next phase. Prolonged care in the field means more material needed to keep patients alive and also more surgical measures that need to be done by lower-level medical personnel.

Cases where areas are under siege will create prolonged care needs for casualties or patients. Another situation is when evacuation distances are very long between different phases. In these situations, when evacuations cannot be done as planned, bottlenecks will form in different phases of the evacuation chain, and material transportation can also be blocked. When evacuations cannot be done to the next

phase, casualties' and patients' possibilities of survival will decrease. The situation may also form cumulative needs for materials. AM offers possibilities to produce needed materials onsite which can be highly important when medical teams have to operate without the possibility to get material support from the basic supply chain. Onsite manufacturing reduces the need to estimate precisely what kind of materials will be needed before transition to the operating area, because materials can be printed when needed. Onsite production reduces material storage and transportation needs which is important, especially when operating in hostile areas.

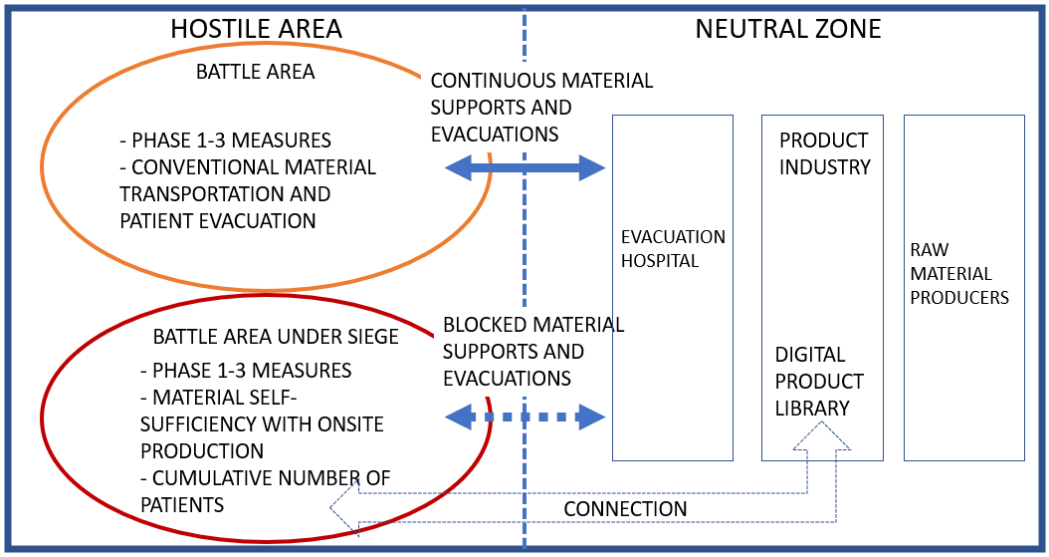


Figure 35. Operating model for Phase 4. The left is divided into two different situations: the upper where materials and evacuations can be completed and the lower where they are blocked. The right shows where non-military elements are producing raw materials end evacuation hospital services.

Self-sufficiency is an important part of the whole system and conventionally materials are stored in normal conditions to increase readiness if they are needed. Medical materials have different lifecycles, i.e. how long the material can be used or stored before it loses its properties. Estimations are based on calculations of how much and when material may be needed. When 3D-printing raw material is in commission and models are ready in digital form, equipment can be printed when needed without long supply chains. Digital products are an important part of AM supply chain. A digital library can be used to maintain and update the STL files of certain instruments and equipment, and this reduces the time needed for

planning and design. The products of the digital library need to be tested to be ready to use when needed.

In normal conditions, material is consumed by training and maintenance of ready materials. Ready material which expires can be used for training purposes which reduces overall material costs and waste. However, several types of medical materials have quite short lifecycles before the material expires. Many materials are also disposable and lose their properties after being used once. A more cost-effective way to supply materials which have a short lifecycle is to produce them when needed without large warehouse capacity needs.

Based on recent wars and armed conflicts it can be expected that limb injuries also have a major role in future wars. Amputated limbs need to be replaced with prostheses to improve the quality of life for injured soldiers. Unique needs for different sizes and types of prostheses can be produced by AM. Imaging and scanning techniques can be used to produce unique data from the amputated limb which can be used to print customised prostheses. Also when 3D- bioprinting matures there may be possibilities to print living cells and organs to reduce their availability problems. These problems which exist in normal conditions will increase in armed conflicts because of the wide scale of injuries. In the future, 3D-printing of living skin can also be very useful in the field medical system to improve casualty care.

8 DISCUSSION AND CONCLUSIONS

Modern wars have shown that many kinds of hostilities are focused on medical supply chains and medical personnel. Even though targeting medical operators and materials is against the rules of war, these cases have been reported from several countries. Conventional medical supply chains are long and vulnerable, especially when a country's self-sufficiency decreases and materials or devices have to be purchased from other countries. Material preparedness for future crises is always estimated, where the margin of error can be huge especially in a long-term perspective. Digitalisation provides elements which can be used for better supply chain handling and material preparedness estimation can be more flexible and closer for real-time situations.

Additive manufacturing technology has many techniques which can be used with a wide range of materials. When these techniques are taken to support field medical systems, it will reduce several problems existing in the current system. AM-based training simulations can be used to improve medical and nonmedical personnel's casualty care skills and knowledge. AM can be used to make training more efficient compared to conventional training systems, and it will also reduce overall training costs.

AM provides different solutions which can be used to improve the medical device supply chain. Conventional medical instruments can be produced by 3D-printing and also instruments' features can be modified to fit the conditions better. AM also provides better opportunities to produce and test totally new kinds of instruments without large and high-cost production series, and these instruments and devices can be tested and improved when needed. Onsite production reduces transportation which has impacts on emissions and product prices.

Nowadays material sustainability requirements and needs for circular economy have increased the development of biobased materials. Biobased materials are

replacing fossil-based materials and are more environment friendly. Material lifecycle sustainability and circular economy reduces emissions and new raw material needs, because material can be used several times for different purposes and does not end up in waste like many conventional materials. Material production needs to plan more efficient production methods and improve processes to reach the needed emission limits.

Some materials need to be on standby in warehouses to make sure that there is no production delay when conflicts suddenly start and medical devices are needed. However, when medical devices are turned into digital form and can be printed into physical objects when needed, and this will release needed warehouse capacity. Most medical materials have tight and specified storage requirements (temperature, moisture, etc.) which the warehouse needs to fulfil. Medical devices also have a limited lifecycle and need to be replaced. AM provides a wide scale of tools to estimate when and where different material are needed, because materials can be produced with real-time forecasts.

Production of AM medical devices needs several tests and evaluation to be used, and instruments need to reach at least the same features that can be found in conventionally produced instruments so that the usability is similar. 3D- printing raw materials need to be optimised for medical purposes so the quality and properties of printed equipment are high enough.

As discussed above, medical instrument production with AM needs tight interaction between the planner and medical personnel, so the printed instruments can be tested by medical staff and the designer can make the needed modifications after feedback. When the instruments fulfil the needs, the digital models can be saved to the digital model library and can be printed when needed. It is important to print these instruments with the same kind of printer and from the same materials which were used in the development phase. If the printer type or print material changes, the instruments need to be tested like earlier to make sure their features and usability have not been changed.

The AM supply chain has several benefits to be used in many kinds of crises, where material needs cannot be estimated precisely and where the conventional supply chain can be risky and unreliable. In the first stage, AM can be used to support the conventional supply chain which already exists and when different AM productions are more mature, they can take a wider role in the system. Local production and short supply chains reduce risk points which can produce major problems when different materials are needed for crises. Flexibility in all phases of the field medical system is the main key to reach efficient care.

3D-printed surgical instruments have been developed in several cases and have benefits which will improve the field medical system. However, instruments need to be tested in different environments and conditions to overtake mechanical measures and usability issues.

An important part of preparing for crises is training. Average injury profiles are different in normal conditions than in armed conflicts, which makes challenges to train for war surgery in normal conditions. For example bullet and explosion injuries can be produced in animals and surgeons can learn how to do surgical operations or its possible to use simulators for training. Using animals for this kind of purpose has ethical issues and there are also differences compared to human anatomy, however it is an important part of training and preparedness to work in real cases. Good medical simulators are highly expensive and have their own limitations. 3D- printing can be used to make medical objects which can be used for medical operation planning and visualisation. When complex surgical operations can be trained with a medical team it will improve the possibilities of success in real cases. Even medical professionals need to have special training for care of war injuries. 3D- printing offers possibilities to produce low-cost and specific models for field medical training. Conventionally produced comparable simulation models are cost are very expensive compared to 3D-printed ones. Other medical materials are needed for training in different phases from every combatant’s first aid skills to complex surgical operation training.

Backcasting can be used for material needs estimations, but estimating material needs for new types of crisis are mainly impossible and at least contain a high

margin of error. Also trying to prepare for every possible crisis scenario with material readiness comes with high costs and huge warehouse capacity needs. Global medical material supply chains are long and in global crises they can be overloaded by surprising and huge material needs. Onsite production with local raw materials gives options and flexibility to keep medical facilities in operational condition.

Of course additive manufacturing also has challenges and limitations which have to be considered. Most conventional production methods can produce huge series of different products, while AM has limitations for series production. AM has huge potential for countless solutions, but it still needs to mature enough to improve its real-world applications. Medical instrument and device production is a highly regulated field because medical materials need to be accepted to be used for health care purposes. Regulations are complex and difficult to implement which has reduced the development of AM medical production and makes companies hesitant to use AM in the health care sector.

9 SUMMARY

The main target of this thesis was to define the main critical problems in casualty care and find AM-based solutions which could reduce those problems. Conventional manufacturing methods have not been able to overcome these very challenging issues, which have direct impacts for casualties surviving war. Improving overall casualty care in wars and crises is a highly challenging but very important part of health care and saving human lives.

AM is a fast-developing manufacturing technique which is used in several fields. Its fast development comes from its manufacturing benefits, which cannot be found from other manufacturing techniques. Another driving force for AM can be found from digitalisation, where it is highly suitable. In addition, awareness of material sustainability and production impacts on the environment have increased the development of AM.

AM provides several possibilities to improve conventional medical supply chains, which has been challenged in recent wars by opponents' hostilities. AM can be used to reduce transportation because of onsite manufacturing. Training can be implemented with lower overall costs because conventionally produced disposable materials have a higher price. 3D-bioprinted models offer possibilities for surgical training, which can reduce the need for animals in war surgery training.

AM-based supply chains are more environmentally friendly compared to traditional supply chains. Models are transformed into digital form to be printed near the end user, which reduces warehouse and transportation needs. Models can be in digital form until they need to be printed, which releases warehouse capacity for other purposes. Warehouses can be destroyed easily but digital libraries and shared local production are more reliable against hostilities. The use of biobased

and renewable 3D-printing materials are effective against problems with fossil-based raw materials which produce more harmful emissions.

Self-sufficiency is highly important for material readiness in different kinds of crises. Global or multinational crises increase the need for certain materials depending on what kind of crisis is in question. This can overheat global medical supply chains and not all the needed materials can be delivered. When AM is used to produce medical instruments and equipment, it reduces overall prices and gives more flexibility for acquisitions.

Fundamentally, AM can be used to solve many problems in the field medical system. However, many more studies and practical tests need to be done with individual medical instruments and equipment. AM production limitations, for example strength properties, need to be tested and modified to fulfil all the requirements. Medical materials have strength and fit requirements but also hygienic and sterilisation requirements, which also need to be tested and proved before being used for living cells and people.

Several further studies are still needed, including studies from medical and engineering fields. Studies are needed to test more 3DP equipment’s properties and studies to get more details of risk handling in the 3D- printing supply chain. Globally there are several studies researching similar areas, which has a positive impact for this development in this field.

Improving training and knowledge are the main keys to take full advantage of AM. The main lack of AM use comes from uncertainty of what it is capable of. In addition, efficient development needs multidisciplinary cooperation between several fields of science.

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