Stefan Berer, BSc

3D Printing
– Quality Assurance for Medical Applications

MASTER'S THESIS

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Supervisors:
Dipl.-Ing. Philipp Url, BSc
Ass.-Prof. Dipl.-Ing. Dr.techn. Wolfgang Vorraber

Institute of Engineering and Business Informatics

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Abstract

At Graz University Hospital, a 3D printing research center has been established in the course of the COMET project *CAMed (Clinical Additive Manufacturing for Medical Applications)*, which aims to manufacture patient-specific implants, anatomical models as well as various tools and aids for medical applications. One of the greatest challenges – currently facing the application of 3D printing technologies in general – is the mostly unmet or missing standardization of processes, methods and workflows. This poses a particular challenge for the quality control of such products.

To address a crucial part of this challenge, the present work, as part of the overall research project, deals with the question of suitable testing methods for quality verification of 3D-printed polymer products for medical applications, in particular after the manufacturing process. The aim of this thesis is to first develop a general methodology in the form of a guideline for the systematic selection of suitable inspection and testing methods that are applicable in the area of interest described before. This methodology was then applied to identify potential testing methods and to subsequently list and systematically select them in accordance with the requirements to be defined from the predetermined use case "patient-specific cranial implants".

The theoretical basis for addressing these issues was formed by a comprehensive literature review, which clarified the relevant key aspects, as well as the application of some appropriate tools enabling to depict and assign the project-specific selection criteria. The selection process was carried out using a value benefit analysis, in which the additional involvement of several specific domain experts within the project was of essential benefit in order to fully consider all requirements and criteria to be defined. By working through the case study in this guided manner, the developed framework was investigated and validated concurrently, allowing to draw conclusions on its applicability to future decision-making processes of similar use cases.

The findings of this thesis indicate that it is best to focus on specific quality requirements to be met when selecting the most suitable testing methods. Dimensional accuracy, surface finish as well as internal structure and defects were found as the most important of these requirements. Accordingly, tactile and laser measuring systems, X-ray micro-CT and the use of surface profiling devices were identified as solutions for the case study, as these achieved the best results in the applied framework. Moreover, this work highlights the significance of clear definitions of requirements, which posed a general challenge to the case study, as standards and the project are still in their development stages. By taking the use case "additively manufactured cranial implants made of polymers" as an example, this thesis contributes to understand the needs and challenges of quality evaluation of such products in the field of medical applications. In a more direct relation, the gained insights support the general progress of the overall project.

Kurzfassung

Am LKH Graz wurde im Zuge des COMET-Projekts *CAMed* (*Clinical Additive Manufacturing for Medical Application*s) ein Forschungszentrum für 3D-Druck eingerichtet, dessen Hauptziel es ist, patientenspezifische Implantate, anatomische Modelle sowie diverse Werkzeuge und Hilfsmittel für medizinische Anwendungen herzustellen. Eine der größten Herausforderungen hierbei – vor der die Anwendung von 3D-Drucktechnologien derzeit generell steht – ist die großteils unzureichende oder fehlende Standardisierung von Prozessen, Methoden und Vorgehensweisen. Dies stellt insbesondere eine Herausforderung für die Qualitätskontrolle solcher Produkte dar.

Um einen wesentlichen Teil dieser Herausforderung anzusprechen, befasst sich die vorliegende Arbeit als Teil des Gesamtforschungsprojektes mit der Frage nach geeigneten Prüfverfahren zur Qualitätsprüfung 3D-gedruckter Polymerprodukte für medizinische Anwendungen, insbesondere nach dem Herstellungsprozess. Ziel dieser Arbeit ist es, zunächst eine allgemeine Methodik in Form eines Leitfadens zur systematische Auswahl geeigneter Prüfmethoden zu entwickeln, die im zuvor beschriebenen Interessengebiet anwendbar sind. Diese Methodik wurde anschließend angewandt, um potenzielle Prüfmethoden zu identifizieren und diese anschließend anhand der Anforderungen aus dem Anwendungsfall „patientenspezifische Schädelimplantate“ aufzulisten und auszuwählen.

Die theoretische Grundlage für die Bearbeitung dieser Fragestellungen bildete einerseits eine umfassende Literaturrecherche, welche die relevanten Schlüsselaspekte beleuchtete, und anderseits die Anwendung einiger geeigneter Werkzeuge, mit denen die projektspezifischen Auswahlkriterien abgebildet und zugeordnet werden konnten. Der Auswahlprozess wurde im Anschluss mittels einer Nutzwertanalyse und der zusätzlichen Einbindung projektspezifischer Fachexperten durchgeführt, um alle zu definierenden Anforderungen und Kriterien vollständig zu berücksichtigen. Indem die Fallstudie auf diese Weise durchgeführt wurde, konnte das entwickelte Framework parallel dazu untersucht und validiert werden, woraus Rückschlüsse auf seine Anwendbarkeit bei zukünftigen Entscheidungsprozessen in ähnlichen Anwendungsfällen gezogen werden konnten.

Die Ergebnisse dieser Arbeit zeigen, dass es am besten ist, sich bei der Auswahl der am besten geeigneten Prüfmethoden auf die jeweils zu erfüllenden Qualitätsanforderungen zu konzentrieren. Für den behandelten Anwendungsfall wurden die Maßhaltigkeit, die Oberflächengüte sowie die innere Struktur und Fehlstellen als die wichtigsten Anforderungen identifiziert. Dementsprechend wurden taktile und Laser-Messsysteme, Röntgen-Mikro-CT und die Anwendung eines geeigneten Oberflächenprofilmessgerätes als Lösungsvarianten ausgewählt, da diese die besten Ergebnisse in angewandten Framework erzielten. Darüber hinaus unterstreicht diese Arbeit die Bedeutung von klar definierten Anforderungen, was eine generelle Herausforderung in der Fallstudie darstellte, da sich Normen sowie das Projekt selbst noch in der Entwicklungsphase befinden. Am Beispiel des Anwendungsfalls „additiv gefertigte Schädelimplantate aus Polymeren“ trägt diese Arbeit dazu bei, die Erfordernisse und Herausforderungen der Qualitätsbewertung solcher Produkte im Bereich der medizinischen Anwendungen zu verdeutlichen. In einem direkteren Zusammenhang unterstützen die gewonnenen Erkenntnisse den Fortschritt des Gesamtprojekts.

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List of Abbreviations

3D	three-dimensional
AM	Additive Manufacturing
ANSI	American National Standards Institute
ASTM	American Society for Testing and Materials
AT	Acoustic Emission Testing
CAD	Computer Aided Design
CAMed	Clinical Additive Manufacturing for Medical Applications
CMM	Coordinate Measuring Machine
COMET	Competence Centers for Excellent Technologies
CT	Computed Tomography
DIN	Deutsches Institut für Normung
FDA	[United States] Food and Drug Administration
FDM	Fused Deposition Modeling
FEM	Finite Element Method
ISO	International Organization for Standardization
MRI	Magnetic Resonance Imaging
NDE	Nondestructive Evaluation
NDT	Nondestructive Testing
NIST	National Institute of Standards and Technology
PEEK	Polyether Ether Ketone
PETG	Polyethylene Terephthalate, Glycol-modified
PLA	Polylactic Acid
PMMA	Polymethyl Methacrylate
PSI	Patient-Specific [Cranial] Implant
QA	Quality Assurance
QC	Quality Control
QM	Quality Management
QMS	Quality Management System
TMS	Testing Method Selection [Framework]
UCTM	Use-Case Technology-Mapping [Framework]
UT	Ultrasonic Testing
VBA	Value Benefit Analysis
VPC	Value Proposition Canvas

Part I.

Research Intent

1 Introduction

As an introductory chapter to the thesis, its motivation and the identified challenges are outlined. Furthermore, the chosen methodology is explained in section 1.2, before an overall summary of the present thesis' structure and content are given in section 1.3.

1.1 Initial Situation and Challenges

As technical development of innovative manufacturing processes continues at a high pace, unlocking new opportunities across a broad range of products and whole industries, 3D printing technologies also keep progressively reaching into highly complex and strictly regulated domains of application such as aerospace and, most notably, the medical industry. However, while on the one hand the increasing interest in research over recent years is accelerating this rapid development even more, for many aspects on the other hand, appropriate norms or general standardization are still insufficient or have not been established yet. This is especially true in the area of testing or validating products fabricated by 3D printing technologies, posing a problem for many manufacturers: Basically they are dependent on testing their 3D printed products for certain properties or their quality by using methods that have become well-established (e.g., industry-specific or in other familiar processes). There is, however, mostly no possibility of assessing or guaranteeing any *standardized* testing or quality parameters suitable for the 3D printing process, as the legal basis in the sense of testing and inspection standards is lacking. Reasons for this lack include, for example, the numerous technology-specific influencing factors that need to be considered, the complex interaction they have while the component is being manufactured and, ultimately, the fact that these technologies are new in most areas of application. Not least because of this, many industries and researchers are making their own efforts and run their own projects towards the development of standardizable testing methods in order to progress their work until the standardization institutes will eventually release official regulations which are currently being under development (American National Standards Institute [ANSI], 2018; Lu & Wong, 2017a; Energetics Incorporated, 2013).

The present work is based on such a project, taking place at clinic of the Medical University of Graz, where a 3D printing research center is being established in the course of the COMET project *CAMed (Clinical Additive Manufacturing for Medical Applications)*, in which patient-specific implants, anatomical models as well as various tools and aids for medical applications are to be manufactured (Medical University of Graz, 2020). Based on the described initial situation on a general level, and in the context of the overall research project, this thesis aims to first examine how the landscape of 3D printing in the field of medical devices is composed at present. Within this context, especially the current state of standardization regarding testing as well as quality verification shall be addressed. This will subsequently help to specify what is important in the process of selecting testing methods for ensuring the quality of 3D printed products. Therefore, by putting the focus on the given use case "Patient-specific cranial implants, made of polymers through Fused Deposition Modeling" this work seeks to address the following challenge:

Enabling the systematic determination of suitable methods for the testing and verification process of 3D-printed products used in the medical device industry by application of a developed framework that is generally applicable as a guideline in the context of similar use cases within the medical device industry.

Furthermore, on a secondary level, the following challenges arise in return:

- Creation of a list of common testing methods that could potentially be applicable,
- Identification of the primary criteria or requirements for these methods, (general technical criteria, knock-out criteria, etc.).
- Identification of additional criteria that need to be considered when selecting a method, (process relevant, organizational, etc.)
- Determination of whose expertise needs to be incorporated in the selection process (concerning the fields of technology/3D printing, medicine/implants, etc.)

These elaborated challenges point out the project-specific value of this thesis since their processing strongly contributes to the feasibility of the project itself, which is described in detail in chapter 6.

1.2 Objectives and Methodology

At an early stage of this thesis, it became clear that a mixture of different approaches and methods are required to target the listed initial challenges in a satisfying manner. This is not least due to the complexity of its underlying and interrelated influencing factors and sub-aspects, but also the necessary expertise in order to address all the stakeholders involved. Therefore, the following tasks are defined in order to successively lead to this work's aspired outcome and contribution:

1. In general, the work covered in this thesis lies in the scope of additive manufacturing (AM) for medical applications. The case study examined in this thesis is in turn based on a given use case that is part of an overall project. Because of the project's novelty in its research area where yet no adequate solution theory exists for specific cases, but also due to its empirical validity and testability, a case study approach is in fact a well-suited way to combine several methods, using mostly qualitative data in order to generate a solution, as concluded by Eisenhardt (1989). While becoming familiar with the practical use case, another part going hand-in-hand in this initial task is to relate it within the concept of the UCTM framework (Vorraber et al., 2019), which will serve as guidance throughout this thesis.
2. The second task is to conduct a comprehensive literature research. This theoretical method enables to gain a broad outline of the involved sub-disciplines which may be of interest in the context of this work on the one hand, but also to learn about related works in this sector on the other hand. Thus, the research should help to clarify the scope of this work and then define and address necessary inputs and key topics to get a more specific point of view. In practical terms, this research should additionally result in a basic list of testing methods that can be built upon in the further stages of this thesis.

3. After the specification and general research process, a holistic view of the project should be provided. The Value Proposition Canvas by Osterwalder et al. (2014) can be applied as a theoretical framework in the third task. This model serves as a well-established tool in order to address all stakeholders involved as well as to display their interrelations with the existing problems and possible solutions within the scope of this project.
4. The fourth task includes to systematically compare and rank possible solutions for the given problem, stating the essential part of this thesis. A Value Benefit Analysis enables to bring in the consolidated knowledge gained from the literature research and the main decision factors to be defined, merging them with the technical professionals' expertise. After the evaluation of the most appropriate testing method(s) based on this decision tool, a final discussion on the selection should be considered within this task.
5. Besides the primary goal described in the previous tasks, the accumulated knowledge and methodology required for the completion of this work should be abstracted to a generic level. Hence, the result of this additional task is a step-by-step framework, which should be tested in the course of the practical part and furthermore be applicable for related future projects dealing with decision-making processes within a similar context.

Summarizing the methodical procedure of this work, Figure 1 gives a brief overview of the steps to be followed: After the problem is identified and the specific challenges are defined, theoretical considerations and hypothesis can be made. Following, the research design is determined and then applied to the present use case in the execution step, eventually leading to the required outcomes. However, the decision on the final result is made in a concluding step, enabling to address missing influencing factors, for example, and discuss further proceedings.

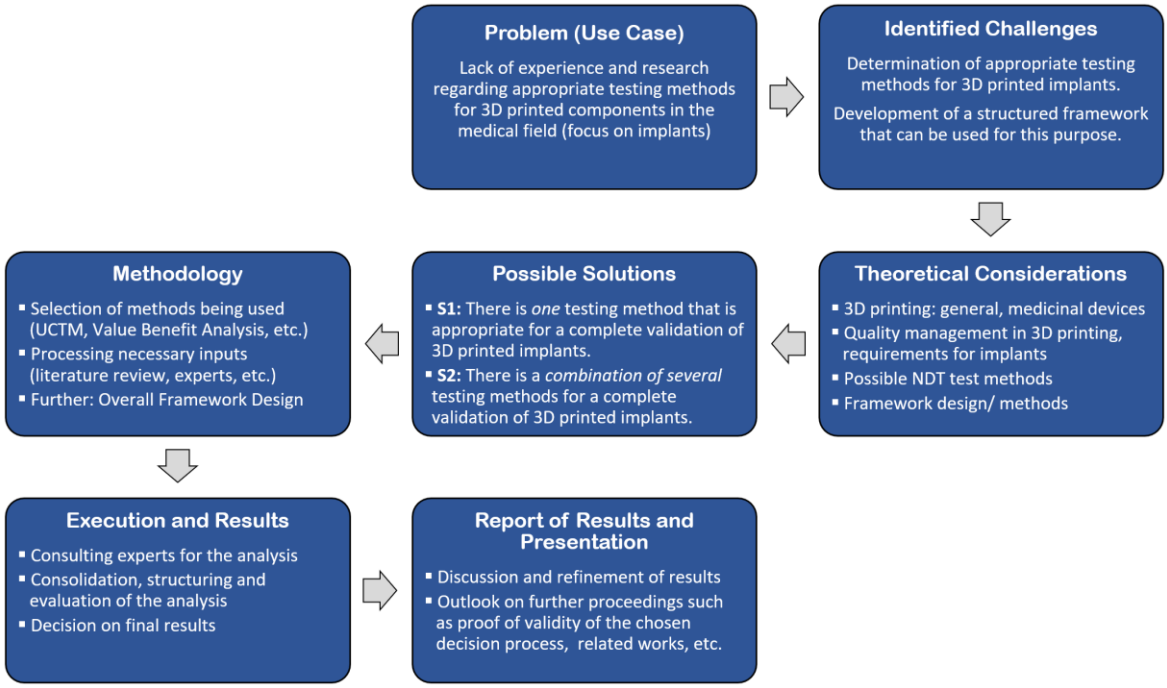


Figure 1: Methodical procedure as a guiding structure for this thesis

1.3 Structure and Content of the Thesis

As depicted in Figure 2, the thesis is basically divided into four blocks and eight chapters. Chapter 1 gives a brief insight into the initial situation, outlines the main challenges and defined objectives. Furthermore, the chosen methods to tackle these objectives are mentioned, too.

Chapter 2, 3 and 4 strive to explain the theoretical aspects that are dealt with in this thesis. As a start, chapter 2 gives a rough outline of additive manufacturing technologies and addresses some relevant topics to promote a basic understanding for this work. Chapter 3 is concerned with the theoretical considerations behind quality management and some major aspects with respect to the development of additive manufacturing, especially in the field of medical applications. Chapter 4, by contrast, adds a technical perspective to the necessary considerations as it discusses the most common methods for testing and quality verification of finished products, with an emphasis on nondestructive testing.

Chapter 5 describes the development of the framework that should serve as a step-by-step guidance for the identification and selection of suitable testing and inspection methods for finished AM parts.

Chapter 6 represents the conducted case study, dealing with the testing of additively manufactured polymer implants. In the course of this case study, also the developed framework was first validated.

Chapter 7 and 8 aim to discuss the overall findings gained from this thesis. The main results of the practical part are evaluated before the limitations and an outlook are described at the end.

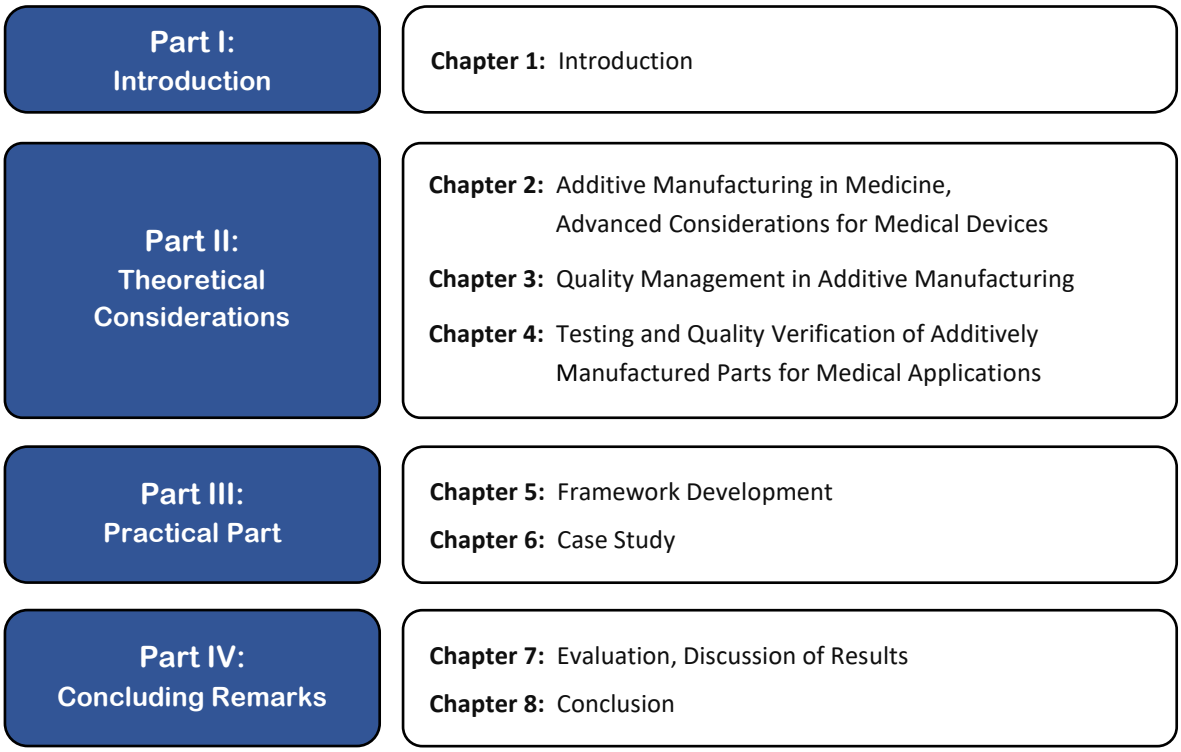


Figure 2: Structure of the thesis

Part II.

Theoretical Consideration/ Literature Research

2 AM in Medicine, Advanced Considerations for Medical Devices

This chapter aims to provide a brief overview of some key aspects in additive manufacturing (AM). First, a general outline of the main processes and some of their inherent characteristics will be given, before discussing AM in the field of medical applications. With emphasis on the case study that was performed in the course of this work, this chapter addresses the most relevant AM related topics that need to be considered in order to provide a solid basis of understanding for the practical part.

2.1 A Brief Introduction to AM

Additive Manufacturing (AM) can be defined as the "process of joining materials to make parts from 3D model data, usually layer upon layer, as opposed to subtractive manufacturing and formative manufacturing methodologies" (F42 Committee, 2015, para. 2.1.2). Being often referred to the term "3D printing" as well in a popular context, throughout this thesis the term "additive manufacturing" will be used mainly, since the former is typically associated with machines used for non-industrial purposes and/or personal usage (International Organization for Standardization [ISO], 2020).

Even though AM is considered a disruptive technology capable of fundamentally reshaping the way products are manufactured across many industries, this kind of technology is not completely new, since historically, it was introduced in the 1980. However, it was initially limited to the production of small products or prototyping only until the yeas 2009, when a significant rise of the development and research about possible applications throughout many industry sectors set in. This was mainly due to the achievement of some important discoveries and milestones, such as the establishment of opensource 3D printers or the manufacturing of some products for medical use (e.g., 3D printed prosthesis in 2008 or blood vessels in 2009). At this point, however, it must be made clear, that the technology is still in its development stages and the manufacturing of complex objects manufactured using different materials in a precise but also fast manner will take time until it reaches the quality of conventional manufacturing processes (e.g., milling). (Saleh Alghamdi et al., 2021)

On the other side, it is difficult to compare AM processes to conventional manufacturing processes in the first place, due to their fundamentally different layer-by-layer approach that builds up the structure in a designed shape. However, there are some similarities with the CNC machining process (Computerized Numerical Control), for example, as it is also a computer-based technology applied to manufacture products. The difference that mainly distinguishes these technologies is that CNC is primarily a subtractive instead of an additive process which requires a block of material of at least the size as the part that is to be made. Gibson et al. (2015) highlighted the differences in terms of main aspects like material, speed, complexity, accuracy, geometry and programming in more detail. (Gibson et al., 2015)

To get a better understanding about the rapid development and the before mentioned milestones of AM, Figure 3 provides a rough outline of the technological roadmap, highlighting the schematics of some main processes. As indicated, among the most recent developments and trends is *4D printing*. The essential difference between 3D printing and 4D printing is the fact that "smart design" is included, meaning that responsive materials are used, which in turn allow for an object's time-dependent deformation when exposed to an external energy source (e.g., osmotic pressure, heat, current, ultraviolet light, or another energy source) (Maniruzzaman, 2018).

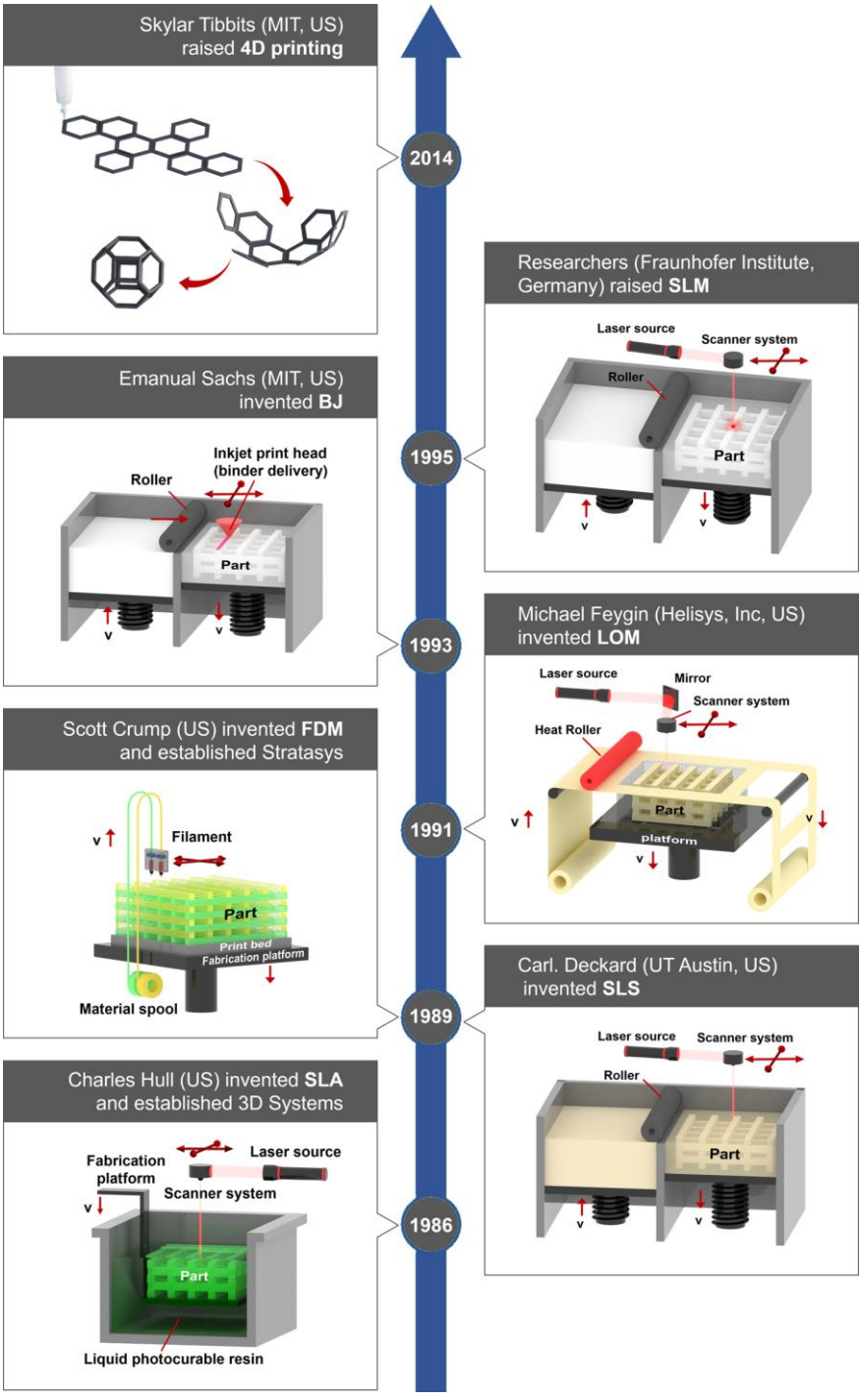


Figure 3: Technological roadmap of additive manufacturing (Liu et al., 2021)

With this accelerating development of AM in a variety of industries and the simultaneous research of a variety of materials (including polymers, metals, ceramics, glasses, biomaterials, and composite materials), a multitude of different types of AM methods has emerged as well. Therefore, a set of standards was established by international standardization organizations (ISO/ASTM 52900:2015) in order to classify the range of AM processes into seven general categories, which are based on the *methodology of formation* of the final components, as presented in Table 1 (F42 Committee, 2015).

Moreover, "AM may be further classified based on the *physical state of the base material* used and processed to form the product. This classification includes solid, liquid, and powder-based processes. It is also classified *based on the medium used to process the base material* such as laser beam, ultraviolet rays, thermal" (Saleh Alghamdi et al., 2021, p. 4). This described classification of AM processes is illustrated in Figure 4.

Table 1: Definition of AM processes (F42 Committee, 2015)

AM Process	Definition according to ISO/ASTM 52900
Binder jetting (BJT)	"additive manufacturing process in which a liquid bonding agent is selectively deposited to join powder materials" (F42 Committee, 2015, para. 2.2.1)
Directed energy deposition (DED)	"additive manufacturing process in which focused thermal energy is used to fuse materials by melting as they are being deposited." (F42 Committee, 2015, para. 2.2.2)
Material extrusion (MEX)	"additive manufacturing process in which material is selectively dispensed through a nozzle or orifice" (F42 Committee, 2015, para. 2.2.3)
Material jetting (MJT)	"additive manufacturing process in which droplets of build material are selectively deposited" (F42 Committee, 2015, para. 2.2.4)
Powder bed fusion (PBF)	"additive manufacturing process in which thermal energy selectively fuses regions of a powder bed" (F42 Committee, 2015, para. 2.2.5)
Sheet lamination (SHL)	"additive manufacturing process in which sheets of material are bonded to form a part" (F42 Committee, 2015, para. 2.2.6)
Vat photopolymerization (VPP)	"additive manufacturing process in which liquid photopolymer in a vat is selectively cured by light-activated polymerization" (F42 Committee, 2015, para. 2.2.7)

As the main process categories in Table 1 only provide an overview and the standardized definitions, they are characterized in a concise way in Table 2. Here, the different processes are summarized and compared according to their main advantages and disadvantages, but also to their resolution, which – besides printing speed – is a critical parameter in process evaluation. (Saleh Alghamdi et al., 2021)

Table 2: Summary and comparison of AM techniques in terms of quality (H. Kim et al., 2018)

Process	Important quality parameters	Advantages	Disadvantages	Advanced skills	Challenges	Resolution
Photopolymer vat processes (PVP)	Resin viscosity, density and temperature Build orientation Laser scan speed Exposure energy Penetration depth	Excellent dimensional accuracy Good surface finish Biocompatible process Microscale fabrication (~10 μm)	Only UV curable polymer resin Material contamination and wastes Mechanical property limited by resin-based polymer Thermal shrinkage	Projection SL technique Accurate custom-design and evaluation processes through MRI and CT Data analytic and algorithm Biomaterial fabrication Nano/micro scale fabrication	Development of variety vat solution Expensive scanning equipment such as MRI and CT Resolution	0.1-100 μm
Material jetting processes (MJP)	Droplet shape, velocity, diameter, viscosity and surface tension Jetting frequency, signal width and voltage magnitude Substrate temperature, evaporation rate Humidity	Excellent resolution Fast process Excellent dimensional accuracy Multiple material printing capability Microscale fabrication (~100 μm)	Nozzle clogging Cell damage in certain temperature or frequency Nano particles agglomerates cause clogging Low viscosity	Drop on Demand (DoD) technique Micro-scale/ Biomaterial fabrication Real-time close-feedback loop for printing correction through image processing on droplet and depth map Self-calibration of print head Quality prediction	Exposure energy Nozzle clogging More fabrication freedom on biomaterials	10-25 μm
Binder jetting processes (BJP)	Powder surface treatment, size, shape, packing density and distribution Binder viscosity, surface tension, droplet size, velocity and temperature Printing layer thickness, orientation, binder saturation and delay time	Excellent quality control ability for ceramic and metal fabrication compared to MJP technique DoD	Poorer accuracy and surface finish compared with MJP technique Infiltration process needed for posttreatment	DoD technique Ceramic and metal fabrication	Interaction performance between binder and powder Accumulative accuracy of deposited layer thickness Droplet placement Delay time of applying new layer Dimensional change in post-process	~100 μm
Extrusion-based processes (EBP)	Layer thickness, build orientation, raster width and angle and extrusion temperature Post-processing (exposure time and chemical temperature)	Fast process with low costs Good material properties Model can be printed using different materials (e.g., color, material properties)	Fair resolution Staircase effect Thermal distortion Thermal shrinkage Low dimensional accuracy	FDM technique Data analytic and algorithm Post-processing Optimal build orientation	Dimensional accuracy Shape change Clogging issues on composites materials	100 μm – 1 cm
Powder bed fusion processes (PBF)	Powder bed temperature Laser/beam output powder Powder size Atmosphere	Wide range of materials Excellent dimensional accuracy Excellent repeatability Good material property	Fair resolution limited by particle size Residual stress Porosity	SLS technique Temperature monitoring system Thermal modeling and image processing Temperature feedback control system Real-time defect detection and *in situ*	Resolution Laser output feedback control system In real time Atmosphere control	50-100 μm
Directed energy deposition processes (DED)	Melt pool temperature Material delivery rate Distance between nozzle and substrate Laser power density	Wide range of materials Good material property	Fair resolution Thermal stress	Closed-loop controller system for real-time feedback of temperature, laser output, clad height and delivery rate	Resolution Surface post-process Atmosphere control	100 μm – 1 cm
Sheet lamination processes (SLP)	Heater temperature Layer thickness Laser speed/power Rolling speed/pressure Chamber air temperature Delay time Orientation	Fast process Sufficient quality on large prototype Good tensile strength in laminated direction	Poor resolution De-cubing or crosshatching process Delamination Shrinkage Poor tensile strength in Z direction Waste	LOM technique Burn-out rule Data analytic and algorithm Online de-cubing process	Resolution, Delamination Consistent sheet thickness Repositioning precision, accumulation error (cut-then-bond process) Vertical surface roughness Material damage by laser cut Tensile strength in Z direction	200-300 μm Depends on the thickness of the laminates

Note: Values for resolution were additionally adopted from Daminabo et al. (2020).

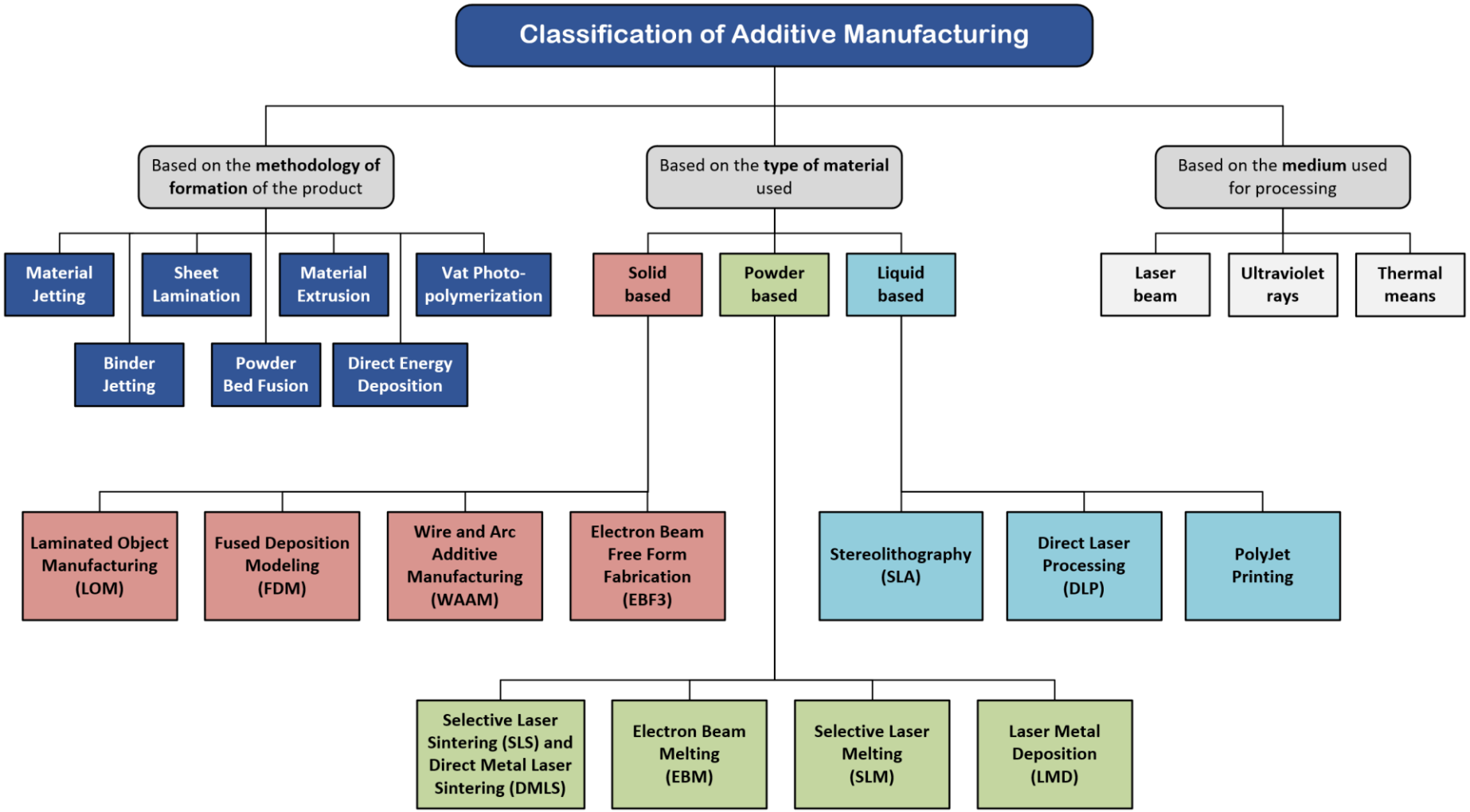


Figure 4: Classification of AM from different contexts (Saleh Alghamdi et al., 2021)

Concerning the **main materials used and the main applications** that are associated with them when using AM, Table X lists these aspects and points out some of their key benefits as well as challenges. As clarified by Ngo et al. (2018) for AM technologies in general, or as particularly concluded for extrusion-based processes (e.g., by Goh et al., 2020; Mohamed et al., 2015; Petersmann et al., 2020), proper selection and inspection of materials are of great significance, as they can affect a part's dimensional accuracy, surface roughness and mechanical properties (Charalampous et al., 2020). These factors are addressed later in this chapter in order to give a holistic view on quality in AM.

Table 3: Applications, benefits and challenges of the main materials for AM (Ngo et al., 2018)

Materials	Main Applications	Benefits	Challenges
Metals and alloys	Aerospace and Automotive Military Biomedical	Multifunctional optimization Mass-customization Reduced material waste Fewer assembly components Possibility to repair damaged or worn metal parts	Limited selection of alloys Dimensional inaccuracy and poor surface finish Post-processing may be required (machining, heat treatment or chemical etching)
Polymers and composites	Aerospace, Automotive Sports Medical, Biomedical Architecture Toys	Fast prototyping Cost-effective Complex structures Mass-customization	Weak mechanical properties Limited selection of polymers and reinforcements Anisotropic mechanical properties (e.g., in fiber-reinforced composites)
Ceramics	Biomedical Aerospace and Automotive Chemical industries	Controlling porosity of lattices Printing complex structures and scaffolds for human body organs Reduced fabrication time A better control on composition and microstructure	Limited selection of 3D-printable ceramics Dimensional inaccuracy and poor surface finish Post-processing (e.g. sintering) may be required
Concrete	Infrastructure and construction	Mass-customization No need for formwork Less labor required especially useful in harsh environment and for space construction	Layer-by-layer appearance Anisotropic mechanical properties Poor inter-layer adhesion Difficult to upscale to larger buildings Limited number of methods and tailored concrete mixture design

As the common basis for all AM processes, their underlying **flowchart** is represented in Figure 5. The initial step is the *design process*, set up either by a standard design (pre-specified sizes, models) or a so-called "patient-matched" device design, created from the image data of a specific patient. After conversion of the device design to a digital file, the *software workflow* prepares this file further for *printing* (e.g., parameter optimization, repair of flaws), while at the same time *material controls* are set for the printing job. When complete, *post-processing* of the component manufactured has to be performed (e.g., cleaning, sterilization, labeling), before it is ready for *testing* and characterization. (Food and Drug Administration [FDA], 2017)

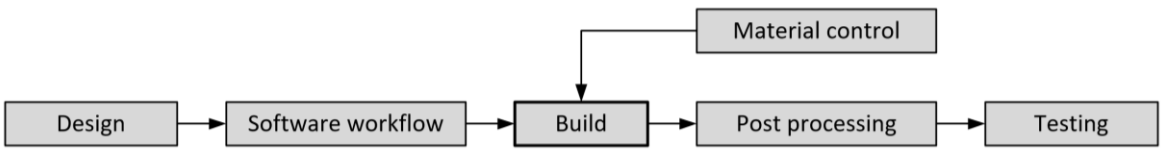


Figure 5: Flowchart of the AM process (FDA, 2017)

Quality control should be included in all of the described process steps to ensure constant overall quality of the built components and to detect any irregularities in the process. Regarding these quality and quality verification aspects, the last steps, dealing with the manufacturing process, and the final testing of parts in particular, will be discussed in great detail in chapter 3 and 4. Therefore, only the software workflow is further addressed at this point.

Figure 6 schematically illustrates and describes the individual steps of data preparation, starting from the 3D CAD model (1), which is processed further to a .STL-file (short for Standard Tessellation Language) (2). This specific format defines surfaces as a collection of triangles ("facets") which fit together perfectly, representing the part to be created (Rybicki & Grant, 2017). Possibly occurring errors are then automatically repaired (3) before the part is virtually being placed in the build envelope (4) and equipped with the necessary support structure (5) (process-specific). During the slicing step (6), the part is broken down into parallel layers which are later built up by the 3D printer. Since this step defines only layer polyline contours, these are filled in the hatching step to create solids (7). Eventually, after the data has been prepared, the build job can be set up to define relevant information (e.g., process parameter, material) (8).

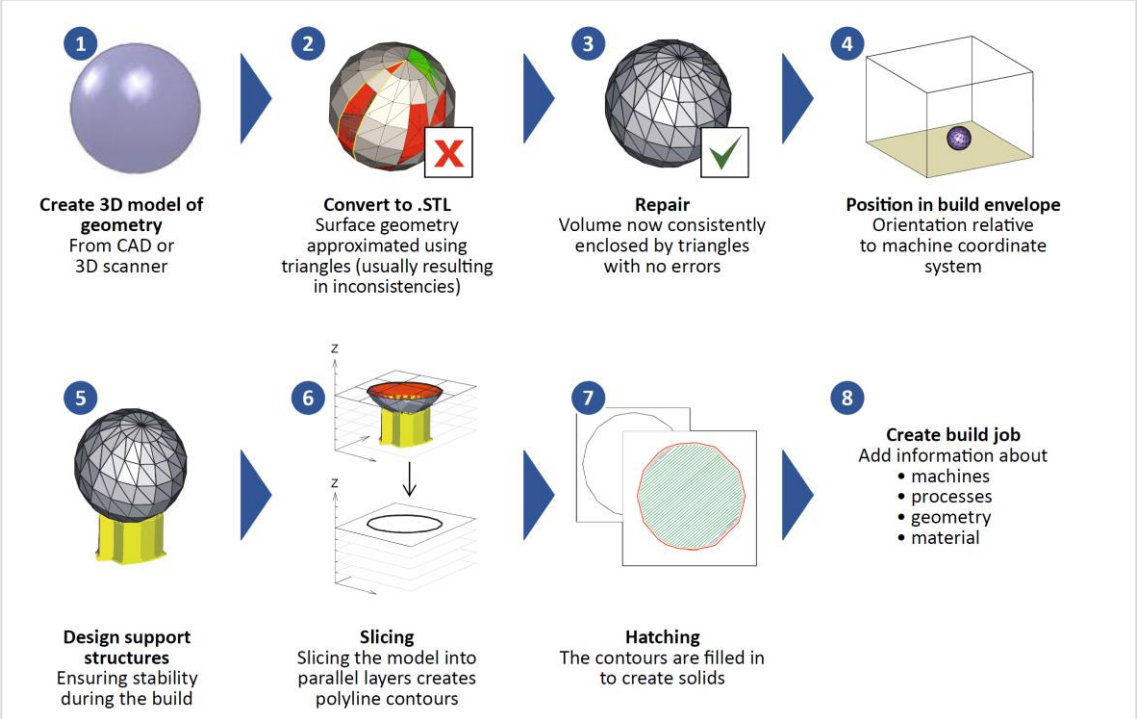


Figure 6: Data preparation process chain (based on Karg, 2008)

2.2 AM Applications in Medicine

AM offers numerous possibilities in medical and dental applications due to its potential personalized and customized solutions (Javaid & Haleem, 2019). When compared with applications in other fields, "medical implants have unique needs, including high complexities, good customization, and small production quantities, and thus, AM is well suited to this field" (Liu et al., 2021, p. 40). Therefore,

after a general overview of medical AM applications, a separate section specifically discusses its use for patient-specific implants. At first, some of the **main benefits of AM in medical applications** are listed exemplarily, including the following aspects:

- "AM gives perfect-fit production of a patient-specific implant";
- "implant manufacturing offers unlimited geometric freedom";
- "precise setting of desired characteristics, such as porosity, elasticity";
- "high biocompatibility";
- "manufacture of the parts in one shot";
- "faster availability and shorter build times (reduced operating room time)";
- "fully automated and digitized manufacturing possible";
- "cost savings and resource conservation";
- "overall improvement with economies of scale and cost saving" (Javaid & Haleem, 2019)

According to Mäkitie et al. (2010), one possible **classification for medical applications of AM** is the following structure:

- *Medical models* (e.g., for preoperative planning, education and training)
  Being based on patient anatomy, medical models are ideal means for pre- and postoperative planning and training, for training of medical students, but also for informing patients. Since the models are usually for demonstration purposes only, they do not need to be sterilized.
- *Implants*
  As will be shown in a separate section, implants can either be directly or indirectly additively manufactured with the purpose to replace defective tissue. Within this classification, also dental applications are included (e.g., crowns and bridges).
- *Tools, instruments and parts for medical devices*
  This group of AM applications is meant to enhance clinical operation procedures by utilizing patient-specific anatomy (i.e., dimensions and shapes). Since they can be invasive, meaning they can be in direct contact with body fluids, for example, for a limited amount of time, these tools or instruments need sterilization. Here, also surgical instruments and orthodontic appliances are included.
- *Medical aids, supportive guides, splints and prostheses*
  According to the named classification, AM parts of this class are external to the body. For customization purposes, they can be combined with standard appliances. Examples of AM applications in this class are external protheses, postoperative supports or fixators.
- *Biomanufacturing*
  This class describes a combination of AM and tissue engineering (TE) which can be needed to meet biocompatibility and body activity requirements, necessitating different materials. An example for such applications can be porous structures with cultivation and a 3D matrix.

2.3 Patient-Specific Cranial Implants

With regard to the conducted case study described in chapter 6, the application of AM for patient-specific implants (PSI), in particular for cranial implants, is highlighted in more detail at this point. As specified in ISO 10993-1, an *implant* is defined as a

> medical device which is intended to be totally introduced into the human body or to replace an epithelial surface or the surface of the eye by means of clinical intervention and which is intended to remain in place after the procedure (ISO, 2018, para. 3.10).

Furthermore, from a more general objective, a *medical device* in this context is

> any instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) … [e.g.,] investigation, replacement, modification, or support of the anatomy or of a physiological process (ISO, 2018, para. 3.14)

The specific application of cranial implants or, more general, of craniomaxillofacial implants (CMF), is associated with the neurosurgical procedure called *cranioplasty* which is performed to reconstruct cranial defects. Such defects are typically resulting from a planned craniotomy (i.e., removal of a small section of skull to provide access to the area of interest), a traumatic head injury, infection or oncological resection for tumor removal (M. M. Kim et al., 2009). As there are cases where the removed bone segment cannot be reused to fill the closure (e.g., damage by a tumor), this loss of the cranial bone needs to be compensated in order to prevent exposure and infection. Furthermore, as stated by Scolozzi et al. (2007), other aspects may be cosmetic and functional in nature, caused by large and complex defects that affect a patient. (Kurtz, 2019b)

As concluded by Zhang et al. (2019), the most commonly used materials for this purpose at present are autologous bones (i.e., bone obtained from the same patient), Titanium meshes (TM), Polymethyl methacrylate (PMMA) and Polyetheretherketone (PEEK), which schematically depicted in Figure 7.

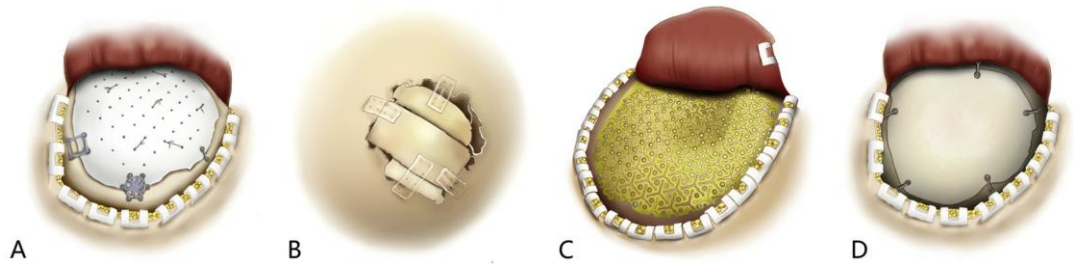


Figure 7: Schematic intraoperative images of current cranioplasty materials: PEEK (A), Autologous bone (B): Titanium mesh (C) and PMMA (D) (Zhang et al., 2019)

When defining the ideal alloplastic material, the trend in the development of cranial implants has been toward PEEK in recent years, mainly due to the material's desirable mechanical characteristics (e.g., having a comparable elastic modulus to cortical bone) and its excellent cell biocompatibility (Vaezi & Yang, 2015).

Further advantages of PEEK are that it can be manufactured into a customized implant shape that closely matches the dimensions of the patient defect on the one hand, and that is highly workable on the other hand, in case further modifications are required in the operating room (using a high-speed drill with a cutting burr). After achieving fit, the implant is fixated to the bony tissue by means of standard facial reconstruction hardware. Moreover, PEEK implants are also resistant to heat and ionizing radiation and can be sterilized repeatedly by steam and gamma irradiation. Another benefit worth mentioning is the fact, that PEEK is translucent to X-rays and nonmagnetic, generating no artifacts in CT, or MRI images, facilitating critical postoperative diagnostic monitoring. The major disadvantage with this promising material, however, is that there is a risk of postoperative infection. (Altiok et al., 2019; Hanasono et al., 2009; Kurtz, 2019a)

According to Vaezi and Yang (2015), several manufacturing techniques have been tested to produce porous PEEK objects for biomedical applications (e.g., injection molding, selective laser sintering). However, as concluded by Rybicki and Grant (2017), material extrusion processes, such as FDM, are nonetheless favored due to their overall economical and simple use. Also, they state that materials tend to be more rugged and strong when compared to other technologies and are mostly cheaper. (Rybicki & Grant, 2017)

Since polymer materials are widely used for medical applications by AM technologies (Daminabo et al., 2020), Figure 8 provides an overview of the respective methods that are officially classified at current. These methods are fused deposition modeling (FDM), stereolithography (SLA), selective laser sintering (SLS), binder jetting (BJ) and 3D plotting.

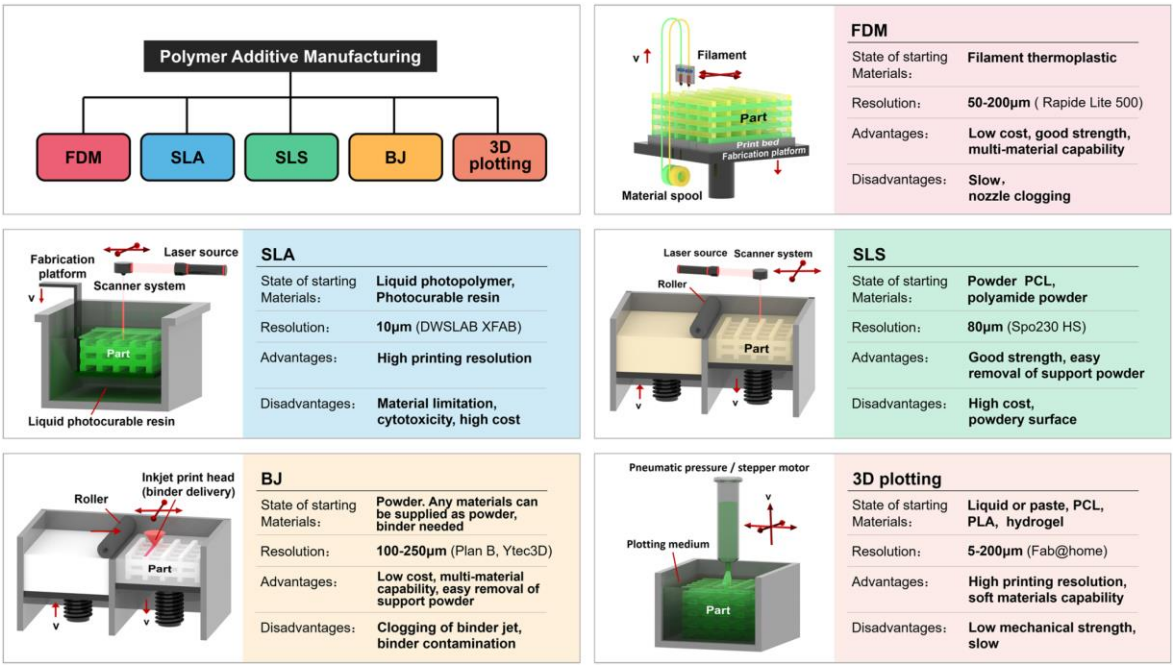


Figure 8: Polymer AM technologies (Liu et al., 2021)

The values for the maximum achievable resolution can deviate from the values shown in Table 2. This can be explained due to different points in time of determination or due to different setups or evaluation parameters**.**

2.4 Technological Process Steps for Manufacturing a PSI

As described in the different classes for medical application of AM, these respective objects also have different process flows, depending on their final usage (e.g., sterilization, post-processing, etc.) like emphasized by Salmi (2021) as well. However, particularly for medical implants, the following detailed process flow, illustrated in Figure 9, can be derived from the generic AM process flowchart that has been presented in Figure 5.

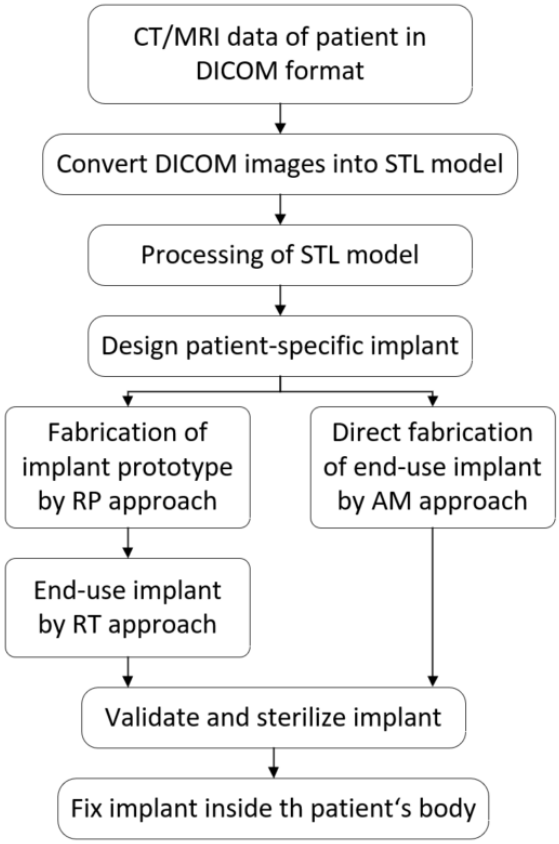


Figure 9: Typical process flow for patient-specific models/implants (Modi & Sanadhya, 2018)

Specifically, the process starts by creating a virtual object which is based on the patient-specific anatomy that is directly obtained via computerized tomographic (CT) for example. This obtained data set is bundled in a special format, called “Digital Imaging and Communication in Medicine” (DICOM), which needs to be further processed in order to make it applicable for a 3D printing device. Therefore, after the data has been prepared, the DICOM file must be converted into the widely accepted STL format which allows to make specific design adjustments of the object as well as to ensure its proper manufacturing (see Figure 6). Subsequently, the final implant created in the STL file can either be manufactured directly or by using a rapid tooling (RT) approach, e.g., if a high-end AM machine is not available. In this case, the manufactured object is then used as a prototype to form a mold which further enables to cast the final implant made of biomaterials as demonstrated, e.g., by D. Singh et al. (2018). The last step, in either way, is the post-processing and testing of the manufactured implant before its final application. (Modi & Sanadhya, 2018; Rybicki & Grant, 2017)

2.5 Process Parameters Influencing the Quality of an AM Part

Since process-specific parameters during the manufacturing of an AM part have a crucial influence on the quality of the final part (Dey & Yodo, 2019; Goh et al., 2020; Saleh Alghamdi et al., 2021), the process parameters of FDM are addressed at this point, as this process is of special interest with regard to the case study conducted in the practical part. Goh et al. (2020) summarize them as follows and furthermore illustrated some of the main parameters as adopted in

- "*layer thickness* [mm]: The height of each slice of the 3D-printed part";
- "*raster angle* [°]: The angle at which the nozzle deposits molten thermoplastics line by line for each layer and it ranges from 0° to 180°";
- "*contours/shell perimeters*: The outermost shells to use for the exterior skin and internal hole of the part. The number of the contours/shell perimeters and the contours width can be used to vary the shell thickness.";

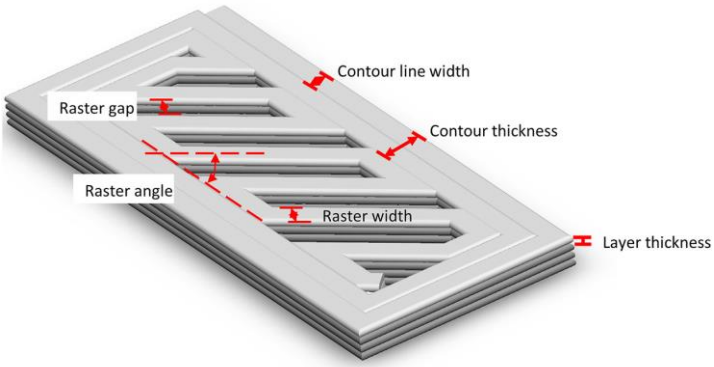


Figure 10: FDM process parameters (Goh et al., 2020)

- "*raster/bead width* [mm]: The width of the extruded filament";
- "*air/raster gap* [mm]: The opening between two adjacent extruded filaments, and a negative air gap means there is overlapping between two adjacent filaments";
- "*deposition speed* [mm/min]: The speed at which the nozzle moves. This is directly related to printing speed.";
- "*fill density* [%]: The amount of material within the part. The higher the percentage of fill, the better the mechanical properties of the part; however, the printing time will be longer and more material will be needed.";
- "*platform/bed temperature* [°C]: Temperature of the build platform. This parameter determines the cooling rate of the extruded filament especially on the first layer and is an important parameter for good adhesion of the first layer and the prevention of warping effect.";
- "*nozzle temperature* [°C]: The temperature at which the material is being extruded. The temperature is normally a few degrees Celsius higher than the melting point of the material.";
- "*chamber temperature* [°C]: Some FFF printers have controlled temperature environment to have a more consistent printing result. This refers to the ambient temperature inside the build environment.";
- "*specimen/build orientation*: It denotes the direction of the printed part on the build platform, about the x- , y-, and z-axes." (Goh et al., 2020).

With special emphasis on how the listed parameters affects the characteristics of a manufactured AM part, Dey and Yodo (2019) carried out a comprehensive survey of the existing literature concerning this topic. In this survey, more than 250 articles from the year 2005 to 2019 were gathered which in particular analyze the impact on dimensional accuracy, surface roughness, build time, as well as mechanical properties of FDM manufactured parts. A concise summary of this survey was created in form of a fishbone diagram, represented in Figure 11. The diagram also indicates that some of the process parameters are interdependent in nature and can therefore affect several other parameters and also have an influence on a number of characteristics of the fabricated part. (Dey & Yodo, 2019)

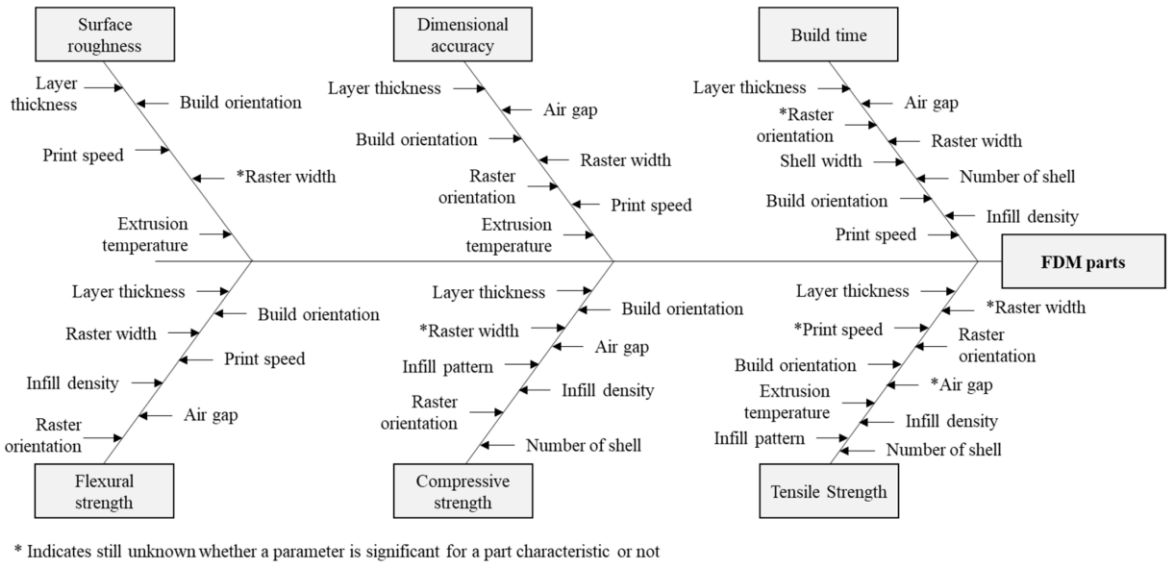


Figure 11: Impacts of process parameters on part characteristics (Dey & Yodo, 2019)

2.6 Process Limitations and Potential Error Sources

Due to the variety of process parameters pointed out in the previous section, there are also a number of potential part limitations that manifest themselves in defects or errors inherent to any AM process. Concerning FDM, some typical challenges and drawbacks commonly encountered in parts include:

- "*stepped layers:* these are visible trails of the material deposited because of a certain distance among subsequent layer's edges.";
- "o*verhang and bridging:* this is an overhang effect, which occurs when elements of a part set at an angle comparative to the vertical axis; the filament may not have support, thereby leading to a collapse.";
- "*stringing:* this is an issue that occurs when the extruder is moving between two discontinues points and leaks some of the plasticized filament from the nozzle due to gravitational forces or loading from the filament.";
- "*warping:* this takes place when the edges/corners of the model deflect because of shrinkage of material and uneven temperature distribution across the model.";

- "*Hygroscopicity:* this is a term, commonly used to refer to occluded or precipitated porosity is a property of polymer materials that makes them more prone to absorbing moisture from the air, thereby leading to parts with more inherent pores.";
- "*Structural inhomogeneity*: this is referring to the heterogeneity of structure particle size and/or insufficient density of a printed part." (Bryll et al., 2018; Daminabo et al., 2020).

Figure 12 illustrates a general overview of influencing parameters for the accuracy of medical AM parts outlined by van Eijnatten (2017) who especially examined the various segmentation methods and their influences on part quality.

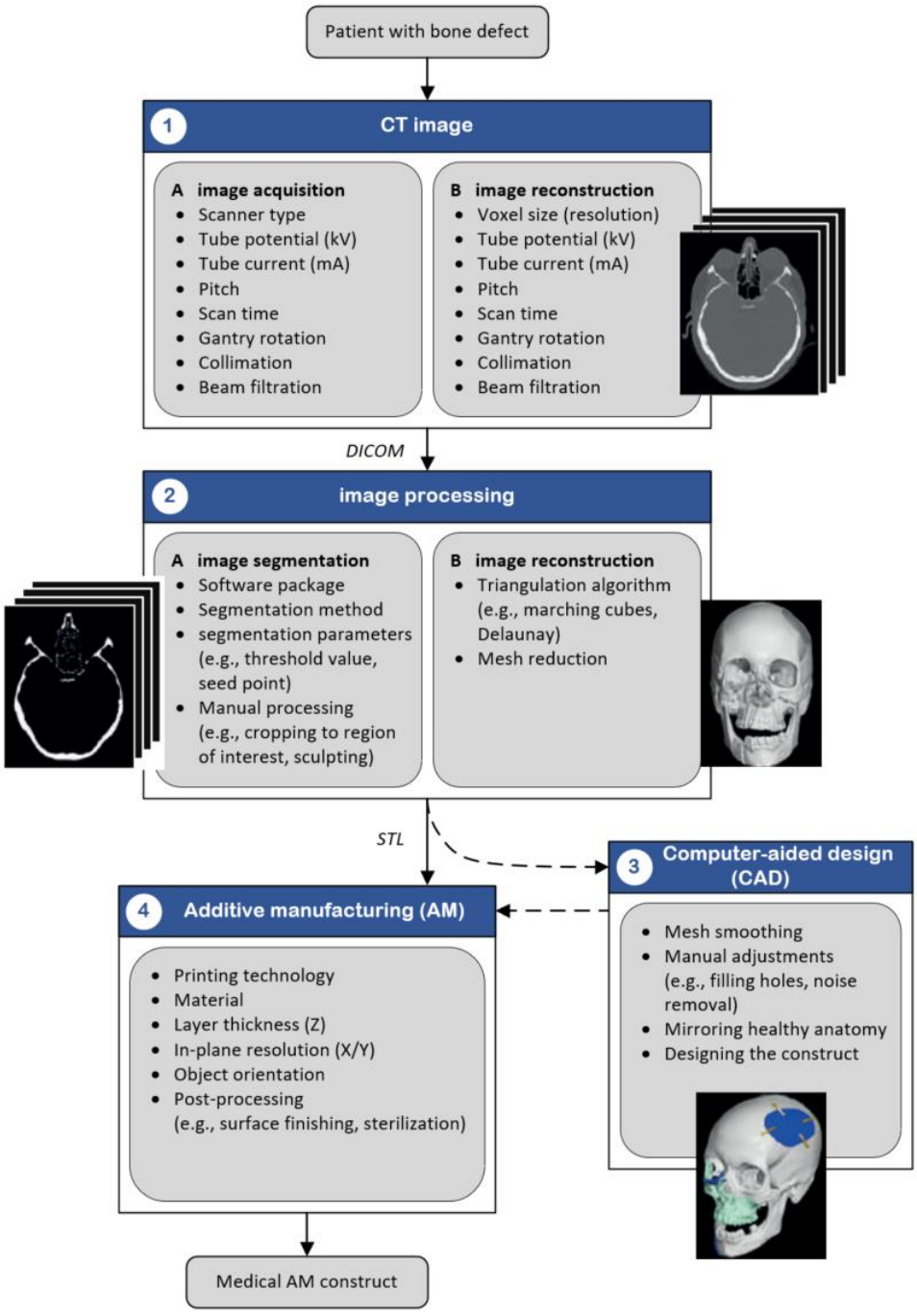


Figure 12: Influencing parameters for medical AM parts' accuracy (van Eijnatten, 2017)

3 Quality Management and Regulations for AM Medical Devices

In order to provide a basic foundation for the next chapter "Testing and Quality Verification in AM", this chapter first outlines some general aspects of quality management and relevant quality models, with particular reference to healthcare. Moreover, some essential regulatory considerations regarding guidelines and standards for medical products and their environment will be discussed. As the third part of this chapter, the current gaps and extensive efforts for standardization in AM are highlighted.

3.1 Basics of Quality Management

When the term "quality" is used in everyday life, it is inherently related to a particular set of attributes of that respective product or service to describe its existing characteristics (*descriptive component*). But not only the presence of a value-neutral sum of observed characteristics is considered this way, usually quality is also associated with something precious and of high value (*evaluative component*). To be able to make value statements regarding an observed unit, the generalized term "requirement" (also "target characteristic" or "reference property") has become established in quality management to describe *expectation* (e.g., individual wishes of a patient) or *requisites* (e.g., legal specifications or guidelines). (Hensen, 2019)

3.1.1 Definitions for the Concept of Quality

Some detailed definitions of quality are given by the well-known American contributors in this field, most notably by W. Edwards Deming, Philip B. Crosby and Joseph M. Juran. The latter, for example, distinguishes two important meanings of the word "quality":

1. "Quality" means those *features of products* which meet customer needs and thereby provide customer satisfaction. In this sense, the meaning of quality is oriented to income. The purpose of such higher quality is to provide greater customer satisfaction and, one hopes, to increase income. However, providing more and/or better quality features usually requires an investment and hence usually involves increases in costs. Higher quality in this sense usually "costs more." (Juran & Godfrey, 1998, p. 2.1)
2. "Quality" means *freedom from deficiencies* – freedom from errors that require doing work over again (rework) or that result in field failures, customer dissatisfaction, customer claims, and so on. In this sense, the meaning of quality is oriented to costs, and higher quality usually "costs less." (Juran & Godfrey, 1998, 2.2)

Juran also strongly contributed to the quality philosophy as a whole by establishing crucial concepts, for example, the "Juran's Ten Steps to Quality Improvement" or "The Juran Trilogy" (Nanda, 2005). The latter concept in particular will be part of discussing quality management in the next sections.

However, since there are a number of definitions of the concept of quality in the literature, depending on the area of application, Garvin (1988) identified the following *five approaches to defining quality* in order to structure the individual definitions accordingly:

- *Transcendent definition*
  Quality is universally recognizable, something unique and only achievable by experience.
- *Product-based definition*
  Quality refers to the presence of all required attributes and characteristics.
- *User-based definition*
  Quality is found on user satisfaction and is very subjective and personal ("fitness for use").
- *Manufacturing-based definition*
  Quality is conformity to specifications and standards, focusing on the process and activity-oriented component of manufacturing.
- *Value-based definition*
  Quality is indicated by the price, as better performance at lower cost is recognized as a quality product (Garvin, 1988).

3.1.2 Quality Management

In order to provide sufficient and consistent quality of a product or service, quality must be made an integral part of every company by specifically embedding its practices in the company's processes. Consequently, this implementation process results in a more mature management system, commonly referred to as *quality management system* (QMS). (Nanda, 2005)

Quality management (QM), on a more precise level, "comprises all activities that are required to plan for quality in an organization, and all activities that are required to satisfy quality objectives" (Nanda, 2005, p. 8). Specifically, Nanda (2005) lists four elements that are included in quality management as shown in Figure 13: *quality planning*, *quality control*, *quality improvement* and *quality assurance*. Moreover, the respective definitions according to the general quality standard ISO 9000 are given based on (ISO, 2015a).

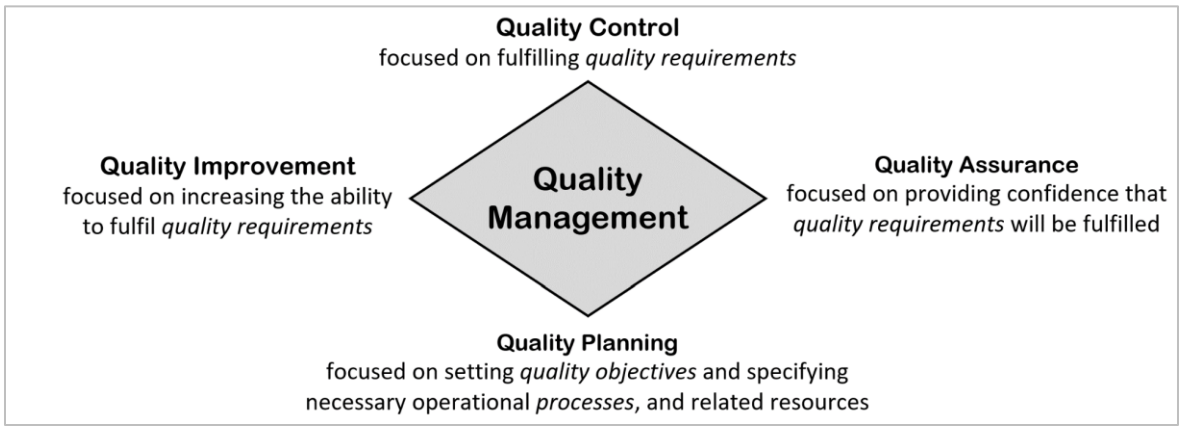


Figure 13: Quality management (based on Nanda, 2005; ISO, 2015a)

Other approaches and definitions are again provided by the concepts of the before mentioned authors, e.g., Deming, who is responsible for the *total quality* movement, proposes to view quality in terms of customer satisfaction and therefore elaborated his philosophy on quality management accordingly ("Deming's Fourteen Points"). Crosby, on the other hand, focuses on conformance to requirements ("Four Absolutes of Quality Management"). (Nanda, 2005)

Similarly, Hensen (2019) states that especially in the field of healthcare, quality management means "management with regard to the fulfillment of quality requirements" (Hensen, 2019, p. 101).

As a rough overview, Table 2 shows a comparison between the quality management principles and concepts defined in the standard ISO 9000, and the EFQM model of 2012 (ISO, 2015a; European Foundation for Quality Management [EFQM], 2012).

Table 4: Principles and concepts of quality management (ISO, 2015a; EFQM, 2012)

Quality Management Principles (ISO 9000:2015)	Fundamental Concepts of Excellence (EFQM 2012)
Customer focus	Adding value for customers
Leadership	Leading with vision, inspiration and integrity
Engagement of people	Succeeding trough the talent of people
Process approach	Managing with agility
Improvement	Harnessing creativity and innovation
Evidence-based decision making	Sustaining outstanding results
Relationship management	Developing organizational capability
	Creating a sustainable future

Based on these principles and concepts, it is possible to outline a general quality management model, as introduced by Zollondz (2011) (Figure 14). All the principles contained therein can be regarded as design and success factors and thus as basic conditions for "modern" QM (Hensen, 2019).

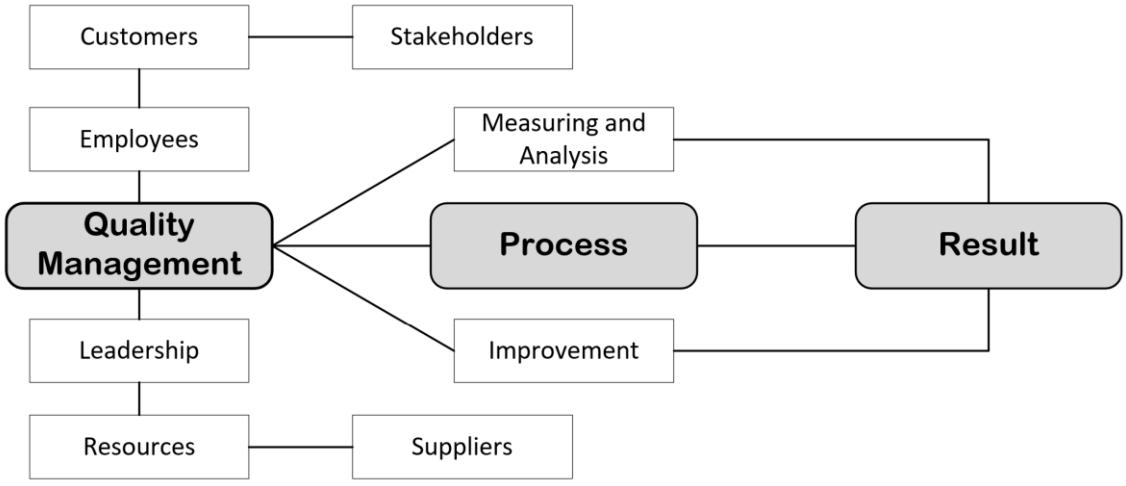


Figure 14: General condition model of quality management (based on Zollondz, 2011)

In the next sections, the individual elements of quality management will be discussed in some detail. In this context, the mentioned *Juran trilogy* is illustrated in Figure 15 to serve as a descriptive model. These particular elements of quality management represent the three primary managerial functions. As can be seen, costs are plotted over poor quality (i.e., what goes up is bad, as resources are wasted). (Juran & Godfrey, 1998)

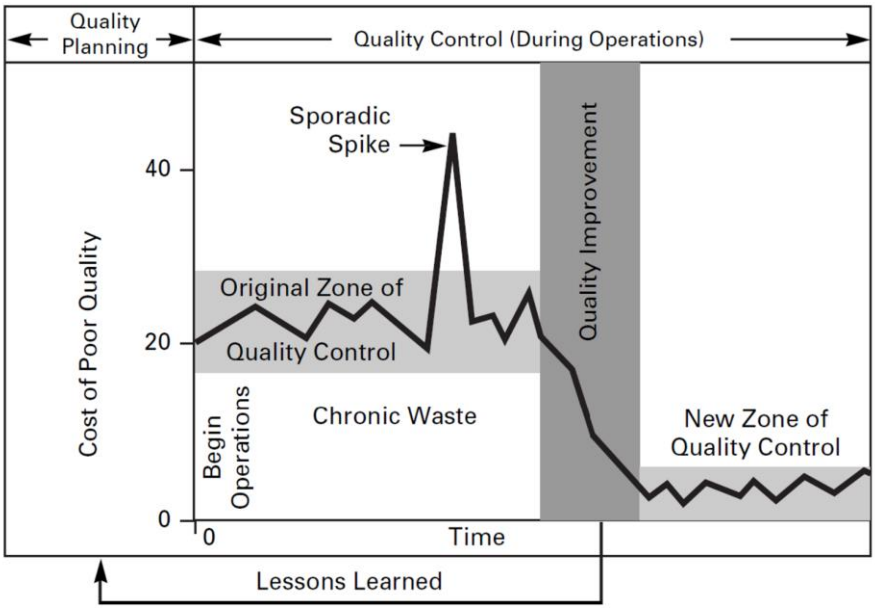


Figure 15: Diagram of Juran's trilogy (Juran & Godfrey, 1998)

3.1.2.1 Quality Planning

Accordance to Figure 15, quality planning can be seen as the starting point of quality management. For an established project or goal, Juran and Godfrey (1998) defined a quality planning roadmap":

1. "Identify who the customers are."
2. "Discover customers' needs."
3. "Develop products with features that respond to customer needs."
4. "Develop systems and processes that allow the organization to produce these features."
5. "Develop controls, deploy the plans to operational levels." (Juran & Godfrey, 1998, p. 14.11)

3.1.2.2 Quality Control

In this area the operation forces are performing activities in order to generally minimize any waste and to meet the quality requirements. This is realized by monitoring a process in order to ensure that its output meets the required quality, and by correcting occurring discrepancies. In other words, the actual quality (performance) has to be assessed and compared to a defined goal (e.g., standards). However, the corrective actions need to be suitable, and when appropriate, should be also performed *during* process execution to detect and eliminate defects in a *reactive* manner. (Nanda, 2005)

With regard to the diagram in Figure 15 again, the focus of all activities is placed on the two "zones of control" in order to provide stability (i.e., prevent adverse change and maintain the "status quo"). In case the level of performance could have been changed for the better (i.e., quality improvement has been achieved) it is important to establish new controls at this level (new zone of quality control). Therefore, using the feedback loop (indicated at the bottom of the diagram) is of major importance to enable quality control and thus to eventually remove sporadic defects. (Juran & Godfrey, 1998)

3.1.2.3 Quality Assurance

Quality assurance (QA) and quality control (QC) are closely related, as both evaluate performance and compare it to goals and both act on difference. However, they differ in their primary purposes: While quality control aims to maintain control through performance evaluation and comparison *during* operation, the main purpose of quality assurance, on the other hand, is to verify that control is being maintained. The evaluation of performance and the provision of the resulting information to relevant operating forces as well as others who have to know is hereby taking place *after* operations. As mentioned earlier, quality assurance activities can therefore be regarded as *proactive* in general, as they primary aim to prevent defects in a (finished) product. (Juran & Godfrey, 1998; Nanda, 2005)

However, it should be noted that the wide range of measures and methods associated with the term *quality assurance* in German-speaking world are more commonly referred to as "quality control" or "quality engineering" in Anglo-American-speaking countries. (Hensen, 2019)

There are also several definitions for the term quality assurance. However, one of the most widely accepted is the following: Quality assurance comprises "all the planned and systematic activities implemented within the quality system that can be demonstrated to provide confidence that a product or service will fulfill requirements for quality" (American Society for Quality [ASQ], 2021).

3.1.2.4 Quality Improvement

Quality improvement refers to an ongoing and continual process, which differs from quality control, since its main purpose is not maintaining the stability of a process, but to change it so that it works, e.g., with less waste or fewer defects. Therefore, quality improvement affects a range of parameters, such as productivity, cycle times (i.e., the time required to carry out processes), human safety (e.g., fail-safe design) and environment (e.g., reduction of toxic emissions). However, as also emphasized by Juran and Godfrey (1998), reduction of waste does not come free, but involves a number of steps which are listed as follows. (Juran & Godfrey, 1998; Nanda, 2005)

1. "Develop the infrastructure necessary to make annual quality improvements."
2. "Identify specific areas in need of improvement and implement improvement projects."
3. "Establish a project team with responsibility for completing each improvement project."
4. "Provide teams with what they need to be able to diagnose problems, to determine root causes, develop solutions, and establish controls that will maintain gains made." (Nanda, 2005, p.7)

One of the most important tools for planning and improving the quality of management systems is the **PDCA methodology** by Deming, representing a cyclic problem solving approach (Figure 16).

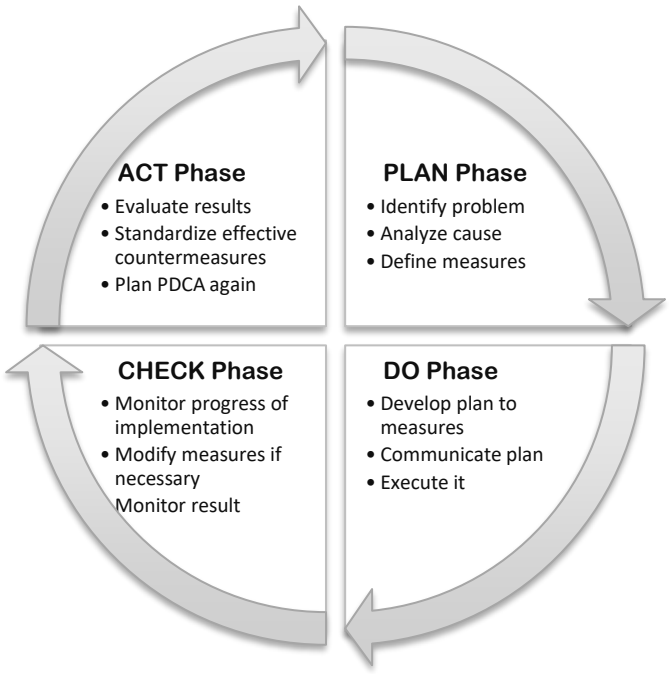


Figure 16: Deming's PDCA cycle (Deming, 2018)

The methodology can be briefly described as follows:

- **P**lan: "Establish the objectives and processes to deliver results and to fulfill requirements";
- **D**o*:* "Implement the processes";
- **C**heck: "Monitor and measure processes or product (e.g., requirements, objectives)";
- **A**ct*:* "Take action to continually improve process performance" (Juran & Godfrey, 1998, p. 4.8).

Another important means of quality improvement are **standards and standardization** in general. "Quality standards form quality requirements that define a desirable or acceptable level of quality. They provide benchmarks that can be used to check, (re)assure and (continuously) improve the quality of structures, processes and results" (Hensen, 2019, p. 97). As Hensen (2019) points out, especially procedural standards (i.e., standards that focus on the actual execution or design of processes) are widely used in quality management. Examples for procedural standards in healthcare are checklists, work and procedural instructions, guidelines and regulations. Standards further serve the following purposes, among others (Hensen, 2019):

- *Avoidance of errors:* Consistent procedures help to avoid errors in execution or at critical process points. Standards ensure the right actions and the right decisions in critical situations.
- *Avoidance of quality fluctuations:* Standards aim to reduce unwanted variability in execution and to maintain a level of quality that is as consistent as possible.
- *Creating quality that meets requirements:* By developing standards, a structured process is taking place, addressing the requirements for one's own services and helping to align them.

3.1.3 Testing and Inspection

Testing and inspection are considered major parts of QC (and QA in a broader sense) (Fox, 1994). Specifically, *inspection* comprises verification activities, such as "measuring, examining, testing and gauging one or more characteristics of a product or service and comparing the results with specified requirements to determine whether conformity is achieved for each characteristic" (ASQ, 2021). Following this definition and also in accordance with the international quality standard ISO 9000, inspection refers to the activity of checking products, whereas audits, for example, are applied to analyzing manufacturing processes and/or systems (ISO, 2015a).

Further, for clear distinction between the purpose of inspection and QC activities, in Figure 17 their schematic block diagrams are illustrated. While inspection is all about judging the product as good or bad by comparing to a standard (conforming or non-conforming), QC, on the other hand, operates by feedback of comparative information and can thus regulate the process. In a more general sense, inspection and quality control both focus on the processes of creating the product or service. QA, on the other hand, is concerned with the entire quality loop to be able to predict and also prevent failures at all levels of an organization. (Fox, 1994)

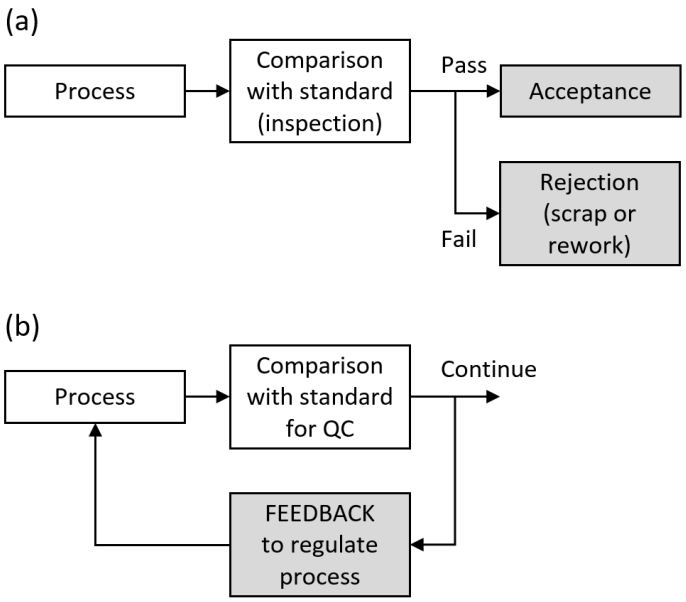


Figure 17: Difference between inspection (a) and QC (b) (Fox, 1994)

As mentioned, inspection relies on the existence of a standard that clearly serves as representative guidance for the operator. Other essential prerequisites for an inspection activity are adequate tools (i.e., calibrated and well-maintained instruments), trained operators and an operating procedure (e.g., instruction, specification). In terms of documentation and further improvement it is also important to provide means for recording and analyzing findings, for highlighting any need for corrective action and for identifying rejected products. (Fox, 1994)

The way an inspection can be carried out is distinguished by two different approaches (Fox, 1994):

- *Attributes inspection:*
  Only a certain characteristic or attribute of a product or service is considered. The result is either "it is acceptable" or "it is not acceptable".
- *Variables inspection:*
  Here, a measurement needs to be taken and compared with a specification to determine if the value is acceptable, which corresponds to a parametric or variables statement.

3.2 Quality Management Models

As Hensen (2019) concludes, quality is measured by the relationship between a realized quality and the requirements placed on it with regard to relevant quality aspects which are usually determined and selected based on pre-formulated models. However, since there exist a multitude of different quality models that are adapted to the respective branches or areas of application, only a few well-established approaches or those specifically designed for the healthcare sector will be discussed here.

As a general framework for quality determination and strategic analysis, Garvin (1988) proposed eight critical dimensions quality, valid for products and services:

- *Performance:* refers to a product's primary operating characteristics;
- *Features:* secondary characteristics enhancing the appeal of the product or service;
- *Reliability:* probability that the product will not fail in a specific period of time;
- *Conformance:* the degree to which a product or service meets its specifications;
- *Durability:* a measure of the product's life;
- *Serviceability:* refers to the speed, the competence and ease of repair;
- *Aesthetics:* how the product looks, feels, sounds, tastes and smells (very subjective);
- *Perceived quality:* quality attributed to a good or service based on indirect measures (e.g., images, advertising and brand names) (Garvin, 1988).

Quality models used explicitly in health care describe criteria that allow to make statements about the expected or required quality of a considered service unit and are usually compiled in the form of *lists of requirements* or *catalogues of criteria* (Hensen, 2019). A broad understanding of quality in this context is offered by a model developed by Maxwell (1984), which is widely used in all areas of social and healthcare systems. This model also served as a basis for other established approaches (e.g., the "Donabedian model", Donabedian, 1988) and consists of the following six dimensions:

- access to services;
- relevance to needs and wants (for the population as a whole);
- effectiveness (for individual patients);
- social acceptability;
- efficiency and economy;
- equity (fairness) (Maxwell, 1984).

3.2.1 The ISO Series of Standards

The ISO 9000 ff. family is a series of standards that deals with quality management systems (QMS), as already addressed in section 3.1.2. Originally developed in the environment of the manufacturing industry, over time, it has become increasingly established in the service sector as well. Basically, it can be applied to any industry or organization as it describes the fundamental concepts and principles of quality management. Thus these standards help to meet customers' and other stakeholders' needs while complying with the specified requirements of a product or service. (Hensen, 2019; ISO, 2015a)

The following four international standards form the basis of quality management according to the well-known EN ISO 9000 series of standards (Hensen, 2019):

- **ISO 9000:2015** (Quality management systems – Fundamentals and vocabulary)
  This standard serves to support introducing and working with quality management systems. The basics (i.e., *fundamental concepts and quality management principles*) are outlined and *terms and definitions* are provided. Besides imparting knowledge for the general handling of the standard series, also the concept of *quality determination* and the definition of *quality criteria* are addressed in detail ("definition standard"). (Hensen, 2019)

  These concepts and definitions (depicted in Figure 18) will be of particular importance in chapter 4, and especially in the practical part of this thesis.

- **ISO 9001:2015** (Quality management systems – Requirements)
  This standard specifies the international requirements for the design of a quality management system (QMS). It also forms the basis for issuing certificates. Any company and organization can be certified to this standard within the scope of the 9000 series of standards. The quality capability of a QMS is given, if the QMS has been realized according to these requirements ("presentation standard"). The core of this quality model is the *process model of quality management*, which is oriented on the PDCA cycle, as shown in Figure 20. (Hensen, 2019)

- **ISO 9004:2018** (Quality management – Quality of an organization – Guidance to achieve sustained success)
  This standard is directly based on the principles of ISO 9001 and provides recommendations or suggestions for the introduction and improvement of a QMS. It serves as a supplement and support for aligning an organization to comprehensive QM approaches. Since it is only a guideline, certification is not possible ("recommendation standard"). (Hensen, 2019)

- **ISO 19011:2018** (Guidelines for auditing management systems)
  In this standard, general guidance is offered on auditing management systems. It provides guidance and recommendations on how to conduct internal and external audits accurately, including audit principles, managing an audit program, and assessing the competence of those involved in the audit process. Thus, the guideline is intended to help organizations implement audits; it is not mandatory ("implementation standard"). (Hensen, 2019)

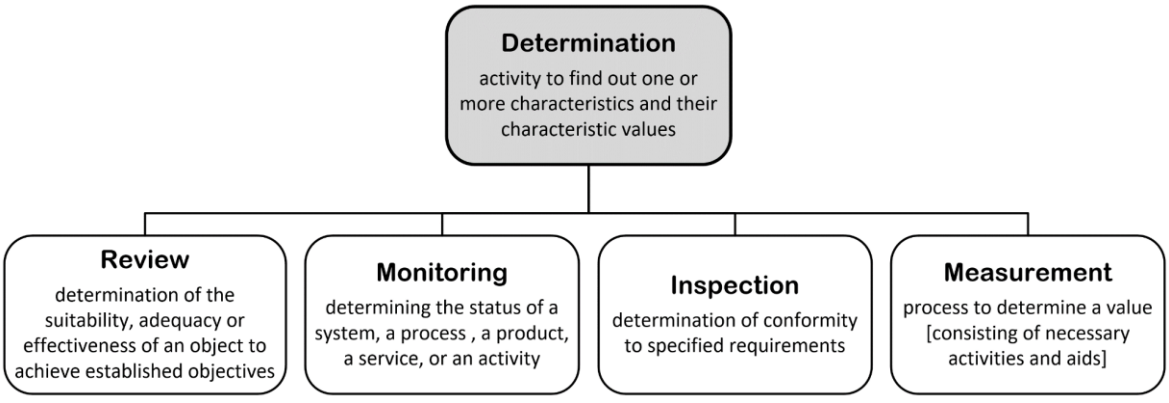


Figure 18: Important terms related to (quality) determination (ISO, 2015a)

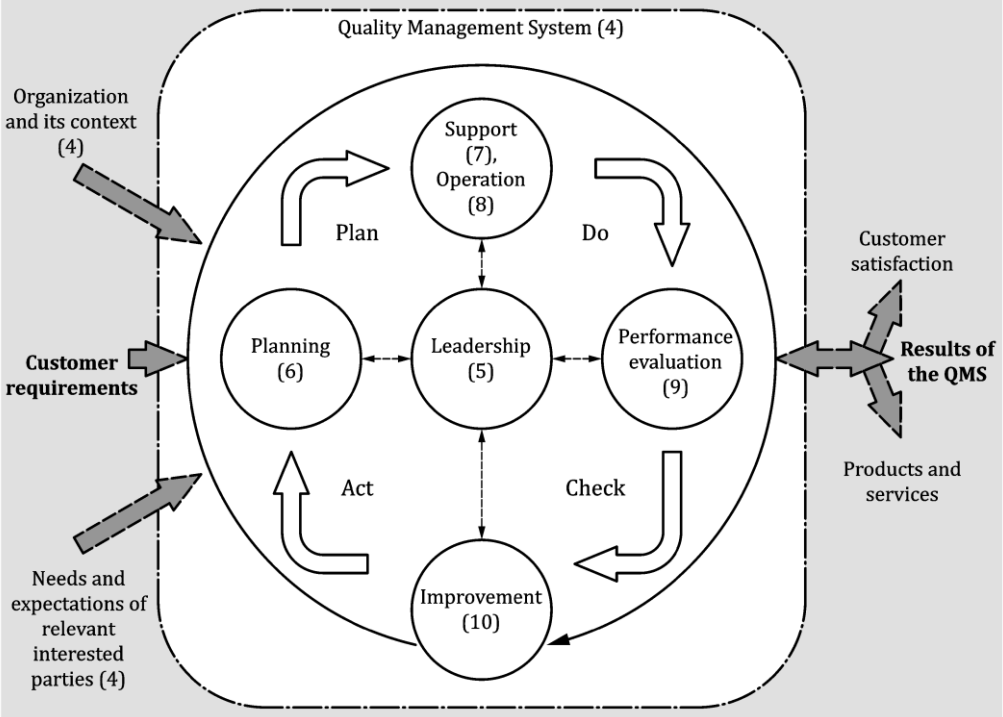


Figure 19: ISO 9001 process model of quality management (ISO, 2015b)

3.2.2 Relevant Models in Healthcare

The EFQM Excellence Model

EFQM (acronym for *European Foundation for Quality Management*) is an independent organization founded in 1989 by 14 representatives of European business groups. The objective was to develop a management approach focused on excellence for the holistic development of organizations in order to improve the overall competitiveness of the European economy in increasingly globalized markets. The basic core of this approach is the so-called "EFQM Excellence Model" which is updated and revised on a regular basis to help organizations determine their current "level of excellence" and where they need to improve their efforts. (Hensen, 2019)

The latest EFQM Model structure is based on the logic of asking three questions (EFQM, 2019):

- "*Why* does this organization exist? What Purpose does it fulfill?
  Why this particular Strategy? (*Direction*)";
- "*How* does it intend to deliver on its Purpose and its Strategy? (*Execution*)";
- "*What* has it actually achieved to date?
  "*What* does it intend to achieve tomorrow? (*Results*)." (EFQM, 2019, p. 9).

The resulting three main criteria (direction, execution, results) of the model are further divided into a total of seven sub-criteria which in turn represent "enablers" (process-oriented) and "results" (result-oriented). Since the EFQM model offers a broad and sophisticated approach to realize QM, it is used complementary to other QM systems or to ISO 9001 in healthcare. (Hensen, 2019)

The KTQ Procedure

KTQ (short for the German expression of *Cooperation for Transparency and Quality in Healthcare*) is a provider of quality management certification for healthcare facilities in Germany and Austria, based in Berlin (Hensen, 2019). Founded in 2001, the organization's goal is to offer a certification process that is voluntary for hospitals, thereby assessing the quality of patient care and promoting its continuous improvement as part of internal QM (Hensen, 2019, as cited in Thüsing, 2005). Following the procedure, healthcare facilities are assessed to what extent they consider its catalog of criteria, which can be used to drive improvements. These criteria form the "KTQ model". (Hensen, 2019)

The JCAHO/JCI Standards

The QM model of the JCAHO (*Joint Commission on Accreditation of Healthcare Organizations*, an independent US-American organization, founded in 1951) is – similarly to the KTQ procedure – strictly speaking not a QM model. Instead, it is primarily a procedure for the determination of quality in healthcare facilities. However, worldwide, it is one of the most prestigious certification processes in the healthcare industry, that consists of a catalogue of criteria and standards (requirements) providing guidelines for "good quality" in healthcare. This procedure enables to assess the quality or the competence and performance of healthcare facilities (accreditation). The JCI standards, on the other hand, evolved from the JCAHO catalogue at the international level in 2000. (Hensen, 2019)

The Donabedian Model

The Donabedian model can be applied for the quality determination in health care. It distinguishes between the three dimensions of structural, process and outcome quality which are related in a linear sequence ("Three-Part-Approach"). *Structure* considers all the structural conditions necessary for healthcare (e.g., financial or human resources), *process* addresses the actions taken and how they are conducted (e.g., diagnosis or treatment), whereas *outcome* comprises all effects resulting from healthcare in terms of patients (e.g., hospitalization or prolongation of life span). (Donabedian, 1988)

3.2.3 Other Models and Concepts

As mentioned earlier in this chapter, QM with all its aspects evolved specifically with regard to each industry or application area, which also led to a variety of different QM models. Examples of some other well-known QM models and approaches worth mentioning are (Leitner & Valastiak, 2019):

- **Advanced Product Quality Planning (APQP)**
  APQP is being used as a typical procedure of a product and process development phase in the automotive industry and thus serves as a significant concept for the quality planning.
- **Total Quality Management (TQM)**
  Quality approach to maximize the competitiveness through customer satisfaction and the inclusion of top management in order to establish continual quality improvement solutions.
- **Six Sigma (6σ)**
  Data-driven approach and methodology in order to eliminate defects (aiming for *six standard deviations* between the mean and the nearest specification limit) in any process.

3.3 Approaches to QA/QC in AM

After introducing to QM and its major aspects at a general level, as well as discussing relevant QMS models, particularly in healthcare, this section covers a brief overview of related efforts regarding QA and QC programs for AM applications in the fields of medicine. Therefore, the use of phantoms for QA will be addressed first, before presenting some examples of proposed QA process models.

3.3.1 Phantom-based QC Programs and Optimization

As stated by Odeh et al. (2019) and as also indicated in the last subsections, QA and QC programs exist for several fields of medicine, such as medical imaging (e.g., ensuring optimal performance of imaging acquisition hardware, dose reduction or reporting of results). However, only a few studies have been conducted for the use of AM in such areas, revealing the need to expand existing QA and QC programs in hospitals to fully utilize these technologies as a clinical resource. The development of new *phantoms*, specifically designed for verifying and validating the performance and accuracy of 3D printing machines and materials, is therefore of major interest as corresponding studies show (Kanters et al., 2019 Leng et al., 2017; Matsumoto et al., 2015). (Odeh et al., 2019)

Since these procedures are critical components of any QMS and are often hard to distinguish, they are explained using some application-specific definitions and examples: *Verification*, in this regard, "refers to ensuring that a part is physically made to product specifications within a given tolerance (e.g., a model of a patient's heart matches the dimensions of the patient's actual heart within ±1mm)" (Odeh et al., 2019, p. 1). *Validation*, however, "ensures that the model will fulfill its intended purpose and meet the customer's needs and expectations (e.g., the model of a patient's heart will allow the surgeon the opportunity to practice the procedure prior to surgery)" (Odeh et al., 2019, p. 2). The general definitions of these terms can be looked up in the corresponding standard (ISO, 2015a).

Especially the verification of AM fabricated parts can bring a number of challenges into the QC process as organic shapes can be complicated to measure (Odeh et al., 2019) or some areas of a part might be impossible to inspect with conventional testing methods (addressed in detail in chapter 4).

As mentioned before, phantoms therefore represent a well-suited means of addressing some of these challenges towards establishing in-hospital clinical 3D printing QC programs. These QC phantoms are specifically designed with AM-relevant features of size and shape and with precisely known dimensions in order to serve as a gold standard for the testing of geometric accuracy and resolution. In this way, the QC models can be printed at regular intervals (e.g., to track the printer's performance, in particular in terms of accuracy and repeatability), or along with every model manufactured for a specific patient and subsequently be compared to the dimensions of the corresponding CAD model. (Matsumoto et al., 2015; Wake et al., 2017)

To provide an orientation about what values to expect when conducting dimensional measurements of QC phantoms, in Table 5 some relevant studies are listed by George et al. (2017). The results of these studies indicate that by using professional hardware, the dimensional errors of most AM processes are commonly below 0.5 mm, which can be considered a negligible level of accuracy for most medical applications (George et al., 2017).

Table 5: Dimensional accuracies of AM models versus design STL models (George et al., 2017)

Tested Geometry	AM technology	Absolute Difference mean ± SD [mm]	Relative Difference mean ± SD [%]
Skull and mandible (El-Katatny et al., 2010)	Professional FDM	0.1 ± 0.1 (0.0–0.2)	0.2 ± 0.2% (0.0–0.6%)
Skull and mandible (Salmi et al., 2013)	SLS, polyamide	0.9 ± 0.4 (max: 1.9)	0.8 ± 0.3% (max: 1.4%)
	Binder jetting	0.8 ± 0.53 (max: 1.7)	0.7 ± 0.4% (max: 1.6%)
	Material jetting	0.2 ± 0.1 (max: 0.5)	0.2 ± 0.1% (max: 0.5%)
Geometric models defined in ISO 12836 for dental restoration (Braian et al., 2016)	SLS, polyamide	Dimensions: 0.06 ± 0.06 (0–0.2) Angles: 0.56 ± 0.47° (0.07°–1.23°)	Dimensions: 0.9 ±1.2% (0.0–4.1%) Angles: 3.4 ± 2.73% (0.4–7.2%)
	Material jetting (equipment A)	Dimensions: 0.02 ± 0.04 (0.0–0.18) Angles: 0.34 ± 0.24° (0.08°–0.64°)	Dimensions: 0.2 ±0.1% (0.0–0.4%) Angles: 2.0 ± 1.4% (0.5–3.7%)
	Material jetting (equipment B)	Dimensions: 0.04 ± 0.03 (0–0.09) Angles: 0.53 ± 0.37° (0.23°–1.05°)	Dimensions: 0.5 ±0.4% (0–1.39%) Angles: 3.2 ± 2.1% (1.4–6%)
Complex models (Teeter et al., 2015)	SLS, stainless steel	0.01 ± 0.02 (0–0.09)	1.5 ± 3.2% (0–17.8%)

A comprehensive study for the design and manufacturing of phantoms was carried out by Leng et al. (2017), who developed two generations: The “first generation” phantom was an image phantom, consisting of groups of line-pair patterns of different sizes to test geometric accuracy and resolution, as well as to develop a QC procedure (Figure 20a). The “second generation” phantom was made more complex (i.e., additional test objects shapes) to test more aspects of the overall manufacturing process (Figure 20b). Moreover, QC phantoms which contain “mirror features” (i.e., positive and corresponding negative shapes) were proposed to allow fit testing replacing physical measurements by inserting one phantom into the corresponding other. (Leng et al., 2017; Rybicki & Grant, 2017)

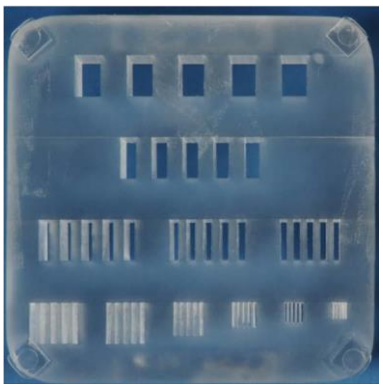
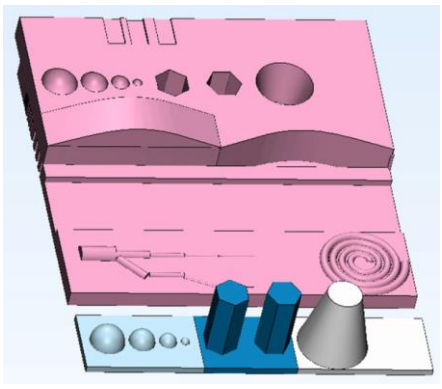
(a)  **(b)** 

Figure 20: QC phantoms: first generation (a), and second generation (b) (Leng et al., 2017)

3.3.2 Process Models for AM Applications in Medicine

Based on the general overview of QM and respective QMS models in this chapter, some insights into developments specifically in the area of AM for medical applications are briefly given at this point. Therefore, some QC process models regarding the manufacturing of patient-specific implants are presented in the following.

A very generic approach for this purpose was developed by Hollister et al. (2015) who followed the design/development process outlined by the Food and Drug Administration (FDA) for regulatory approval which was part of the Q*uality Systems Regulation* (QSR) (FDA, 1997). This systematic design/development process, known as *Design Control*, was adopted as a guideline for achieving design requirements for AM parts in the medical field. Figure 21 (right side) depicts the unidirectional phases of the original "Waterfall Model" for design control (FDA, 1997).

On the left side of Figure 21 the five steps of the adopted process are illustrated: The first two steps of *design inputs* consider all parameters for the design and modeling of the part to fulfill the specific requirements. The *design outputs* contain the necessary tests that need to be conducted to evaluate the design input (i.e., mostly destructive testing). The purpose of *design verification* is to make sure that the fabricated part fulfills the design input (i.e., geometric and mechanical evaluation by different means of testing). During the *design validation*, on the other hand, pre-clinical models and clinical implementations of final parts are tested. This entire process is continuously documented (in design review meetings), resulting in a *Design History File*, which includes all the necessary information that eventually led to the final design or process (e.g., reasons for specific choices and corrections). (Hollister et al., 2015)

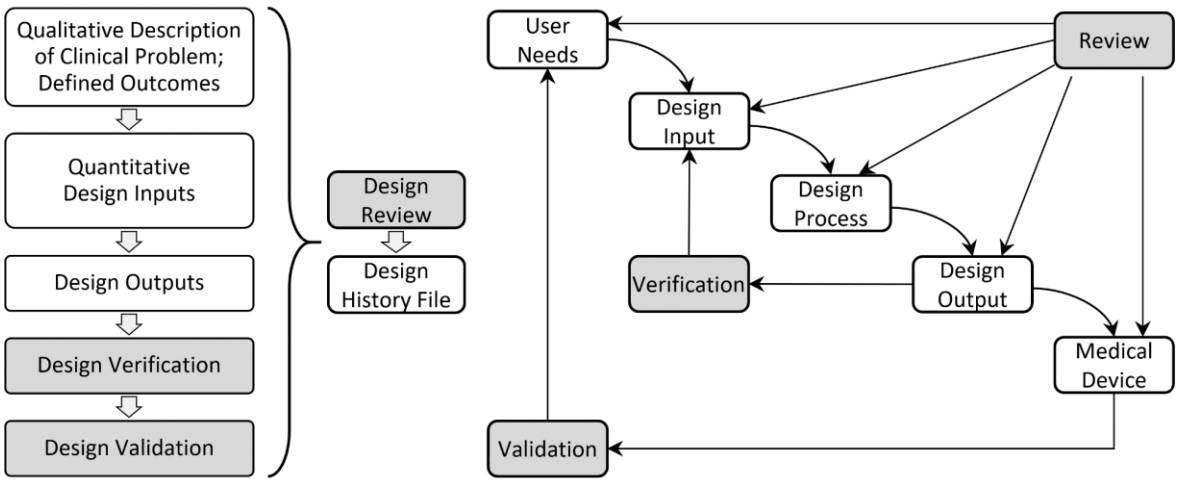


Figure 21: Schematic of the design control process (Hollister et al., 2015)

A more detailed schematic approach, however, also with a similar basic structure, is illustrated in Figure 22. The authors of this process model established a systematic approach for the production of AM patient-specific craniomaxillofacial reconstructions, which divides the process into three parts: the implant *design* (including FEM simulations for optimization), the *fabrication* process (i.e., quality testing of the raw material, adjusting the process parameters and printing, post-processing) and the *clinical application* of the PSI (including final inspection and sterilization). (Du et al., 2020)

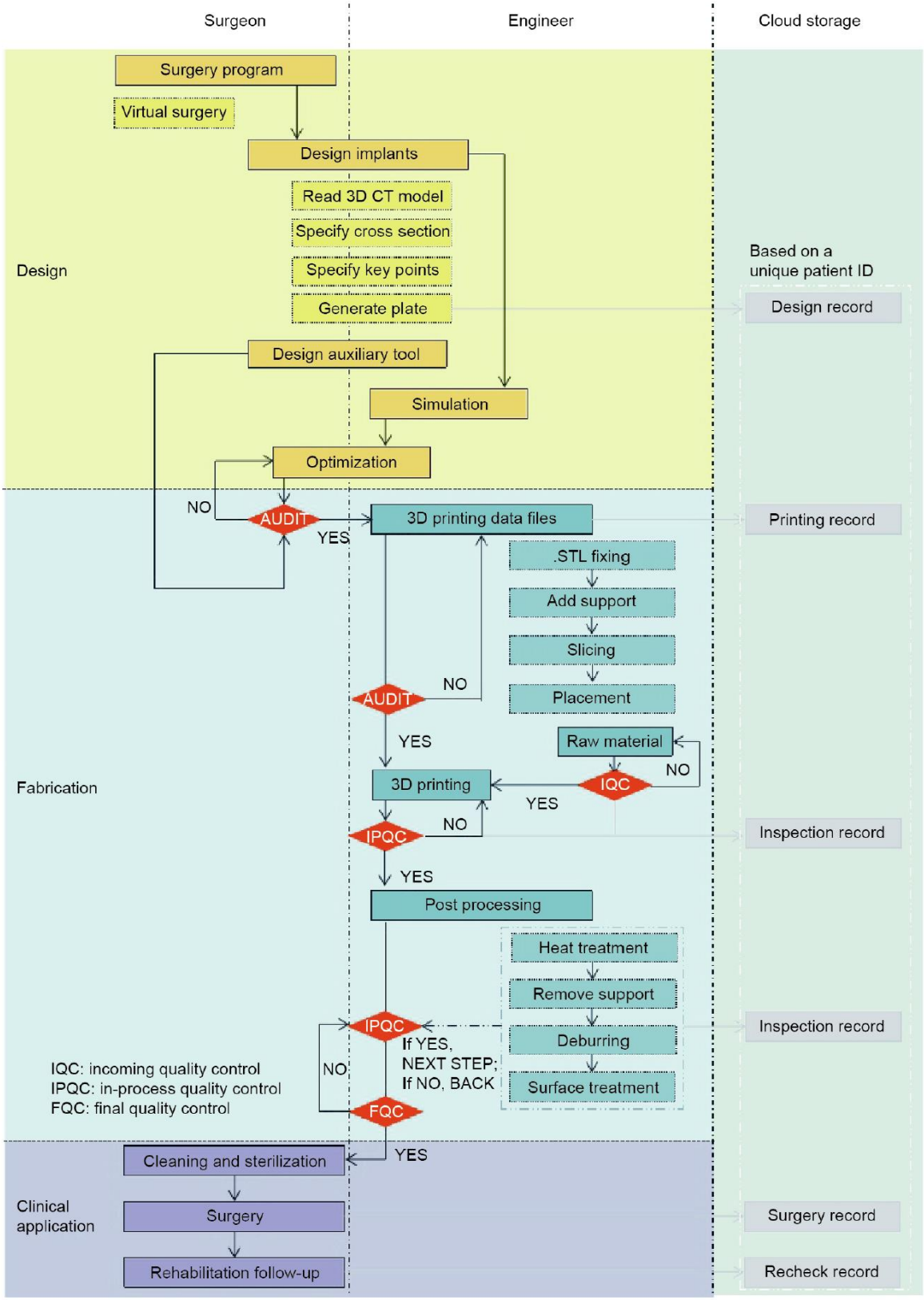


Figure 22: Systematic approach for making AM patient-specific implants (Du et al., 2020)

3.4 Regulatory Considerations for Medical Devices

The medical device industry, is one of the most stringently regulated areas of application in general, since respective authorities are charged with protecting and promoting the public health by ensuring that products are safe and effective (Di Prima et al., 2016). Besides medical devices, these various regulatory requirements are also applied to pharmaceuticals and biologics and govern premarket applications, manufacturing practices, and postmarket adverse event reporting. (Georgantis et al., 2020). However, regarding the application of AM in this sector, the numerous opportunities offered by this technology also present unique challenges when it comes to meeting regulatory standards related to manufacturing quality assurance (Morrison et al., 2015).This section aims to outline the most important regulations for medical devices with regard to both the U.S. and European markets.

3.4.1 Classification of Medical Devices

Medical devices are categorized into three different regulatory *classes*, based on the complexity, their material characteristics, and risks related with their use in patients, in order to assure their safety and efficacy. This categorization in turn is based on the regulation of the respective countries, (which is why there exist slight variations in the definitions). For the European Union, for example, it was made by performing a number of biocompatibility tests according to the relevant guidelines of ISO 10993 (ISO, 2018), which basically rely on the nature of body contact and contact duration. Following, with regard to body contact, medical devices are classified into *surface contact devices*, *externally communication medical devices* and *implant medical devices*, whereas the classification according to contact duration distinguishes between *limited* (≤24 h), *prolonged* (24 h to 30 days) and *permanent* (>30 days) exposure. (ISO, 2018; Timiri et al., 2020)

The beforementioned classification according to the European *Medical Device Regulation* (MDR) is shown in Figure 23. As indicated in the descriptions, the regulatory control intensifies from Class I to Class III, as medical devices of the latter potentially pose the highest risk on the patient or user.

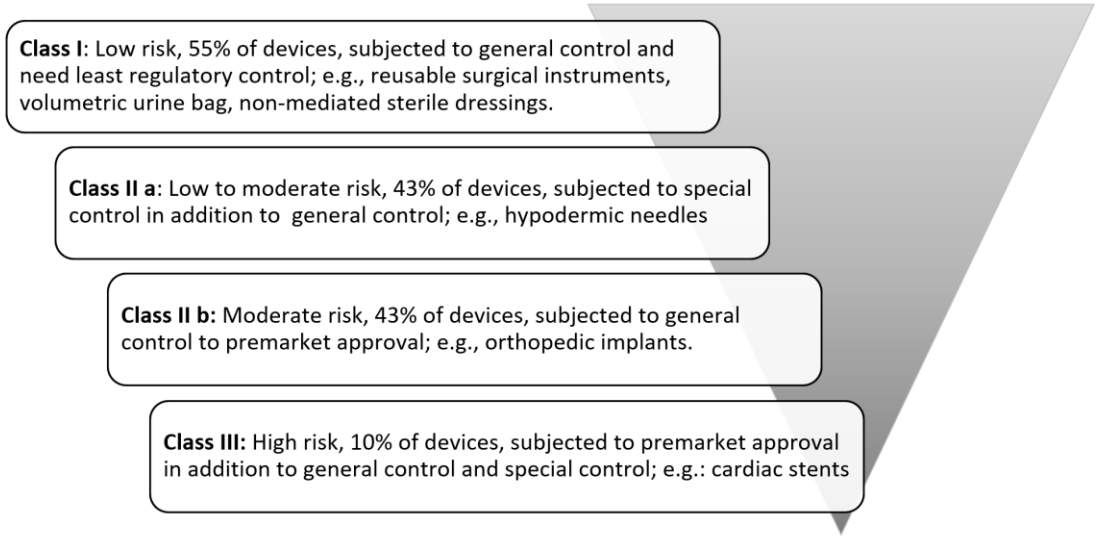


Figure 23: Classification of medical devices (based on Timiri et al., 2020)

3.4.2 Medical Device Regulations

Since *risk assessment* is generally one of the most important components in ensuring the safety and efficacy of medical devices, there are several regulatory guidelines for this purpose that address the continuous monitoring of a device and confirmation of its overall safety. The term "risk" is defined as the "combination of the probability of occurrence of harm and the severity of that harm" (ISO, 2019, para. 3.18). Consequently, besides a general QMS, each manufacturer of medical devices must also establish a risk management system according to the specific regulations of a country (manufacturers of Class I certified devices are exempt from the requirements). (Timiri et al., 2020)

For the U.S. market all the relevant regulations to be considered are specified and monitored by the *Food and Drug Administration* (FDA), while for European counties the *Medical Device Regulation* (EU MDR) is applied to ensure safety of medical devices. Especially the European regulations are complemented or detailed by dedicated ISO standards for purposes like a risk management approach. In order to make these regulations more concise (especially for ease of adaptation for manufacturers), specific efforts are made, e.g., by the *International Medical Device Regulators Forum* (IMDRF) (International Medical Device Regulators Forum [IMDRF], 2020b) or the former existing *Global Harmonization Task Force* (GHTF). The latter summarized the three stages of regulatory control (i.e., premarket, placing in the market, and postmarket) which functions are similar in most countries' regulations as shown in Table 6. (Timiri et al., 2020)

Table 6: Common framework for medical device regulations (Timiri et al., 2020)

Stage	Premarket	Placing on Market	Postmarket
Control/ Monitor	product	sales	after-sale/ use
Person	manufacturer	vendor	vendor/ user
Items or activities regulated	*Device attributes* • Safety and performance Manufacturing • Quality systems *Labeling (representation)* • Accurate description of product • Instructions for use	*Establishment registration* • List products available or in use • Requires vendor to fulfill aftersale obligations *Advertising (representation)* • Prohibits misleading or fraudulent advertisement	*Surveillance/vigilance* • Aftersale obligations • Monitoring device's clinical performance • Identification of problems and alerts

Like its predecessor, the GHTF, the IMDRF, created in 2011, is a voluntary group of representatives from national medical device regulatory authorities from around the world, which aims to accelerate harmonization and convergence of the different regulatory frameworks (IMDRF, 2020a). Since these efforts take time, the organization strategically focuses on two key objectives in the next five years:

- "Managing regulatory challenges for medical devices and innovative technologies by providing timely and appropriate guidance";
- "Strengthening post-market surveillance for medical devices and implement regulatory life cycle processes" (IMDRF, 2020b, p. 8).

3.4.3 Important Regulatory Bodies

3.4.3.1 USA – Food and Drug Administration (FDA)

In the U.S. the product types are regulated by different offices within the FDA, those regulations for manufacturing, relabeling, repackaging and importing of medical devices sold are governed by the *Center for Devices and Radiological Health* (CDRH) (FDA, 2020b). More generally, the FDA is a federal agency of the United States Department of Health and Human Services and a regulatory authority, which is in charge of monitoring and controlling a wide range of medical products and other products that are not directly related to food or drugs. (Timiri et al., 2020)

The *Code of Federal Regulations*, title 21 ("21 CFR") specifies fundamental regulatory requirements for medical device manufacturers who want to distribute their products in the United States. Among those requirements are Establishment Registration & Medical Device Listing, Premarket Notification 510(k), Premarket Approval (PMA) or Quality System (QS) Regulation (FDA, 2020b).

For person-specific devices (i.e., instruments for surgical assistance, implants or external protheses), the FDA assesses the long-time performance of devices within their intended purpose. Therefore, their safety and effectiveness are checked with regard to the information specified by the device manufacturer. These specifications are important since the FDA does not approve specific materials for their general use for medical devices (either traditionally produced or made by AM) but approves finished medical objects and instruments for their safety and efficiency instead. In 2017, the FDA therefore issued a guidance for manufacturers to outline technical considerations associated with AM medical devices, particularly regarding their design, manufacturing and testing. (FDA, 2017, 2020a)

3.4.3.2 Europe – Medical Device Regulation (EU MDR)

The pendant for the European market is called the *European Medical Device Regulation* (EU MDR), or as it goes by its official name, Regulation (EU) 2017/745. It was entered into force in May 2017 and will replace the currently applicable EU directives (i.e., *Medical Device Directive* [MDD] and *Active Implantable Medical Devices* [AIMDD]) as of May 26, 2021. In contrast to this, the previous *In Vitro Diagnostic Medical Devices* (IVDMD) remains separate from the new MDR and will instead be replaced by the *In Vitro Medical Device Regulation* (IVDR). Table 7 resumes this transition from the currently applicable directives to the new legislation. (European Commission [EC], 2021)

Table 7: Overview of medical device regulations within the EU (EC, 2021)

Currently applicable	⇨ New Legislation to be applicable
1993: Directive 93/42/EEC on *Medical Devices* (MDD)	May 26, 2021: Regulation (EU) 2017/745 on *Medical Devices* (MDR)
1990: Directive 90/385/EEC on *Active Implantable Medical Devices* (AIMDD)	
1998: Directive 98/79/EC on *In Vitro Diagnostic Medical Devices* (IVDMD)	May 26, 2022: Regulation (EU) 2017/746 on *In Vitro Diagnostic Medical Devices* (IVDR)

Since the new regulations contain a series of highly important improvements in order to modernize the existing legal framework, some of the key changes and aspects are listed. Among these are:

- "stricter previous control for high-risk devices via a new premarket control mechanism with the involvement of a pool of experts at EU level";
- "reinforcement of the criteria for designation and processes for oversight of notified bodies";
- "inclusion of certain aesthetic devices that present the same characteristics and risk profile as analogous medical devices under the scope of the regulations";
- "a new risk classification system for *in vitro* diagnostic medical devices (IVDR) in line with international guidance";
- "improved transparency through a comprehensive EU database on medical devices and a device traceability system based on a unique device identification (EUDAMED)";
- "introduction of an *implant card* containing information about implanted medical devices";
- "reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorising multi-centre clinical investigations";
- "strengthening of postmarket surveillance requirements for manufacturers";
- "improved coordination mechanisms between EU countries in the fields of vigilance and market surveillance" (EC, 2018b, p. 1 ff.).

In contrast to directives which give a direction open to interpretation, regulations are robust and need to be followed, bringing the new legislation much closer to FDA requirements (Timiri et al., 2020). Accordingly, to fulfill the obligations of the regulation both the device and the manufacturer must comply with the new MDR. Besides assessing the conformity of their devices, manufacturers need to consider numerous other aspects, like clinical evaluation, risk management, QMS, and postmarket surveillance to obtain the "CE Mark". (EC, 2018a)

To comply with these regulations, Table 8 lists the ISO standards applicable to medical devices.

Table 8: Relevant standards for medical devices

Standard	Title of the standard
ISO 10993	Biological evaluation of medical devices
ISO 22442	Medical devices utilizing animal tissues and their derivatives
ISO 14971 and **ISO 24971**	Medical device risk management
ISO 21534	Nonactive surgical implants—joint replacement implants
ISO 16061	Instrumentation for use in association with nonactive surgical implants
ISO 13485	Medical devices—quality management systems—requirements for regulatory purposes
ISO 19227	Implants for surgery—cleanliness of orthopedic implants
ISO 14155	Clinical investigation of medical devices for human subjects
ISO 11607	Packaging for terminally sterilized medical devices

Especially the standard **ISO 13485**, as well as the earlier addressed **ISO 9001**, on which it is based on, are very important guidelines for manufacturers of medical devices in the EU (Geremia, 2018). While in ISO 9001 basic requirements for a QMS are specified, ISO 13485 specifically defines those QMS requirements "where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements. Such organizations can be involved in one or more stages of the life-cycle" (ISO, 2016, para. 1). However, on a voluntary or contractual basis, these defined requirements are also applicable for any supplier or other external party that provides products to such organizations (ISO, 2016).

Generally, concerning the medical device development and industrialization, a manufacturer must demonstrate compliance with the essential requirements for a product and can refer to "harmonized" technical standards, in order to be allowed to place these products on the respective market. Common examples for such standards are the just mentioned ISO 13485 for QMS requirements, ISO 14971 for risk management or ISO 10993 for biocompatibility testing. According to the certification process and the targeted market, manufacturers can decide which standards are applicable. (Geremia, 2018)

3.5 Standardization Efforts in AM

Since AM is now being viewed as a serious method of manufacturing that has significant impact on the way companies can manufacture products, the development of industry standards is becoming a prerequisite to adopt AM for the production. Standards are necessary to enable companies to qualify and certify their AM processes (e.g., for medical applications), materials and products, but also to promote industry knowledge and to encourage the implementation of the technology. For efficient development of standards, inclusion of relevant stakeholders and experts is essential. Relevant users are considered to be suppliers of medical devices and implants, original equipment manufacturers (OEMs) in Aerospace and Automotive as well as general in High-Tech equipment, universities and R&D organizations, and AM equipment and material suppliers.

The general benefits through standardization in AM can therefore be seen as the following:

- "systematic development, modification and use of processes of joining materials from 3D model data (AM) resulting in innovative products";
- "assistance to users within the assessment of different additive processes resulting in using the appropriate technology for the specified product demands";
- "specification of quality parameters of different processes for standardized test procedures";
- "specification of appropriate test procedures, thereby ensuring uniform interpretation and evaluation of quality parameters";
- "standardization of AM technology process chains secure functionality and compatibility";
- "standardization of vocabulary required to define the product and to find a common speech";
- "standardization of data formats, structures and metrics for AM models" (ISO, 2020, p. 1).

As these standards are already demanded by many manufacturers and industries which want to take advantage of the possibilities offered by AM, several committees and working groups within the Standards Development Organizations (SDOs) are currently dealing with AM standardization issues. At international level, three main SDOs can be named, composed of several Technical Committees (TC), which are (AM-motion, 2018):

- The *International Organization for Standardization* (ISO)
  The **ISO Technical Committee 261 on Additive Manufacturing (ISO/TC 261)** originates from a standardization initiative from DIN in 2011 and is divided into five working groups.
- The *American Society for Testing Materials* (ASTM)
  The **ASTM International Committee F42 on Additive Manufacturing Technologies** was organized by industry in 2009. Its aim is to develop consensus standards supporting the adoption of AM across multiple industrial sectors and is also divided similar to the ISO/TC.
- The European Standardization Organizations (*European Committee for Standardization* [CEN]; *European Committee for Electrotechnical Standardization* [CENELEC])
  These are non-profit organizations striving to develop and define standards that are meant to support the implementation of European legislation. A European Standard published by the **CEN Technical Committee on Additive Manufacturing (CEN/TC 438)** must be adopted by each national standards body or committee to avoid any conflicts and to establish national standard in all the member countries.

To progress these standardization efforts in an efficient way (i.e., reduce the risk for duplication of work, as well as the risk of contradiction between standards), ASTM F42 and ISO/TC 261 agreed on a **collaboration** in October 2011, aiming to jointly develop international standards in the field of AM (AM-motion, 2018). Thereby, the following key strategies were identified to outline the structure of joint ISO/ASTM standards:

- "for efficiency and effectiveness, ISO/TC 261 and ASTM F42 should begin the work together and therefore in the same direction [i.e., start of Joint Group for a new work item]";
- "one set of AM standards to be used all over the world";
- "common roadmap and organizational structure for AM standards";
- "use and build upon existing standards, modified for AM when necessary";
- "emphasis on joint standards development" (AM-motion, 2018, p. 8).

The **common roadmap and organizational structure for AM standards** (illustrated in Figure 24) that resulted from the agreement, consists of the following three levels:

- "*General standards*: general concepts, common requirements, or are generally applicable to most types of AM materials, processes, and applications";
- "*Category standards*: requirements specific to a material category or process category";
- "*Specialized standards*: requirements specific to a material, process, or application" (ISO, 2020, p. 7).

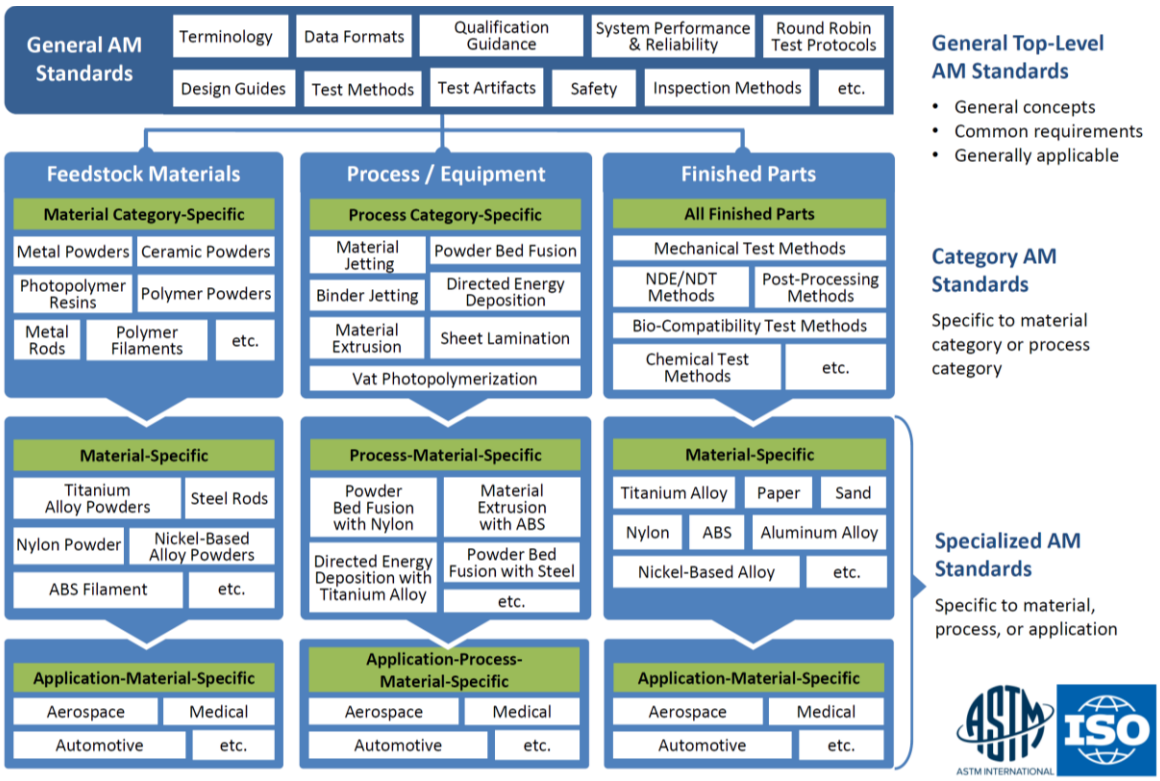


Figure 24: Common ISO/ASTM structure of AM standards (ISO, 2020)

Besides the described main SDOs and their cooperative relationships between ISO, ASTM and CEN AM committees, there are also several other SDOs that aim at addressing the global standardization efforts in AM. These organizations, initiatives and collaborations released a range of roadmap studies and reports as well, of which some important are:

- *America Makes & ANSI*: AMSC
  America Makes, the US AM innovation institute that partnered with the American National Standards Institute (ANSI), launching the *Additive Manufacturing Standards Collaborative* (AMSC) in March 2016. In 2018, the collaboration published one of the most comprehensive reports at current which addresses the gaps and challenges in AM in detail. (ANSI, 2018)
- *National Institute of Standards and Technology* (NIST)
  The NST released some detailed roadmaps that specifically deal with the challenges for AM concerning measurement in metal- as well as in polymer-based applications. These will be addressed in detail within chapter 4. (Energetics Incorporated, 2013; Pellegrino et al., 2016)
- *National Aeronautics and Space Administration* (NASA)
  A good example for the research efforts of organisations outside a specific industry sector is the “State-of-the-Discipline Report” published by the NASA in 2014. As AM provides some promising applications in the field of Aeronautics, especially the current possibilities for metal-based processes have been examined, in particular the challenges concerning testing of AM parts. (Waller et al., 2014)

The current status of standards published or under development by ISO/TC 261 is updated regularly and is available on the ISO website (ISO, n.d.).

4 Testing and Quality Verification in AM

In this chapter a general introduction to metrology and testing is provided before the most common methods for testing and quality verification of finished products are outlined. The focus is put on the use of nondestructive testing methods, as these represent the fundamental basis for the inspection of AM parts. The most appropriate methods, especially for polymer parts in medical applications, are described in detail as well as the specific challenges arising when inspecting AM parts in general.

4.1 General Introduction to Metrology and Testing

Generally, measurement and testing are the means to characterize objects of interest in science and engineering (Czichos et al., 2011). In order to gain a clear understanding of these important topics, a few basic definitions and backgrounds are given:

> *Measurement* is the process of experimentally obtaining quantity values that can reasonably be attributed to a property of a body or substance. *Metrology* is the science of measurement. *Testing* is the technical procedure consisting of the determination of characteristics of a given object or process, in accordance with a specified method. (Czichos et al., 2011, p. 3)

A detailed overview of how these disciplines can be related to each other was further enabled by Czichos et al. (2011) by structuring them to a unified general scheme, as can be seen in Figure 25. Methodologies of measurement are shown in light gray, while those of testing appear in dark gray.

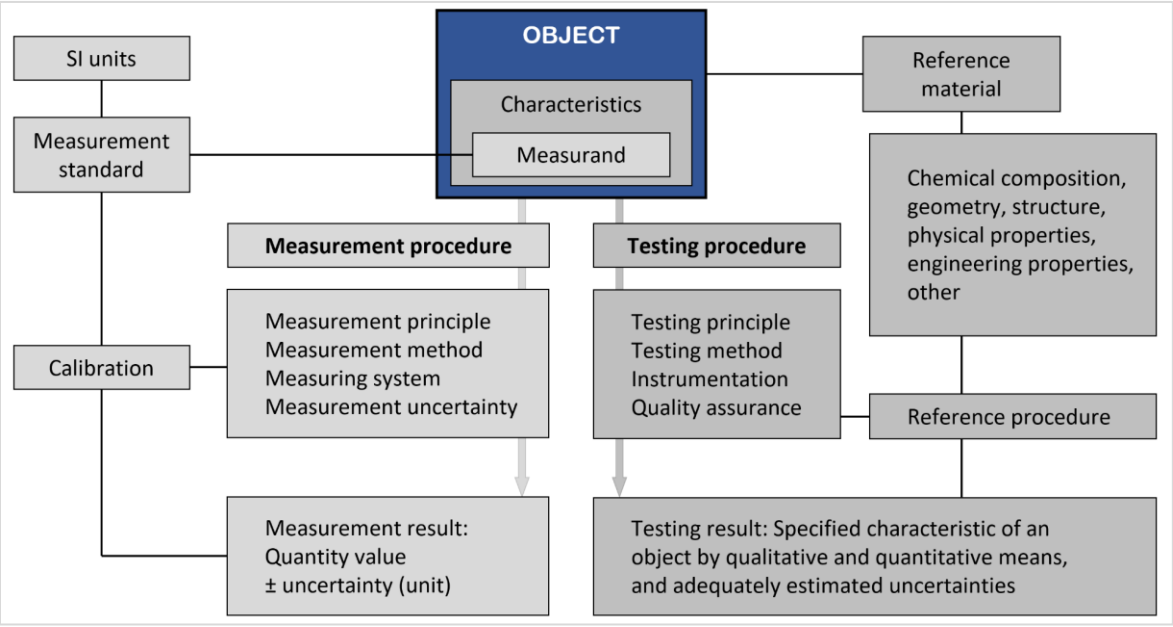


Figure 25: Methodologies of measurement and testing (based on Czichos et al., 2011)

Measurement starts by defining the measurand, which represents the quantity that is to be measured. In the next step, the measurand must be put in relation to the measurement standard, described as "the realization of the definition of the quantity to be measured" (Czichos et al., 2011, p. 3). The measurement procedure, in turn, is defined as "a detailed description of a measurement according to a *measurement principle* and to a given *measurement method*" (Czichos et al., 2011, p. 3). Besides the mentioned basic features of a measurement procedure, there are the *measurement system* (i.e., instruments or devices to obtain quantity values) and *measurement uncertainty*. (Czichos et al., 2011)

Testing or *inspection*, however, seeks to "determine characteristics (attributes) of a given object and express them by qualitative and quantitative means, including adequately estimating uncertainties" (Czichos et al., 2011, p. 6). Metrology thereby serves as a vital basis for making test results comparable (e.g., by determining the units of measurement). The basic tools to support testing are *reference materials*, *certified reference materials* and *reference procedures*. (Czichos et al., 2011)

Metrology, in a larger context, is also concerned with the establishment of units, the development of measurement protocols as well as the creation of special artifacts (i.e., phantoms or test samples) to be used as measurement standards enabling to analyze the accuracy and uncertainties of a method (Badadhe, 2006). Due to their high potential in medical applications, such as the use case presented in the practical part of this work, the use of test artifacts will be discussed separately in this chapter. Furthermore, as Vora and Sanyal (2020) conclude, metrology and testing are playing a very essential role for the quality enhancement in the AM industry, as these methods are applied to

1. confirm whether the parts are within the required tolerances;
2. characterize different AM processes and;
3. establish standard methods that help minimize inspection costs and maximize measurement accuracy (Vora & Sanyal, 2020).

According to Badadhe (2006) , there are several ways in which measurements types can be classified, such as *direct* (e.g., comparing to a standard) or *indirect* (e.g., the end result has to be calculated), *fundamental* (absolute method), *comparative* (comparing to a known value of the same quantity) and *substitution* (direct comparison by replacing the measurand by a known value with same quantity). With regard to the type of practice, other ways of distinguishing measurement and testing methods are *contact* or *contactless*, *real-time* or *off-time*, *in situ* or *ex situ* or, *destructive* or *nondestructive* (Vora & Sanyal, 2020). As the latter are of most interest in the context of this work, they are treated extensively in the next sections.

Before delving into the topic of nondestructive testing, however, another important definition, or distinction, must be made to ensure a clear understanding throughout the next sections: the difference between methods and techniques. According to the respective standard (i.e., ISO 9712, which is dealt with in more detail later in this section), a *method* is defined as a "discipline applying a physical principle in non-destructive testing", while a *technique* in the context of NDT is a "specific way of utilizing an NDT method" (ISO, 2012, para. 3).

4.2 Nondestructive Testing and Evaluation in AM

Among the many generally applied testing methods in industry, such as chemical analysis, various mechanical testing, and metallurgical methods, the wide group of *nondestructive testing* (NDT) techniques is the most significant in the field of QC procedures in AM. The reason for their preferred use is the following fundamental difference in how the testing procedure affects a part: The before mentioned methods are mostly destructive in nature, meaning, that the part being tested is either damaged or destroyed during the inspection process, and further, that only a limited number of testing samples of a batch can be inspected. In contrast, NDT enables to examine a part without destroying it or wearing it down in any way. (Charalampous et al., 2020)

To give a more comprehensive explanation, Hellier (2003) provides the following general definition:

> NDT is an examination, test, or evaluation performed on any type of test object without changing or altering that object in any way, in order to determine the absence or presence of conditions or discontinuities that may have an effect on the usefulness or serviceability of that object. Nondestructive tests may also be conducted to measure other test object characteristics, such as size; dimension; configuration; or structure, including alloy content, hardness, grain size, etc. … *Nondestructive examination* (NDE), *nondestructive inspection* (NDI), and *nondestructive evaluation* (NDE) are also expressions commonly used to describe this technology. (Hellier, 2003, p. 1.1)

In a broader sense this means, NDT can effectively be used to inspect a component or even an entire process unit without the need of damaging any equipment or stopping an ongoing production, which clearly is one of its major advantages. Especially concerning its applications in industry, NDT gives the opportunity to perform tests to assure and inspect the quality of a product in its different levels of manufacturing and even throughout its entire life cycle while being used:

1. “examination of raw materials prior to processing”;
2. “evaluation of materials during processing as a means of process control”;
3. “examination of finished products”;
4. “evaluation of products and structures once they have been put into service” (Hellier, 2003, p. 1.2).

In manufacturing, NDT can be used to determine if a part is acceptable for its desired application (e.g., ensuring that the part is able to last a certain amount of time or cycles before a damage occurs) (inspectioneering, 2021). It must be noted, however, that mechanical tests, which are mainly of destructive nature, must be performed to gain useful quantitative information of a material, such as its ultimate tensile strength or specific hardness and thus cannot be replaced by NDT (Hellier, 2003).

Since this thesis is concerned with the testing of finished parts performed prior to their application, the specific knowledge about, or the suitability of the materials being used is taken as a precondition. Therefore, with further focus on NDT, Table 9 summarizes the fundamental conclusions of Hellier (2003), who outlined the general benefits and limitations of these methods or techniques.

Table 9: Benefits and limitations of NDT (according to Hellier, 2003)

Benefits of NDT	Limitations of NDT
The part is not changed or altered and can be used after examination	Some methods do not provide permanent records of the examination
Every item/ a large portion of the material can be examined with no adverse consequences	NDT methods do not generally provide quantitative data
Materials can be examined for conditions internal and at the surface	Orientation of discontinuities must be considered
Parts can be examined while in service	It is usually quite operator dependent
Many NDT methods are portable and can be taken to the object to be examined	Evaluation of some test results are subjective and subject to dispute
Nondestructive testing is cost effective, overall	While most methods are cost effective, some, such as radiography, can be expensive
	Defined procedures that have been qualified are essential

As a follow-up completion to this comparison, Hellier (2003) states further, that the listed benefits and limitations have to be viewed in the light of the following "conditions" which play a vital role for the effective performance of NDT:

1. *The product must be "testable".*
   This condition refers to method-specific limitations that are inherently tied to each method. Therefore, the selection of when to best use which testing method is depending on the knowledge about these specific limitations.
2. *Approved procedures must be followed.*
   The application of NDT methods must be based on procedures that have been developed and approved in accordance with the commonly agreed requirements and specifications. In order to qualify a procedure, the ability to detect discontinuities or conditions must be proven.
3. *Equipment is operating properly.*
   E.g., periodical performance or calibration tests, but also mandatory "functional" checks prior to every performed test to assure the used equipment's integrity.
4. *Documentation is complete.*
   Proper documentation is a significant part at the end of every performed examination. All key elements (e.g., calibration data, procedure used, identified discontinuities) need to be considered in a comprehensible and legible manner.
5. *Personnel are qualified.*
   As one of the most crucial factors, personnel must be qualified, and furthermore certified. Regular training, testing and defined experience are implied by qualification (Hellier, 2003).

Summarized, while most of the main benefits in Table 9 have already been mentioned previously, some of the limitations, on the other side, clearly point out the importance of well-trained personnel as well as qualified (and consistent) procedures, for example. Especially the just listed conditions for effective NDT, again, consequently underline the need for clear guidelines and standards in order to provide uniform definitions for the testing examination, documentation or qualification in this area. Therefore, since the basic and most crucial aspects concerning QC and the associated standardization effort (as well as its gaps) in the AM technologies sector have been discussed in the previous chapter, this section concludes with a detailed view on the currently existing landscape of NDT methods for AM parts and the challenges that emerge in this aspect.

Being among the most important influencing factors when performing NDT, the "Qualification and certification of NDT personnel" has been regulated and described by the correspondent ISO standard (ISO, 2012) in Europe. This standard is built in accordance to the most commonly applied NDT methods, which is why it also serves as a good basic overview of these very methods in the context of this work (Figure 26).

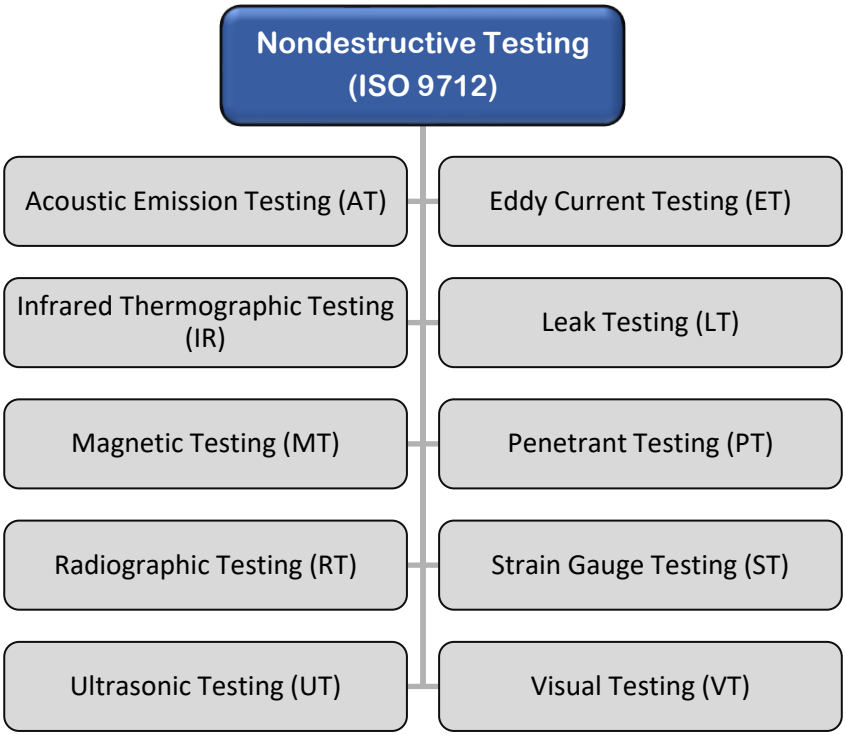


Figure 26: Structure of NDT methods (according to ISO 9712)

The methods included in Figure 26, especially those suitable for testing polymer parts and thus to be considered for the use case that is addressed in this thesis, are described in more detail in this chapter.

As described in the chapter 3, there are various other NDT standards (e.g., ASNT, ASTM, ASME), mostly dealing with the oil and gas and chemical processing industries. The depicted ISO standard, on the other hand, takes a more general approach and mainly focuses on the *conventional* methods (i.e., methods or techniques that have already reached a mature level over time and therefore, also have become well-documented in codes, standards, and best practices). (inspectioneering, 2021)

For a rough guideline of the applicability of these conventional testing methods, Table 10 provides a basic overview of which methods are generally suited for evaluating a particular AM part quality concern, as discussed in section 2.6. Again, the author of this analysis (Sharratt, 2015) focused on the post-manufacturing quality evaluation or in-service checking of AM fabricated parts only. The following ratings were used: *Y - applicable, N - not applicable, S - surface-sensitive* (i.e., accuracy is dependent on the surface finish of the part) and *I - internal or through-thickness*.

Table 10: Applicability of conventional NDT methods to the primary quality concerns in AM (adapted from Sharratt, 2015)

Methods	Micro-structure	Cracks, Porosity, Voids	Mechanical Properties	Geometric Accuracy	Surface Roughness	Residual Stresses
Acoustic Emission Testing (AT)	Y	Y	Y	Y	Y	Y
Eddy Current Testing (ET)	Y	S	N	N	N	N
Infrared Thermographic Testing (IR)	N	Y	N	N	N	N
Leak Testing (LT)	(not specifically addressed by the cited source)					
Magnetic Testing (MT)	Y	S	N	N	N	Y
Penetrant Testing (PT)	N	S	N	N	S	N
Radiographic Testing (RT)	Y	S, I	N	S, I	S, I	N
Strain Gauge Testing (ST)	N	S, I	N	N	N	Y
Ultrasonic Testing (UT)	Y	S, I	Y	Y	N	Y
Visual Testing (VT)	N	S	N	S	S	Y

It can be observed that several of these methods are capable to evaluate the microstructure of a part on the one hand. On the other hand, however, there are only a few possibilities available allowing to draw conclusions about its mechanical properties, or to measure its geometric accuracy or surface roughness.

Further, even though the system specified in the cited standard is applicable to other NDT methods or to new techniques within an established NDT method (ISO, 2012), these methods represent only a fragment of the overall existing testing or inspection techniques. There are several *advanced* NDT techniques in addition that are more specific in nature or are a particular form of a conventional one (inspectioneering, 2021). A major driver for such advanced techniques or NDT methods in general is the ongoing development of new technologies. As the listed conventional approaches might not be appropriate or sufficient to address the challenges associated with these technologies, this simultaneously increases the need for adapted or technology-specific NDT methods (ANSI, 2018).

4.3 Challenges for NDT in the Context of AM

In terms of AM, an entire industry has evolved that demands new ways of dealing with a variety of challenges. One of the main origins of these challenges that come with AM technologies are the inherent types of errors and discontinuities. Since these types have already been addressed in detail in chapter 2, only a brief remark is made at this point.

Therefore, in Figure 27 some typical AM defects are shown as summarized by Vora and Sanyal (2020). An exemplary extrusion-based AM process is depicted, which highlights potentially occurring defects, such as (lack of) dimensional accuracy, poor surface finish, or porosity, also known from other more mature processes. However, there can also occur a range of other defects (e.g., residual stresses, inclusions) which are very unique to the specific AM technology used for manufacturing a product. These are mainly caused by the layer-by-layer manner of creation, instead of forming a component by a conventional subtractive technology. But even if some commonalities in the types of defects exist when compared to conventional manufacturing processes, currently there is only limited knowledge about how the numerous processes and vast processing parameter, for example, affect these defects specifically in AM. Therefore, since NDT is seen as an essential means of encompassing the most appropriate solutions to the challenges encountered with AM technologies, its needed improvement in this field has been discussed extensively in recent years. (ANSI, 2018)

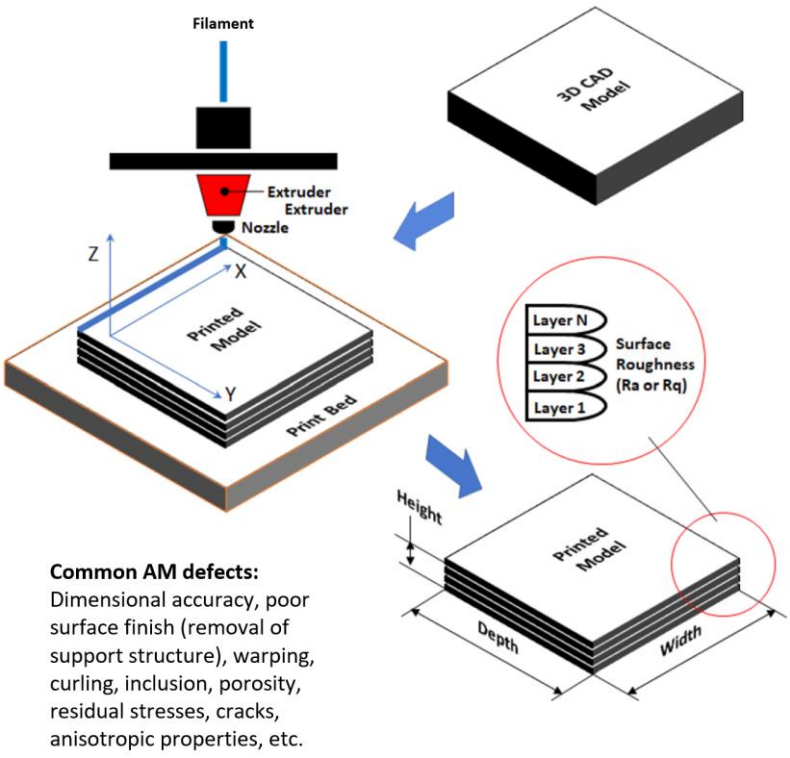


Figure 27: Evolution of common AM defects (according to Vora & Sanyal, 2020)

As already described in the previous chapter, a series of roadmap studies were conducted by different institutions and organizations in order to point out the existing gaps and challenges in these sectors. Especially the vital topic of process, material and finished part inspection proved to be one of the most significant of these challenges, as, e.g., explored by the participants of the *Roadmap Workshop on Measurement Science for Metal-Based Additive Manufacturing* organized by the NIST in 2013: "A key barrier for AM processes and equipment is that existing NDE methods and techniques are not optimized for AM processes, materials, or parts" (Energetics Incorporated, 2013, p. 20). The resulting report of this workshop mainly focuses on metal-based processes within AM, however, the challenges identified can be generalized to the industry as a whole (Energetics Incorporated, 2013)

To provide a well-structured overview of these important challenges concerning the technology as well as metrology (and testing) in AM, they were split into four groups: *AM materials*, *AM processes and equipment*, *AM qualification and certification*, and *AM modeling and simulation* (Figure 28).

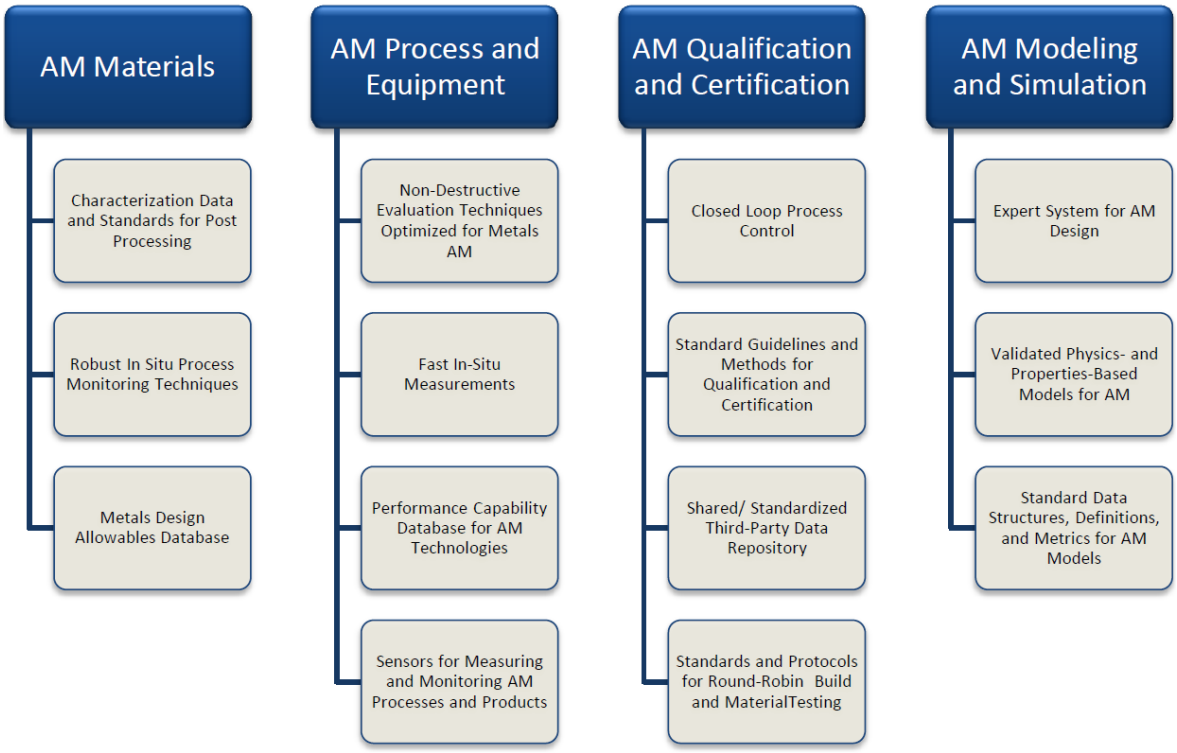


Figure 28: Technology and measurement challenges for AM (Energetics Incorporated, 2013)

As mentioned before and also concluded in the report, several of these challenges enumerated have ”cross-cutting elements” in AM throughout the whole manufacturing process, for example:

- *standards and protocols*, concerning all aspects of AM (as discussed in chapter 3);
- *measurement and monitoring techniques and data*, ranging from feedstock materials to final part inspection, but also effective process controls and the enhancement in understanding and predicting outcomes eventually resulting in fewer product defects;
- *insufficient research on AM materials*, identified as one of the most crucial factors overall;
- *modeling systems that couple design and manufacturing*, as a driver for the development of materials, products as well as new processes technologies;
- *closed loop control systems for AM*, being vital for processing and equipment performance, but also to enable the effective qualification and certification of both, parts and processes (Energetics Incorporated, 2013).

On a larger scale, it becomes apparent that NDT is affected and thus challenged in all areas listed, starting with materials inspection and ending with the support of modeling and simulation aspects.

As a further remark it should be noted that in 2016 – as a counterpart to the cited event – there was also a workshop held by the NIST focusing on *polymer-based AM*. The outcomes of this event were similar to the former one: again, with a strong emphasis on (lack of) standardization and the needed effort towards improved *in situ* monitoring. Besides the derived cross-cutting challenges (e.g., *life cycle and sustainability*, the goal of *surpassing conventional manufacturing capabilities* in 10 years), the medical market was named as a key future growth target. (Pellegrino et al., 2016)

Waller et al. (2014) conducted a gap analysis specifically for NDT methods used in the AM industry to determine the main challenges to be faced. They detected the following gaps:

- *Undefined critical defect types, sizes and shapes*
  As stated at the beginning of this section, some of the types of errors and discontinuities that are typical for parts manufactured by AM might be known from conventional and therefore mainly well-controlled processes. However, because AM technologies are inherently very different, the associated defects cannot be compared directly, but instead need to be defined specifically for each technology. Some reasons for this are the greater ranges of porosity in finished AM parts, the partially occurring lack of fusion (respectively bonding of layers) and the distribution of defects throughout the part. Because of these characteristics it is difficult to identify and quantify the relevant flaw types and sizes of defects that must be detected by NDT methods for AM parts. In addition, there is no clear consensus on what defines a *critical* defect in a part made by AM, as the necessary information is yet to be obtained during the ongoing development of the various technologies. By the time this knowledge is available, Waller et al. suggest, to better validate NDT techniques to not miss standard-sized flaws with a high certainty, instead of focusing on defining critical defect sizes.
- *Complex geometry*
  Being among the biggest advantages of AM on the one hand, the complex geometries that can be created pose a great challenge for conventional NDT methods on the other hand. The resulting limited accessibility of such parts makes it difficult to assess their internal structure. For this reason especially contactless NDT methods are favored for inspecting AM parts.
- *As built rough surface finish*
  Another major challenged faced by NDT methods when assessing parts made by AM is the rough surface finish of most of these technologies. As already noted in Table 10, some NDT methods are surface sensitive, which means that their accuracy or overall applicability can be limited to a great amount. Consequently, to enable the evaluation using such methods, an additional surface treatment (i.e., post-processing) is required for the parts to be inspected.
- *Lack of mature in-process monitoring techniques*
  Effective in-process monitoring is considered to be a “game changer” in the AM industry, especially for improving some broad manufacturing aspects (e.g., repeatability consistency) and the qualification and certification of AM parts (Energetics Incorporated, 2013). This gap is therefore of great significance, as it is aimed to be able to reduce the generally difficult NDT of complex AM parts to a great extent. In addition to using conventional methods such as infrared monitoring, algorithms are also being developed for the different AM processes that can automatically detect defects during the build process.

- *Lack of physical reference standards*
  The design and fabrication of reference standards is currently just starting for AM processes. However, such standards form the basis for NDT processes by enhancing the understanding of what a particular NDT method or technique is capable of with regard to a specific material.
- *Lack of written inspection procedures tailored for AM processes*
  Standard procedures are needed in order to specify the required quality characteristics of an AM part, which the upcoming standardized NDT methods must follow.
- *Qualification and certification*
  Currently, there are no NDT protocols for evaluating the quality, workmanship, and overall acceptability of a part made by AM. This gap, however, is dependent on the solution of many of the above mentioned (e.g., critical defects are understood, reference standards available).

4.4 Requirements for NDT Methods in AM

The determination of requirements generally provides the basis for the subsequent validation process of any method, as these allow an assessment of how well it fulfills the demanded characteristics. However, it must be pointed out that currently there is no clear definition of such requirements, since – similarly to the description of the numerous challenges – the necessary information or knowledge (e.g., based on further research and studies) is yet to be derived. In addition, this aspect is complicated by the various AM technologies, their respective process parameters and especially by the flaws and discontinuities typically occurring in a part, which in turn depend on the AM process that was used. (Waller et al., 2014)

Therefore, it should be focused on a fundamental set of NDT requirements specifically determined for the assessment of finished AM parts. In a presentation dealing with this issue in NDT, the speaker, Chris Williams, gave insight into his research findings and identified the following characteristics of NDT methods as ideal if they are:

- *fast to perform* (i.e., allowing short testing durations);
- *inexpensive* (both in terms of necessary equipment and testing procedure);
- *able to evaluate part irrespective geometry, surface and material*:
  - investigate inaccessible features;
  - assess large part sizes and fine features at the same time;
  - applicable also for parts with rough surface finish;
- *able to detect AM typical errors*:
  - feature location deviation;
  - feature size (part mass) deviation;
  - deeply embedded flaws;
  - variations in microstructure (e.g., anisotropic structures, porosity, foreign particles) (American Society of Mechanical Engineers [ASME], 2021).

In a more general sense, there are also a number of important requirements that are placed on test methods in order to be able to evaluate parts or processes or make assumptions about their integrity (Kromidas, 2011). Some of these "performance characteristics", as referred to by Kromidas (2011) in an analytical context, are listed in Table 11.

Table 11: Performance characteristics for testing methods (according to Kromidas, 2011)

Requirements	Description
Accuracy of the mean, freedom from bias	The most common approach used to proof accuracy is to test an appropriate reference material, that has certified values uncontested as known and true. Other methods are, e.g., the use recovery studies or application of mass balances.
Capability **– machine capability** **– process capability**	The machine or process capability (c_{PK}) is a very significant index largely addressed by statistical process control that measures the ability of how close a machine or process is working to its specifications. A high index of a respective machine or process indicates that it is unlikely to produce parts outside the specs. (Perez-Wilson, 1989)
Calibration	Calibration represents the first step in quality assurance, as it can be regarded as an essential prerequisite for a meaningful measurement. Some of the most important preconditions are standards with almost ignorable uncertainty, constant precision of the whole working range and a useful model (i.e., shape).
Precision **– repeatability** **– reproducibility**	A definition for precision is the "measure of dispersion between separate results of measurements" (Czichos et al., 2011, p. 84). As measures of precision it is possible to use e.g., the standard deviation under repeatability, reproducibility or intermediate conditions. Limits of repeatability or reproducibility can be obtained from the standard deviation (according to ISO 5725).
Recovery	Recovery can be defined as "the ratio of a measured mean value under repeatability conditions to the true value of the analyte in the sample" (Czichos et al., 2011, p. 84).
Robustness	A method can be called robust (or rugged) "if minor variations in the practice of the method do not lead to changes in the data quality. Robustness therefore is the degree of independence of the results from changes in the different influence factors" (Czichos et al., 2011, p. 84).

Stability	By contrast to the capability of a machine or process, stability refers to its consistency concerning its most important process characteristics (e.g., a key feature to be measured or variations). Therefore, a process is stable (or in control) if its behavior is consistent over time. (Wachs, 2009)

However, as also stated by the cited authors, the general requirements listed in Table 11 are to be seen only as a basic reference, since there are numerous other requirements which may be of concern. Therefore, the actual set of characteristics need to be adjusted with respect to the current problem. As another recommended approach for this purpose, it is useful to define specific selection criteria. (Czichos et al., 2011)

4.5 Applicable NDT Methods along the Processing Steps of AM

In section 4.2 the application areas for NDT in the different stages of manufacturing of a product have been described. In the literature, it has also become practicable to structure the various quality control processes in AM technology according to the individual steps along the manufacturing flow. Consequently, in this section, suitable NDT methods are discussed with respect to the categorization illustrated in Figure 29. The stages within the dashed frame represent the manufacturing process in which NDT methods will be investigated. The emphasis is furthermore placed on methods that are suitable for the evaluation of finished parts and here, in particular, for **extrusion-based processes**.

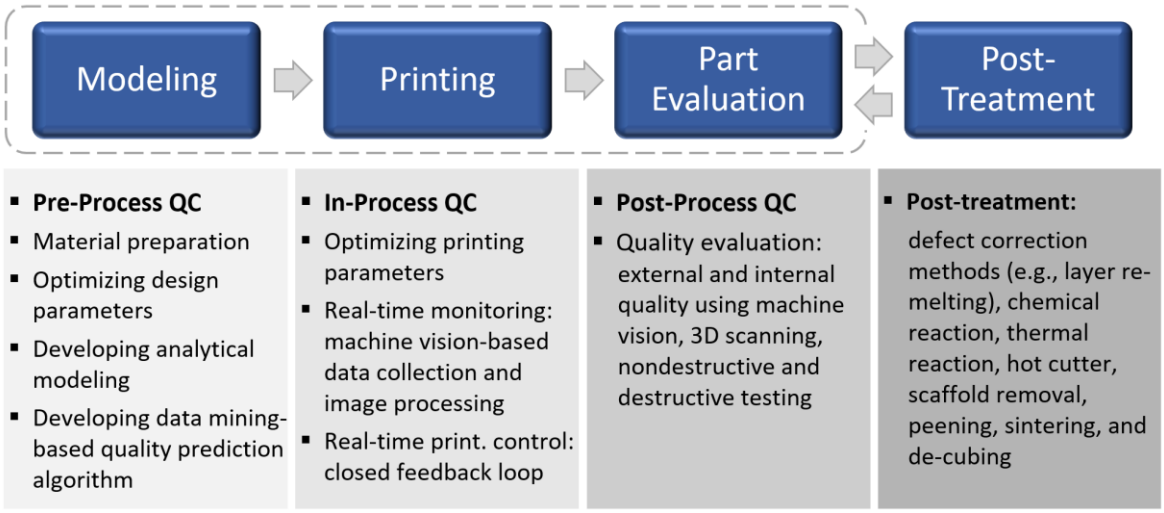


Figure 29: Main process classification in the AM workflow (adapted from H. Kim et al., 2018)

As shown, this structure is in alignment with the schematically outlined design control process adopted by Hollister et al. (2015) for categorizing steps in order to meet the design requirements, which was already used as an example within chapter 3. Based on this, the categorization depicted in Figure 29, proposed by H. Kim et al. (2018), was derived and structured into a more detailed approach to specifically consider the QC tasks individually performed in the manufacturing process.

4.5.1 Pre-Process Quality Control Methods

As exemplified in the first column of the manufacturing flow in Figure 29, pre-processing can include various activities and measurements, such as optimization of design parameters or the development of analytical or predictive models and algorithms, depending on the point of view (H. Kim et al., 2018). In their studies Hollister et al. (2015), for example, pointed out the value of optimized design variables and printing parameters (e.g., layer thickness, infill pattern or printing speed) in order to meet clinical requirements. According to the subject of this work, however, the focus is put on the quality aspects and investigation methods to be considered in this stage, which mainly relate to material preparation. The most important tasks to be performed here are the general quality inspection of the feedstock materials as well as the confirmation regarding their suitability for the products to be manufactured, meaning, to ensure that they fulfill the desired functionality (Charalampous et al., 2020). Not least, the dimensional accuracy, surface roughness and mechanical properties of a part highly depend on proper material quality and thus on inspection, as clarified by several studies (e.g., Ngo et al., 2018). Following, different methods for the pre-process QC are listed and explained in short, based on the findings of a study performed by Charalampous et al. (2020).

One testing method that is preferably used to inspect the filaments in extrusion-based processes is **X-ray tomography**, which is able to detect inclusions and porosity in the filament material. While the former can cause nozzle blockages, porosity, when occurring in high percentages, can result in deteriorated mechanical properties of the manufactured parts. (Du Plessis et al., 2016)

Another X-ray process is **energy dispersive X-ray analysis (EDX)**, which can be applied to identify the chemical composition and metallographic structure of the feedstock material. This is done by generating spectra that represent the elements from which the examined specimen is comprised of. (Cuiffo et al., 2017)

Different (vibrational) spectroscopy methods, such as **Raman spectroscopy**, can be used to obtain information on the crystal structure and molecular vibrations. In further consequence, this method enables to identify and characterize the feedstock material in AM processes. (Cuiffo et al., 2017)

The use of a **scanning electron (or optical) microscope** is a method which is especially applied for powder-based AM technologies, as it allows to measure important material parameters (e.g., shape, distribution, particle size, aspect ratio). The former mentioned method uses an electron microscope to generate images of the examined sample by scanning its external surface with a beam of electrons that creates a topography of that sample's surface. (Spierings et al., 2011)

To measure the density of metal powders used as feedstock materials, the **Archimedes'** as well as **gas pycnometric methods** can be used. The Archimedes' method – in simple terms – is based on comparing a measured density to a reference density using a precision balance (i.e., a reference object attached to the balance is immersed in a liquid, its buoyancy directly indicates the fluid's density). A gas pycnometer, on the other hand, evaluates the density of the feedstock material (i.e., powder) using a specimen (filled with powder) and a reference volume (filled with gas). (Obaton et al., 2018)

4.5.2 In-Process Quality Control Methods

The second stage of the underlying categorization is concerned with the in-process quality control (i.e., *in situ*), which is considered from the setup of the printing process to the completion of the part. Once again, optimizing the printing parameters is one of the most crucial aspects in order to enhance the part quality, rather than having to accept additional expensive and time-consuming rework or treatments during post-processing. (H. Kim et al., 2018)

The application of NDT techniques as inspection methods for real-time monitoring can significantly contribute to saving these resources. This can be achieved, on the one hand, by aborting the procedure if a failure is detected. On the other hand, defects can be eliminated – or at least reduced – by directly incorporating the data obtained into the feedback control system of the AM process. Therefore, the sensors needed to gather this data would be integrated into the build process, allowing any anomalies in the process or built part to be detected and to consequently take potential countermeasures and adjustments while the part is still being produced. Besides process control, *in situ* and real-time characterization offers the additional benefit of qualification and certification of the produced parts, which in turn enables to evaluate reproducibility. (Lu & Wong, 2017a; Charalampous et al., 2020)

It must be noted, however, that the diversity of AM processes and their associated defects require specific solutions, respectively equipment, for each of these technologies, as illustrated in Figure 30. In this Venn diagram, Charalampous et al. (2020) showed some possibilities for real-time monitoring in the currently most used AM processes.

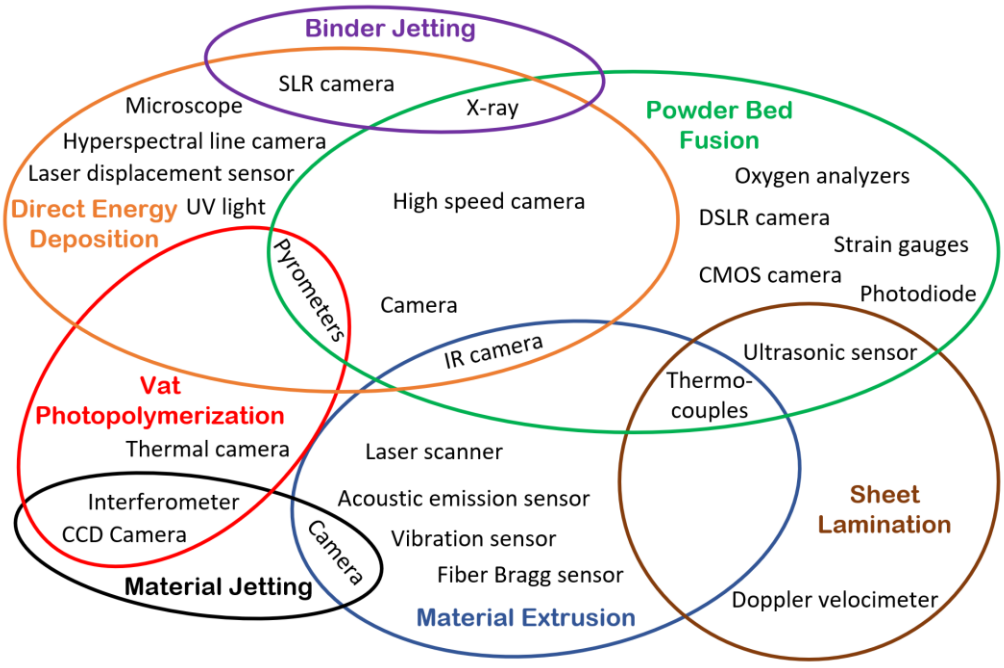


Figure 30: Necessary equipment for *in situ* monitoring (Charalampous et al., 2020)

Among the most promising methods in this regard, but also for post-process QC, are **thermography** and **acoustic emission testing** (Lu & Wong, 2017a) which are addressed in more detail as follows. Moreover, a special emphasis is put on methods that apply in particular to extrusion-based processes.

4.5.2.1 Thermography

Infrared thermography (IR) is used in NDT through the imaging of the temperature field (also called "thermograms") of an examined part's surface. The basic principle of this method relies on different thermal behavior of the internal structure of an object under investigation and its potential flaws. Since discontinuities in the object affect the heat flow and have different heating or cooling rates as the material from which the object is made of, temperature differences occur at the object surface. These temperature differences are consequently cause variations in the emitted radiation that can be detected by thermal imaging devices, usually referred to as "infrared cameras". (Lu & Wong, 2017a)

Generally, there are two approaches of how thermography is used for inspection: *passive* and *active*. Passive thermography measures the natural heat distribution that is emitted across the surface of an object to be inspected, without introducing any energy into that system, making it an ideal application for temperature monitoring purposes. The active approach, on the other hand, is widely used in NDT, applying an external stimulus (i.e., energy is usually brought into the material under investigation). This stimulus generates a thermal contrast on the subsurface defects which again can be detected by quantifying the temperature profile over the examined object. According to Usamentiaga et al. (2014) there are three components involved in an active thermography, as shown in a possible set-up in Figure 31: an excitation source (e.g., a laser), an infrared camera, and a data-processing algorithm, used for the improvement of the obtained thermographic data. (Lu & Wong, 2017a)

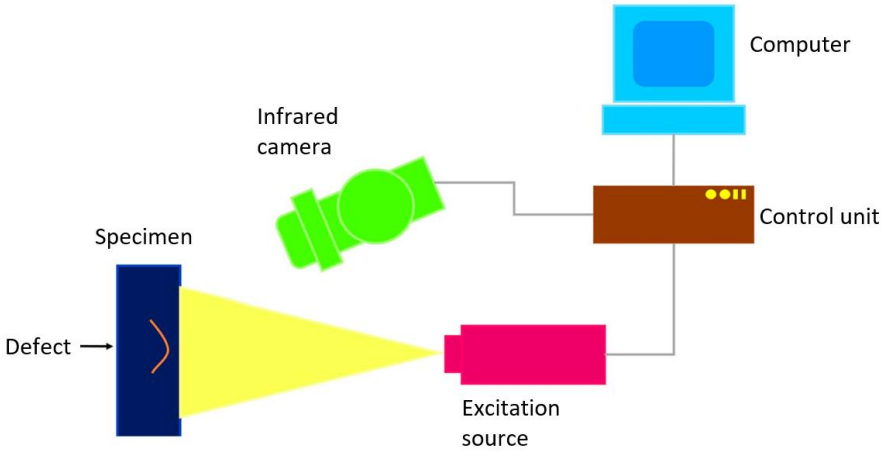


Figure 31: Active thermography set-up (Lu & Wong, 2017a)

In their studies, (Lu & Wong, 2017a) conclude that active thermography is a relatively fast technique, enabling to inspect even inaccessible surfaces of a parts and that is also less sensitive to the influence of a part's surface roughness. However, its penetration capability is limited to a few millimetres and it strongly depends on experience, needed for proper setup and calibration (i.e., influence of material, geometry, sensitivity). (Lu & Wong, 2017a)

Being well-suited method for *in situ* monitoring, active thermography is used for different purposes in AM, such as weld pool-characterisation of metal processes (Waller et al., 2014), but also to rate the process stability SLM or to generate 3D quality reports (Krauss et al., 2014). Moreover, regarding IR's post-processing capabilities, several studies have been conducted, that confirmed its suitability in AM, and especially FDM (e.g., Malekipour et al. (2018); Metz et al. (2018) and Sels et al., 2020).

4.5.2.2 Acoustic Emission Testing

As indicated by Lu and Wong (2017a), the basic principle of acoustic emission testing (AT) is the transmission of sound waves generated by a sudden redistribution of stress in an object to be tested. This phenomenon is utilized when an object is exposed to an external stimulus such as a change in pressure or temperature, resulting in a rapid release of energy from localized sources. These sources, in turn, can be stress and strain fields resulting from e.g., plastic deformations, fractures or cracks. According to Shull (2016), a vital aspect of AE is that signals are also produced by the material itself. Based on this principle, this method gives the possibility to localize occurring discontinuities and to draw conclusions about an object's structural integrity in further consequence. (Lu & Wong, 2017a)

The schematic set-up of acoustic emission testing can be seen in Figure 32: As small stresses are introduced to the test object by cracks or other discontinuities, the generated acoustic emissions are detected by a transducer, converting the sensed wave pulses into electrical impulses. Following, after amplifying, filtering and processing the data are can be observed on a computer. (Lu & Wong, 2017a)

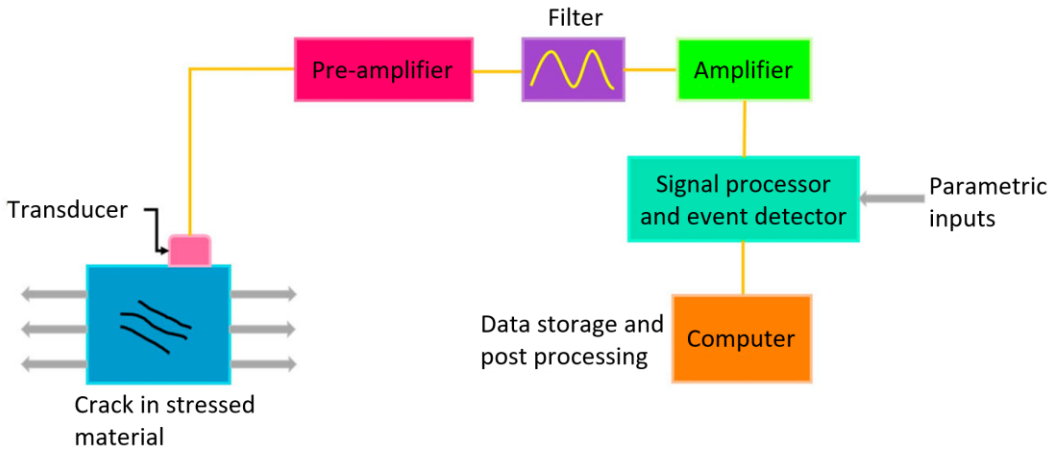


Figure 32: Schematic set-up for acoustic emission testing (Lu & Wong, 2017a)

AT is regarded one of the most sensitive NDT methods, being able to detect cracks as small as 25 µm, and also as one of the most appropriate methods for continuous monitoring or assessing a part's structural integrity. This is not least due to the fact that AT allows for a complete volume inspection, and identification and location of cracks and their propagation. (Lu & Wong, 2017a)

On the other hand, the pending development of different sensors and other equipment are some limiting factor for *in situ* monitoring of AM processes at current. In addition, similar to infrared thermography, experience of the operators plays an important role for the successful performance of this method. (Hossain & Taheri, 2020)

Concerning its application for post-processing, the quality of an AT evaluation depends on the size of the object to be measured (i.e., necessary for proper coupling of the sensor), but also on the surface finish and the object's curvature. Another finding from the conducted literature research is that the Young's modulus of a material affects the inspection, as "soft" materials (i.e., 1.500 MPa for most polymers) mitigate the wave propagation due to their internal damping properties. (Hellier, 2003)

A more detailed investigation with respect to extrusion-based processes, such as FDM, is also given by the study of Charalampous et al., 2020. They summarized the main and the latest real-time QC methods by structuring them according to the most crucial defects associated with this specific AM technology. These typical process-related defects have already been outlined in section 2.6; the respective methods, on the other hand, will be listed in the practical part of this work (see Table 13).

4.5.3 Post-Process Quality Control Methods

The stage of post-process QC and metrology focuses on the deployment of NDT methods for the quality evaluation of a part after the manufacturing process. As indicated in Figure 29, this stage is strongly intertwined with the *post-treatment* of manufactured parts, which includes measures to improve different aspects of the part quality. However, due to the scope of this work, the focus is set on the testing of external and internal part properties, structured according to a finished part's main quality characteristic, again with an emphasis on extrusion-based processes.

4.5.3.1 Dimensional Accuracy

The most accurate method to measure the external dimensions of an AM part is coordinate metrology or more specifically in terms of the used device, by means of a **coordinate measuring machine (CMM)**. According to Sładek (2016), a CMM is a measuring device consisting of contact (tactile) probes to physically sense an object's surface, a mechanical structure moving the probe in the three axes, and a drive (manual or automatic) which records the 3D coordinates data of each of the axes. CMMs can differ in their types of probes (contact or contactless, single or multiple) as well as their mechanical structure or drive controller (Sładek, 2016). As stated by Wyant (2002), using contactless probe systems (e.g., optical sensors) helps to increase the measurement speed and thus, the number of measurement points per time unit.

Another optical measuring method is **structural light 3D scanning**. The basic principle of this technique is to project a spotlight or a beam on the object to be tested in order to obtain a point cloud generated by the light's endured deformation on the object's surface (Charalampous et al., 2020). Barone et al. (2016) found this tool to be cost-effective, enabling to compare an object's external surface with its respective CAD model for validation.

Similarly, **3D laser scanning** can be applied for the same purpose. By using a line of laser light the external geometry of an object can digitally be captured as a point cloud, which is why this technique is favorable for the dimensional accuracy measurements of AM parts. (Stavroulakis & Leach, 2016)

4.5.3.2 Internal Structure and Defects

Being the only technique that is applicable to all materials, **radiography**, or commonly referred to as **X-ray (micro-)computed tomography** (CT or micro-CT) relies on the generation of ionizing radiation (e.g., X-rays) penetrating the material in order to obtain cross-sections of an object. These cross-sections are image-projected onto a film that is sensitive to X-ray radiation, representing the X-ray shadow of the object's interior, called radiograph. If there are flaws, the absorption of the radiation beams will vary in such material areas, being documented on the film. (Lu & Wong, 2017b)

Figure 29 illustrates a schematic set-up of an X-ray computed tomography: Regions with a relatively high absorption of X-rays are producing white areas on the film (i.e., no defects), whereas grey areas indicate low absorption and thus, defects. Furthermore, as another benefit of this technique, the projected radiographs captured from different angles can be used to recreate a 3D model of the investigated object through computer algorithms. These 3D CT reconstructions can then directly be compared to the CAD model of the respective part allowing for various examinations. (Shull, 2016)

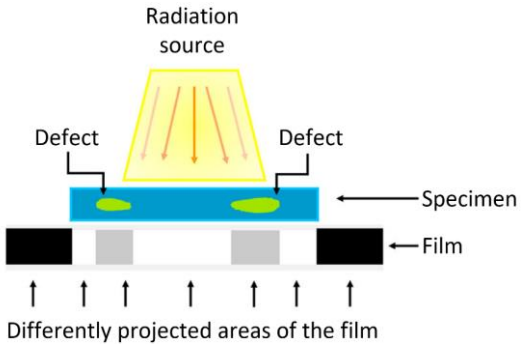


Figure 33: Schematic radiographic set-up (Lu & Wong, 2017b)

Due to its additional capability of characterizing the internal microscopic features of a material, which in turn give information about its mechanical or thermal properties, X-ray micro-CT is also among the best suited NDT methods in AM. However, as outlined by Hellier (2003), there are also limitations to this method, such as the need for highly experienced operators for the analysis and interpretation of the radiographs, safety issues (due to the X-rays as well as the high voltage required to generate them). Other important factors are that X-ray machines are very costly and the overall procedure form obtaining the radiographs to analyzing them tends to be very time-consuming. Also, regarding the practical use, there are thickness limitations and dependencies on the orientation of discontinuities in the material. For most critical applications, on the other hand, the before mentioned advantages prevail, as X-ray CT is mostly unmet in accuracy and permanent record and uninfluenced by material characteristics, like surface or shape. (Lu & Wong, 2017b)

Extensive studies in the field of AM part inspection were also conducted, e.g., by Du Plessis et al. (2018); Thompson et al. (2016) and, especially concerning FDM, by Kio et al. (2018).

Another widely used method for the evaluation of internal voids and cracks, but also for detection of surface features of a manufactured part is **ultrasonic testing (UT)**. The fundamental principle of this nondestructive method is to introduce short, high-frequency pulse signals (i.e., ultrasonic waves) into the inspected object to identify flaws. These waves are generated as well as received by a transducer, as they are reflected by discontinuities in the material (e.g., a surface, feature, flaw or defect). The time difference between the transmitted and received waves after reflection can then be set in relation to the depth or distance from the transducer at which the reflection occurred and further be illustrated on a visual display. Furthermore, measuring these waves allows for general conclusions about the material's integrity to be drawn. Usually, a couplant (e.g., grease or oil) is applied to the specimen to enhance the transmission of ultrasonic waves between the transducer and the specimen's surface. (Lawley, 2015)

Generally, the "three basic methods of ultrasonic inspection include the normal incident pulse-echo, angle beam pulse-echo, and the through-transmission method" (Lu & Wong, 2017b, p. 308).

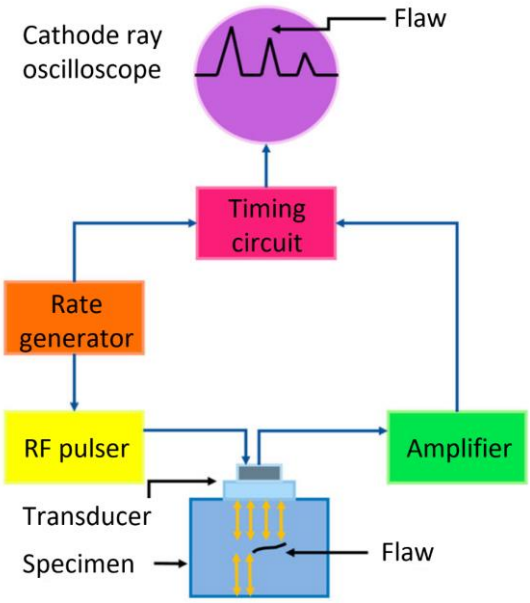


Figure 34: Set-up of a normal incident pulse-echo inspection (Lu & Wong, 2017b)

However, the basic principle of transforming the detected signals back into electrical pulses and reproducing them on a cathode ray tube is the same for all these methods. (Lu & Wong, 2017b)

This principle is exemplified in Figure 34, which shows the schematic set-up of a normal incident pulse-echo inspection as well as a respective pulse-echo display to detect flaws in the material. Concerning the presentation of results, these are commonly illustrated by either A-, B-, or C-scans. While a conventional A-scan can only give one-dimensional information about a flaw (by means of additional calculations), B-scans can display a cross-sectional view of the specimen (i.e., length and depth of a flaw). C-scans, on the other hand, enable to reveal defects parallel to the test surface by rotating the presentation by 90° (i.e., results are shown in the plane of the scan). (Shull, 2016)

Besides X-ray CT, ultrasonic testing is one of the most efficient methods for the detection of internal defects in materials, such as inclusions, slag and porosity (Lu & Wong, 2017b). Also, UT has proven to be a very robust and versatile NDT technique, being applicable for a wide range of materials, using light and portable equipment, and well-suited for "Go/No-Go" testing of manufactured parts without great demands (i.e., no special license, consumables or evacuation of personnel). On the other hand, similar to X-ray CT, UT requires skilled operators for the interpretation of results as well as testing equipment that can be expensive. Some major drawbacks of this method are its inability to detect defects oriented parallel to the surface or such that are smaller than the material's grain structure, as well as its dependency on the examined object's surface roughness. (Hellier, 2003; Shull, 2016)

In a direct comparison to X-ray CT, ultrasonic testing is not as time-consuming, but also not as accurate and, most significantly, not applicable for objects with complex geometries (Obaton et al., 2018).

The application of UT has also been tested for *in situ* monitoring of AM processes, however, mainly for metal-based ones. Nevertheless, as Honarvar and Varvani-Farahani (2020) note, this approach was also followed for FDM in various recent studies. Specifically with respect to the use of UT for post-process QC of parts made by extrusion-based processes, efforts were made, for example, by Tatarinov and Panov (2015) as well as Na and Oneida (2018), who characterized a finished part's surface flatness, internal defects and fusion conditions. Further, they suggested a validation method to qualify and certify FDM-based AM machines applying a standardized part with various features, like discussed in the next main section (Na & Oneida, 2018).

As noted in section 4.5.1, **Archimedes' principle** is another, very simple method to calculate the density of an AM part allowing to infer the object's overall porosity by comparison with the reference one. However, more detailed investigations (e.g., distribution or size of porosities) are not possible. (Obaton et al., 2018)

4.5.3.3 Surface Finish

One of the most accurate methods to quantify an object's surface quality is **atomic force microscopy (AFM)**. This method allows to perform surface roughness measurements in the range of nanometers by using an ultra-fine needle, being attached to a cantilever beam. As the deflection of the cantilever is calculated by a detector, it is converted into an electrical signal, whose amplitude is in turn proportional to the displacement of the cantilever and thus reflects the surface roughness of the object under inspection. (Charalampous et al., 2020)

Grimm et al. (2015) employed a **contact surface profilometer** for their studies of surface roughness measurement. This technique simply monitors the tracing movement of a tip as it falls and rises along with the surface of the examined object. Being a contact method, tactile surface topography, as it is also called, requires a slower measurement speed, and also might cause damage or contamination of the surface (Vora & Sanyal, 2020).

Optical surface profiling, on the other hand, is a contactless method, based on the wave properties of light. The optical path deviation between the reference and the investigated surface are correlated, enabling to measure and visualize the external surface and features. (Palanivel et al., 2016)

With regard to surface measurement methods for extrusion-based processes, the literature research revealed that due to the inherent limitations of the process and the associated known surface finish issues, a wide range of studies focuses on the pre- and post-processing treatment of such AM parts instead. More precisely, according to the research of D. Singh et al. (2018) and Tiwary et al. (2019), enhancement of surface roughness can best be achieved by either optimizing the process parameters (e.g., build orientation, material used, etc.), or by performing particular post-processing treatments. In Table 12 the findings of D. Singh et al. (2018) are presented, which can be used as basic overview of the most suitable pre- and post-processing techniques for FDM parts with regard to surface finish.

Table 12: Pre- and post-processing techniques for FDM parts (D. Singh et al., 2018)

	Technique	Expected surface roughness value
Pre-processing	Adaptive slicing Tessellated CAD and Direct Slicing)	10–100 µm (depending upon part size, geometry)
	optimal part-built orientation (along X-Y-Z axis)	10–100 µm (values for 90° orientation along X-axis)
	optimizing FDM parameters (e.g., orientation, layer thickness, air gap, raster angle, temperature)	20–150 µm
Post-processing (values depend on process parameters and cycles amount)	Barrel Finishing	5–60 µm
	Vapor smoothing	1–20 µm
	Chemical treatment	5–20 µm
	Hot cutter machining	15–90 µm
	Abrasive flow machining	50–80 µm
	Abrasive jet de-burring	50–90 µm

They specifically addressed the improvement of surface finish when they examined the application of AM-fabricated patterns as alternative to conventional wax patterns in investment casting for the production of biomedical implants. These findings indicate that the greatest improvement can be achieved by means of vapor smoothing and chemical treatment. However, it must be kept in mind, that these techniques imply the removal of surface material, which is why post-treatment processes must be considered during the design process. (D. Singh et al., 2018)

Vora and Sanyal (2020) provide an extensive elaboration of the various (general) post-processing methods for parts produced by a specific AM process in order to improve their quality aspects.

4.5.3.4 Chemical Composition

Energy dispersive X-ray analysis (EDX), already being listed among the pre-process QC of materials, can also be applied for the characterization of a finished part's chemical composition as well as to check the deposited layers' chemical homogeneity. Moreover, this technique enables to evaluate the influence of processing conditions as they might affect the part's chemical composition. (Makvandi et al., 2018)

According to Chartier et al. (2017), **spectroscopy**, on the other hand, allows to compare the spectra from the feedstock material and the fabricated part, as resumed by Charalampous et al. (2020).

4.5.3.5 Residual Stresses

Residual stresses are mostly caused by rapid cooling rates – typical in AM processes – which lead to thermal stresses or eventually to part distortions and/ or cracking (Sharratt, 2015). Being a result of the interaction of unfavorable process parameters and conditions, these stresses are mostly evaluated by using **diffraction techniques** (e.g., Raman, neutron or X-ray diffraction). These NDT techniques rely on producing a diffraction by means of a high energy beam through the material to be examined. The internal defects from the diffraction further enable to calculate residual stresses. Like with other specialized NDT methods, experienced operators and respective equipment are crucial for effectively applying these techniques. (Szost et al., 2016)

Other approaches to infer residual stresses are by means of the **finite element method (FEM)** (e.g., Antony Samy et al., 2021; Mayer et al., 2020), but also by using **UT** (Acevedo et al., 2020). A special **combination of FEM and CMM** will furthermore be discussed in the practical part of this thesis.

As a concluding remark to this section, it must be clarified that the presented methods and techniques represent only a fracture of NDT (in AM) as a whole, since several others have not been considered. Some of them are only applicable for metal-based processes (e.g., eddy current or magnetic particle testing), and others are not sufficient for the QC of parts which are used for medical applications (e.g., visual inspection, liquid penetrant testing). (ANSI, 2018)

A comprehensive list of testing methods applicable at respective stages of extrusion-based processes will be provided in section 5.3.1 as part of the framework development. More general listings of testing methods for parts fabricated by common AM processes can be found in the studies of e.g., Charalampous et al. (2020); Lu and Wong (2017b) as well as Vora and Sanyal (2020).

4.6 Use of Test Artifacts for Method Validation

As mentioned in section 4.4, once a method has been selected, a range of relevant requirements lays the foundation for the further validation process. Some of the main goals of validation, in turn, are the "establishment of short- and long-term stability of the method of measurement, and setting of control limits, fine-tuning of the standard operating procedure (SOP)" as well as the "identification of influencing factors" (Czichos et al., 2011, p. 81). Especially if a new method must be developed or adapted for a specific purpose – like in the case of NDT in general applied in AM technology – evaluating its performance by defined requirements and confirming its suitability are vital aspects of method validation (Czichos et al., 2011).

Therefore, besides the mentioned testing methods that are applicable for the present field of interest, the use of test artifacts (called "phantom" in the medical field, section 3.3.1) is treated at this point. These are of great benefit for the above described validation process, as well as for benchmarking tests in AM, as shown by various studies conducted (e.g., Kanters et al., 2019; Leng et al., 2017).

As the literature review reveals, test artifacts are used for a variety of purposes, which include:

- quantitatively evaluate the performance of a machine or process, and compare to others;
- test the capabilities and limitations of a machine or process, identify areas of improvement;
- include features to be extracted for mechanical testing to obtain mechanical properties;
- evaluate a machine's accuracy and repeatability by fabricating the same test part many times;
- evaluate general process issues across AM (e.g., surface roughness due to stair-stepping) (Moylan et al., 2014).

To enable these listed evaluation features and generally, as a means to enhance metrology efforts, Moylan et al. (2014) defined a set of "rules" for the design of test artifacts, such as: having many features of a "real" part (e.g., thin walls, holes), being easy to measure, or having rather basic geometrical shapes, enabling perfect definition and easy control of the geometry. Accordingly, they proposed a suitable artifact, which is illustrated in Figure 35.

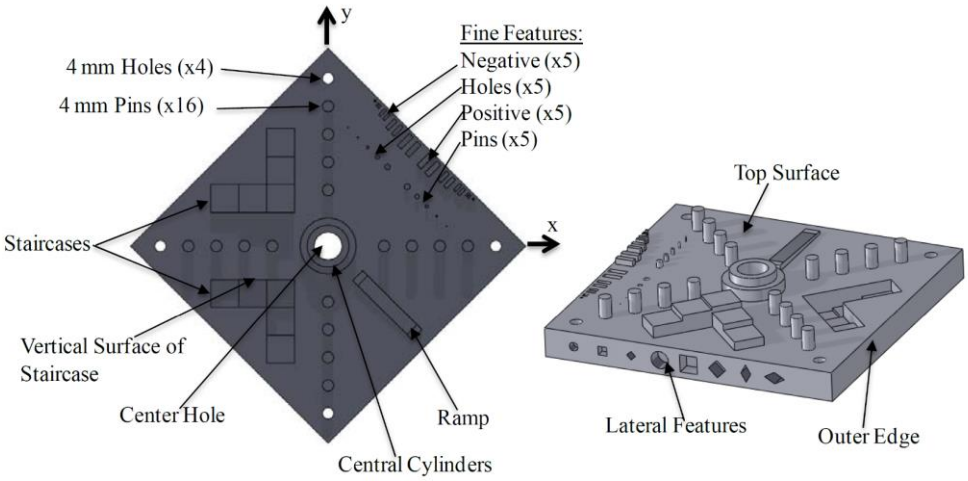


Figure 35: Example for a test artifact highlighting important features (Moylan et al., 2014)

Part III.

Practical Part/
Empirical Research

5 Framework Development

As previously announced in chapter 1.2, it is one of the main objectives of this thesis to abstract the accumulated knowledge and methodology to a generic level. This will be accomplished by establishing a generally applicable step-by-step framework for future projects dealing with similar decision-making processes in the field of medical applications. To ensure a transparent workflow and a better understandability of how this framework relates to the overall project, this concept will be designed to fit into the Use-Case Technology-Mapping framework (UCTM) in turn. Generally, the UCTM framework will serve as the main guiding structure throughout this thesis.

At the beginning, the concept of the UCTM framework as the leading structure is explained. Further on, the main requirements and the intended range of validity of the to be developed "Testing Method Selection (TMS) Framework" are defined. These methods, that will eventually be applied in the course of the use case within chapter 6, are described in detail in chapter 5.3. Finally, in chapter 5.4 the complete framework is presented thoroughly.

5.1 The UCTM Framework

In many situations, decision-makers and stakeholders are facing the crucial question of how to choose the right technology for the improvement of a specific process and furthermore, how to best implement this new technology into an existing or new infrastructure. This *mapping* process between technology on the one side, and suitable use cases on the other side, is fundamentally what the UCTM framework developed by Vorraber et al. (2019) is dealing with. Originally designed for the implementation of dynamic capabilities in business model and service innovation, this framework is applicable for a wide range of scenarios and projects as it provides a general guidance on how to identify, select and eventually implement different use cases and technologies in a systematic way. Figure 36 exemplifies an application for mountain rescue missions in the Alps. (Vorraber et al., 2019)

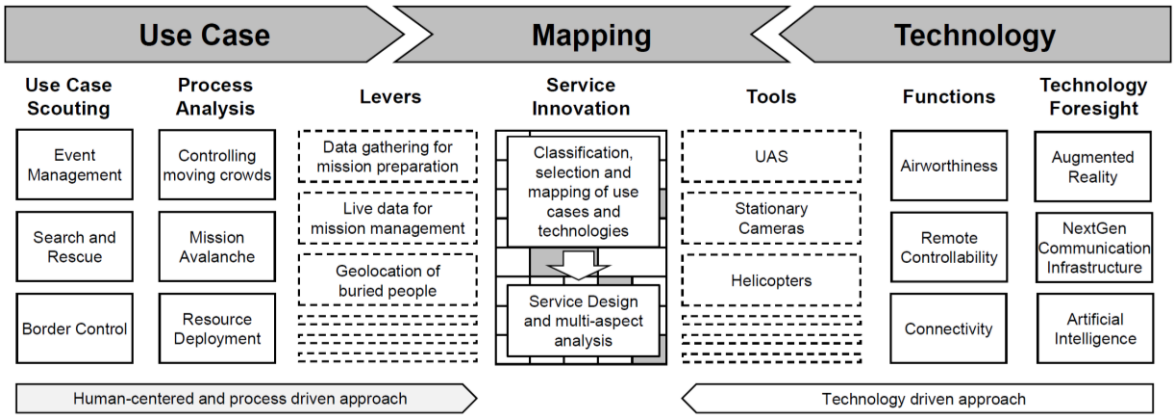


Figure 36: Use-case technology-mapping (UCTM) framework (Vorraber et al., 2019)

The approach is reflected in its structure, resulting in two basic concepts (Vorraber et al., 2019):

- The *human-centered and process-driven approach* strives to identify the specific needs of the individuals of an organization. This is mainly achieved by requirements engineering and human-centered analysis, finally leading to possible improvement levers represented by specific use cases (*use-case triggered path*, indicated by the figure's bottom left arrow). However, another way of selecting these use cases can be by including the experience and knowledge of experts – which is particularly true in the present use case.
- The *technology-driven approach* is based on enabling innovation through recombination of existing influencing factors. To turn this into practice, an analysis of the current as well as the estimated future development needs to be done in order to learn about any possibilities of meeting user needs by creating appropriate tools and services (*technology-triggered path*.)

Ultimately, these comprehensive bottom-up and process-driven approaches result in three main process steps which are executed in a simultaneous and iterative manner. The illustrated *Use Case* respectively *Technology* arrows meet in the center, connected by the *Mapping and Design* arrow, which symbolizes the process of matching the most promising use cases to the best fitting technical solutions in order to create innovative concepts. In this way, the UCTM framework enables not only the analysis of the arising technical possibilities, but also the continuous sensing of processes on various levels as well as continuous technology sensing and assessment. The latter will act as an inspiration and interface for the framework to be developed. (Vorraber et al., 2019)

5.2 Requirements for the Framework

After the UCTM framework has been discussed in order to gain a general understanding of the underlying idea of effectively combining suitable use cases and technologies, preconditions as well as the intended field of application for the associated TMS framework will be elaborated at this point.

A clear definition is crucial to ensure an as straightforward as possible development process on the one hand, but also to facilitate a seamless transition between the two frameworks on the other hand. The general interface will therefore be set up at the *Mapping* step of the initial UCTM framework, since this is where the TMS framework to be developed is being established and will serve as a subsequently applicable guidance for the selection and decision of appropriate technologies (e.g., testing methods in the case of this project). By stating this, the following requirements are placed on the framework, leading to a principal scheme, which is roughly outlined in conclusion in Figure 37:

- *Provision of a knowledge basis*
  With particular regard to its practical intention, the to be developed framework is expected to include a comprehensive pool of methods or possibilities, out of which the most eligible ones are to be selected in the total process. This can be realized in the form of a structured list or catalogue which is supposed to serve as a starting point of the whole process.

- *Clarity*
  A vital aspect for the design of the framework is to make it a simple and easy to follow process model. This should be achieved by a clear and well-structured layout that specifies a fixed sequence of essential process steps allowing to put the focus on the actual content that needs to be processed. Moreover, a noticeable distinction between the main process sections of selection and decision should facilitate the overall understanding.
- *Provision of suitable tools*
  Additionally, to underline its practicability, the framework should specifically offer a range of well-proven tools or measures for each particular process step, which are suitable to perform the defined task of that very step. The suggested tools should fit into the overall concept of a complex decision process model and further provide a basic infrastructure in order to increase productivity and accelerate the development of solutions.
- *Content specifications*
  Similar to the previously mentioned aspect, brief descriptions and guidelines with respect to its specific content and purpose should be provided for each process step to increase the framework's ease of use. Also, further remarks or explanations can be placed in this section to contribute to the clear arrangement of the main workflow.
- *General applicability and flexibility*
  Again, with the UCTM framework as a reference, a general goal of this TMS framework is to act as an adjustable and therefore widely useable tool. By leaving enough room for specifically necessary adaptions and flexibility, this approach should be able to suit different selection and decision-making processes throughout the field of medical devices and their applications.

As mentioned before, Figure 37 elaborates on the basic layout for the framework to be developed, directly derived from the determined requirements above and further refined in the next sections.

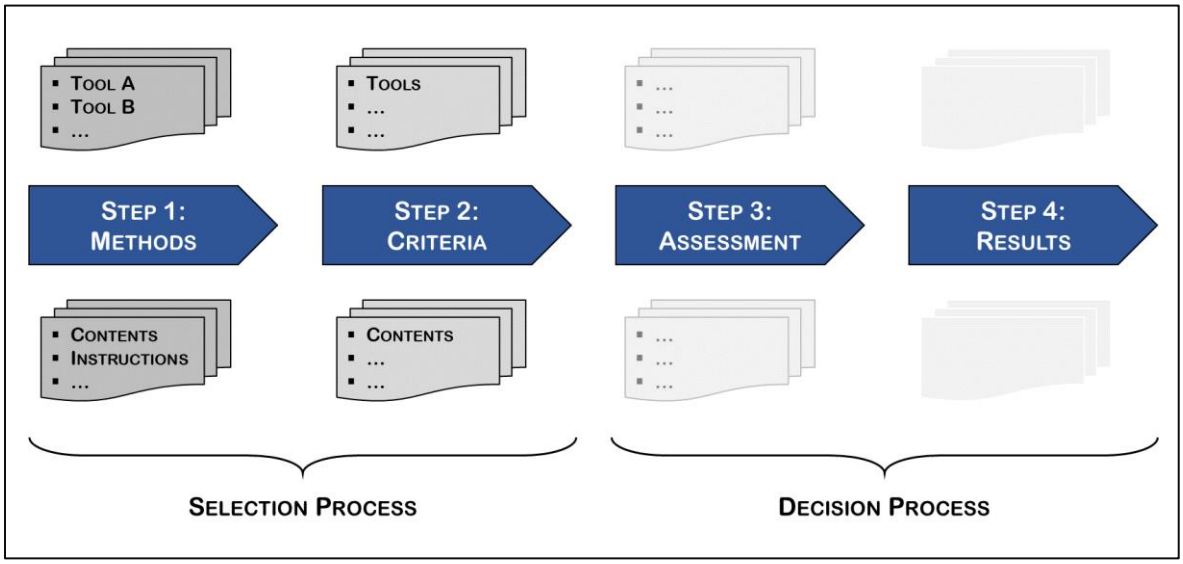


Figure 37: Fundamental scheme of the TMS framework, derived from the requirements

5.3 Process Design and Chosen Application Tools

Through the identification and clarification of the necessary requirements, the foundation for the development of the TMS framework has been laid, enabling to derive the main steps of the generic process scheme. Figure 38 depicts these steps, which are presented in more detail throughout the next subsections. At the same time, those methods ("tools") that are applied during the respective process steps in the present use case (chapter 6) will be presented and explained in this context.

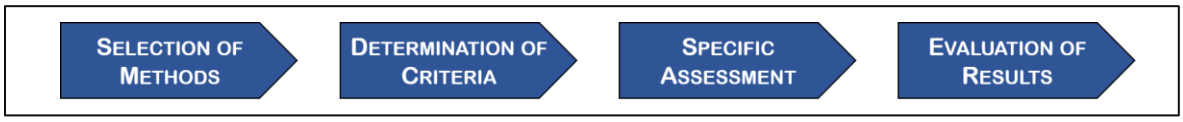


Figure 38: Basic steps of the TMS framework

5.3.1 Step 1: Selection of Methods: Existing Databases and Catalogues

The framework's initial main process step *Selection of Methods* directly complies with the first identified requirement of providing a fundamental knowledge basis in order to set a starting point for the overall selection process. As suggested in the description of the requirement, this can best be implemented through a comprehensive list or a catalogue of potentially appropriate and relevant methods, which further can systematically be structured and filtered according to some initial criteria. In case this fundamental list does not fully cover all eligible methods for an examined application, an additional screening of suitable methods and possibilities in related other disciplines might be necessary at this stage, e.g., through an optional update of literature or consultation of experts or researchers as shown in Figure 39.

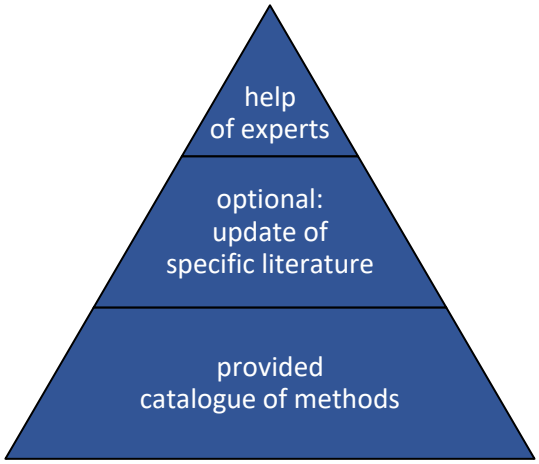


Figure 39: Possible approach for listing suitable methods

As essential basis of this pyramid-like model, the basic catalogue of methods has originally been created within this section, presented in Table 13. This catalogue is based on a literature review representing the current state of development in the field of product testing or inspection, focusing on methods that might as well be appropriate for 3D printed objects, of which some important ones have already been discussed earlier in chapter 4. As an important constraint, only methods which have at least been successfully applied in FDM manufacturing, were included in the list. In particular, the shown catalogue provides information about the specific part characteristics that can be evaluated and also the required machines or tools for doing so. To facilitate a rough overview and filtering of the overall list, a general subdivision was established according to the process stage of manufacturing addressed by a particular testing method (*pre-*, *in-* and *post process quality control* and *others*), partly based on some of the most recent and comprehensive papers resulting from the literature research. These are listed on top of the catalogue. In the present use case of this work only post-processing methods will be considered.

Table 13: List of testing methods

Testing Method for Quality Control (QC)	Type of Inspection	Test Equipment/ Tools	Main Source
*Which **method** is suitable for the quality control and verification?*	*Which **property of the product** is tested or **defect prevented**?*	*What **machines or tools** are required for testing the part?*	** Charalampous et al. (2020)* *** Lu and Wong (2017a; 2017b)*
Type I: Pre-Process QC			
X-ray tomography of filaments	defects in filament material	X-ray tomograph	Du Plessis et al. (2016)*
Energy dispersive X-ray analysis (EDX)	chemical composition (feedstock)	EDX analysis detector	Cuiffo et al. (2017)*
Spectroscopic techniques (e.g. laser, Raman, X-ray)	chemical composition (feedstock)	various spectroscopic devices	Cuiffo et al. (2017)*
Type II: In-Process QC			
Optical methods	filament breakage (prevention)	optical sensor, camera	Nuchitprasitchai et al. (2017)*
Acoustic emission (AE) testing techniques	filament breakage (prevention)	AE sensor	Wu et al. (2017)*, Yoon et al. (2014)**, Hossain and Taheri (2020)
Acoustic-based techniques	failure of first layer (prevention), extruder monitoring	AE sensor	Wu et al. (2015)*
Theoretical-practical technique (dynamics simulation), vibration sensor	nozzle clogging (prevention)	vibration sensor	Tlegenov et al. (2017)*
Modular two-dimensional laser triangulation scanning	geometric errors (prevention)	laser scanner and camera	Faes et al. (2016)*
Vision-based methods (single- or double-camera system monitoring)	geometric errors (prevention)	camera set-up	Nuchitprasitchai et al. (2017)*
Thermography (infrared imaging)	temperature control, monitoring	infrared camera, calibration tool	Seppala and Migler (2016)*, (Lu & Wong, 2017a) (reference)
Three-dimensional image correlation	defects detection, geometrical errors (prevention)	cameras	Holzmond and Li (2017)*
Fiber Bragg grating sensors	residual stresses (prevention)	fiber Bragg sensor	Kousiatza et al. (2019)*

Type III: Post-Process QC			
Coordinate metrology (tactile or optical)	dimensional accuracy	coordinate measuring machine	Salmi et al. (2013)*, Vora and Sanyal (2020) (reference)
Structural light 3D scanning	dimensional accuracy	3D structural light scanner	Barone et al. (2016)*
Three-dimensional laser scanning	dimensional accuracy	3D laser scanner	Stavroulakis and Leach (2016)*
X-ray micro-computed tomography	internal structure and defects	industrial computed tomograph	Du Plessis et al. (2016)*, Du Plessis et al. (2018; Kio et al.);
Ultrasonic testing	internal structure and defects	ultrasonic scanner	Obaton et al. (2018)*, Honarvar and Varvani-Farahani (2020)
Thermography	internal structure and defects	excitation source, infrared camera, data processing algorithm	Siegel et al. (2020), Carvalho et al. (2019), Lu and Wong (2017a) (ref.)
Acoustic emission (AE) testing	internal structure and defects	excitation source, AE sensor	Lu and Wong (2017a) (reference)
Archimedes' Principle (Scales)	density (reference for porosity)	Archimedes scales	Obaton et al. (2018)*
Atomic force microscoping (AFM)	surface finish	atomic force microscope (AFM)	Grimm et al. (2015)*
Tactile surface profiling	surface finish	contact surface profilometer	Grimm et al. (2015)
Optical surface profiling	surface finish	optical sensor device	Palanivel et al. (2016)*
Diffraction techniques (neutron, XRD)	residual stresses	X-ray diffractometer	Szost et al. (2016)*
Ultrasound (Electrical, Magnetic) Methods	residual stresses	(no specific information for extrusion-based processes)	Charalampous et al. (2020) (ref.)
Energy dispersive X-ray analysis (EDX)	chemical composition	EDX analysis detector	Makvandi et al. (2018)*
Spectroscopy methods	chemical composition	various spectroscopic devices	Chartier et al. (2017)*
Others: Learning-based Approaches (In-Process QC; examples)			
Support vector machine-based method	printing faults and errors (prev.)	various IT assets, etc.	Hu et al. (2019)*
Machine vision techniques	printing faults and errors (prev.)	various IT assets, etc.	He et al. (2019)*
Artificial neural networks and Taguchi's parameter design	printing condition monitoring (prediction, optimization)	various IT assets, etc.	Sood et al. (2009)*
Shape deviation predictive technique	dimensional accuracy	various IT assets, etc.	A. Wang et al. (2017)*

5.3.2 Step 2: Determination of Criteria: Value Proposition Canvas

During the second main step of the framework, resulting from the requirements to be met, all criteria that have to be considered in the context of the discussed project, and by means of which the selection of appropriate methods is further narrowed down, are determined. This step is very important, since at this stage of the process the final examination of the essential requirements, general influencing and decision factors, but also the expectations regarding a possible method to be chosen takes place. Therefore, taking enough time for thoroughly getting familiar with the overall project situation is crucial in order to address all the aspects and members involved. Not least, the complexity and effort of the subsequent decision-making process are strongly dependent on the degree of work put into specifying these relevant selection criteria: the more precisely the criteria are being defined, the more confidently the decision can be made.

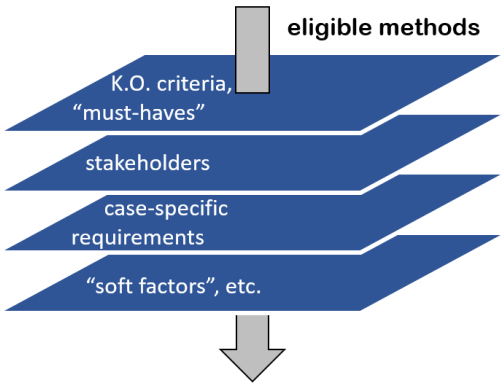


Figure 40: Stepwise filtering model for selection criteria

In order to gain a clearer understanding of how to determine specific criteria and how they help to narrow down the pool of suitable methods in a structured manner, Figure 40 offers a schematic approach for a stepwise selection process: In an initial step, the eligible methods have to pass the first "filter", represent the absolute "must-have" characteristics that a method specifically needs to be able to comply with in the scope of the use case it is matched to. Furthermore, the stakeholders and their individual interests should be thought of at this point. There also might be case-specific criteria or "soft factors", such as organizational preferences or scalability concepts, which can be taken into consideration and/ or discussed here. All in all, it becomes apparent, that during this main step all parties need to come together in order to state their interests and expectations, but also in order to clarify their interdependent relations.

Therefore, among many available methods and concepts for fulfilling this demand, the so-called *Value Proposition Canvas (VPC)* by Osterwalder et al. (2014) is chosen to analyze the present use case. This tool is ideal to identify and display the stakeholders' needs as well as possible solutions for further deriving the mentioned decision factors in a structured and easy-to-understand manner.

Being an integrated tool of the founder's well-established broader concept of the *Business Model Canvas*, which generally facilitates the creation of values for a business, it directly takes a detailed look at the relationship between two of its fundamental parts, value proposition and customer segments. In this way, the Value Proposition Canvas can be used to ensure that a product or service is being developed just according to what the customers really value and need, but also to place the spotlight on the fit between the product and market. (Osterwalder et al., 2014)

Figure 41 illustrates the provided framework that is used later on in the course of the present project, highlighting at first glance its two building blocks and their respective composition which are described in more detail in the following.

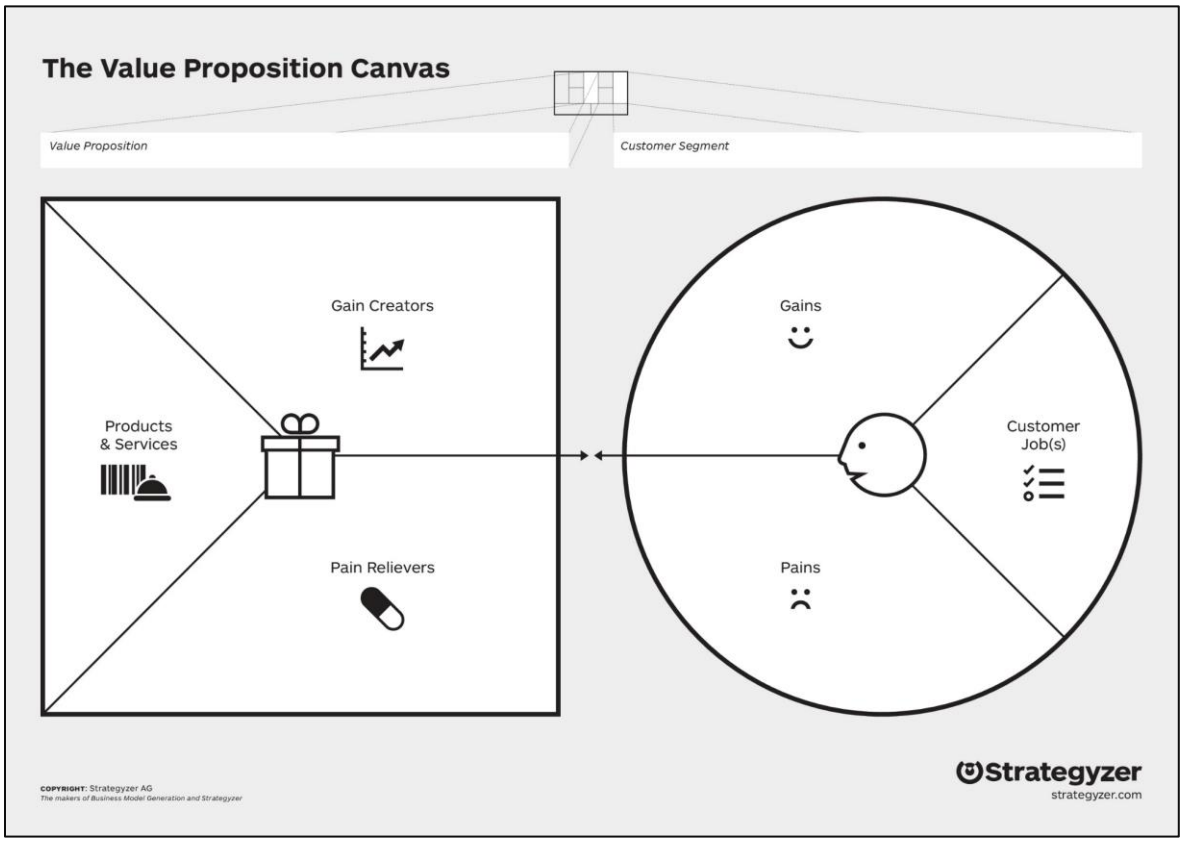


Figure 41: The Value Proposition Canvas (Osterwalder et al., 2014)

On the right side, the *Customer Profile* is positioned, used as a tool to visualize what matters to specific segments of customers, or respectively all the stakeholders and decision-makers involved in case of a project. More precisely, Osterwalder et al. (2014) further break customers down into:

- *Customer Job(s)*
  In this section the general things a customer wants to achieve are described, ranging from performing or completing a task, through solving a problem, to satisfying specific needs. Attempting to evaluate jobs from the customer's point of view, or, at best, involving them directly if possible (e.g., by means of questionnaires or interviews), is key here. Moreover, the fact that not all jobs are of equal importance to a customer should also be considered in order to set the focus accordingly.
- *Pains*
  Customer pains can be anything annoying a customer along the whole process of getting a job done or keeping them from doing so. They may be undesired outcomes or problems, obstacles or risks in terms of negative consequences in case something goes wrong. Like the customer jobs, pains can also be rated, specifically based on their severity.
- *Gains*
  Desired benefits and outcomes of the customer, such as functional utility, social gains or cost savings, are described as gains within this framework. These can occur as required, expected, desired but also as unexpected gains, going even beyond customer expectations.
  A particular gain relevance can express whether a gain is essential or rather a "nice to have".

As a representation of how values should be created for the customer, i.e., how to ease pains and create gains in detail, the *Value Map* on the left side of the presented canvas forms the functional counterpart of the Customer Profile. Similarly, the Value Map is composed of three parts, namely, products and services, pain relievers and gain creators (Osterwalder et al., 2014):

- *Products and Services*
  As already given away by its definition, this section simply lists all the products and services that the value proposition itself arises from, on the one hand, and which enable customers to get their various kinds of jobs done or satisfy basic needs, on the other hand. Similarly to the customer jobs, it is true for the offered products and services, that they are of different relevance to the customer, as they depend on the entire customer profile.
- *Pain Relievers*
  The extent to which specific customer pains are addressed and how exactly this can be accomplished through the offered products and services is described here. Focusing on a few (extreme) pains can be most alleviating and therefore be rated as of high relevance.
- *Gain Creators*
  In contrast to the pain relievers, the gain creators specify the way the offered products and services are creating customer gains in order to target the previously described desired outcomes and benefits. Same again, those gain creators should be given priority that are likely to be most relevant to customers.

Once the Value Map is filled with information about the products and services, as well as their respective attributes, mapping them to the customer's pains and gains within the Customer Profile is the next step, as intended by Osterwalder et al. (2014). This step, called achieving *Fit*, forms the essence of value proposition*:* Each match identified is ranked according to its value to a customer, further enabling to focus on the important jobs, alleviate extreme pains and create essential gains. However, it should also be made clear, that not all customer pains and gains can be addressed. The ability of products and services to create value is always related to the situation of the customers. (Osterwalder et al., 2014)

Summarized, the VPC serves as a suitable tool for the elaboration and illustration of the customers' needs, pains and gains and the respective services and products. Having created this well-structured visualization of the whole project situation and its complexity, specific assessment criteria can be derived at the end of this main process step. These criteria, in turn, will further help to decide on which testing methods are most suitable for a current situation.

At this point it should be noted that extracting these assessment criteria from the VPC is a very individual process that varies from use case to use case: Some criteria might emerge directly from an important pain or gain of the Customer Profile (e.g., "must-have" criteria) or from the input of an involved stakeholder. Other criteria might become apparent only in a more detailed view or can be captured through combination of several findings of the Value Map and/or the Customer Profile.

Nevertheless, other specific and limiting aspects that can potentially not be perceived through the VPC must also be considered (e.g., specific regulations, circumstances of a project). For this reason, experts and scientific literature should also be involved in identifying criteria.

5.3.3 Step 3: Specific Assessment: Value Benefit Analysis

After all eligible methods have been captured and listed, and the criteria for the selection process have been determined and visualized by means of specific tools, the developed framework then leads into the second main section, the decision process. Here, the just mentioned findings are to be condensed into a joint step, on which basis a comprehensive and transparent decision can be enabled for a certain scenario. For this step, defined as *Specific Assessment*, a set of methods and tools are available that are intended to be used for different kinds of decision-making situations. These can be distinguished into qualitative and quantitative methods, to be applied depending on the stage of the technology assessment. In accordance with Schuh and Klappert (2011), qualitative methods should be used during the early (detection) phase of new technologies of a business to gain insights about their potentials and limits facilitating the overall technology decision process.

Consistent with this specification, the so-called *Value Benefit Analysis* (also known as *Scoring Model*) is a well-suited procedure for the multi-criteria assessment of a variety of complex strategy alternatives, e.g., with regards to the decision process between different testing methods for 3D printed products as applied in the next main chapter. Using this method, a wide range of qualitative criteria can be quantified and thus be made comparable with one another through the subjective assessment of experts. The result of the step-by-step methodology described below is a ranking of the technologies or methods evaluated and the assessment criteria used (Schuh & Klappert, 2011). The involved steps of this procedure are the following:

1. Determination of the assessment criteria
   (already done in the second step of the framework)
2. Weighting of the criteria
3. Assessment through the subjective rating of experts
4. Calculation of the specific values of benefit

Since the analysis will be conducted thoroughly as an essential part during the practical part of this thesis, only a rough outline of the underlying concept shall be elaborated in this section.

Prior to the assessment, the weighting factor for each criterion needs to be determined, which is done, for example, by a pairwise comparison, that additionally results in a ranking of all criteria. The specific weighting factors are then incorporated into the decision matrix, exemplarily depicted at the top of Figure 42. There, they are multiplied with the assessment grades assigned by experts to directly relate the determined criteria to each alternative by their net values, ultimately resulting in a total net value of benefit for the respective method. Based on these total values, representing all the relevant criteria as well as the experts' opinions, the ranking is finally made.

This possibility of providing a quantified comparison between a wide range of alternatives for a decision process is one of the method's major advantages, forming a solid basis for further in-depth discussions.

Assessment Criteria	Weighting	Strategy Alternatives					
		Mehtod A		Mehtod B		Mehtod C	
		DoF	Value	DoF	Value	DoF	Value
Criterion 1	15	3	45	2	30	4	60
Criterion 2	3	0	0	0	0	4	12
Criterion 3	9	2	18	4	36	0	0
Criterion 4	11	4	44	0	0	1	11
Criterion 5	23	0	0	4	92	1	23
Criterion 6	15	2	30	4	60	0	0
Criterion 7	24	0	0	2	48	4	96
Total Value	**100**		**137**		**266**		**202**
Ranking			**3**		**1**		**2**

	Assessment Grades				
Degree of Fulfillment (DoF)	**––**	**–**	**0**	**+**	**++**
Number of Points	0	1	2	3	4

Figure 42: Characteristics of a Value Benefit Analysis (based on Schuh and Klappert, 2011)

5.3.4 Step 4: Evaluation of Results: General Discussion

Having a complete list of all alternatives that eventually made it through the selection process and which subsequently have been compared and ranked in full consideration of the decision criteria, the framework's final main step is dedicated to the *Evaluation of Results*. Generally, since this is the last step of the proposed process model, its importance is especially emphasized at this point. Because even though a structured preparation of all information to be included in the decision process has already been given by the previous step, there should still be left room to refine the overall decision process in order to promote both, a more detailed examination of the specific alternatives and acceptance of the subsequently selected solution (Schuh & Klappert, 2011).

Hence, this concluding step represents an incomplete array of tasks that may be carried out during a general discussion before agreeing on a set of final alternatives (respectively methods):

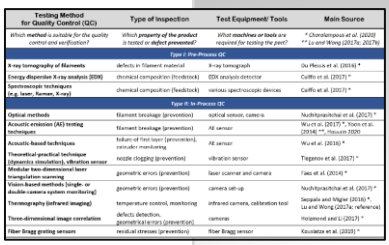
- Ensure that the whole process, from selecting the relevant criteria, up to deciding about the most appropriate alternative, is being understood by all stakeholders.
- To prove the validity of the decision method used, i.e., in terms of ranking the results, a (minor) modification of some criteria's importance can be performed in order to see if major changes in the outcome occurred or the ranking maintained. Also, iterations within some of the process steps could be performed or even become necessary.
- If possible, field tests or experiments should be conducted for every major alternative to additionally gain insights about influencing factors that may have been missed during the actual process and which further could be significant for the final decision.
- Also, an individual comparison of the results obtained and the initial expectations of stakeholders might be an essential enhancement, possibly leading to a "mixed-approach" that could not even have been contemplated before.

5.4 Framework Completion

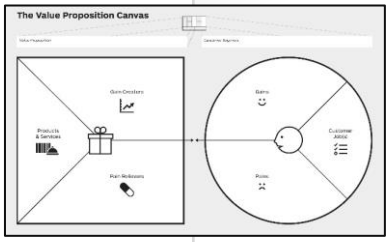
The previous sections of this chapter provided a detailed characterization of how each step of the established generic TMS framework should be interpreted and performed to ultimately lead to a solid and well-thought-out decision that is based on suitable tools and methods. Also, in chapter 5.2 requirements for this framework have been considered, which then served as a guideline throughout its development.

The complete framework is illustrated in full detail in Figure 44. It shows the four main process steps in the center, which are subdivided into the selection and the succeeding decision process. Moreover, a range of suitable tools proposed for each step and a short description of its individual content, specific purpose as well as subtasks are provided to meet the determined requirements. The bold tools in the framework are the ones being applied in the present use case, as separately summarized in Figure 43.

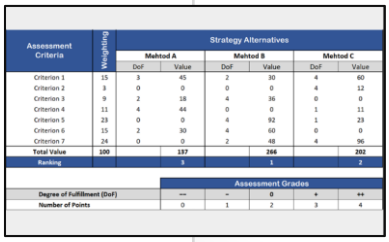
Step 1: **List of Testing Methods**



Step 2: **Value Proposition Canvas**



Step 3: **Value Benefit Analysis**



Step 4: **Stakeholder Discussion and Final Decision**

Figure 43: Summary of methods used in the TMS framework

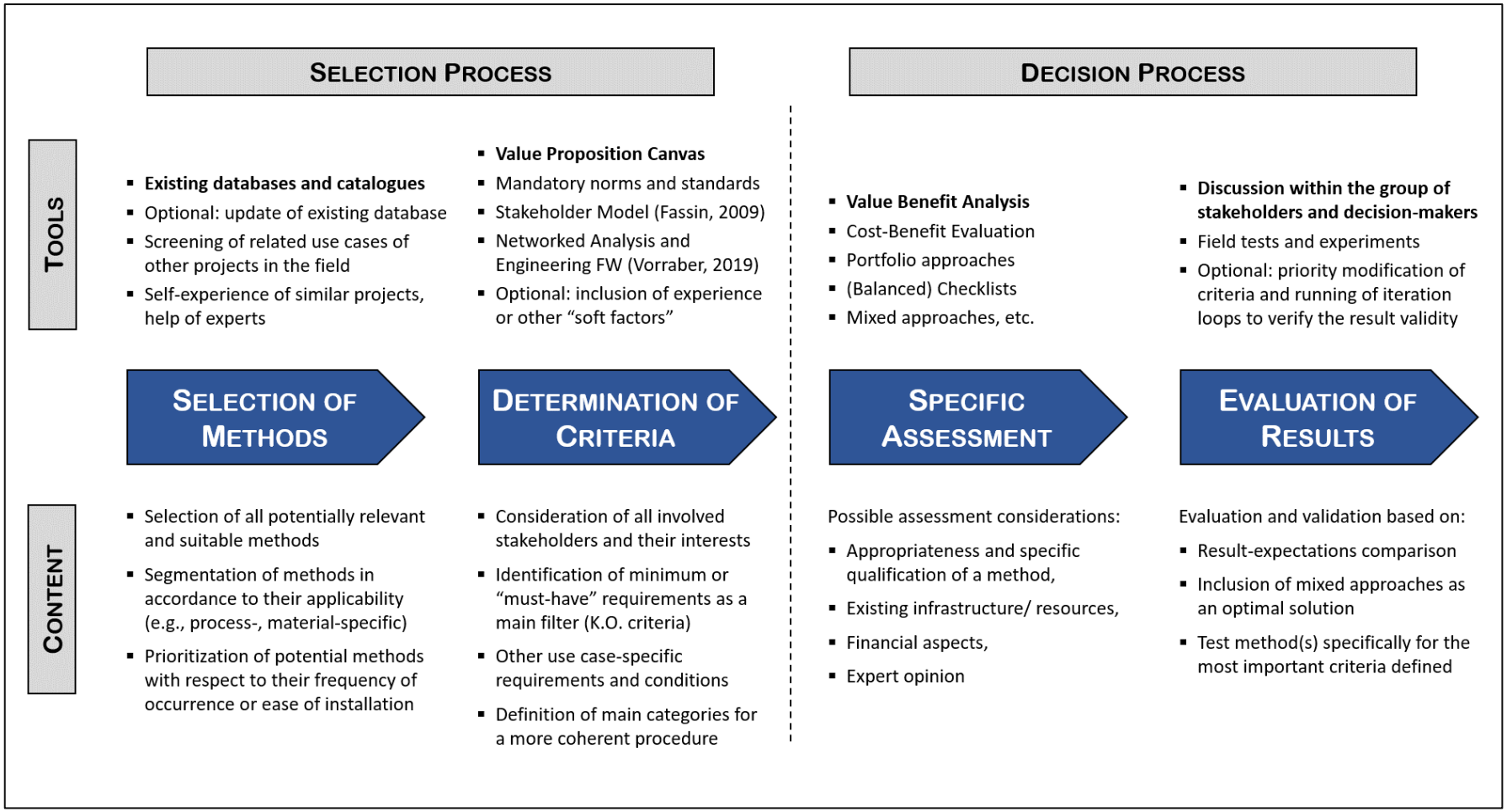


Figure 44: Complete TMS framework, detailed form (illustration based on Lichtenegger, 2011)

6 Case Study

As the present thesis is concerned with AM for medical applications in a general context, this chapter focuses on the selected case study which specifically deals with testing methods for cranial implants made of PEEK. After highlighting the environment and the goal of the overall project in more detail, the application of the TMS framework developed in the previous chapter follows. On the one hand, this leads to the selection of suitable testing methods as the final result for the present case study, and simultaneously serves as a direct proof of the framework's validity on the other hand. Finally, this chapter closes with the presentation of the most suitable testing and investigation methods.

6.1 Project CAMed

In the course of CAMed, a broad spectrum of scientific and industry partners is brought together, which subsequently form an interdisciplinary network of clinicians, medical scientists and engineers. This allows all members to contribute specific knowledge and expertise on the one hand, but also to benefit from the overall findings and developments along the project on the other hand. The primary goal of the project is to progress the development of AM for medical purposes, in order to enable the production of patient-specific implants and protheses for various medical applications directly in the clinic, as stated above. Further applications to be realized in this project include patient-specific anatomic models for the education of students and likewise for pre-surgical planning, surgical aids, up to the big future goal of printing soft structures as well, such as different kinds of artificial tissues. Thus, the technical processes to be developed in this project range from the acquisition of necessary patient data via MRI and CT, to material research and application design, to the simulation and evaluation of future implants by its partner institutions. (Medical University of Graz, 2020)

Due to the complexity of the overall project, CAMed is split into two main areas (polymer materials, metals and ceramics) which in turn are subdivided into a total of six individual research projects, in which various AM technologies as well as materials will be examined for their clinical applicability. More specifically, subproject P1.3, for example, deals with the topic of "FFF-generated craniofacial implants made of thermoplastic polymers by means of 3D scanning". The first task, enabling the production of a 3D-printed patient-specific cranial implant during the patient's surgery, was already completed in a previous project. The development of a comprehensive 3D scanning method for clinical practice, however, is still under research by another team of the Technical University of Graz.

6.2 Motivation for AM of Cranial Implants

Since the above-mentioned subproject is the most advanced field of research within CAMed's main area of polymer applications it was therefore chosen as a suitable basis for the area of investigation of the present case study. Therefore, its underlying motivation is specifically addressed at this point. Some reasons necessitating cranioplasty (e.g., reconstruction following tumor-associated surgery, trauma) as well as the technological solutions offered by AM have been explained in chapter 2.

Here, a direct comparison between the current clinical routine and the envisioned future procedure is provided (i.e., in-house manufacturing) to facilitate a clear understanding of this project's intention and its potential value for the clinic. Moreover, this understanding will also be of great benefit when discussing the applied TMS framework.

6.2.1 Current Clinical Routine

At present, the design and manufacturing of cranial implants is carried out by – respectively *at* – professional companies, posing a crucial bottleneck in the overall process chain of cranioplasty and making it, most of all, a very costly and time-consuming procedure (Li et al., 2020). In a case study, published by an involved manufacturer of metal AM machines, where a brain tumor was to be removed, the typical process steps after completing the surgery were described as follows:

- acquisition of imaging data (e.g., postoperative head CT scan) (in the *clinic*);
  - *transfer* of the head CT scan of the patient to a third-party manufacturer;
- segmentation of the skull in the imaging data (at the *manufacturer*);
- conversion of the skull to a 3D CAD model (*manufacturer*);
- patient-specific implant design and manufacturing based on the model (*manufacturer*);
  - *transfer* of the manufactured implant to the clinic;
- conduction of a second surgery, implantation (*clinic*) (Li et al., 2020; Renishaw plc, 2017).

A detailed overview of an entire ordering process is shown in Appendix A (DePuy Synthes, 2011). As the cited case study also reveals, several (online) coordination meetings between the surgeons in the clinic and the manufacturer's technicians, high efforts both in distance and time, and a resulting high financial burden for the healthcare system – to name only a few – need to be taken into account, to make such a project work (Renishaw plc, 2017). Besides that, it becomes evident very quickly that there is a number of problems currently existing at various levels. Although these problems will be captured in more detail in the Value Proposition Canvas – as part of the applied TMS framework – in a succeeding chapter, the most significant ones are listed within this section:

- generally high dependencies on external manufacturers resulting in long waiting and overall processing times (up to several weeks), which in turn cause:
- necessity of a second surgery (implantation/ closing the cranial opening);
- additional high incurred costs (personnel and equipment resources);
- difficult communication between hospital (doctors) and manufacturer (production expert);
- additional logistic effort, especially in case implant does not fit and needs to be reworked;
- unpleasant condition for patients (cope with temporary treatment until the second surgery);
- additional risk of infection for the patient during the possibly long waiting time;
- risk of loss of accuracy of the manufactured implant during the possibly long waiting time (e.g., due to changes of the shape of the cranial opening).

6.2.2 Future In-house Manufacturing

After highlighting what constraints the current routine is generally associated with, the most effective optimization to the summarized workflow clearly are to eliminate an external party in both aspects, patient-specific design as well as the manufacturing of (cranial) implants. However, eliminating these dependencies (e.g., professional experience, commercial design software) requires a set of powerful *in-house* capabilities. As mentioned before, these particular efforts are run by a working group of the Technical University of Graz, focusing on a combination of a fully automated solution for the implant design and the printing process, resulting in the following future procedure, illustrated in Figure 45:

- acquisition of imaging data (e.g., head CT scan);
- segmentation of the skull in the imaging data;
- fully automated modeling of the patient-specific implant by a software (based on the difference between the post- as well as a pre-operative CT scan as input);
- automated transfer of the surface model to the 3D printer;
- on-site manufacturing of the implant by a 3D printer in the operation room (Li et al., 2020).

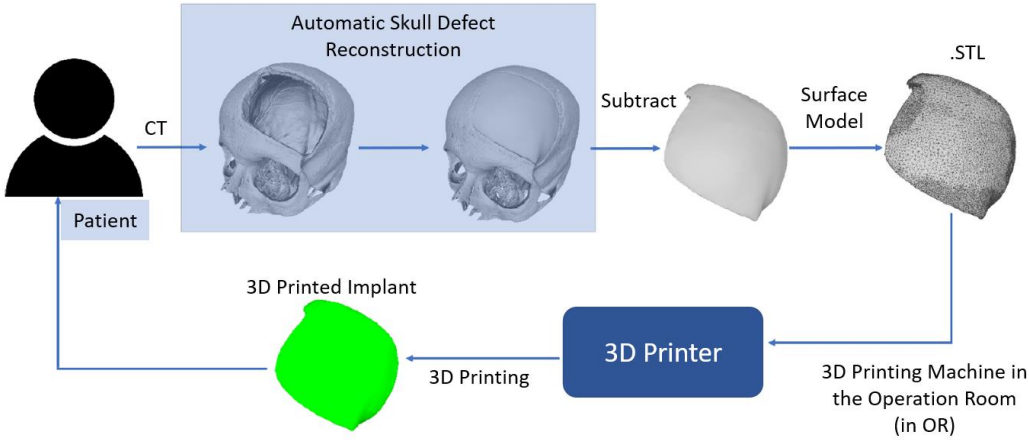


Figure 45: Possible workflow for cranial implant design and manufacturing (Li et al., 2020)

Looking at the workflow compared to the previous (i.e., current) one, it shows that the potential of optimization is enormous, as the possible savings on various levels contribute not only towards a much more efficient clinical routine in terms of overall autonomy, waiting times and costs, but also to a reduction of the patient suffering, having no need to undergo a second surgery. (Li et al., 2020)

6.3 Requirements for AM Cranial Implants

As with any new product (or process) being introduced for a specific purpose, a crucial part of this development process is to identify the existing requirements representing the key characteristics and features of that product. Thus, on the one hand, an effective approach, and on the other hand, the success of the product itself are ensured. This is especially true for the high-quality environment of medical implantable devices. Therefore, not only a number of legal constraints and regulations must be strictly complied with, as stressed within chapter 3, but also (part-)specific characteristics are decisive in terms of an implant's suitability and integrity.

However, besides the general requirements regarding the materials applicable for this purpose, specific information on the requirements for medical implantable devices made by AM is scarce, as most relevant projects are still under development. Furthermore, some of these characteristics for AM cranial implants in particular are:

- "*chemical properties* (e.g., biocompatible, nondegradable, etc.)";
- "*physical or mechanical properties*, ensuring full functionality (e.g., not impeding or limiting patient, maintaining corrosion resistance, withstanding external stress)";
- "*ability to be sterilized* using hospital-based processes – must be able to be sterilized without damaging the implant and must have microorganisms equal to or less than 1×10^{-6}";
- "be *readily available* within a hospital setting – to be attainable for clinicians within the National Health Service in terms of time, manufacturability, and cost";
- "be *designable* using medical-based software applications" (Maniruzzaman, 2018, p. 454)

Some of the mentioned requirements have to be identified (as well as quantified, if possible) to serve as a reference for the evaluation and subsequent selection of suitable testing and inspection methods (e.g., check, if a method is capable of measuring with a certain accuracy). However, these specific requirements are yet to be determined in the course of the case study that will be described in the next sections. One essential set of characteristics that needs to be defined, for example, will be the necessary g*eometric properties* of an implant. It must satisfy criteria for boundary, thickness and shape consistency, since its shape has to fit precisely within the defected region on the skull, as illustrated in Figure 46 (Li et al., 2020). Also, aesthetic results might play an important role in this aspect (DePuy Synthes, 2011).

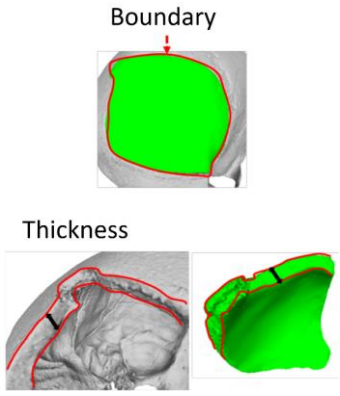


Figure 46: Intended fit of an implant (Li et al., 2020)

6.4 Application of the TMS Framework

This section serves as an in-depth description of how each step of the TMS framework elaborated in chapter 6 was applied within the outlined case study. First, the relation to the UCTM framework is shown before discussing the individual steps that eventually lead to the decision for some methods.

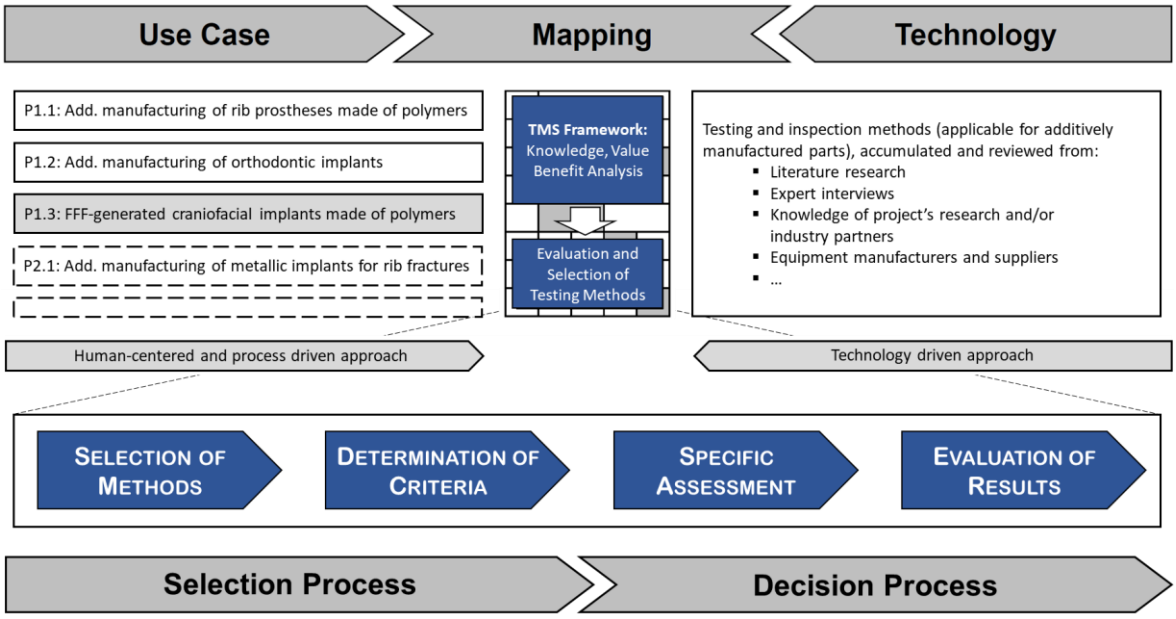


Figure 47: Application of the extended UCTM framework for the present use case (illustration based on Vorraber et al., 2019)

Figure 47 illustrates the UCTM framework applied to the overall project, however, in a slightly adapted or extended form: On the left side (i.e., *use-case triggered path*) the specific subprojects of CAMed are shown, highlighting the previously outlined subproject this thesis is mainly dealing with. On the right side (i.e., *technology triggered path*), in turn, applicable testing and inspection methods are listed that have been accumulated from different sources. The Mapping step in the center of the framework, connecting the Use Case and Technology section, originally aims to determine best fit between use cases and the most suitable methods. For the current application, however, where the use case is already set, this process is instead represented by the TMS framework on a separate level, resulting in the evaluation and selection of methods for this very case.

6.4.1 Step 1: Selection of Methods

Since this case study deals with the selection of suitable (final) testing and inspection methods for FDM fabricated products (i.e., medical implants as well as models for different medical purposes), only methods for the post-process quality control listed in Table 13 will be considered further.

To provide a more specific overview of these eligible testing methods, they have been extracted and further arranged to a more practical structure, which is presented in Table 14. Here, the focus has been placed on the type of inspection, meaning which property of an object can be verified by means of a method. This structuring was also used by Charalampous et al. (2020).

Table 14: Testing and inspection methods for post-process QC (structure based on Charalampous et al., 2020)

Type of Inspection	Testing Method for Quality Control (QC)	Test Equipment/ Tools
Dimensional Accuracy	**Coordinate metrology (tactile or optical)**	coordinate measuring machine
	Structural light 3D scanning	3D structural light scanner
	Three-dimensional laser scanning	3D laser scanner
Surface Finish	**Atomic force microscoping (AFM)**	atomic force microscope
	Tactile surface profiling	contact surface profilometer
	Optical surface profiling	optical sensor device
Internal Structure and Defects	**X-ray micro-computed tomography**	industrial computed tomograph
	Ultrasonic testing	ultrasonic scanner
	Thermography	excitation source, infrared camera, processing algorithm
	Acoustic emission (AE) testing	excitation source, AE sensor
	Archimedes' Principle (Scales)	Archimedes scales (density)
Residual Stresses	**Diffraction techniques (neutron, XRD)**	X-ray diffractometer
	Ultrasound Methods	no FDM-specific information
Chemical Composition	**Energy dispersive X-ray analysis (EDX)**	EDX analysis detector
	Spectroscopy methods	various spectroscopic devices

As can be recognized, these groups of part requirements or specific quality characteristics are already in direct alignment with established standards, e.g., EN ISO 17296-3 (ISO, 2014), or others recently announced. This fact creates confidence that also for the testing methods considered in this table there will be standard procedures released in the near future – at least to a certain extent.

6.4.2 Step 2: Determination of Criteria

Referring to the explanations in the corresponding chapter of the framework's theoretical elaboration it has been emphasized that the thorough determination of assessment criteria as well as their clear definition are among the most vital aspects for the significance of the analysis. Some fundamental "K.O. criteria" had already been considered while creating the initial catalogue of testing methods:

- Only methods that have been applied to objects created using *extrusion-based AM processes* such as FDM (i.e., in previous research) were listed,
- Only methods for *nondestructive testing (NDT)* are to be considered since these will be applied to implants that are intended for use in the operation room directly after inspection,
- The methods must be suitable for unrestricted *application in the in-house 3D printing lab*, involving required resources (e.g., general knowledge, staff training), medical approval, etc.

However, to facilitate the identification of more project-specific criteria or those originating from involved stakeholders, for example, the Value Proposition Canvas was chosen as an appropriate tool to visualize the overall project situation, as shown in Figure 48. In the following, the individual fields of the canvas, as they are reflected for the CAMed project, are explained in more detail.

The canvas makes it possible to concisely represent all stakeholders in the project, and show how they relate to the current (i.e., *Pains*) as well as the desired future clinical practice (i.e., *Gains*), as described in chapter 6.2. The stakeholders and their respective interests or tasks – called *jobs* – are:

- *Technical staff* (3D printing lab):
  Their jobs range from (operating and) maintaining the 3D printer, over carrying out the to be established quality verifications of the manufactured objects, to optimizing the processes.
- *Medical staff* (mainly surgeons, medical researchers at the clinic):
  The surgeons' main jobs involve data acquisition from the patient needed for the generation of the implant, conducting the surgery, and contributing to further developments of the lab.
- *Patients* (in need to be treated):
  In terms of the VPC, the patient's "job" is having the surgery and subsequently having satisfied his need of receiving an implant that was created specifically for his or her demands.

According to these tasks, problems or needs of the listed stakeholders, the following *Pains* and *Gains*, summarized in Table 15, can be concluded (e.g., from interviews with the respective stakeholders):

Table 15: Pains and Gains of the stakeholders involved

Mainly Affected	Pains	Gains
Medical staff	dependencies on external knowledge, manufacturers, (commercial software)	more flexibility and gained autonomy concerning processes and planning
	long, inflexible processing times	More efficient use of personnel and OR
	high costs for needed resources	reduced operating room (OR) cost
Technical staff ***(Medical staff)***	lack of knowledge and standards (in terms of product testing and QA)	seamless integration of processes in the hospital's existing infrastructure
	general doubts about new technology and/or overall the project's success	improved public relations, additional recognition in the fields of research
	-	stronger involvement of stakeholders
Patients ***(Medical staff)***	need for second surgery	-
	hospitalization and general waiting time	faster treatment for affected patient
	fit of implant may no longer be given	implant requires no further reworking
	high risk of infection for the patient	-

This comparative list of pains and gains clearly shows that for almost every (currently existing) pain there is a directly or indirectly related (future) gain, that can subsequently be associated with the introduction of the 3D printing lab or, more precisely, with the possibility of 3D printed implants. Moreover, this already indicates a high need – and potential effectiveness – of the ongoing project.

Besides examining the stakeholder-specific aspects of the project in the *Customer Profile*, the second main part of the VPC, called *Value Map*, provides a detailed description of the products and services that should address the before listed pains and gains. The current project aims to offer the following products and services, whose delivered contributions are enumerated in Table 16:

- *Patient-specific 3D printed polymer cranial implants (PSI)*
  (main focus of manufacturing within this project)
- *Patient-specific 3D printed anatomic models* and *surgical aids*
  (subject to later manufacturing within CAMed or succeeding projects)
- *In-house testing and quality assurance knowledge and capabilities*
  (main focus of this thesis and to be further developed and integrated)

Table 16: Pain Relievers and Gain Creators of the products and services offered

Product/ Service	Pain Relievers	Gain Creators
3D printing lab	generally eliminates (most) dependencies to external parties	provides manufacturing capabilities for 3D printed products
	strongly reduces overall processing and subsequently also hospitalization times	provides a general basis for further development and projects
	eliminates patient waiting time and thus lowers risk of infection	establishes a whole range of novel manufacturing technologies, materials and methods in the clinic (CAMed)
	-	enables direct cooperation of all involved parties
PSI	eliminates the need for a second surgery and thus strongly reduces overall costs	fulfills patient‘s fundamental need of getting a fast, specifically designed treatment
Testing and QA	provides most appropriate testing methods for 3D printed products	provides general basis for further development and projects
	-	contributes to the development of specific procedures and standards

Since the *Fit* between the products and services offered, and the pains and gains described previously can be assumed as given in multiple ways (i.e., according to the various directly emerging matches), it is not discussed in more detail at this point.

Instead, the insights obtained with the VPC were used, in combination with the knowledge of experts involved and related research literature, to derive relevant criteria for the assessment and selection of suitable testing and inspection methods, as part of the project's defined service "Testing and QA". At the same time, the VPC was helpful in an additional way to identify those experts who could contribute valuable inputs and/ or serve as interview partners in a later step.

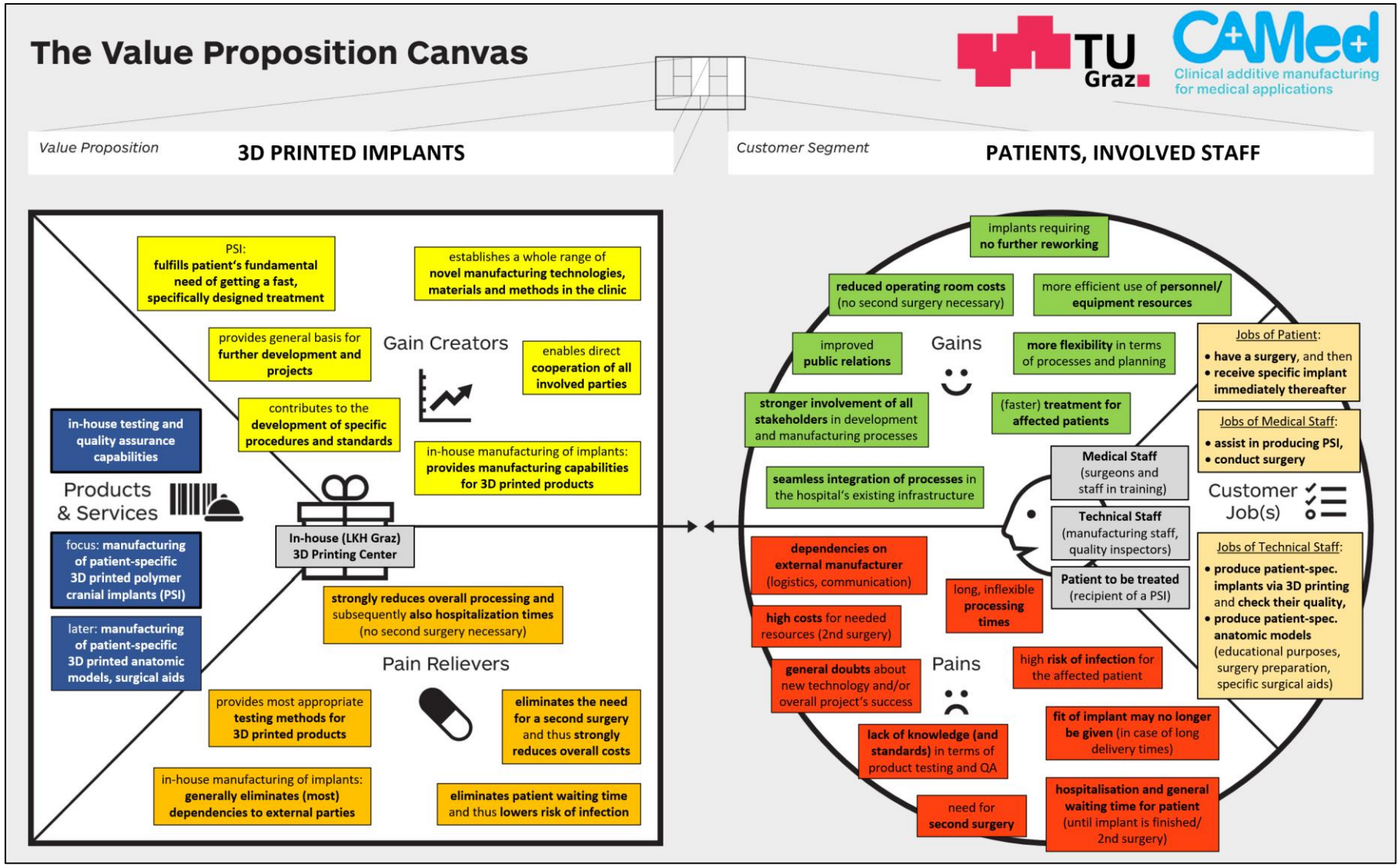


Figure 48: VPC: application for the use case "3D Printed Implants" (Osterwalder et al., 2014)

Resulting from the described inputs, Table 17 finally lists the determined assessment criteria (i.e., requirements to the testing methods). In total, 14 requirements were identified, which are primarily referred to as *criteria* in the following of this work and further divided into four categories:

- *Technological criteria:*
  Containing all capabilities that the testing methods must cover (in total) to be able to verify the given requirements for a component (e.g., implant). This includes geometrical, surface and important mechanical properties. Also, general technical specifications are listed here.
- *Process relevant criteria:*
  Here, those criteria are enumerated that are crucial for the final decision on implementation. Costs, stability of operation, its overall versatility and not least the associated resources that are needed for the implementation and operation of a method should be carefully considered.
- *Organizational criteria:*
  Being of minor importance in a first instance, these criteria might be significantly relevant in the long run to even be allowed to use a method (e.g., complying with standards).
- *Starting effort:*
  This category considers criteria that are helpful in distinguishing between different methods regarding their required effort until a status of "daily operation" can be achieved with them. The time for this level of development and required qualification are used as measurements.

Table 17: List of assessment criteria

Category	Assessment Criterion	Description
Techno-logical criteria	**Shape/ Dimensional Accuracy**	method's ability to verify deviations in shape and dimensions
	Surface Finish	method's ability to verify the quality/ roughness of the part's surface
	Detectability of Internal Cracks	method's ability to detect cracks inside of a part
	Residual Stresses	method's ability to indicate internal part stresses
	Testing Duration (Time)	method's amount of time needed to test one 3D printed part
	Sufficiency as stand-alone Method	method's ability to capture more than one feature of the part integrity
Process relevant criteria	**Process Costs**	costs incurred by the method (investment costs/machine hour rate)
	Process Stability/ Robustness	method's ability to maintain consistent and predictable performance over time
	Implementation Effort (Resources)	e.g., useability of already existing resources (facilities, personnel's skills)
	Applicability for other Materials	method's suitability to also be used for other materials and/ or purposes

Organi-zational criteria	**Validity in Europe**	method's degree of certification for given purposes (European standards)
	Workplace Safety Standards	effort to fulfill the workplace safety standards for the use of the method
Starting effort	**Development Effort (Time)**	duration of start-up phase until process is running stable
	Qualification of Operators	effort to establish and maintain the staff's competence to use the method

6.4.3 Step 3: Specific Assessment

In the TMS framework's third step, a comprehensive *Value Benefit Analysis (VBA)* was performed to incorporate the relevant information and insights accumulated into the decision-making process. This section guides through the application of this method with respect to the present use case and explains how the four steps of the procedure were executed in order to evaluate and rank the different alternatives (i.e., testing methods) at the end.

6.4.3.1 Determination of the Assessment Criteria

In accordance with the detailed description provided in chapter 5.3.3, the starting point of the VBA, the *determination of the assessment criteria*, was already carried out in the framework's second step. This was primarily done to underline the importance of this particular activity, but also to create a fluent transition into the second main section, the decision process (as depicted, e.g., in Figure 47). This means, that the assessment criteria previously listed in Table 17 could be taken over directly.

6.4.3.2 Weighting of the Criteria

The second step of the VBA is the *weighting of the criteria*. This is where the strength of the analysis to additionally consider project-specific influencing factors becomes apparent for the first time: At this point, the determined assessment criteria have to be ranked according to the individual opinions of different stakeholders. For this task, experts representing different disciplines within the project were consulted in order to obtain a broad and well-balanced range of assessment perspectives:

- *Scientific Director & Area Leader Polymers:*
  The leader of the main research area "polymer materials" is in charge of the overall project at the same time, making this person the ideal *expert in terms of any project-related aspects*. Also, this contact is intended to represent a more holistic view of matters within the project.
- *Technical Manager 3D Printing Lab:*
  As this person is significantly engaged in the development of the 3D printing lab and all its technology-related issues, the project's technical manager was the logical choice to act as *expert for technical aspects*. These are, e.g., AM in general and potential testing equipment.
- *Principal Investigator Orthodontics:*
  In order to include an *expert for surgical aspects* in the weighting of the assessment criteria, the principal investigator of a related subproject (orthodontics) was debriefed in this regard.

Once the suitable experts had been chosen, and thus a meaningful outcome of this prioritization could be ensured, they were asked to rate each criterion or requirement in terms of its relative importance to each other. Hence, based on each of these expert interviews, a pairwise comparison of the criteria was conducted to determine their specific weighting factors for the VBA and to derive their ranking. To demonstrate the procedure just described, the assessment matrix of such a pairwise comparison is exemplarily shown in Table 18, carried out according to the interview with the scientific director. The detailed assessments by the other two interviewees can be found in Appendix B.

An insightful comparison of the conducted expert interviews is provided in Figure 49, in which all the individual results have been overlaid in a radar chart. Most interestingly, the expert-specific differences in how they prioritized the individual criteria – based on their perspective of matters – are clearly visible here:

- For all three interview partners most of the *technological assessment criteria* (light red circumference) stand out significantly, whereas for the other criteria a more differentiated profile can be observed.
- According to the role as scientific director of the overall project, the most important concern for this expert is the broadest possible usability of the selected testing methods. Hence the high rating for *Process Stability/ Robustness* and *Applicability for other Materials*.
- Among the less vital assessment criteria, based on this poll, are the *organizational criteria* (yellow) and the *starting efforts* (orange). This presumably stems from the fact, that these aspects – in the overall comparison – are to be addressed only at a later stage of the project.

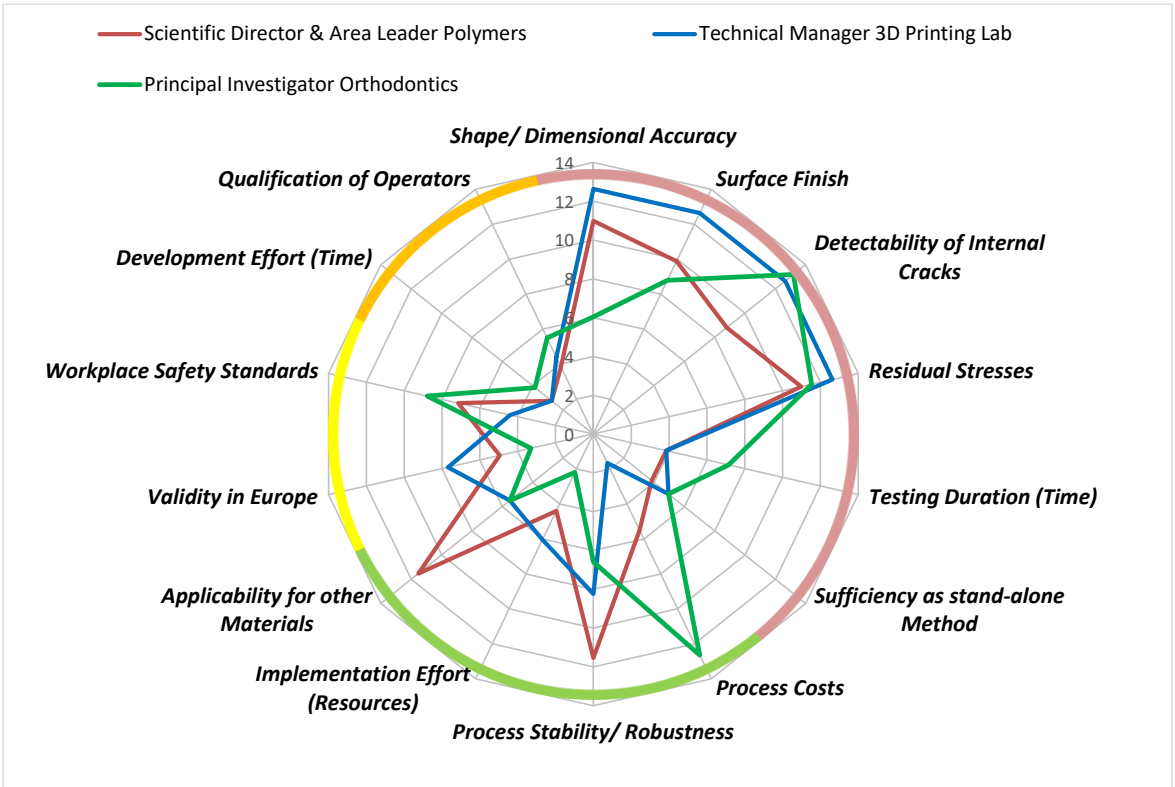


Figure 49: Expert-specific prioritization of assessment criteria (unsorted)

Table 18: Assessment matrix for the ranking of criteria (results shown for the interviewee "scientific director")

		Technological criteria						*Process relevant criteria*				*Organiz. cr.*		*Start effort*			
	Evaluation Guidlines: **0** = less important than other criterion **0,5** = equally important as other criterion **1** = more important than other criterion	**Shape/ Dimensional Accuracy**	**Surface Finish**	**Detectability of Internal Cracks**	**Residual Stresses**	**Testing Duration (Time)**	**Sufficiency as stand-alone Method**	**Process Costs**	**Process Stability/ Robustness**	**Implementation Effort (Resources)**	**Applicability for other Materials**	**Validity in Europe**	**Workplace Safety Standards**	**Development Effort (Time)**	**Qualification of Operators**	**Total Points**	**Weighting [%]**
Technological criteria	**Shape/ Dimensional Accuracy** method's ability to verify deviations in shape and dimensions		1	0,5	0,5	1	1	1	0,5	1	0,5	1	0,5	1	0,5	**10**	**11,0**
	Surface Finish method's ability to verify the quality/ roughness of the part's surface	0		0,5	0,5	1	1	0,5	0,5	1	0,5	1	0,5	1	1	**9**	**9,9**
	Detectability of Internal Cracks method's ability to detect cracks inside of a part	0,5	0,5		0,5	1	1	0,5	0	0,5	0	1	0,5	1	1	**8**	**8,8**
	Residual Stresses method's ability to indicate internal part stresses	0,5	0,5	0,5		1	1	1	0,5	1	0,5	1	0,5	1	1	**10**	**11,0**
	Testing Duration (Time) method's amount of time needed to test one 3D printed part	0	0	0	0		0,5	0,5	0	0,5	0	0	0,5	0,5	1	**3,5**	**3,8**
	Sufficiency as stand-alone Method method's ability to capture more than one feature of the part integrity	0	0	0	0	0,5		0,5	0	0,5	0	0	0,5	1	0,5	**3,5**	**3,8**
Process relevant criteria	**Process Costs** costs incurred by the method (investment costs / machine hourly rate)	0	0,5	0,5	0	0,5	0,5		0	0,5	0	0,5	0,5	1	0,5	**5**	**5,5**
	Process Stability/ Robustness method's ability to perform in a consistent & predictable manner over time	0,5	0,5	1	0,5	1	1	1		1	0,5	1	0,5	1	1	**10,5**	**11,5**
	Implementation Effort (Resources) e.g., useability of already existing resources (facilities, personnel's skills)	0	0	0,5	0	0,5	0,5	0,5	0		0	0,5	0,5	0,5	0,5	**4**	**4,4**
	Applicability for other Materials method's suitability to also be used for other materials / purposes	0,5	0,5	1	0,5	1	1	1	0,5	1		1	0,5	1	1	**10,5**	**11,5**
Organiz. crit.	**Validity in Europe** method's degree of certification for given purposes (European standards)	0	0	0	0	1	1	0,5	0	0,5	0		0,5	0,5	0,5	**4,5**	**4,9**
	Workplace Safety Standards effort to fulfill the workplace security standards for the using the method	0,5	0,5	0,5	0,5	0,5	0,5	0,5	0,5	0,5	0,5	0,5		0,5	0,5	**6,5**	**7,1**
Start effort	**Development Effort (Time)** duration of start-up phase until process is running stable	0	0	0	0	0,5	0	0	0	0,5	0	0,5	0,5		0,5	**2,5**	**2,7**
	Qualification of Operators effort to establish and maintain the staff's competence to use the method	0,5	0	0	0	0	0,5	0,5	0	0,5	0	0,5	0,5	0,5		**3,5**	**3,8**
																91	**100**

As a conclusion to this step of the VBA, Figure 50 summarizes the results of the expert interviews in a more concise form. By using a stacked bar chart that is sorted on the accumulated importance of the assessment criteria, the fundamental trends can be seen at a glance. For the remaining steps of the analysis, the averaged values obtained by the interviewees, shown on the right side, will be used.

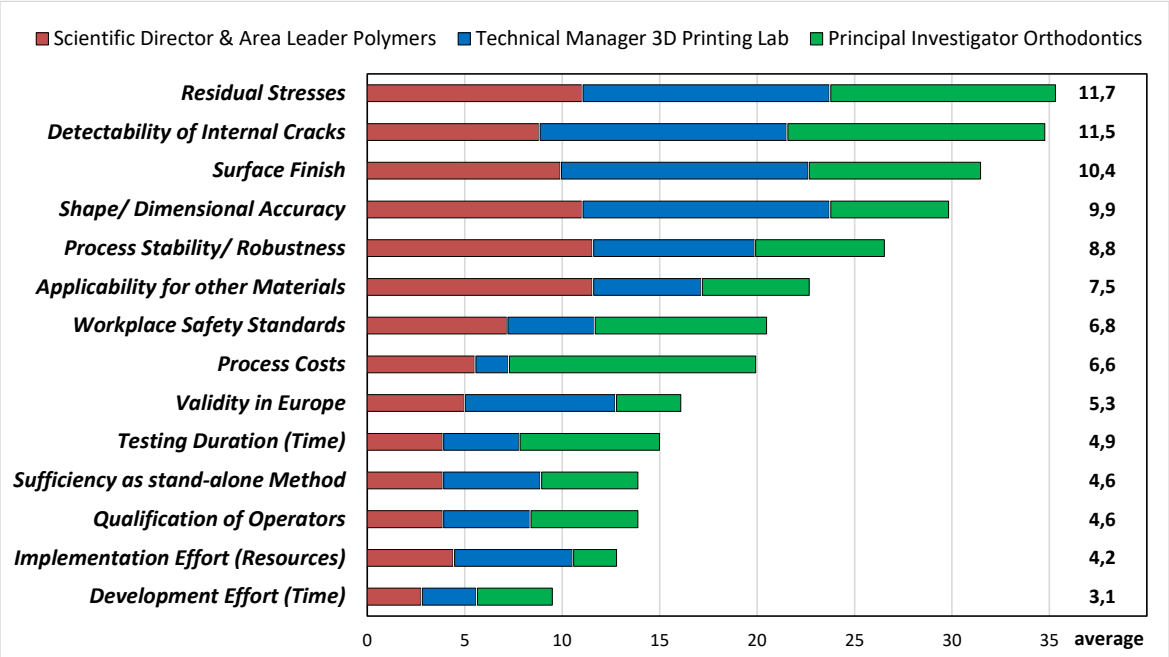


Figure 50: Overall ranking of the assessment criteria (sorted)

6.4.3.3 Assessment through the subjective Rating by Experts and Calculation of the specific Values of Benefit

This part of the VBA represents its essential core, as it brings together both, the influencing factors and relevant information determined for the presented use case (i.e., weighted assessment criteria), as well as the different alternatives to be selected from (i.e., suitable testing and inspection methods).

However, before going into detail, some additional remarks are made on the assessment criteria, and a general explanation is provided regarding the further proceedings and scope of this work:

Meaningfulness and evaluability of some criteria

As the criteria were determined, the focus was put on considering all aspects that might become of relevance to a testing method at some stage. When researching concrete data on the eligible methods, however, it turned out that, at least for some of the selected criteria, no information was available yet that could have been adopted for the given use case. More precisely, these concerned criteria include *residual stresses* and *process stability/ robustness.*

The described lack of information is partly rooted in the nature of the research topic (i.e., its novelty in the field of application). On the other hand, it was not possible to gather data within the project either, until the time this work was carried out, since most of the testing equipment had not been validated yet for the objects to be manufactured, let alone purchased for the 3D printing lab.

In conclusion, this means that the previously mentioned criteria are *not* applicable for the assessment and selection of testing methods – in *this* use case – after all, because of the currently limited data. Consequently, they must be removed from the assessment list for the further course of the analysis.

Nevertheless, listing these criteria from the beginning was a useful contribution in the project, as it clearly underlines their importance, following the results of the weighting process. This also means, that great emphasis should be put on these criteria as soon as the project's progress allows for it.

Intended scope of application (focus categories of testing methods)

The structuring of the testing methods to be assessed by means of the final decision matrix is intended to be based on the grouping which has been established in Table 14 for further usage in this thesis. Also, according to standards announced, such as EN ISO 17296-3 (ISO, 2014), these groups represent the quality requirements of an AM object in general, what makes them an ideal template for this purpose, as the assessed testing methods will be used to validate exactly such objects in the future.

However, a similar issue as with the assessment criteria arises at this point, since one of these groups specifically addresses methods that are capable of testing an AM component for its *residual stresses*. Again, in this particular area of interest, there are a number of pending issues that are currently being researched, especially in the AM domain. After consulting with the experts who are also dealing with this topic in their part of the project, it can be confirmed that there are no explicit testing methods for the detection of residual stresses, as industry-specific experience is generally essential in this field. In this regard, since information is scarce at present, these methods will not be part of the analysis.

Because this aspect can be of vital importance for the quality and the associated usability of an object, on the other hand, this topic will be taken up and discussed separately in the final part of this work.

One further related remark that needs to be made at this point, addresses the group of testing methods referring to an object's *chemical composition*. This group does not need to be included in the analysis, since for the given use case generally only such materials are used that have been certified for medical applications (i.e., medical grade). This means the chemical properties of a manufactured object can be taken for granted and do not need to be examined any further at this stage.

In the overall context, the considerations described above and the adjustments subsequently made lead to the following structural key points of the decision matrix, that are schematically summarized in Figure 51:

- The weighted assessment criteria representing the given requirements are applied to grade each of the testing methods accordingly. For improved clarity they are marked in groups.
- The main focus of testing methods will be set on those enabling the validation of an object's *dimensional accuracy*, *surface finish* as well as its *internal structure and defects*. Therefore, these quality aspects will serve as *focus categories* to subdivide the methods accordingly.
- This arrangement allows to clearly determine the best method for each category separately.

	Method Focus Category 1: **Dimensional Accuracy**			Method Focus Category 2: **Surface Finish**			Method Focus Category 3: **Internal Structure & Def.**		
Decision Criteria	**Method *DA 1***	**Method *DA 2***	**Method *DA 3***	**Method *SF 1***	**Method *SF 2***	**Method *SF 3***	**Method *IS&D 1***	**Method *IS&D 2***	***Method IS&D 3***
Technological criteria									
Process relevant criteria									
Organizational criteria									
Start effort									
Total Value Benefit	###	###	###	###	###	###	###	###	###

Figure 51: Basic structure of the VBA applied for the present use case

After the scope has been clarified extensively and some resulting limitations have been pointed out, the performed assessment can finally be demonstrated and discussed.

The most eligible methods that are dealt with in the analysis had been preselected from Table 14 based on the technology screening that, in turn, was made in coordination with the technical experts of the 3D printing lab at the clinic.

For this preselection, among other things, the fact was considered that for some of the listed testing methods, concrete devices had already been ordered for the trial phase of the project's quality control. By consulting experts and producers of testing equipment, this fact was also exploited to provide very concrete scales of values that define how the score for each criterion is distributed or determined. These determined scales of values, which are shown in Table 19, allow to clearly reveal and compare the strengths and weaknesses of the different testing methods. The detailed information collected on the specific devices (e.g., manufacturers, datasheets) made it possible to dispense with an explicit rating by experts for some criteria.

Therefore, since the individual ratings of each method as well as their final results (i.e., total values of benefit) were determined in the same spreadsheet, the last step of the VBA, *calculation of the specific values of benefit*, was integrated into this section.

The final decision matrix is illustrated in Table 20 (*dimensional accuracy* and *surface finish*) and Table 21 (*internal structure and defects*). Those methods that achieved the highest overall score in their category are highlighted in green.

Table 19: Auxiliary table – determination of the scales of values for the assessment criteria

		0	1	2	3	4
	Decision Criterion	**Unsatisfactory**	**Barely Acceptable**	**Satisfactory**	**Good**	**Very Good**
Technological criteria	**Shape/ Dimensional Accuracy**	> ±1 mm	< ±1 mm	< ±0.5 mm	< ±0.1 mm	< ±0.05 mm
	Surface Finish	> Ra 12,5 µm (rough)	-	< Ra 12,5 µm (smooth)	-	< Ra 6,3 µm (very smooth)
	Detectability of Internal Cracks	not detectable	-	detectable to a depth of a few millimeters, no localization possible	detectable to a depth of a few millimeters, + localization possible	detectable to a depth of a few centimeters, + localization possible
	Testing Duration (Time)	t > 120 min	120 > t > 90 min	90 > t > 60 min	60 > t > 30 min	t < 30 min
	Sufficiency as stand-alone Method	-	-	can measure only 1 criterion	-	can measure 2 or more criteria
Process relevant crit.	**Process Costs** [1]	cost range E (very expensive)	cost range D (relatively expensive)	cost range C (moderate costs)	cost range B (relatively cheap)	cost range A (among cheapest)
	Implementation Efforts (Resources)	equipment not available, must be purchased	-	partly available/ shared; OR: is being acquired	-	equipment available, no additional purchase
	Applicability for other Materials	applicable only for current polymer material (PEEK)	applicable only for spec. polymer groups	applicable for all polymer materials	appl. for min. one other material (metal/ ceramic)	applicable also for metals and ceramics
Organiz. crit.	**Validity in Europe**	non-state of the art (at present)	-	any other process: state of the art; OR: approved by FDA, etc.	-	already approved or state of the art in AM
	Workplace Safety Standards	not fulfilled; major adaptations required	-	fulfilled; additional user trainging required		fulfilled; no additional effort required at all
Start Effort	**Development Effort (Time)**	> 12 months	-	12 - 3 months	-	≤ 3 months
	Qualification of Operators	specific training required (certificate, licence, etc.)	-	only short in-house training required	-	no major additional training required

[1] sensitive data was restricted for publication; concrete values are known to the author

Table 20: Decision matrix – dimensional accuracy and surface finish

Scale of Values according to VDI 225 **0** Unsatisfactory **1** Barely Acceptable **2** Sufficient **3** Good **4** Very Good		Method Focus Category 1: **Dimensional Accuracy**									Method Focus Category 2: **Surface Finish**								
		Coordinate Measuring Metrology (CMM)			**3D Scanning (Structural Light or Laser)**			**Tactile/ Noncontact Metrology (ScanArm)**			**Tactile/ Optical Inspection (e.g. Reference Samples)**			**Atomic Force Microscoping (AFM)**			**Surface Profiling (Contact or Optical)**		
		Hexagon *GLOBAL S (Bridge CMM)*			**Artec** *Leo*			**FARO** *8-Axis Quantum^{S} V2 2.5m*			**VDI 3400 - Surface Finish Comparison Samples**			**nanosurf** *FlexAFM*			**Bruker alicona** *InfiniteFocusG5 plus*		
Decision Criterion	Weighted [%]	Rating	weighted	Comment	Rating	weighted	Comment	Rating	weighted	Comment	Rating	weighted	Comment	Rating	weighted	Comment	Rating	weighted	Comment
Shape/ Dimensional Accuracy	9,9	4	0,396	(1,5+length) /333 µm MPEE (18 - 22 °C)	3	0,297	± 0,1 mm	4	0,396	laser: ± 0,025 mm tactile: 0,043 mm	0	0,000	rough determination (OK/ not OK)	0	0,000	N/A	4	0,396	7 µm (at 2.5x objective magnification)
Surface Finish	10,4	2	0,209	no information	0	0,000	N/A	2	0,209	laser: ± 0,025 mm tactile: 0,043 mm	0	0,000	rough determination (OK/ not OK)	4	0,418	too detailed for given use case	2	0,209	7 µm (at 2.5x objective magnification)
Detectability of Internal Cracks	11,5	0	0,000	N/A	0	0,000	N/A	0	0,000	N/A	0	0,000	N/A	0	0,000	N/A	0	0,000	N/A
Testing Duration (Time)	4,9	0	0,000	2-3 h (incl. programming of measuring points)	3	0,148	30-40 min (without post-procesing of data)	4	0,198	laser: < 0,5 h tactile: ~ 1,5 h (no progrmmg. requ.)	3	0,148	~ 0,5-1 h (estimated)	2	0,099	no information	4	0,198	~ 0,5 h
Sufficiency as stand-alone Method	4,6	4	0,183	also applicable for: Surface Finish (surf. coordinates)	2	0,092	-	4	0,183	also applicable for: Surface Finish (to certain degree)	2	0,092	-	2	0,092	-	2	0,092	-
Process Costs	6,6	0	0,000	cost range E (very expensive)	4	0,264	cost range A (among cheapest)	2	0,132	cost range C (moderate costs)	2	0,132	no information	2	0,132	cost range C (moderate costs)	2	0,132	cost range C (moderate costs)
Implementation Effort (Resources)	4,2	2	0,084	is being acquired/ soon be available	2	0,084	is being acquired/ soon be available	4	0,168	available	2	0,084	partly available	2	0,084	partly available/ being shared	4	0,168	available
Applicability for other Materials	7,5	4	0,300	independent of material	4	0,300	independent of material	4	0,300	independent of material	4	0,300	independent of material	4	0,300	independent of material	4	0,300	independent of material
Validity in Europe	5,3	4	0,212	generally applicable	4	0,212	generally applicable	4	0,212	generally applicable	4	0,212	generally applicable	2	0,106	-	4	0,212	generally applicable
Workplace Safety Standards	6,8	4	0,271	-	4	0,271	-	4	0,271	-	4	0,271	-	4	0,271	-	4	0,271	-
Development Effort (Time)	3,1	4	0,125	fast start-up is expected, (automatable)	4	0,125	fast start-up is expected, (intuitive handling)	4	0,125	fast start-up is expected	2	0,062	intuitive approach; but might take time to gain experience	2	0,062	too detailed for given use case	4	0,125	might take time to gain experience
Qualification of Operators	4,6	2	0,092	-	2	0,092	-	2	0,092	-	4	0,183	-	2	0,092	-	2	0,092	-
Total Value Benefit	**100**		**1,87**	**#3**		**1,88**	**#2**		**2,29**	**#1**		**1,49**	**#3**		**1,66**	**#2**		**2,19**	**#1**

Table 21: Decision matrix – internal structure and defects

Scale of Values according to VDI 225 **0** Unsatisfactory **1** Barely Acceptable **2** Sufficient **3** Good **4** Very Good		Method Focus Category 3: **Internal Structure and Defects** (Cracks, Inclusions, Porosities, etc.)															
		X-ray Micro-Computed Tomography (µCT)			**Ultrasonic Testing (UT)**			**Archimedes' Principle (Density Balance)**			**Infrared Thermography (IR)**			**Acoustic Emission Testing (AT)**		
		Bruker *SkyScan 1276*			**FUJIFILM VisualSonics** *Vevo3100*			**KERN** *ABT 320-4NM*			**InfraTec** *VarioCam HD head 900*			**Physical Acoustics** *MISTRAS PCI2 System*		
Decision Criterion	Weighted [%]	Rating	weighted	Comment	Rating	weighted	Comment	Rating	weighted	Comment	Rating	weighted	Comment	Rating	weighted	Comment
Shape/ Dimensional Accuracy	9,9	4	0,396	5 µm (spatial resolution); not main purpose	0	0,000	N/A	0	0,000	N/A	0	0,000	N/A	0	0,000	N/A
Surface Finish	10,4	4	0,418	5 µm (spatial resolution); not main purpose	0	0,000	N/A	0	0,000	N/A	0	0,000	N/A	0	0,000	N/A
Detectability of Internal Cracks	11,5	4	0,462	18 µm (pixel size of X-ray detector) det. of cracks >35 µm	3	0,346	detection of cracks >0.5 mm (gives too little info)	2	0,231	only rough evaluation; no distribution or size detectable	3	0,346	dependent on flaw depth (size of cavity = max. flaw depth)	3	0,346	detect. of cracks up to 25 µm, localization possible
Testing Duration (Time)	4,9	1	0,049	50 min, size-related; data processing: 2-3 h (5 µm sections)	2	0,099	~ 1 h	3	0,148	< 0,5 h (estimated)	2	0,099	~ 1 h excl. data analysis; depending on param.	3	0,148	~ a few minutes; but: test setup and data analysis: up to 1h
Sufficiency as stand-alone Method	4,6	4	0,183	also applicable for: Shape/Dim. Accur., Surface Finish	3	0,137	also applicable for: Residual Stresses (not considered)	2	0,092	-	2	0,092	-	2	0,092	-
Process Costs	6,6	3	0,198	cost range B (relatively cheap)	3	0,198	cost range B (relatively cheap)	4	0,264	cost range A (among cheapest)	1	0,066	cost range D (relatively expensive)	4	0,264	cost range A (among cheapest)
Implementation Effort (Resources)	4,2	4	0,168	available	4	0,168	available	0	0,000	not available	0	0,000	not available	0	0,000	not available
Applicability for other Materials	7,5	3	0,225	hardly applicable for metals	4	0,300	-	3	0,225	used fluid has to match with material	3	0,225	dependent on type of material; specific limitations	3	0,225	dependent on type of material; specific limitations
Validity in Europe	5,3	4	0,212	already widely used in AM; (considered gold-std.)	4	0,212	already widely used in AM	2	0,106	full validity unlikely in AM	2	0,106	-	2	0,106	-
Workplace Safety Standards	6,8	2	0,136	-	2	0,136	-	4	0,271	-	4	0,271	-	4	0,271	-
Development Effort (Time)	3,1	2	0,062	might take time to gain experience	2	0,062	-	4	0,125	relies on very simple principle	2	0,062	requires a lot of experience (material, geometry)	2	0,062	requires a lot of experience (setup and analysis)
Qualification of Operators	4,6	0	0,000	high efforts required	0	0,000	high efforts required	4	0,183	very easy to use	0	0,000	(setup and analysis)	0	0,000	high efforts required
Total Value Benefit	**100**	**2,51**		**#1**	**1,66**		**#2**	**1,64**		**#3**	**1,27**		**#5**	**1,51**		**#4**

6.4.4 Step 4: Evaluation of Results

After the most eligible testing methods were incorporated into the VBA and rated in accordance with the specified requirements, their total values of benefit were calculated, allowing for a ranking within each method category. Based on this quantified comparison between the different alternatives a final evaluation and discussion within the project could take place, as intended by the last main step of the TMS framework. This discussion was also part of the presentation held in front of the project team.

As already mentioned during the elaboration of the framework, this final step generally represents several possibilities to refine or adapt the decision process. This can be important, in order to examine specific alternatives or to achieve shared acceptance for the selected ones. However, since the overall discussion will be followed in the next chapter, only the main results are described in this section.

First, in order to get a better understanding of the rating in the overall context, Figure 52 illustrates the category-specific outcome and further provides a concise representation of the entire analysis.

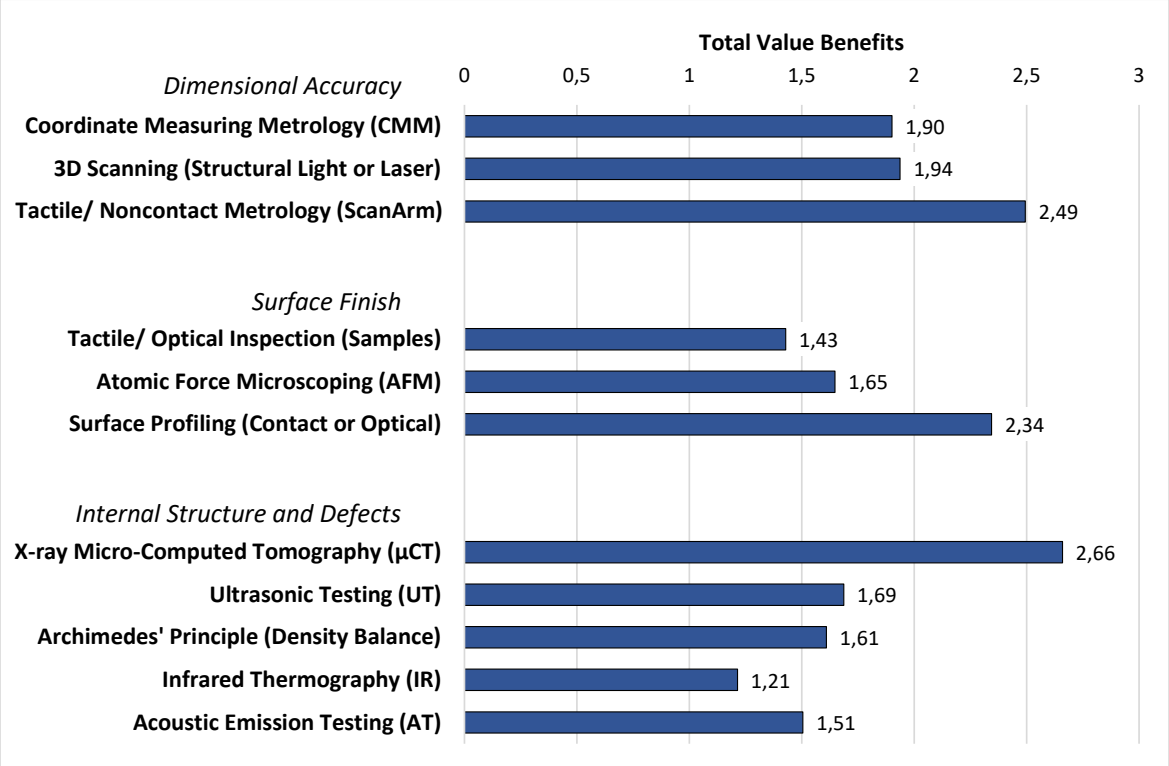


Figure 52: Overall results of the VBA – total value benefits

It can be seen that some of the testing methods fall into a similar range of values, making it difficult to choose among them and thus providing a particular reason to examine these alternatives in more detail with the respective stakeholders of the project. On the other hand, the chart clearly shows that within each of the defined focus categories one testing method stands out from the rest significantly, as its specifications fulfill the assessment criteria the best. Therefore, in order to review these possible solutions, they will be described more closely in the following.

6.4.4.1 Best rated Testing Method concerning *Dimensional Accuracy*

The "winner" in this focus category is the FARO Quantum^S ScanArm as illustrated in Figure 53. This portable CMM can be used for e.g., reverse engineering, 3D inspections, CAD comparisons or dimensional analysis, making it an ideal tool for quality verification purposes. The intuitive and ergonomic design as well its capability to meet rigorous international measurement quality standards (e.g., ISO 10360-12) enable to employ this device in a broad variety of environments. However, the ScanArm's most practical feature is its capability of attaching a highly accurate laser line probe to the (tactile) hard probe in a simple plug-and-play way. The hard probe and the laser line probe can digitize interchangeably without the need to remove either component. Simple features can therefore be digitized using the hard probe of the Arm, allowing for measurement independent of a surface material's contrast, reflectivity or part complexity. The laser line probe, on the other hand, based on blue laser technology and further consisting of a state-of-the-art camera and specialized scanning optics, enables to scan challenging part surfaces (e.g., dark, reflective) at high resolution and high speed at the same time. This is made possible by an extra wide scan stripe and a fast frame rate (giving a scan rate of 600,000 points per second) and the support by noise reduction technology. (FARO Technologies, Inc, 2017)

Figure 53: FARO *Quantum^S ScanArm* (FARO Technologies, Inc, 2017)

6.4.4.2 Best rated Testing Method concerning *Surface Finish*

In the analysis carried out, the InfiniteFocusG5 plus from the manufacturer Bruker alicona was rated as the most suitable device for the surface roughness measurement of produced implants, as it is a highly accurate, fast and flexible optical 3D measurement system. This device allows to verify a component's dimensional accuracy as well as to measure its surface roughness by only one sensor. This is based on the technology *Focus-Variation* (i.e., combining the small depth of focus of an optical system with vertical scanning to provide topographical as well as color information from the variation of focus) making the range of measurable surfaces almost unlimited. By applying *Vertical Focus Probing*, an extension of *Focus-Variation*, also vertical surfaces can be probed in lateral direction. Since the sensor is mounted in a vibration-isolating hardware, form and roughness measurement is possible even of large and heavy components. To ensure precise stage movement, all axes of InfiniteFocus are equipped with highly accurate encoders. With an automation interface, fully automatic measurements in production are possible as well. (Alicona Imaging GmbH, 2021)

Figure 54: Bruker alicona *InfiniteFocusG5* (Alicona Imaging GmbH, 2021)

6.4.4.3 Best rated Testing Method concerning *Internal Structure and Defects*

The leading role of micro-CT for the evaluation of a part's internal structure and defects could be clearly confirmed, as this method also received by far the highest rating within the performed case study. This is mainly because of its unparalleled versatility and, most of all, its overall accuracy. The chosen device for the 3D research lab is the Bruker SkyScan 1276, a high performance, stand-alone, fast, desktop *in vivo* micro-CT. Its enables to scan small laboratory animals (e.g., mice, rats) and biological samples, such as bone and tissue samples on an image field of view of up to 80 mm width and 300 mm length with a spatial resolution down to 2.8 µm pixel size due to its continuously variable magnification. Also the X-ray energy is variable, in order to ensure optimal image quality, which is additionally supported by a number of filters. Scanning cycles down to 3.9 sec and the combination of high resolution with low radiation dose (concerning animal experiments) makes this device the leading *in vivo* micro-CT bone solution. Also, by use of specific software tools, various measurement tasks as well as 3D reconstruction (i.e., transformation of 2D projection images into 3D volumes) are possible. (Bruker Corporation, 2021)

Figure 55: Bruker *SkyScan 1276* (Bruker Corporation, 2021)

The mentioned reconstruction capabilities and general suitability of the micro-CT have already been demonstrated for the inspection of AM fabricated sample cranial implants, as the device is available in a cooperating hospital department. Some exemplary reconstruction results are shown in Figure 56. These 3D reconstructions were obtained from a total of 259 files with an image pixel size of 35 µm.

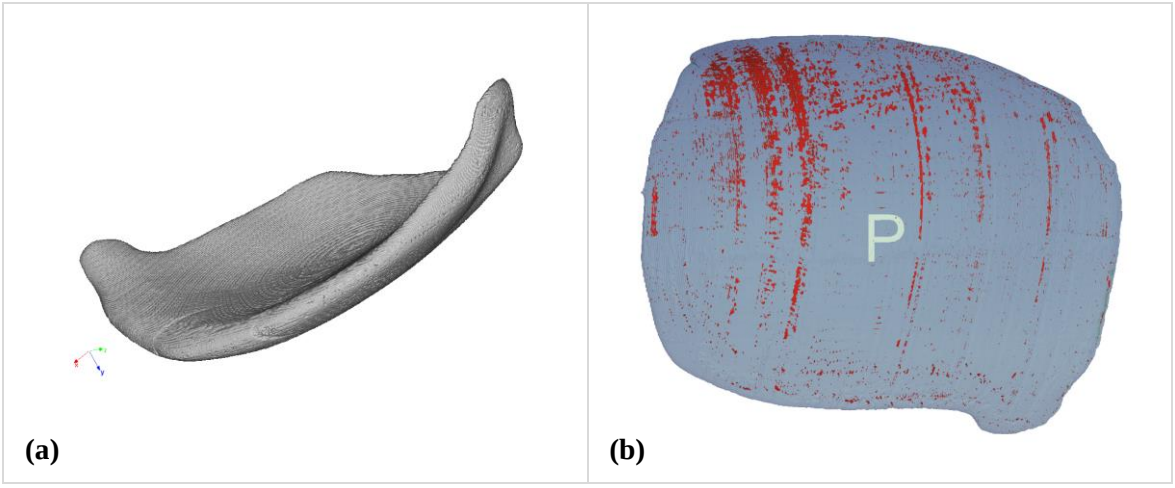


Figure 56: Sample picture of a micro-CT scan of a cranial implant: Rendered 3D reproduction (a) and top view with highlighted gaps (b) (Medical University of Graz)

Especially the porosity evaluation of manufactured implants is a crucial task enabled by micro-CT, since currently, its influence on the mechanical performance is being investigated in the project, and furthermore, the image acquisition is used to gain insights on how to improve the printing process.

The reconstructed 3D model in Figure 56b reveals, e.g., that the implant (printed from right to left) has a relatively high concentration of porosity in the upper layers (represented in red), indicating that some process parameters need to be adjusted accordingly. This is particularly significant since this local concentration (i.e., in a group of layers) may lead to major changes in the mechanical behavior. In a series of test samples, an average part porosity of 0.2 % was calculated before washing and sterilization. However, according to the author of the represented data, there is yet no information available, of whether this is sufficient for the use of AM implants or not, as clinical studies are still to be conducted.

6.4.5 Remarks to the Analysis conducted

Moreover, besides the presentation of the main results, there are some project-related aspects that need to be highlighted here:

- *Expressiveness due to the range of experts conducted*
  Only main stakeholders representing a specific domain in the project were asked about their use case specific prioritization of requirements concerning the testing methods to be selected. Therefore, the expressiveness of the obtained results is limited to the consulted experts.
- *Stage of development of the project*
  For the entire context of the analysis conducted, it must be stated, that the described research center is still in its early stages of development. As a result, the analysis presented might not have reached its full potential at the time of execution (e.g., test patterns, test artifacts yet to be evaluated).
- *Pre-selection of some methods*
  There could also be a bias in the (pre-)selected test methods in the analysis, as some of the corresponding devices had already been ordered for use in the 3D printing research center.
- *Scope of the analysis conducted*
  Another important remark to be made is that material-specific properties, such as chemical (e.g. biocompatibility, hygroscopy) and especially mechanical properties, were deliberately disregarded. These examinations were defined as the responsibility of other project partners. Therefore, the successful execution of relevant measurements and tests as well as the overall determination of these data was considered a prerequisite for the present analysis.

Further remarks concerning the main limitations of the analysis and the overall use case evaluation are described in great detail in the corresponding chapters.

Part IV.

Concluding Remarks

7 Discussion of Results

In the light of the challenges identified in the introduction and after completion of the tasks resulting from the given use case, this chapter aims to discuss the overall findings gained from the practical part of this work in detail. Section 7.1 reviews the developed TMS framework applied for the present use case, whereas in section 7.2 a comprehensive examination of the analysis and some important aspects to it are provided.

7.1 Validation of the TMS Framework

The developed framework was designed in accordance with the requirements elaborated in chapter 5.2 and is generally based on the UCTM framework by Vorraber et al. (2019). Basically, it represents a methodological workflow that should alleviate getting through complex decision processes in the field of medical applications. As this "Testing Method Selection Framework" was first used within this work, its applicability is validated by checking how well it was able to fulfill its requirements:

- *Fulfillment of "provision of a knowledge basis"*
  Serving as the very basis for the decision process, this requirement was fulfilled in form of a structured catalogue of testing methods that is provided within the framework's first step.
- *Fulfillment of "clarity"*
  The general request for a clear and well-structured layout was met by defining four main process steps and an additional subdivision into *selection* and *decision*. However, as it turned out on an overall level, a clear *terminology* of established terms is crucial as well to avoid misunderstandings and should therefore be thought out carefully. This was the lesson from some of the assessment criteria being asked during the expert interviews, for example.

  Fulfillment of "provision of suitable tools"
  As can be seen in the complete framework shown in Figure 44, this required condition has been accomplished extensively. Only a limited statement can be made about their suitability, though, since in each step only one tool could be evaluated. Nevertheless, it can be affirmed that especially the Value Proposition Canvas and the Value Benefit Analysis have proven to be well suited tools in the present use case.
- *Fulfillment of "content specifications"*
  No validation of this claim was possible, since until this point in time, this framework has not been tried out independently by anybody else than the author himself.
- *Fulfillment of "general applicability and flexibility"*
  Having conducted only a single case study for a specific application, a generalization of the developed framework's validity is yet to be tested. This could be achieved by examining further case studies, e.g., in the course of the project. Once, its applicability would be proven, it could also be utilized for the selection of pre- or in-process quality control methods.

7.2 Interpretation of the Conducted Analysis

Since the final results of the analysis have been described in the fourth step of the TMS framework, this section highlights some key aspects that could only be addressed to a limited extent in the study conducted. In order to provide a well-comprehensible evaluation, these aspects will be discussed in the context of the assessment criteria introduced in this work.

7.2.1 Disproportionality of some Existing Criteria

In this section those assessment criteria are enumerated that had been considered in the VBA but might have been portrayed in a very simplified or disproportionate way. Therefore, in the following, they are additionally viewed from a more holistic perspective than the analysis was able to capture.

- *Achievable measurement accuracies*
  As mentioned earlier, one of the major challenges that have been encountered during this work is the fact that no specific requirements have yet been quantified for the implants to be manufactured within this use case. Consequently, these target values can only be estimated or derived from the findings of the literature research and from suppliers of conventionally produced (i.e., precision-milled) implants so far. In a comparable study, Sharma et al. (2021), for example, gained results with an overall root mean square error (RMSE) of 0.55mm in surface deviation, which can be used as a reasonable reference for the current application. When compared to the achievable measuring accuracies from the methods listed in the VBA, it can be seen that they all exceed these values by far and are therefore sufficient alternatives.

  Generally speaking, on the one hand, the literature research clearly showed that there are numerous factors affecting the dimensional accuracy of a FDM manufactured part, like the type of material used, build orientation, part thickness and post-processing techniques, as listed by Dimitrov et al. (2006) as the most important. Concerning the present use case on the other hand, an interview with an experienced surgeon revealed that a deviation of up to 1-2 mm in shape or even measurement were tolerable, depending on different factors: First, an aesthetic appearance has to be guaranteed in general, and second, measurement deviations are tolerable as long as it is possible to fix the implant in the patient's cavity without further rework. However, the latter case will be avoided in any case by the project's very intent (i.e., timely implantation of the PSI directly after surgery).

- *Unknown requirements for surface finish*
  Similar to the criterion discussed above, reference values concerning the necessary surface finish could not be provided in the project due to the lack of general requirements at the time of the analysis. As already concluded from the literature research in the theoretical part of this thesis, however, it can generally be stated that FDM manufactured products suffer from inferior surface finish as well as lower dimensional accuracy, when compared to other AM technologies (e.g., Tiwary et al., 2019). According to R. Singh et al. (2017), among others, this is mainly due to the staircase effect, which in turn decreases the dimensional accuracy.

  The main process factor influencing the surface roughness of FDM parts is therefore the layer thickness, as it causes the just mentioned effect. On the one hand, there are several

post-processing treatments to improve the surface finish of a printed part (e.g., chemical treatment), while on the other hand, research has shown that for some applications rougher or untreated surfaces can even be beneficial. As Han et al. (2019) found out in their studies, this can especially be the case for medical implants: They fabricated PEEK samples via FDM and further modified them in order to achieve a set with different levels of surface roughness. By placing a human cell line on these samples, its cellular response was systematically investigated by observing various characteristic parameters (e.g., cell adhesion, metabolic activity or its reproduction), but also the samples' wettability in relation to their specific surface roughness. As the analysis revealed, the untreated (and specially structured) surfaces obtained the best results. These untreated PEEK surfaces had Ra values of e.g., 22.28 ± 15.26 µm, which may have provided a larger surface area for cell proliferation. (Han et al., 2019)

Similar results in this context were also obtained in a study by Modi and Sanadhya (2018).

These results could also be close to the present use case when it comes to guaranteeing an optimal healing process for the patient. Therefore, since there was no data available, test measurements were carried out by means of different samples, in order to be able to assess the current development towards such an (optimum) surface finish. For the test measurement a mobile tactile roughness measurement device was used (JENOPTIK GmbH, 2014) to examine three flat plates with different layer thickness (hence, with different surface finish), as well as three sample cranial implants, also with different layer thickness. The test samples were made of PLA and PETG respectively, and fabricated by a desktop FDM printer. Figure 57 summarizes the test. The obtained surface roughness values are listed in Table 22.

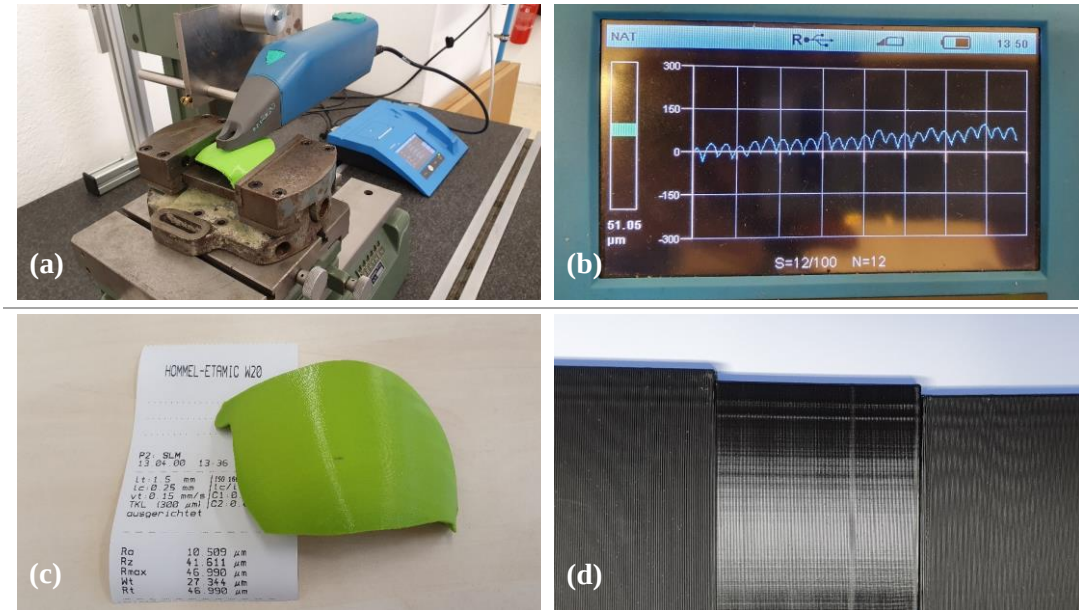


Figure 57: Test setup (a), exemplary measurement curve (b), sample cranial implant and printout of measured values (c) and sample plates (d)

Due to the strong curvature of the sample cranial implants it was only possible to set a rather short measuring length of about 1.5 mm, before the tactile needle lost contact and the respective graph dropped. However, this is where the flat sample plates served as a reference in order to get reliable results on a measuring length of 4.8 mm as depicted in Figure 57b.

Table 22: Results of surface roughness test measurements

Samples	Ra [µm]	Rz [µm]	Layer Thickness [mm]	Material
Plate 1	20.120	87.684	0.20	PLA
Plate 2	14.236	63.748	0.16	PLA
Plate 3	8.774	47.045	0.12	PLA
Implant 1	10.209	42.420	0,12	PLA
Implant 2	10.509	41.611	020	PLA
Implant 3	9.911	42.257	0.12	PETG

Having performed these test measurements and gathered information about realistic or even "optimal" roughness values, it would be possible to use such samples as reference objects in order to gain a clearer understanding of this overall aspect. As can be seen in Table 22, the above mentioned "optimal" surface roughness values (in terms of implant integration) of about 22 µm can already be realized by a desktop 3D printer and are therefore useful results.

- *Overall consideration of costs*
  To assess the cost of a method, the respective machine hourly rate was used as an appropriate basis for comparison. It should be noted, however, that this might reflect a distorted view, as acquisition costs in particular will also play a significant role when deciding which testing equipment to use in the future. An additional inclusion of this aspect might change the overall picture. Not least, this is a vital aspect to consider for achieving an economic implementation of these procedures into clinical routine. Accordingly, specific analyses need to be conducted (e.g., Total Cost of Ownership, Cost Benefit Analysis) to address this aspect.

- *Norms and standards: validity in Europe*
  When looking at Table 20, where the scales of values for the individual assessment criteria were determined, it can be noted that the criterion *Validity in Europe* belongs to those with a very small range. Most testing methods have been rated as "already approved or state of the art in AM", but it must be emphasized that only the latter is true for most of them – there are not many methods that are specifically approved by AM standards, yet. However, this affects a whole range of areas within the AM industry at present: starting from harmonized medical image acquisition, over the generation of the 3D printed model and its processing (e.g., patient identifier, labels, etc. for medical models), to the QC program, including regular mandatory accuracy checks of a 3D printer using standardized test artifacts for example (Chepelev et al., 2018). Therefore, the joint efforts carried out by the ISO and the ASTM are highly anticipated to clarify or alleviate common challenges. On the other hand, it might take some more time until regulations or guidelines for particular processes or areas of application will be established. Examples for such remaining uncertainties are the great gap that has emerged between the available AM standards for metallic and polymer materials (Garcia-Dominguez et al., 2020) or the still existing lack of standards for the geometric dimensioning and tolerancing of additively manufactured parts as concluded by Moroni et al. (2020).

7.2.2 Uncertainty or Lack of some Criteria

As already stated in section 6.4.3.3, before the conducted VBA was presented, some of the identified assessment criteria had to be discarded for the given case study as there was no specific information available (yet) that would have been necessary to use them in the analysis. However, in the conducted expert interviews these criteria had proven to be of great significance for the selection process of testing methods, which is why they are examined in more detail within this section.

- *Possibly existing residual stresses*
  Residual stress poses an inherent problem to parts made by AM as it can cause distortion or even failure of a part as a consequence of cracking (Waller et al., 2014). Again, in order to be able to make assumptions about how this aspect affects the quality of manufactured parts, extensive investigations are required to gather practical experience. This is not least because of the complex interactions of several process parameters (discussed in chapter 2) which can contribute to strong or discontinuous heat inputs. As it is very difficult to detect or measure residual stresses in a part and knowledge is generally scarce in this regard, it can only be referred to diffraction techniques mainly, although these are reported to be of limited use in AM due their surface sensitivity (Mercelis & Kruth, 2006). According to a specialized expert within the project team, a more promising approach in this regard would be to print a series of different benchmarking models whose nominal geometry is known and which are then measured using CMM, for example, in order to infer residual stresses via FEM. This expert further recommended, that this was a good solution in the context of the project in general: To build up a base of experience by measuring and recalculating benchmarking models or phantoms. This experience could further enable to define certain "confidence ranges", which, in turn, would allow to make statements about residual stresses with a very high probability for certain component sizes or geometries that were manufactured under known parameters. Further post-processing treatments, on the other hand, such as annealing, applied to mitigate the effects of residual stresses, were found to be infit for clinical applications, as stated by Sharma et al., 2020. They reported the occurrence of shrinkage and dimensional deviations, especially noticeable in the tested complex-shaped cranial implants. As noted in chapter 4, the general trend of evaluating the quality of finished parts is to improve *in situ* monitoring (e.g., predicting distortions by Antony Samy et al., 2021) to avoid defects in the first place.

- *Process stability and robustness of testing and measuring devices*
  In Table 11, some descriptions of these important process characteristics were given. They were originally included in the list of assessment criteria to provide an opportunity to rank some *long-term* aspects against other (e.g., technical) criteria that might seem most relevant or obvious at first glance. By doing so, the interviewees had to deal not only with weighing technical data of the respective methods (or devices). Instead, they also had to evaluate their importance in comparison with criteria that can only be determined over time. As a finding, however, it must be noted that some of the interview partners had difficulty in understanding the meaning of this criterion, indicating that it was not specified clearly enough to that time. Nevertheless, these long-term aspects represented by this criterion should not be neglected when deciding on which testing methods to select or eventually keep once the research lab is integrated into the daily routine. Similar to how several studies were conducted to evaluate

the process stability or robustness of 3D printers (Leng et al., 2017) or the whole process chain of in-house manufacturing (Kanters et al., 2019) by using phantoms as benchmarking models, these can be adapted to draw (long-term) conclusions about the testing devices.

- *Applicability of testing methods in clinical routine*
  Since most of the selected or already ordered testing devices were not delivered yet to the 3D printing research lab, but also because the products to be manufactured there are still in their development stages, the potential assessment criteria *applicability* of the testing devices could not be taken into consideration. Given the fact that these devices should be easy and effective to operate in daily clinical routine by appropriately trained personnel, this aspect is likely to become one of the most important for the final decision. Therefore, at least for the FARO measuring scan arm (described in section 6.4.4.1) that arrived at the clinic shortly after the case study was finished, some applicability tests could be performed. After first-time installation and calibration of the scan arm the actual scanning process could be tested using a sample cranial implant (Figure 58c). Of course, the implant must be scanned from two sides in order to capture the entire geometry. The referencing and superimposition of the two scans is performed automatically by the software in a subsequent step (Figure 58b). After a few manual adjustments, the complete 3D scan model is obtained (Figure 58a,) and can further be used for comparison with the originally designed CAD model, for example. Because of the simple and intuitive handling of the measuring scan arm, the entire process took only about 15 minutes (guided by a technical trainer of the producer).

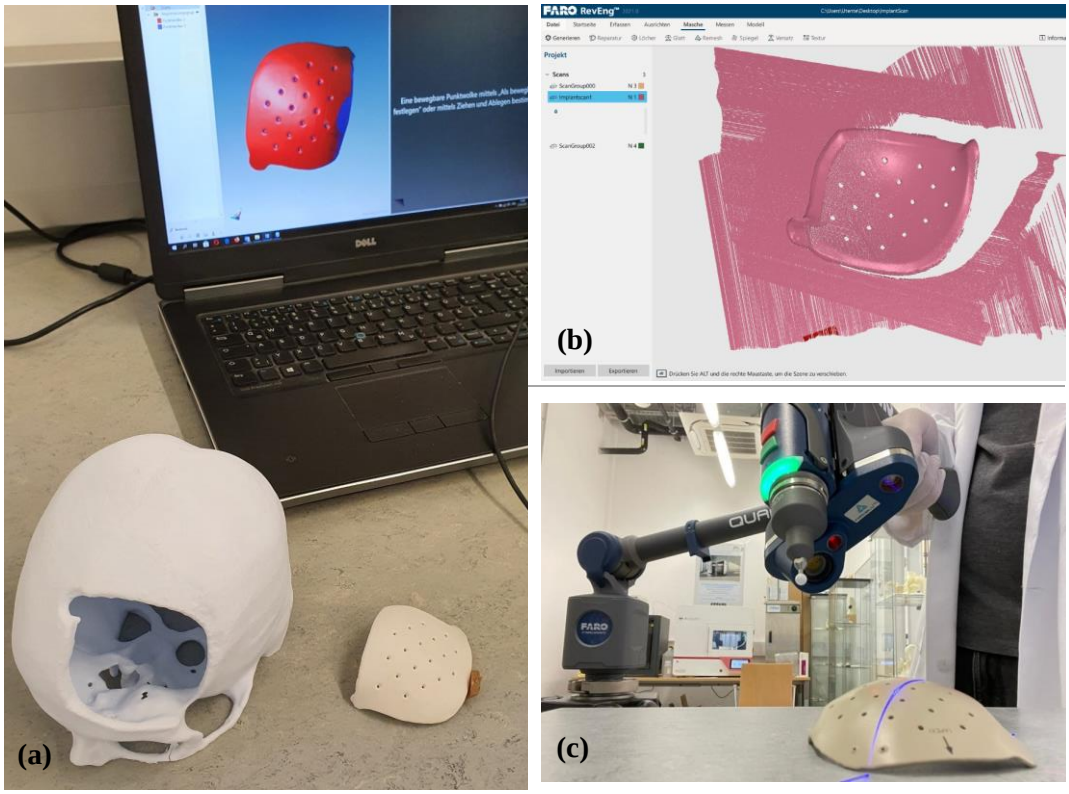


Figure 58: Application of the FARO measuring ScanArm: objects to be scanned (a), intermediate scan result (b), scanning process (c)

8 Conclusion

This chapter seeks to concisely recapitulate the findings of this thesis. While section 8.1 provides a brief outline of the theoretical considerations covered, section 8.2 highlights the main results of the practical part. At the end, in section 8.3 and 8.4 the limitations and an outlook are described.

8.1 Summary

This thesis deals with the systematic identification and selection of suitable testing methods for the QC of medical devices produced by AM. In order to accomplish this task, a step-by-step framework is developed to serve as a guidance for such decision-making processes. The applicability of this framework is subsequently demonstrated on the basis of a given case study, which is concerned with FDM-manufactured cranial implants made of high-performance polymers. Applying this framework consequently leads to the NDT methods most suitable for this specific use case. The findings of this work should further contribute to the successful implementation of a quality control system in the 3D printing lab established at the Medical University of Graz.

After the challenges for this work were defined and the initial situation was described in chapter 1, a literature research was pursued to gather the necessary knowledge for addressing these challenges. To provide a basic orientation among the numerous topics associated with this thesis, chapter 2 first provides a brief overview of AM in general before delving into the field of AM in medicine more specifically. In addition, this chapter also covers advanced considerations for medical devices, in particular AM implants and the technological process steps involved in their manufacture. One of the most important areas of interest within this work, quality management in AM, is outlined in chapter 3. There, the focus is put on the ongoing development of standardization in this field since this represents one of the most crucial issues for AM at the moment. As the final part of the literature research, chapter 4 deals with the currently most eligible testing methods for products made by AM. Due to the nature of the case study performed, the validation of the developed framework is restricted to NDT methods that are applicable for the quality control of a final product. The above-mentioned step-by-step methodology was elaborated in chapter 5. The specific requirements for the resulting TMS framework (i.e., Technology Method Selection) were defined in section 5.2 at first, leading to a layout consisting of the following four steps:

- Step 1: Selection of methods
- Step 2: Determination of (assessment) criteria
- Step 3: Specific assessment (of the selected methods)
- Step 4: Evaluation of results

In the course of the elaboration of the framework a catalogue of testing methods was compiled and structured specifically for the above described specifications of a use case of this kind. Moreover, as another set requirement, suitable tools were identified to be used for each of these steps.

Chapter 6 consists of a detailed discussion of the framework's application to the present use case. First, the post-process QC methods were selected from the created catalogue. For the determination of relevant assessment criteria a Value Proposition Canvas was used to outline a well-structured abstraction of the overall situation of the use case. Together with the consultation of domain experts from within the project, as well as through the findings gained from the previous literature review, this model helped to derive a set of criteria. These determined criteria were subsequently ranked according to expert interviews and transferred into the Value Benefit Analysis where they eventually were used for the assessment and comparison of the pre-selected testing methods. Based on this qualitative analysis, a project-specific decision on the most suitable testing methods could be made.

8.2 Main Results

Referring back to the introduction, this thesis has achieved both of its initially specified challenges: First, it has established a systematic and multi-applicable step-by-step framework that allows for a transparent and comprehensible selection process. In this way, it has then identified the post-process QC methods that are most suitable for the verification of medical implants manufactured with FDM.

In more detail, the analysis conducted in the course of this framework indicated that it was best to focus on specific quality requirements to be met when choosing eligible testing methods. Following this approach, three "main focus categories" were derived, which are based on the most relevant quality requirements of manufactured implants: *shape and dimensional accuracy*, *surface finish* as well as *internal structure and defects*. For these named categories, the following testing methods were identified as the highest scoring, ranked by their affiliation: a specialized tactile measuring scan arm, surface profiling systems and X-ray micro-CT.

On the one hand, within this use case, the analysis resulted in clear "winners" in each category. This can be interpreted as proof for the superiority of some technologies in their fields of application, like the tactile measuring scan arm, which combinatory approach of both, tactile and laser measuring ability represents a key advantage. Or, most notably, X-ray micro-CT, which was also confirmed during the literature study as being the most promising technology for the overall validation of AM fabricated products, due to its ability to be used for all materials and to validate several characteristics regarding the quality of a product (e.g., Charalampous et al., 2020; Lu & Wong, 2017b).

On the other hand, also the individual disadvantages of the selected methods must be considered in the end, like the high acquisition costs or processing times of an X-ray micro-CT, as one example of aspects that could not directly be addressed in the VBA. A number of similar conclusions, condensed into two further sets of vital aspects, could be drawn during the detailed evaluation of results:

First, the concrete requirements for patient-specific implants are currently still under research, posing a major challenge when it comes to specifying the requirements actually placed on the respective testing equipment. This was especially experienced for the investigated quality criteria of *shape and dimensional accuracy* and *surface finish*. At this point, also some general difficulties of the interface technical specifications – medical requirements came into play, as for the surgeon interviewed, these implant characteristics were sufficient, as far as they "felt good" according to his own experience.

Since this specific experience cannot be quantified directly, the author suggests some measures that might serve as an interim solution to this particular problem: One possible remedy are surface finish comparison plates based on VDI 3400 which were already proposed as an alternative in the analysis conducted. These comparison samples could support the process of determining target values that "feel good" enough to the surgeon so that they could be used for implantation. Another solution that was found to be of great significance, as revealed by the literature study, is the use of test artifacts. As concluded by Leng et al. (2017), by precisely defining the size and geometry of a phantom it can serve as a gold standard for quantitative comparisons and therefore assist by providing benchmarks. This approach, however, was not considered in the VBA, because it does not represent a concrete measuring *method*, but rather a means to validate the accuracy and – when collecting data in larger volumes – the process stability of the production machine (i.e., the 3D printer) or, in further sequence, of the testing method applied.

The above-mentioned topic of *process stability* leads directly to a second group of aspects, which can be shared as another key finding: The fact that the products (i.e., patient-specific implants) are still in their developmental stages introduces uncertainties and limits the informative value of this present work, since some of the quality requirements for the testing methods could not be evaluated. As indicated earlier, the related assessment criterion of a method's *process stability* and, moreover, its ability to support the detection of *residual stresses* are among these open issues to be solved in the further progress of the project in order to strengthen the quality of the performed assessment.

In order to begin addressing some revealed uncertainties or open issues, basic measurement attempts towards the determination of the possibly required surface finish have been conducted to provide some reference values. In addition, the already acquired measuring scan arm has been evaluated for its general clinical applicability, being one of the first practical activities that can build on this work.

8.3 Limitations

Throughout this thesis multiple sources were used to best represent the different domains covered. A literature research served as a basis for the necessary theoretical input, while expert interviews and the consultation of different stakeholders and producers were applied to conduct the given case study. However, the present work is subject to a number of limitations:

Some extensive limitations are *resulting from the single case study design or project-related factors:* As the framework was validated with one specific application only (cranial PSI), the transferability of the findings for other scenarios might be limited. The VBA, used as the main tool in the selection process, was restricted only to nondestructive testing methods of extrusion-based AM processes, such as FDM. Due to the defined scope of the use case, only post-process quality control methods were investigated and only specific manufacturing materials (i.e., medical grade PEEK mainly) were considered. Finally, as found during the determination of assessment criteria in section 6.4.3.3, there are a number of quality aspects (e.g., residual stresses) that could not be quantified due to the project's status of development to the time this work was carried out (further detailed in section 7.2).

Furthermore, the main limitation *regarding the nature of the analysis* is the subjective rating of the interviewed experts in order to weight the assessment criteria for the given use case. Being of great benefit to include valuable expertise, this is one of the major drawbacks of the VBA at the same time since the results are not purely factually obtained and therefore not transferable to similar scenarios.

Lastly, also limitations *due to the general status quo in the AM industry* need to be mentioned here. As addressed earlier in this work, there is a general lack of (harmonized) guidelines and standards because of the novelty of AM in many areas of application such as medical. Hence, it is especially difficult to confidently evaluate the quality of an AM component (using NDT methods, for example) – while facing the issue of unknown requirements like in the given project on the other side.

8.4 Outlook and Future Research

First of all, concerning the developed framework for the selection of testing methods, efforts towards the generalizability of this single case study are yet to be undertaken by a strategic selection of further cases, for example, as suggested by Seawright and Gerring (2008). Once the framework has proven its validity in several other use cases, e.g., in the course of the CAMed project, it can be used for a broad range of applications, including selection processes for the pre- and in-process QC of products.

Regarding the future work within this project, the next important steps will be to determine the requirements given for the specific applications as the product development proceeds, and to further implement the chosen testing methods successively in the 3D printing lab. Based on the findings of this thesis, the author suggests the usage of test artifacts and test series, for example, in order to thoroughly evaluate or compare the applicability of different testing methods. Subsequently, these tests will essentially contribute to the determination of the currently neglected assessment criteria. This, in turn, will support both, future decisions on testing equipment and, most importantly, the quality of implants manufactured directly in the clinic as well as the patients' improved well-being.

In order to give a general outlook on the future development of nondestructive QC methods in AM, the literature study indicated a general trend towards intensified efforts regarding the in-process QC: The rising application of sensors during different AM procedures, or the development of statistical and mathematical predicting models, especially applied in FDM procedures, are only some measures taken to reduce or even eliminate the overall costs for specialized post-process QC equipment and the time needed for inspection (e.g., Charalampous et al., 2020; H. Kim et al., 2018). Another essential factor for the progression of AM will be the fast and comprehensive release of standards. These are hoped to vanish or alleviate a lot of the challenges most manufacturers and industries are currently struggling with, such as trying to find a common agreement for testing and inspecting their products.

As for the overall proceedings of the project, its next main step will be the conduction of a clinical study after an advanced level of production as well as the associated QC has been reached within the 3D printing lab. In this phase, the outlined processes, such as the overall quality validation of the implants produced, will be reviewed, before eventually being implemented into the clinical routine.

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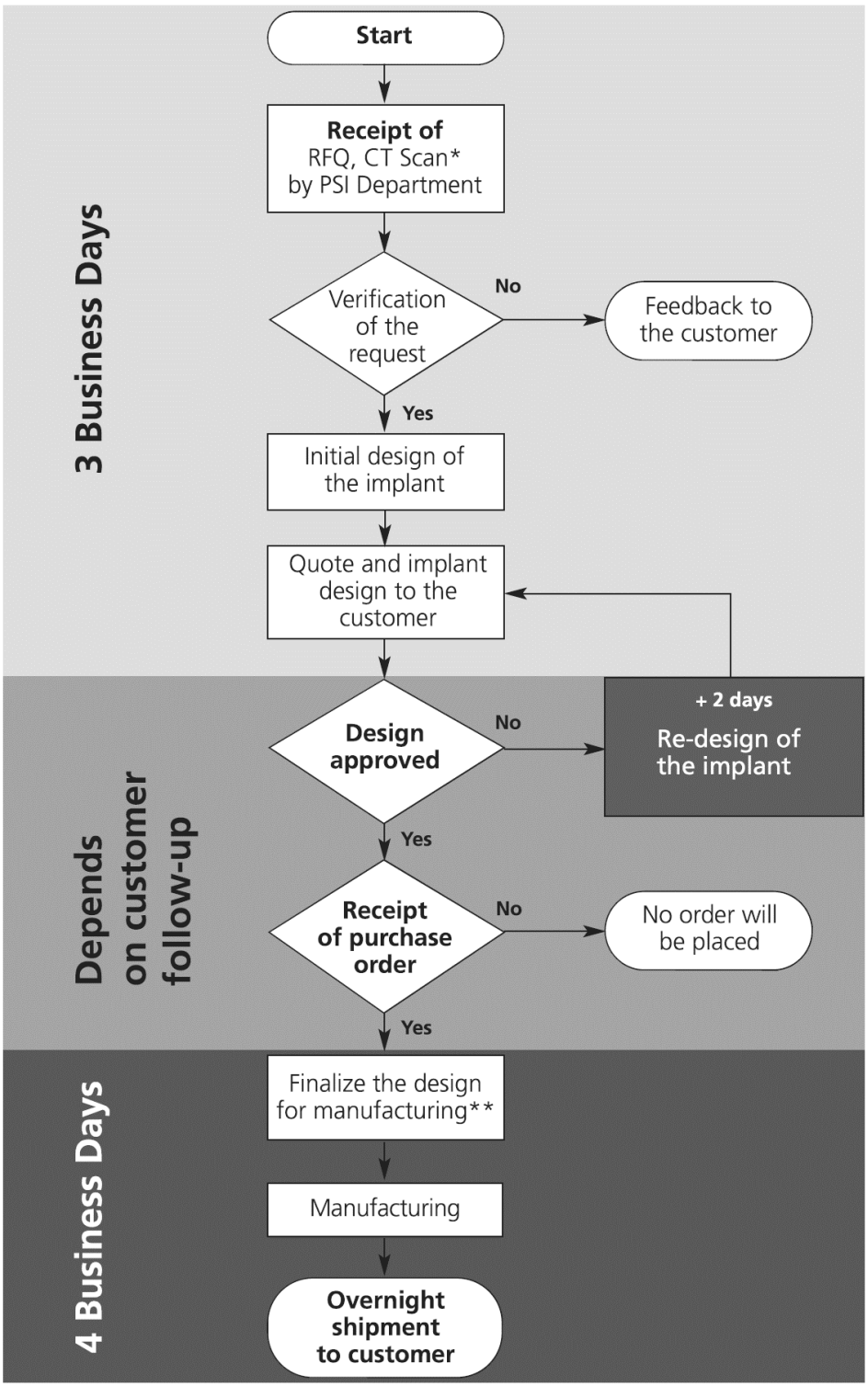
Part V.

Appendix

A. PSI Ordering Process



*Following Synthes CT Scanning Protocol
**Additional manufacturing time is necessary for PEEK PSI involving the midface or orbit, and for all Titanium PSI. Delivery timelines for these PSIs will be communicated at time of quote.

Figure 59: Ordering process of a PSI (DePuy Synthes, 2011)

B. Assessment Matrices

Table 23: Assessment matrix for the ranking of criteria (results shown for the interviewee "technical manager of 3D Printing Lab")

		Technological criteria						*Process relevant criteria*				*Organiz. cr.*		*Start effort*			
	Evaluation Guidlines: **0** = less important than other criterion **0,5** = equally important as other criterion **1** = more important than other criterion	**Shape/ Dimensional Accuracy**	**Surface Finish**	**Detectability of Internal Cracks**	**Residual Stresses**	**Testing Duration (Time)**	**Sufficiency as stand-alone Method**	**Process Costs**	**Process Stability/ Robustness**	**Implementation Effort (Resources)**	**Applicability for other Materials**	**Validity in Europe**	**Workplace Safety Standards**	**Development Effort (Time)**	**Qualification of Operators**	**Total Points**	**Weighting [%]**
Technological criteria	**Shape/ Dimensional Accuracy** method's ability to verify deviations in shape and dimensions		0,5	0,5	0,5	1	1	1	1	1	1	1	1	1	1	**11,5**	**12,6**
	Surface Finish method's ability to verify the quality/ roughness of the part's surface	0,5		0,5	0,5	1	1	1	1	1	1	1	1	1	1	**11,5**	**12,6**
	Detectability of Internal Cracks method's ability to detect cracks inside of a part	0,5	0,5		0,5	1	1	1	1	1	1	1	1	1	1	**11,5**	**12,6**
	Residual Stresses method's ability to indicate internal part stresses	0,5	0,5	0,5		1	1	1	1	1	1	1	1	1	1	**11,5**	**12,6**
	Testing Duration (Time) method's amount of time needed to test one 3D printed part	0	0	0	0		0,5	1	0	0	1	0	0	0	1	**3,5**	**3,8**
	Sufficiency as stand-alone Method method's ability to capture more than one feature of the part integrity	0	0	0	0	0,5		0,5	0,5	0,5	0,5	0,5	0,5	1	0	**4,5**	**4,9**
Process relevant criteria	**Process Costs** costs incurred by the method (investment costs / machine hourly rate)	0	0	0	0	0	0,5		0	0	0	0	0	1	0	**1,5**	**1,6**
	Process Stability/ Robustness method's ability to perform in a consistent & predictable manner over time	0	0	0	0	1	0,5	1		1	1	0,5	1	1	0,5	**7,5**	**8,2**
	Implementation Effort (Resources) e.g., useability of already existing resources (facilities, personnel's skills)	0	0	0	0	1	0,5	1	0		0,5	0	1	1	0,5	**5,5**	**6,0**
	Applicability for other Materials method's suitability to also be used for other materials / purposes	0	0	0	0	0	0,5	1	0	0,5		0	1	1	1	**5**	**5,5**
Organiz. crit.	**Validity in Europe** method's degree of certification for given purposes (European standards)	0	0	0	0	1	0,5	1	0,5	1	1		0,5	0,5	1	**7**	**7,7**
	Workplace Safety Standards effort to fulfill the workplace security standards for the using the method	0	0	0	0	1	0,5	1	0	0	0	0,5		0,5	0,5	**4**	**4,4**
Start effort	**Development Effort (Time)** duration of start-up phase until process is running stable	0	0	0	0	1	0	0	0	0	0	0,5	0,5		0,5	**2,5**	**2,7**
	Qualification of Operators effort to establish and maintain the staff's competence to use the method	0	0	0	0	0	1	1	0,5	0,5	0	0	0,5	0,5		**4**	**4,4**
																91	**100**

SORTED

Percentage Share	Criterion
12,6	Shape/ Dimensional Accuracy
12,6	Surface Finish
12,6	Detectability of Internal Cracks
12,6	Residual Stresses
8,2	Process Stability/ Robustness
7,7	Validity in Europe
6,0	Implementation Effort (Resources)
5,5	Applicability for other Materials
4,9	Sufficiency as stand-alone Method
4,4	Workplace Safety Standards
4,4	Qualification of Operators
3,8	Testing Duration (Time)
2,7	Development Effort (Time)
1,6	Process Costs

Table 24: Assessment matrix for the ranking of criteria, results for the interviewee "Principal Investigator of Orthodontics"

		Technological criteria						*Process relevant criteria*				*Organiz. cr.*		*Start effort*			
	Evaluation Guidlines: **0** = less important than other criterion **0,5** = equally important as other criterion **1** = more important than other criterion	**Shape/ Dimensional Accuracy**	**Surface Finish**	**Detectability of Internal Cracks**	**Residual Stresses**	**Testing Duration (Time)**	**Sufficiency as stand-alone Method**	**Process Costs**	**Process Stability/ Robustness**	**Implementation Effort (Resources)**	**Applicability for other Materials**	**Validity in Europe**	**Workplace Safety Standards**	**Development Effort (Time)**	**Qualification of Operators**	**Total Points**	**Weighting [%]**
Technological criteria	**Shape/ Dimensional Accuracy** method's ability to verify deviations in shape and dimensions		0,5	0,5	0	1	0	0	0	0,5	0	1	0	1	1	**5,5**	**6,0**
	Surface Finish method's ability to verify the quality/ roughness of the part's surface	0,5		0,5	0	1	0,5	0	0	1	0,5	1	1	1	1	**8**	**8,8**
	Detectability of Internal Cracks method's ability to detect cracks inside of a part	0,5	0,5		1	1	1	1	1	1	1	1	1	1	1	**12**	**13,2**
	Residual Stresses method's ability to indicate internal part stresses	1	1	0		1	1	0,5	0,5	1	1	1	0,5	1	1	**10,5**	**11,5**
	Testing Duration (Time) method's amount of time needed to test one 3D printed part	0	0	0	0		1	0	0,5	1	0,5	1	1	1	0,5	**6,5**	**7,1**
	Sufficiency as stand-alone Method method's ability to capture more than one feature of the part integrity	1	0,5	0	0	0		0	0,5	0,5	0	1	0	0,5	0,5	**4,5**	**4,9**
Process relevant criteria	**Process Costs** costs incurred by the method (investment costs / machine hourly rate)	1	1	0	0,5	1	1		1	1	1	1	1	1	1	**11,5**	**12,6**
	Process Stability/ Robustness method's ability to perform in a consistent & predictable manner over time	1	1	0	0,5	0,5	0,5	0		0,5	0,5	0	0,5	0,5	0,5	**6**	**6,6**
	Implementation Effort (Resources) e.g., useability of already existing resources (facilities, personnel's skills)	0,5	0	0	0	0	0,5	0	0,5		0,5	0	0	0	0	**2**	**2,2**
	Applicability for other Materials method's suitability to also be used for other materials / purposes	1	0,5	0	0	0,5	1	0	0,5	0,5		1	0	0	0	**5**	**5,5**
Organiz. crit.	**Validity in Europe** method's degree of certification for given purposes (European standards)	0	0	0	0	0	0	0	1	1	0		0	0,5	0,5	**3**	**3,3**
	Workplace Safety Standards effort to fulfill the workplace security standards for the using the method	1	0	0	0,5	0	1	0	0,5	1	1	1		1	1	**8**	**8,8**
Start effort	**Development Effort (Time)** duration of start-up phase until process is running stable	0	0	0	0	0	0,5	0	0,5	1	1	0,5	0		0	**3,5**	**3,8**
	Qualification of Operators effort to establish and maintain the staff's competence to use the method	0	0	0	0	0,5	0,5	0	0,5	1	1	0,5	0	1		**5**	**5,5**
																91	**100**

SORTED

Percentage Share	Criterion
13,2	Detectability of Internal Cracks
12,6	Process Costs
11,5	Residual Stresses
8,8	Surface Finish
8,8	Workplace Safety Standards
7,1	Testing Duration (Time)
6,6	Process Stability / Robustness
6,0	Shape/ Dimensional Accuracy
5,5	Applicability for other Materials
5,5	Qualification of Operators
4,9	Sufficiency as stand-alone Method
3,8	Development Effort (Time)
3,3	Validity in Europe
2,2	Implementation Effort (Resources)