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COMPARISON OF THE DESIGN, PROCESS AND MANUFACTURING OF PRODUCING CUSTOM-MADE ANKLE FOOT ORTHOSIS WITH TRADITIONAL AND ADDITIVE MANUFACTURING TECHNIQUE

Master’s thesis

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PATSIENDIKOHASE HÜPPELIIGESE ORTOOSI TAVAPÄRASE VALMISTAMISE JA KOLMEDIMENSIONAALSE PRINTIMISE TEHNIKATE VÕRDLUS - KAVANDAMINE, TOOTMISPROTSESS JA VALMISTAMINE

Magistritöö

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Author’s declaration of originality

I hereby certify that I am the sole author of this thesis. All the used materials, references to the literature and the work of others have been referred to. This thesis has not been presented for examination anywhere else.

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Abstract

Background: Three-dimensional (3D) printing as additive technique has become increasingly widespread in medical area. 3D printing is a multi-process technology, in which the objects usually are generated virtually from a digital model of 3D scanning and can be in any size or shape. 3D printing is used in different medical fields and custom-made orthosis manufacturing is no exception. Traditional custom-made orthoses manufacturing technique is time consuming, labour-intensive and quite expensive. However, orthoses are playing an important role in patient rehabilitation and they have to be of high quality and at the same time quickly available. In this case, 3D printing technique can be a good opportunity to be used in this medical field as well. *Aim:* The aim of this thesis is to investigate the feasibility of custom-made ankle-foot orthosis (AFO) manufactured with 3D technique. *Method:* Three different methods were used: descriptive and thorough data review to support the aims of the work, questionnaire to have practical experience in addition to theoretical overview and finally, to assess the feasibility of AFO manufacturing with 3D technique there was practical experiment. *Results:* The feasibility of using 3D printing technique in orthosis manufacturing is seen and proven according to the literature review, questionnaire responses and personal practical experiment. 3D printed custom-made AFOs can be compared with the traditionally manufactured custom-made AFOs. Moreover, 3D printed AFOs mechanical and physical properties are similar to traditionally manufactured AFOs. AFO production has to be proper and suitable materials and techniques have to be selected, so the walking ability, durability, long-term benefits and patient satisfaction can be improved. *Conclusion:* The overall feasibility about usage of 3D printing technique in AFOs manufacturing has to be shown by additional clinical research. There should be considered correct legal aspects and proven clinical efficiency and effectiveness of this method. Only after further research and choosing the right technique, 3D printed AFOs as medical devices can be actively used in a clinical practice.

This thesis is written in English and is 63 pages long, including 5 chapters, 8 figures and 3 tables.

Annotatsioon

Patsiendikohase hüppeliigese ortoosi tavapärase valmistamise ja kolmedimensionaalse printimise tehnikate võrdlus-kavandamine, tootmisprotsess ja valmistamine

Kolmemõõtmeline ehk 3D-printimine kui kihtlisandustootmise tehnika on meditsiini valdkonnas üha laialdasemalt kasutatav. 3D-printimine on mitmest protsessist koosnev tehnoloogia, mis võimaldab objekte valmistada kiht kihi haaval. Antud objektid on tavaliselt 3D-skaneerimise ja hiljem digitaalse tarkvara abil genereeritud ning need võivad olla mis tahes suuruses või vormis. Mõnedes Euroopa riikides ja eriti Ameerikas kasutatakse 3D-printimise tehnikat ka eri tüüpi eritellimusel valmistatud ortooside tootmise puhul. Traditsiooniline eritellimusel valmistatud ortooside valmistamise tehnika on aeganõudev, töömahukas ja üsna kallis. Lisaks vajab see erilisi oskusi ja kogemust. Peab aga meeles pidama, et ortoosidel on oluline roll patsientide taastusravis ning seetõttu need peavad olema kvaliteetsed ja samal ajal kiiresti kättesaadavad. 3D-printimine võib olla väga hea asendus või lisaabiline traditsioonilisele ortoosi valmistamise tehnikale.

Töö eesmärk: Uurida 3D-tehnikaga eritellimusel valmistatud hüppeliigese ortooside teostatavust, ning võrrelda omavahel seda traditsioonilise valmistamise tehnikaga.

Meetod: Eesmärgi saavutamiseks kasutati kolme erinevat meetodit. Esimeseks meetodiks oli kirjanduse põhjalik ülevaade. Lisaks koostati küsimustik, et koguda praktilist infot kasutatavate tehnikate kohta. Kolmandaks valmistati praktilise kogemuse saamiseks ning ka 3D-tehnika kasutamise hindamiseks kaks eritellimusega soovitud hüppeliigese ortoosi.

Tulemused: Vastavalt kirjanduse ülevaatele, küsimustiku vastustele ja praktilisele katsele saab öelda, et 3D-printimise tehnikaga eritellimusel hüppeliigese ortooside valmistamine on teostatav. Peale selle on kihtlisandustootmise tehnikaga toodetud hüppeliigese ortoosid võrreldavad traditsiooniliselt valmistatud ortoosidega. Samuti on nende ortooside mehaanilised ja füüsikalised omadused sarnased.

Kokkuvõte: Eritellimusel hüppeliigeste valmistamine peab olema täpne ja kvaliteetne, valida tuleb sobivad 3D-materjalid ja 3D-tehnikad. Selleks, et näha veel suuremat antud meetodi tõenduspõhisust ja efektiivsust on vajalikud täiendavad kliinilised uuringud. Ainult peale seda saab 3D-prinditud eritellimusel valmistatud hüppeliigese ortoose võtta kasutusele meditsiiniseadmetena kliinilises praktikas.

Lõputöö on kirjutatud inglise keeles ning sisaldab teksti 63 leheküljel, 5 peatükki, 8 joonist, 3 tabelit.

List of abbreviations and terms

ABS	Acrylonitrile butadiene styrene
AFO	Ankle-foot Orthosis
AM	Additive Manufacturing
CAD	Computer-aided design
CFRP	Carbon fiber reinforced polymer-based
CP	Cerebral Palsy
CT	Computed (Axial) Tomography
DICOM	Digital imaging and communications in medicine
DLP	Digital light processing
EBM	Electron beam melting
FDM	Fused deposition modeling
LENS	Laser engineering net shape
LOM	Laminated object manufacturing
MRI	Magnetic Resonance Imaging
PC	Polycarbonate
PE	Polyethylene
PLA	Polylactic acid
PP	Polypropylene
RP	Rapid Prototyping
SHS	Selective heat sintering
SLA	Stereolithography
SLS	Selective laser sintering
STL	Stereolithography file format
UAM	Ultrasound additive manufacturing
UV	Ultraviolet
3D	Three-dimensional

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Introduction

Over the last decades, three-dimensional (3D) printing as an additive technique has become increasingly widespread in the medical area. 3D printing is a multi-process technology, whereby a three-dimensional firm object will be completed. The completed objects usually are generated virtually from a digital model of 3D scanning and can be in any size or shape [1]. In short, 3D printing is a manufacturing method, which is used to make physical objects from digital models [2].

3D printing as additive manufacturing (AM) is used in different medical fields. For example, to produce custom surgical instruments, make surgical planning and training, print organs and implants, drug delivery, dental industry, external prosthetics and orthotics [3], [4]. This work is focused on different orthosis manufacturing techniques and mainly on ankle-foot orthosis (AFO) production.

An orthosis is defined as an externally applied assistive device, which is used to support the upper or lower limb. The orthosis can be used to limit the range of movement or assist in movement considering existing structural and functional characteristics of the patient skeletal system [5], [6]. AFO is used to support the lower leg, ankle and feet. It can be used for adults or children and can be custom-made [7], [8]. All kinds of orthoses are very important part of patient rehabilitation and can be used with different diagnoses and problems. Nowadays, the most popular manufacturing method is manual plaster casting. Unfortunately, the current method of producing custom-made AFOs is time-consuming, requires special education and skills and can be expensive for the hospital and patient [5], [9], [10]. Recently, 3D printing as AM has been widely used in some countries as an alternative to the current method in AFOs manufacturing. There are a lot of studies, which describe and compare different approaches used in AFOs manufacturing while bringing out the advantages and disadvantages of them. There is a lot of potential in novel technique and it can be a good option in some cases, as 3D printing can reduce costs of AFO production, is a less time-consuming process, and finished product physical and mechanical properties remain the same [8], [11].

In Estonia AFOs are widely used in adult or children lower limb rehabilitation and can be prescribed by physician or physical therapist. Custom-made orthoses with plaster cast technique can be done by qualified orthotists in two places – Haapsalu Neurological Rehabilitation Centre in Haapsalu and Ortoosimeister OÜ in Tallinn. Despite small market, Estonian healthcare has the same problems as mentioned before within the current method used. 3D printing technique is not used right now in Estonia for orthosis manufacturing and therefore it is important to introduce new innovative opportunities which can be further explored and deployed.

The aim of this thesis is to investigate the feasibility of custom-made AFOs manufactured with the 3D printing technique. In addition, brief description of the 3D printing concept, transformation processes and materials used, description of current techniques used, representation of different processes and steps passed within currently used plaster casting and AM technique. In order to achieve these goals, a literature review and analyze was performed using different databases. In addition, to get more thorough and practical description of both techniques author conducted a questionnaire. To get additional information regarding different 3D printing processes passed practical experiment was made by printing out with a 3D printer one pair of AFOs for the neurological patient of Tallinn Children's Hospital.

The thesis concentrates on the following research questions:

1. Does 3D printing of custom-made AFO have a potential to replace a traditional technique used nowadays?
2. Is the 3D printing efficient and effective method to manufacture a custom-made AFOs, because this is fast, repeatable, flexible to design modifications and cheaper technique?
3. Is manufacturing of custom-made AFOs with the 3D printing technique more comfortable to the patient and to the maker (e.g. orthotist)?

1 LITERATURE REVIEW

The rapid development of AM and usage of 3D printers in medical field have made it possible to study usage of new applications made by these techniques in biomedicine and medical industry [12].

1.1 Types of 3D printing and materials used

Over the years 3D printing technologies have been developed and renewed. 3D printing technologies have been divided into seven groups. Different materials and targeted applications are used for each group [13].

Types of 3D printing technologies:

- First is quite simple, cheap and fast technology – the binder jetting. For this technique can be used materials as metals, sands, polymers, hybrid and ceramics. Liquid binding agent is placed to join powder particles, so these powder particles can glue together. This technique can be good to print large objects.
- Second is directed energy deposition. Example of this technology is laser deposition and laser engineered net shaping (LENS). This is quite complex 3D method and is used to repair or add some material to already existing parts. Materials used- ceramics, polymers, metals and metal-based hybrids (wire or powder).
- Third technology is widely used materials extrusion. Best example is fused deposition modelling (FDM) and the main material used is polymer. Object is produced layer-by-layer by heating and extruding thermpolastic filaments.
- Fourth is a materials jetting technology. Wide range of materials can be used: polymers, ceramics, composite, biologicals and hybrid. In the course of this technique layer-by-layer solid object is formed when photosensitive material drop by drop is hardened under ultraviolet (UV) light.
- Fifth is the powder bed fusion. This process includes three techniques: electron beam melting (EBM), selective laser sintering (SLS) and selective heat

sintering (SHS). As materials can be used metals, ceramics, polymers, composite and hybrids. Main example is fast and accurate SLS technology. An electron beam or laser is used to melt the material together.

- Sixth is the sheet lamination technique, where the sheets of material are connected together to produce an object or a part of it. Examples are laminated object manufacturing (LOM) and ultrasound additive manufacturing (UAM). This technique is quite cheap, materials are easy to handle and materials can be recycled.
- Seventh and the last technology is frequently used vat photopolymerization. Materials used are liquids, which under laser, light or UV are hardened. Stereolithography (SLA) and digital light processing (DLP) are main examples of this technology [13].

In order to produce a high-quality product with the 3D printing technique all of the materials used have to be in an appropriate quality. Therefore, different necessary procedures, requirements and agreements of material controls are established [13]. Wide range of materials is used:

- Metals: aluminum, cobalt-based, nickel-based and titanium alloys, stainless steel
- Polymers: polylactic acid (PLA), acrylonitrile butadiene styrene (ABS), polypropylene (PP), polyethylene (PE)
- Ceramics: alumina, bioactive glasses, zirconia
- Composites: carbon fibers and glass fibers reinforced polymer composites
- Smart materials: shape memory alloys and shape memory polymers
- Special materials: food, lumar dust and textile [13].

1.2 Overview of the concept of 3D printing in medical field

First ideas of 3D printing were developed from the early 1970', when the first methods were described. In the early 1980's was developed SLS. However, commercial usage of 3D printing known as AM technique started in the end on 1980's, when the first SLA systems were introduced [1], [14]. Nowadays, 3D printing known as additive technique can be used in different areas. Few decades ago, medical 3D printing was unknown domain and seemed impossible. However, currently 3D printing in medical field is a real opportunity to support medical and pharmaceutical companies to make individual and specific products, in order to improve quality and availability of the products or service [1]. First trials of 3D printing usage in medical field goes back into beginning of the 1980s. In the following years this area has been rapidly and successfully developed, which allows to make medical products quickly, effectively and individually. 3D printing also called as AM allows to create a physical object from 3D digital data by printing it out layer by layer, which is important to create accurate and patient-specific designed products [1], [15], [16].

1.2.1 Manufacturing technologies, capabilities and software used

3D printing technology can be new innovative possibility to help medical and pharmaceutical companies to design patient-specific products, specific drugs, medical implants, planning of the procedures and surgeries [1].

To produce an end-product with the 3D printing technique there is a need to go through several processes. These steps or processes are affected by several factors. For example, what kind of materials are used, how complicated is the product, different costs, size of the product and the environment. Despite all factors there are three major steps: modeling, printing and finishing the product [17].

To look in more detail and to produce the final model there are five technical steps, which are important [1]:

1) Selection of target area anatomically
2) 3D geometry processing via medical images (Computed Tomography (CT)/ Magnetic Resonance Imaging (MRI) scan) or scanning with the special 3D scanner
3) Choosing the best variation of the files, so the physical printing can take place
4) Selection of the materials and 3D printer
5) Printing: approval and control of the quality

3D scanning is best practical solution to capture human anatomical area or the shape of the limb. There are different scanners and scanning systems, which are light-based techniques in order to define a 3D position in room of the different points that in turn make the surface of an object. Later computer software can be used to rebuild the surfaces and then the computer-aided (CAD) model is received [9].

Different scanners are used to take measurements of the body parts, which can be changed into digital data and later printed out as a final 3D product. Scanners can be static or dynamic (which can be attached to phone or iPad). In addition, there are different scanning technologies used: single image for reconstruction, structured light technologies, lasers and for stereo reconstruction different algorithms. Laser and structured light technologies are more commonly used in order to reconstruct the shape of human body. Laser techniques are used with the laser dot or line from a hand-held device. Sensor measures of the distance from object to the surface are done with a charge-coupled or a position sensitive device. For static objects it is easier, as data is taken from internal coordination system. For dynamic objects, position of the scanner must be set correctly. Structured light technologies can be used as well. In this case, projector-camera system with the already pre-defined settings is projected on the object. Unfortunately, this method is not the best to use in order to scan some parts of the human anatomy as the received data is more precise. For example, the back of the flexed knee, space between fingers or armpits [9],[18].

Next step after scanning is designing of 3D object with the CAD software. It is important that optimization of the geometry according to the 3D printer is done. Virtual 3D CAD model is developed layer-by-layer from data to a physical solid object. Next manufacturing process- virtual 3D CAD model has to be converted to a standard stereolithography file format (STL), which is including only the 3D geometry [9],[19].

1.2.2 Transformation processes and materials used

3D printing can be done in different ways and with the different materials, but at any event printing is based on the principle of layer-by-layer development of a solid 3D object. Nowadays, there are a lot of different smart printers, where every printer has their own suitable material to use. To produce 3D object, as a nano, micro or macro material can be used- plastic, metal, ceramic, different powders, liquid and living cells [4]. Materials can be used separately or together to form structured material as bio-nanocomposite implants in AM techniques [20], [21], [22]. It is very important to choose the correct material and it is also related to the selection of the suitable 3D printer. One very important factor is requirements of the model. In medical applications different anatomical structures need different technical and mechanical properties- rigid or soft materials. For example, bones are inelastic and rigid, but ligaments are elastic and soft [1]. In addition, patient specific materials can be made with the help of using digital imaging and communications in medicine (DICOM) (CT and MRI) scan data [20]. Later on, this kind of scanned data can be converted to 3D model with the CAD software, then converted to STL file and printed out.

Despite this, that materials can be patient specific, in most cases materials with specific properties are used. There are hundreds of different materials, which can be used or combined. The most common materials for FDM are polycarbonate (PC) and ABS or a mix of both. Properties of these materials are similar to thermoplastic material [9]. Other materials such as thermoplastics, biomaterials, different polymers, metals, powders or nylon-based materials may be used as well. Appropriate material should be used in order to get desired strength, price, durability, usage properties and final design [9], [23].

1.3 Overview of key applications of 3D printing in medical field

3D printing is a big opportunity to help medical and pharmaceutical companies in order to get a patient-specific product. Nowadays, development of devices and expansion of the list of materials shows that additive manufacturing technologies are growing rapidly. Most actively 3D printing in medical field is used in the United States of America (USA). However, in Europe there also have been different clinical trials and researches regarding usage of 3D printing in medical field [1], [3], [4], [18].

1.3.1 Different fields of 3D printing applications worldwide in medicine

The use of 3D printing technologies in medical field have shown increased performance, faster learning, management and improvement of the treatment quality in some cases. In addition, it has a huge benefit in medical student education- reproducibility and opportunity to simulate different situations without harming the patient [10]. There are several medical areas, where 3D printing can be effectively used:

Table 1. Different fields of 3D printing applications

Area	Main applications
Dentistry	Possibility to create restorations (implants, bridges, crowns), physical models, surgical guides, orthodontic appliances [1], [4].
Personalized presurgical treatment and preoperative planning	It is possible to have a physical 3D model of the desired patient anatomy that could be used to plan the best surgical approach; possibility to choose before the implantation the size of the prostheses; especially used in craniofacial and maxillofacial surgery [1], [4].
Surgical tools	Surgical tools, guides and instruments can be customized [1].
Medical devices	Producing of prototypes or improvements/extras to already existing devices [1].
Medical education	Printing is used for production of patient-specific models [1].
Drug printing and formulation	Possibility to print personalized the powdered drug layer (it dissolves faster); producing the exact amount of the drug [1], [4].
Prostheses and orthoses	Printing of custom-made upper or lower limb orthoses or prostheses; possibility to print braces and casts [1], [4].
Bioprinting	Printing of organs and tissues, which can be implanted to the patient; bioprinted organs to analyze toxicity of new drugs, to test cosmetics [1], [4].

3D printing has different benefits for the patients, medical stuff, medical students and overall for the healthcare system. Usage of 3D printing in medical field can improve the techniques and processes overall, outcomes of the surgical procedures can be improved significantly, decreased waiting times and costs. In addition, 3D companies get benefit as well by producing products for the healthcare specialists [3], [14].

1.3.2 Evidence-based 3D printing and legal aspects of this method

Diment *et al*. showed that despite of AM shows a lot of beneficial aspects and offers a lot of great products it is still need more researches to be done. A lot of 3D printed devices or objects have been clinically trialed, but most of the studies have been in poor quality, demonstrated statistically not significant results or are made in a narrow field (e.g. dental industry). Moreover, in some cases there were not enough of the devices tested and control group was small or absent at all [10].

In addition, proper legal status must be achieved in order to use 3D printing in medical field. According to the Regulation (EU) 2017/745 of the European Parliament and of the Council of the 5 April 2017 all of the 3D printed products are custom-made devices. From a legal point of view, the main problems can be related to the protection of property rights and the assessment of the product liability. It is important to have an end-product control, so that it corresponds to safety and performance requirements. The regulation present that custom-made or investigational devices do not have to bear the CE marking. Although, medical device has to comply the Medical Devices Act and be clinically evaluated (in some cases with thorough clinical trials) [1], [3], [6], [24], [25].

1.4 Traditional manufacturing technique to produce orthoses

Mostly, majority of the rehabilitation devices are designed, modeled and hand-crafted by orthotist. Orthotist is a qualified specialist, who has special skills and experience in orthosis manufacturing field. All kind of orthoses are very important part in the patient rehabilitation and can be used with different diagnoses and problems. As the manufacturing process is fully manual and require special skills and time, result is patient-specific and precise [9].

Orthoses are externally applied assistive devices that are designed to provide support, correct joint alignment, assist for muscle weakness and protect the limb [9], [11]. These assistive devices can be used: for neurological conditions, different limb injuries and congenital deformities. Upper or lower limb orthoses can be divided into two main groups [11]:

1) Standard prefabricated orthoses for general use
2) Custom-made orthoses, which are made manually by orthotist

Standard prefabricated orthoses are used for more common disorders- after injury, without any deformity in the limb. Custom-made orthoses are for more complex conditions. Both of them can be prescribed by neurologist or any other physician. For upper limbs are mainly used- elbow and wirst orthoses. Lower limbs orthoses have a wide range of use and they are designed for hip, knee and ankle joints [11]. Different orthoses are used on different purposes and have specific mechanical properties [26]. In this work the main aim is to focus on lower limbs and only on one type of orthoses, which is called AFO.

1.4.1 Production of custom-made ankle-foot orthosis

AFOs are orthoses that includes the ankle joint and the whole or part of the foot. AFOs are intended to control walking, correct deformity and compensate the muscle weakness of the leg/foot. AFOs are the most commonly used orthoses in the lower limb, making up about 26% of all orthoses provided in the United States [27]. In addition, these assistive devices are the mostly used type of orthosis in children with cerebral palsy (CP) [28]. AFOs are prescribed by neurologist, any other physician or physiotherapist, mainly, to increase walking speed and reduce the energy cost, to correct abnormal gait and support gait training, functional activities in children with CP [26]. AFOs are named so, because they are proximally ended below the knee joint and extended distally over the foot. AFOs are used in order to provide stability in the ankle joint and to perform control above and below of ankle [11]. They are used to improve functions of the lower leg, ankle and foot, to prevent or reduce deformities and to assist weak and spastic muscles [2]. Therefore, main functions of the AFOs are [11], [26]:

- Improvement of walking ability
- Support of the lower part of the leg
- Improvement of function during ADL
- Improvement of balance, coordination and stability
- Training facilitation

There are various types of AFOs for different diagnoses and biomechanical aims. Different types of AFO are made in order to achieve various goals. Flexible AFO is made to assist dorsiflexion in ankle joint. Rigid AFO is used to block ankle movements. These two types are the most used. In addition, there are AFO with Tamarack Flexure joint and anti-talus AFO, which are used for more specific aims [12]. Solid ankle foot orthosis (SAFO), which is rigid to support ankle and to prevent any possible movement in the ankle. Dynamic ankle foot orthosis (DAFO) is used to ensure subtalar stabilization. This kind of orthosis allows ankle joint to move into dorsiflexion and partially limits the plantar flexion. Another type of dynamic AFO is the hinged ankle foot orthosis (HAFO), which let the ankle joint move into dorsiflexion during walking. Moreover, HAFO is usually used to limit the motion of ankle joint within the sagittal plane. Next is the ground reaction ankle foot orthosis (GRAFO), which has the solid part before the knee (pre-tibial support) in order to reduce excessive knee flexion (knee can't move forward). Improvement of the functional quality of locomotion and control of plantarflexion during heel strike and swing phases (foot drop) can be achieved with the posterior leaf spring ankle foot orthosis (PLS AFO). All previously mentioned AFOs are made for specific goals and therefore have different characteristics as well [11]. Figure 1 shows some examples of different types of AFO.

Figure 1. Some examples of Ankle-foot orthosis (AFO). Source: the internet [29].

Based on previous findings, AFOs come in various shapes and sizes. Additionally, AFOs also have various level of stiffness values, which usually corresponds to different levels of movement flexibility. Main parameters which give to AFO its characteristic properties are geometrical shape, stiffness and material type. Many material types can be used to manufacture AFOs. For example, metal, plastic, synthetic fabrics or compsites. These materials can be used separately or in combination. However, mainly used material is plastic, as it is light, cosmetic and providing support and better contact with the body [11]. Nowadays, the mostly used AFO manufacturing method is plaster casting [7], which is mainly used in Estonia as well. Orthotist takes necessary measurements of the leg and feet with the measuring tape and makes the cast mold by wrapping leg in a plaster wrap. AFOs are usually handmade by orthotist from plaster of Paris casting [30]. Positive foot model is made by pouring liquid plaster into the negative mold. Next step is heating and vacuum of thermoplastic sheets, which are forming into a plaster mold. Plaster mold is left to cold and later it can be cut into the suitable AFO shape. Commonly used thermoplastics are PP and PE. Unwanted or excess material is removed and smoothed before the fitting to the patient. The plaster mold can be modified, or additional components added depending on the patient's needs [7], [30].

AFO have to be manufactured according to the patient specifications (size, diagnosis, deformities). High quality custom-made orthosis must be light, durable, easy to use, prevent and reduce deformities, perform pain and contracture control, and ergonomical and suitable for the patient's foot, so there is no possibility that pressure points can cause skin abrasions. AFOs have to reduce the consumption of energy during walking. Moreover, it has to be done in short time, cheap and be resistant to the environmental factors [11].

1.4.2 Processes in traditional manufacturing technique

Different steps are included in the traditional plaster molding process to manufacture a custom-made AFO. Orthosis manufacturing fully depends on the skills and experience of the orthosis master [2]. Assessment of the patient, casting and correction of positive cast impressions are made according to prosthetic and orthotic (P&O) standards [12]. Firstly, the orthosis master should make some measurements, which include ankle and foot length, successive girths, mediolateral and posterior dimensions. In order to ensure some spring action, the cast can be taken with 5 degrees of dorsiflexion for flexible AFO [2]. Secondly, making of the negative impression with a plaster of Paris bandage or a fiber resin tape. Tubular stockinette bandage is used to cover the ankle and foot to create a protective interface and to manage the position of soft tissue structures. In addition, some specific landmarks or guidelines (e.g., bone prominence) are marked on this stockinette layer. After that a thin layer of plaster of Paris or fiber resin tape have to be applied. Orthosis master have to support the ankle and foot in the desired position (slight corrective force can be applied) until the mold sufficiently hardens. Next step is careful removing of the cast by cutting it. However, it is important to maintain the shape and contour as well as alignment of the cast. Thirdly, in order to create a positive model a liquid plaster of Paris is poured into the negative impression mold. The mandrel is added to the positive model, so the model can be maintained for the rest of the production process. In fourth step, additional plaster can be added to relief pressure points. Moreover, orthotist can apply additional forced if needed. Surface of the positive plaster mold is smoothed and polished. Next step includes heating of the thermoplastic sheet (PP, PE, PP-PE copolymer) in an oven until it reaches a plastic state. Plastic is wrapped around the model, formed to it with the vacuum and left to cool until returning to its solid state. Unwanted material is removed, and edges are completed by smoothing. Lastly, finished product is fitted to the patient to get the feedback about the fit and function [2], [12].

1.4.3 Technical challenges related to this method

There are some factors, which are important in order to achieve successful thermoforming process and to make an AFO in a good quality. First of all, the right heating temperature have to be used. It depends on the type of polymer used and stays between 165-180 °C. Next important factor is heating duration, which can vary according to the thickness of the sheet. Additionally, it is important to ensure that the heats in the oven spread equally and that sheets are not sticking [23]. Usually, traditional manufacturing can take time from some weeks to few months [2]. However, usually because of high demand and handcrafted labour intensive process the waiting times are longer. Moreover, this technique can be expensive and is fully dependent on the orthosis maker experience, skill and education. In addition, the manufacturing process can cause discomfort to the patient while obtaining the shape of the foot. The final AFO can cause skin abrasions due to the pressure points, which can occur as the shape is captured under static condition [9], [30].

1.5 Use of 3D printing technique in orthoses manufacturing

Usage of 3D printing in medical field gives the opportunity to develop and manufacture patient specific orthoses with this technique. 3D printing technique is used to manufacture different types of functional devices, which are used for rehabilitation purposes: splints, AFOs, arm prostheses [9]. There are different technologies used in order to acquisit 3D anatomical data: CT, 3D scanning, optical motion capture system and photogrammetry. Depending on the technology used data can be expressed in different ways as well: point cloud, voxels (3D volumetric pixels) or 3D coordinates of different anatomical points [9],[23]. Most common way of measuring the limb for the 3D printing technique is to use 3D scanners. There are different scanners, which use the laser or light to gather the necessary data. The subject's limb is scanned in desired stable position and later on data is modified in modeling software. Another way to capture the limb is to use photogrammetry. This kind of technique allows to generate a 3D CAD model from the series of pictures. Photogrammetry can be used for anatomical parts only if the patient can hold the stable position during the imaging process [23]. According to Maso *et al.,* photogrammetry is a cheaper and suitable way to obtain the data around the ankle. Pictures have to be taken from different angles and must include all neccessary information related to the desired area. Moreover, images have to be in a good quality and the background monochrome or should include color patterns which can help during the alignment. As well as with the 3D scanning the patient have to hold the desired part of the body still and remain the same position throughout the imaging process. Therefore, it is important to enable the comfortable position for the patient and the image maker. Next step is to load the photos, which are taken from different angles into the suitable software in order to obtain the 3D model [16]. For any of the data acquisition techniques next step is to import the data into a CAD modeler. Different types of CAD software can be used and it can be selected according to the software technical parameters, price or 3D orthosis maker skills. Next steps are modeling and conversion into a STL format and lastly the 3D printing with the printer. Modeling of orthosis is divided in three parts: inner surface, outer surface modeling and shaping [9]. Orthosis have to be designed as durable good quality product in order to resist different factors during the wearing. There are different ways to evaluate the comfort and quality of the 3D printed device. For example, finite element modelling (FEM) stimulation can be carried out, to measure specific functions of the device. It is very important to select the right materials for orthotic devices, as inappropriate material or incorrect method of the design may cause manufacturing of uncomfortable or poor quality device. Main materials used to manufacture orthotic devices are thermoplastics, composites and foams [9], [16], [31].

1.5.1 Additive manufacturing to produce custom-made ankle-foot orthosis

Custom-made AFOs manufactured with the 3D printing technique can be done according to the patient specifications in different designs and sizes. 3D printing allows to manufacture AFO based on the individual biomedical requirements, so the function, aesthetics and performance are improved. Different methods and materials can be used to produce 3D printed AFOs. The most suitable techniques to manufacture 3D printed AFO are SLA, SLS, FDM and inkjet head 3D printing (3DP) and appropriate materials are PE, PP, PLA and PETG [7], [8], [20], [23], [30]. For all of these techniques some of the manufacturing processes can be automated, which means that labour costs of AFO production can be reduced [8]. Few techniques or questionnaires can be used in order to assess the 3D printed AFO properties and functions. Assessment of the patient include: walking ability via 3D gait analysis, patient satisfaction via Quebec User Evaluation of

Satisfaction with Assistive Technology (QUEST) and dimensional accuracy between CAD model and 3D printed AFO. In addition, to assess the patient satisfaction interviews can be used as well. Moreover, mechanical properties (stiffness, energy dissipation, destructive testing) can be evaluated with the special equipment [30].

1.5.2 Processes in 3D printing technique to produce custom-made ankle-foot orthosis

Processes of orthosis printing can include 3D scanning, data manipulation, 3D modeling and 3D printing. However, the sub-processes can vary between the concrete techniques used [20]. The AM is included in the field of rapid prototyping (RP) techniques, so the 3D model is produced fully without a machining process. Manufacturing of custom-made AFO through the RP technique include the 3D scanning of the lower leg and foot, 3D surface reconstruction, building of CAD model and converting it to STL format and finally printing via 3D [33] (Figure 2).

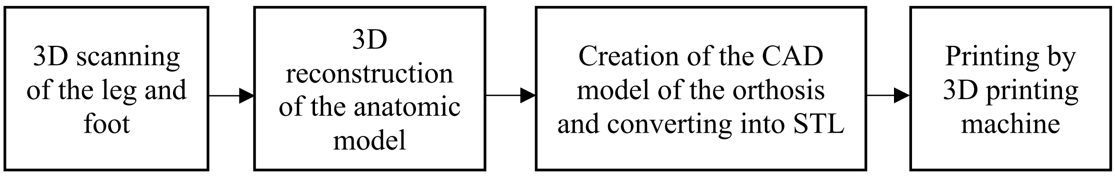

Figure 2. Phases of rapid prototyping (RP). Source: the author based on the article [33].

3D scanning is the most practical and convenient method to capture human anatomical topography. Multiple scans of the patient lower leg and foot have to be taken from different angles, so all important parts of the anatomy needed for the AFO manufacturing will be captured. Scanning have to be done slowly and the patient have to stay stable during the scanning [20]. Next step is the reconstruction of the 3D surface with the special computer software. Creation of the model starts with the different softwares, which can be used to reconstruct surfaces from the point cloud. Creation of the CAD model is next step and it can be done in two ways. First way: special software can be used to generate the model starting from the 3D reconstruction model. Second way is to generate the model from standard dimensions using CAD software. 3D model is modified to achieve the desired design by using a variety of software tools. 3D model is modified to achieve the desired AFO design by using a variety of CAD software tools. CAD model is converted into STL file format, so the 3D model is converted into machine language and then is ready to 3D printing. Last step is post-processing of the AFO and fitting to the patient [9], [20], [33].

1.5.3 Evaluation of the clinical usefulness of the 3D-printed AFOs

Advantages of using additive manufactoring in orthotics: reduced costs, fast delivery, can be used for different conditions, measurements of the leg without plaster, ability to produce different textured surfaces, lighter orthosis [9]. Wojciechowski *et al.*, concluded that 3D printed AFOs can be compared with the traditionally manufactured custom-made AFOs. Comparement can be done based on the mechanical and biomedical properties, stiffness, energy dissipation and ankle kinematics. 3D printed AFOs have to light, flexible and easy to use. These devices are usually prescribed for the patients with conditions such as: cerebral palsy (CP), Charcot-Marie-Tooth (CMT), after stroke, multiple sclerosis (MS) and other neuromuscular disorders [30]. Based on the previous studies, the AFOs manufactured by 3D printing technique have positive as well as negative aspects. Effectiveness of the 3D printed AFO can be evaluated by different methods. For example, 3D gait analysis can be used to assess the kinematics and biomechanical properties of the AFO. 3D gait analysis can be performed with the traditionally manufactured AFO, 3D printed AFO and without the AFO. It has been found that the function of the 3D printed AFO in some cases can weaker compared to the traditionally manufactured AFO. Moreover, the traditionally manufactured AFO can be more effective if the 3D printed AFO is made with the unappropriate material (too flexible). However, the 3D printed AFO is lightweight and easy to use [32]. Use of 3D printing technique in AFO manufactoring seems to have many potential. The feasibility of the 3D printing technique in orthosis manufacturing is fully dependent on the printing method, material, software used and design required. Therefore, additional research is crucial before 3D printed AFOs can be used in the clinical practice. Thorough research is needed to evaluate 3D printing AFOs, to determine the most appropriate printing technique and optimal materials, so the walking ability can be improved. There is a need to make an evaluation of innovative 3D printed AFOs in specific groups, such as children or adults with neuromuscular disorders. Evaluation have to include the assessment of the biomechanical function of the AFO, comfort and fit, pain as well as overall patient satisfaction with the new device [30].

1.5.4 Technical challenges related to this method

Despite that innovative 3D printing technique has a lot of benefits and is quite easy to implement, there are some challenges, which can occur during the 3D printing processes. It is crucial to choose the right 3D scanning and printing method, material and software, so the risk of failure can be reduced. Further research have to be made to determine the optimal printing material, printing method, print orientation and post processing to obtain the best durability and long-term usage of the product. For example, SLS printed AFOs requier longer time to "warm up" and "cool down", which can increase the labour time. [30].

1.6 Previous studies

There are few previous studies that have researched feasibility of AFO manufacturing with 3D printing technique. One is made in Estonia and is still going on. Namely, Haapsalu Neurological Rehabilitation Centre (HNRK) is also testing, in cooperation with the Latvian start-up company Custom 3DTech WIDE, innovative AFO’s for children, which are manufactured using innovative technology. Using 3D-printed orthoses to improve the patient's gait function or to support the position of the leg. The core business of the WIDE team is to make 3D printable individual orthoses and prostheses for patients and improve their comfort. HNRK provides eligible patients for testing and conducts patient-related activities in the hospital. The aim of the project is to compare 3D-printed ankle orthosis with conventional orthosis, especially in terms of functionality, fit and appearance. The collaboration began within the ProVaHealth project. The Interreg Baltic Sea Region Program 2014-2020 is the provider of the tests. First AFO was made to the patient at the end of 2018. Until now they have been performed nearly 20 tests for patients who require dynamic (to support gait function) or static (positional support) orthoses to use, including overnight use. During the test process, they collect the patient's inputs by scanning the leg or gypsum and transmit them to WIDE, which produces a 3D model based on the scans and measurements and produces an orthosis with the 3D model. The plastic part of the finished orthosis reaches HNRK during the second week of inpatient treatment. The orthosis master at the HNRK, evaluates the suitability of the orthosis with the Pediatric Department's physiotherapist. The goal is to complete the entire process within a maximum of 12 days of the patient's arrival at the hospital. There is an agreement with the patient involved in the project to provide us with periodic and standardized feedback for approximately 4 months, evaluating the suitability of the orthosis in various aspects and comparing it to a conventional orthosis, based on previous and/or parallel experience of wearing. One of the benefits of 3D-printed orthoses is certainly the ability to create a customer-specific product with less craftsmanship and more flexibility, since the main production process with a 3D printer is possible outside of office hours. The advantages of the product over conventional orthoses are the lightness of the material and the ability to create differently structured surfaces, orthosis as a pattern surface incitements and children's own relief images. The advantage of the process is that in some cases, due to the nature of the patient's foot, the input can be collected without gypsum imaging, i.e., by scanning the foot. The results of the testing will be disclosed in the beginning of 2020 [35].

Between the years 2009 to 2013 (across 48 months) there was a project called A-FOOTPRINT in Europe. This project was performed to integrate new technologies and materials in order to make possible the production of patient specific products in orthotic industry. Idea was to develop innovative foot and ankle orthoses, which are personalized and are ready within 48 hours. Moreover, to achieve improved fit and comfort, functionality, appearance, simplicity in use and with better clinical and cost effectiveness. Project was organized as nine integrating work packages. Results of the project were as follows: there is a need to develop a software-based Patient Information System; to develop CAD software for personalized ankle-foot and foot orthotics; to develop design optimization software routines and to evaluate rapid manufacturing techniques; to integrate these results and to have an effect on relevant health and policy (EU health strategy). Based on their case study the innovative technique of orthosis manufacturing can reduce medical device costs for a 15% and opportunity to receive these medical devices will be able within 48 hours [36].

Another study about 3D printed AFO’s was conducted in 2015 as a pilot project in the Gonzaga University, USA. Group of students researched and developed a 3D printed, rapid prototyping process, which can be used for AFO manufacturing. Aim of their case study was to develop and improve the AFO design process by lowering the costs and reducing the AFO production time. First of all, they used a 3D scanner to collect the patient's ankle and for measurements. After the measurements were taken, the 3D model was designed with the special software and then AFO was printed with the 3D printer. In order to find the most suitable material, researchers tested different types of 3D printing materials (including PLA, PP, carbon fiber PLA, PETG and Nylon). After the testing it was found out that the most suitable materials to make a 3D printed AFO are PLA and PETG. These materials were suitable, as both of them are strong and functionally suitable while reducing the material cost. In addition, they cut down the production time to two days and reduced costs of labour significantly as well [37].

Furthermore, there are few articles that explore the feasibility of AFO's manufacturing with the 3D printing technique. However, despite these previous studies and articles there are only few studies that describes the processes of the techniques used.

2. AIM OF THE STUDY

The aim of this thesis is to investigate the feasibility of custom-made AFOs manufactured with 3D printing technique.

Sub-aims:

- To make a brief description of the 3D printing concept, transformation processes and materials used, use of it in medical field
- To collect data about usage of 3D printing technique to produce custom-made orthoses
- To describe traditional AFO manufacturing technique
- To describe AFO manufacturing technique with AM 3D printer
- To describe and analyze traditional and 3D printing technique process of the AFO manufacturing based on the conducted questionnaire
- To make a practical experiment by printing one pair of AFOs for the child with the 3D printer
- To make a comparison of two techniques – 3D printed and handmade orthosis technique

3. MATERIALS AND METHODS

In order to achieve the aims, three different methods were used. Firstly, descriptive and thorough data overview to support the aims of the work. Secondly, questionnaire to have practical experience in addition to theoretical overview. Thirdly, to assess the feasibility of AFO manufacturing with 3D technique there was practical experiment.

The research approach of this qualitative case study can be described in the following figure:

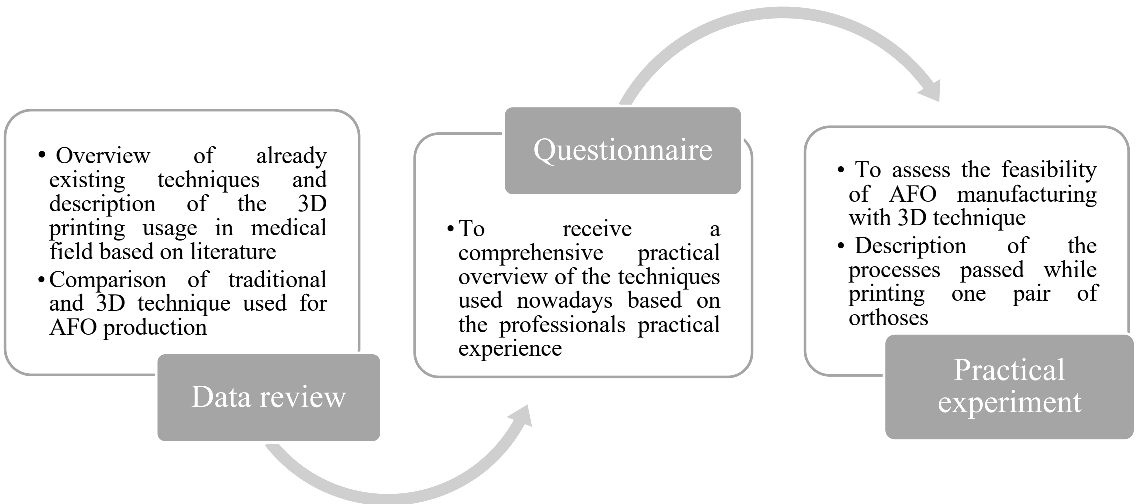

Figure 3. Research approach. Source: the author.

3.1 Overview of techniques used in medicine to produce AFO

To identify different techniques used nowadays to produce AFO's and to have comprehensive overview of these techniques, the author of this thesis searched two databases. The review in Med Line was performed using PubMed, as well Google Scholar database was searched. The search strategy included citations mainly from 2015 to 2020. However, two articles were published in 2013 and they were included in the work as relevant articles to this topic. Moreover, AFO manufacturing guideline was published in 2006 and was used in this work as well. This guideline was important in order to get the thorough and proper description of the traditional manufacturing process. The search was conducted by using simple search terms (free text) which were developed by the author and applied to the two databases according to the construction of the database. The terms were: 3D printing in medicine; ankle-foot orthosis printed on 3D; ankle-foot orthosis (AFO); additive manufacturing; 3D scanning; orthosis manufacturing; plaster cast; custom-made AFO.

The key inclusion criterion was that the study was available in full text and it was in English. The main question for the study was that it was about usage of 3D printing in medicine, AFO manufacturing using plaster cast, AFO manufacturing using 3D printing technique, feasibility of custom-made AFO's manufactured with the 3D technique. After receiving initial 50 results, the author of this thesis started to apply the inclusion/exclusion criteria. 6 citations were excluded, making the final list of 44 citations. A total of 44 studies that fit the search criteria were identified.

Data overview was important in order to answer the questions set by the author:

1. Does 3D printing of custom-made AFO has a potential to replace a traditional technique used nowadays due to it feasibility?
2. Is the 3D printing efficient and effective method to manufacture a custom-made AFO's, because this is fast, repeatable, flexible to design modifications and cheaper technique?
3. Is manufacturing of custom-made AFO's with the 3D printing technique more comfortable to the patient and to the maker (e.g. orthotist)?

3.2 Questionnaire

The questionnaire was composed by the author based on the literature overview. The questionnaire was formed in Microsoft Office Word and was 1,5 pages long. There was no possibility to use already existing similar questionnaires, because of the specificity and complexity of the topic. The idea of the questionnaire was to receive a comprehensive practical overview of the technique used nowadays to produce custom-made orthoses for the patients. The questionnaire was composed in English and consisted of four sections. The first section was about general information – description of AFO and production of AFO's. The second part was referred to custom-made AFO manufacturing and consisted of nine questions. The third section was about materials, which can be used to produce products. Last section was about usage of 3D printing as AM in their work.

3.2.1 Questionnaire participants

Participants were four different companies, who are producing different types of orthoses, braces and casts. The questionnaire was conducted in March 2020 and was sent once to the participants via email address. It was sent for two orthosis master companies in Estonia – Ortoosimeister OÜ orthotist Sander Sirp and orthotist from Haapsalu Neurological Rehabilitation Cenrtre Martin van Schie. In addition, for two 3D printing companies in Latvia – CastPrint and Custom 3DTech WIDE, both of these companies are focused on 3D printing usage in medical field. To have better understanding of 3D printing, author contacted Latvian companies via phone and Skype.

3.3 Experimental part: AFO manufacturing with the 3D printing technique

The aim of the experimental part was to make an intervention, in this case printing AFO orthoses for the child, then describe the process of orthosis printing on 3D printer. The practical part was consisting of 3D scanning of the lower leg anatomy, data manipulation, 3D modeling, and 3D printing. Experimental printing was necessary to have practical experience to be able to describe processes passed when custom-made AFO is produced with the 3D printing technique.

As model was invited young patient from the Tallinn Children's Hospital, with the cerebral palsy- spastic diplegia diagnose. Model legs were in good condition and did not have a lot of bone or muscle deformities. However, because of the spasticity in the legs the ankle was in valgus position. Therefore, the scanning of the leg was more difficult, as it was important to achieve and maintain a right anatomical position in the ankle.

3D printing was done together with the Latvian company CastPrint. CastPrint is collaborating with the most innovative traumatology specialists in Latvian Children Hospital and other healthcare institutions in Latvia. They are printing mainly casts, but having some experience with the orthoses as well. All of the equipment was provided, and all of the activities were supervised by CastPrint and were done in Estonia and Latvia by author and CastPrint team.

Equipment used: 3D scanner, software to process the data and model the AFO, 3D printer. Scanner was attached to the iPad via USB port. Structure Sensor had the high-quality IMU, wide angle camera and is performed as a mobile Structure Light System (SLS). To process the data acquired from the scanner was used original Generic Structure Scanner app. In order to model and modify the AFO were used three programs- Rhino3D, MeshMixer and Ultimaker Cura. Finally, the product was printed with the Ultimaker 2+ Extended 3D printer and material used- PLA.

3.4 Ethical consideration

As practical experiment sees using a child as a model for the AFO manufacturing the author of the work certify that none of the personalized data was used, consents to do it has been obtained in writing from the Tallinn Children's Hospital neurologist Valentin Sander, and there is no ethics committee approval required (Appendix 1). Additionally, verbal approval was taken from questionnaire participants, so that the knowledge gained from the questionnaire answers will be used and analyzed in this thesis. None of the personalized or company inside information will be outlined in this work.

4. RESULTS

The next chapter describes the results of the work done. The results from the literature review, questionnaire and the practical printing with 3D printer are complementary to each other. The first part concentrates on the background analysis results, the second part follows a discussion, where the previous chapter is supported by the questionnaire and interviews. The third part of the results describes the practical part of the work.

4.1 Summary of literature review

Nowadays, mainly two techniques to manufacture orthoses are used – traditional technique, when orthosis is made manually by orthotist and additive manufacturing known as 3D printing, when most of the processes are automated. According to the literature review both techniques can be used to produce custom-made AFOs [12], [30]. Traditional plaster molding process to manufacture a custom-made AFO include different steps. Firstly, some measurements should be done manually with the measuring tape. Secondly, the shape of the leg is captured by negative impression or cast, which is usually made with a plaster Paris bandage. Thirdly, positive model is made by pouring the liquid material into the negative impression mold. Fourth step is modeling of the positive model by polishing and adding additional plaster. Last step is to shape the orthosis by wrapping it with the thermoplastic material and smoothing of the edges. All steps are visualized in Figure 4.

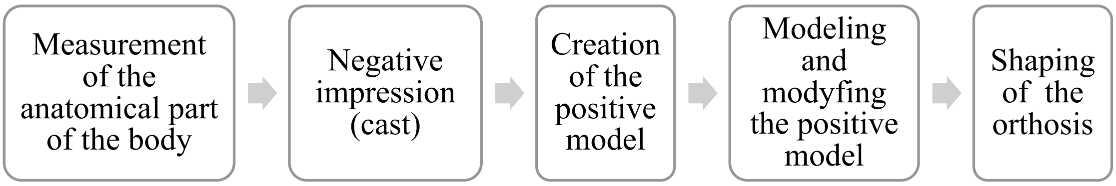

Figure 4. Traditional technique of producing an AFO. Source: the author.

Traditional approach needs to have a special skill and experience, in order to make a good and usable custom-made AFO. In some cases, it can be labour-intensive, can be expensive and time-consuming. All of the materials and moulds can't be reused, which is also an important factor. In addition, it can be uncomfortable to the patient (especially children) and if orthosis is damaged or broken then all of the processes have to be repeated.

It was found that 3D printed orthoses are also good option for different problems. Especially in pediatric patients, as processes are less unpleasant and usually fast passable. The use of 3D printing to manufacture AFOs has many potential benefits. As advantages of this technique can be brought out: reduced costs in some cases, fast delivery, measurements of the leg and feet capturing without the plaster, ability to produce different surfaces and the weight of the orthosis. Furthermore, manufacturing methods have been developed this way that some of the processes are automated and this can reduce the labor time and costs as well. There are different scanners, CAD and STL softwares, materials and 3D printer, which can be used for orthosis manufacturing. It all depends what kind of financial capabilities are available in companies or hospitals. However, all of them have to pass the same steps in order to get a good and usable orthosis [2], [16], [30]. All of the steps are showed in the Figure 5. More thorough description of the processes according to the practical experiment will be described in the Chapter 4.3.

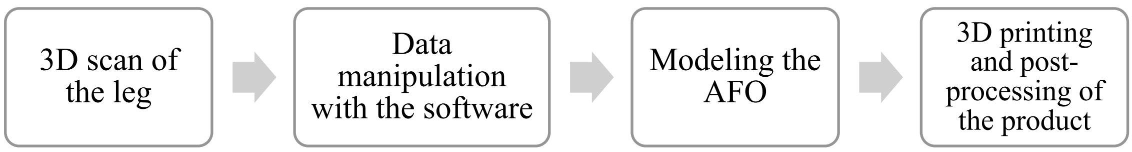

Figure 5. Additive manufacturing of AFO. Source: the author.

4.2 Questionnaire

The questionnaire was sent to two companies in Estonia which are producing custom-made AFO’s with traditional technique. In addition, the questionnaire was sent to two companies in Latvia which are using 3D printing technique to produce braces, orthoses and casts. They received questionnaire digitally by email. All selected companies did respond to the questionnaire. All answers were received after the first email sent to the companies. The full questionnaire is provided in Appendix 3.

According to the general information, all of the companies answered that they can produce a custom-made AFO’s. Definition of custom-made AFO was the same for all of the participants, but everyone used their own words. Briefly, a custom-made AFO is an orthosis, which is created specifically for the patient considering his individual needs, specificity and shapes. All of the participants answered that in addition to custom-made AFO's there are already many different prefabricated foot orthoses as well. Prefabricated orthoses are made for the most common problems and for an average body shape and size. For example, both of the Estonian companies use them as well. However, if there is a different problem or patient have several problems with deformities then it is very complicated to find a good and suitable prefabricated orthosis.

Answers for the second and third part of the questionnaire concerning the traditional, nowadays used technique are summarized below:

Table 2. Traditional technique to produce custom-made AFO

Manufacturing techniques used to produce custom-made AFO's	Thermoplastic and carbon fiber lamination technique
Measurement of the lower part of the leg	Some parts of the lower leg and feet are measured with the measuring tape (to control model later)
Capturing the shape of the feet	Plaster bandage (plaster casting) technique is used to capture the full shape of the lower leg and foot; in some cases it is enough to draw a line of the outer shape of the leg; also, 3D scanner can be used (rarely)
All parts are hand-made/ some parts are prefabricated	Metal joints are prefabricated
Materials used	Thermoplastics: polyethylen; different padding materials: colorform, plastazote, coloring paper; Lamination technique: aluminum/titanium on joints. carbon and class fiber, stockinettes perlon/cotton; resin
Reusage of materials	Materials are not reusable
Technical challenges	The most difficult is to get a good positive mold to work around; process is quite time-consuming; sometimes orthosis can have a pressure points and then it can rub the patient leg
Storage of the casts	Casts are usually stored for 3-4 weeks
Time to produce one pair of AFOs	Depends on the type of AFO- can be few days to few weeks

Price (approximately) for one pair	Price depends on different factors, approx. is 530 EUR per pair
Duration of usage (approximately)	For children usually 10-12 months (because of the growth); adults 3-4 years

Latvian companies, which are printing medical devices with the 3D printer answered the questions about their experience with the orthosis manufacturing. Answers for the questionnaire concerning the 3D printing technique are summarized below:

Table 3. 3D printing technique to produce custom-made AFOs

Manufacturing techniques used to produce custom-made AFO's	Additive manufacturing- 3D printing
Measurement of the lower part of the leg	Usage of 3D scanner and physical measurements with the measuring tape to make orthosis in a right size (Appendix 4)
Capturing the shape of the feet	Manually via 3D scanner
Scanners used	Structure sensor with Iphones/iPads; DigiScan 3D
Software used	Generic Structure Scanner app; Rhinocerous CAD software; Meshmixer; WIDE software
3D printers used	Ultimaker various printers (2+ Extended, S5); 3D printers for PP; Industrial 3D printers
All parts are hand-made/ some parts are prefabricated	All parts are made by developers via 3D models/3D prints
Materials used	3D print materials- PP; PLA plastics, TPU 95A plastics
Reusage of materials	Right now, materials are used once, first prototypes of recycable machines have been made
Technical challenges	Scalling issues (scan errors), model issues (error in created 3D model), print issues (slicing and printing errors)
Time to produce one pair of AFOs	Depends on orthosis: modeling 1-2h, printing 10-15h (one orthosis)
Price (approximately) for one pair	Depends on orthosis: approx. 150-200 EUR;

Duration of usage (approximately)	At least 1 year

CastPrint company brought out that despite usage of 3D printing technology in orthosis manufacturing not all cases can be done by this technique. Mostly, due to the limited types of materials, in case of extra rigidness or movable parts, traditional methods could be considered more efficient at the moment. However, for basic custom-made AFOs, 3D printing could be considered as a viable option.

4.3 Description of the processes passed based on the experimental 3D printing

Preliminary work or scanning was done in Estonia (Tallinn Children's Hospital). Scanning of the patient’s lower leg and foot was done with a 3D scanner attached to the iPad and manual measures were taken by the author. Model was able to walk small distance independently and the condition of the ankle was quite good. However, because of the spastic diplegia both of the ankles are starting to move into valgus position. The scanning of the legs took around 1-1,5 hours as the author did it for the first time and it was important to maintain the neutral position of the ankle. All of the activities were supervised by CastPrint and if needed instructed and reorganized. During the scanning model was quite calm and excited. Scanning was done from a distance and did not cause any unpleasant feelings. In addition to scanning, manual measurements were taken with the measuring tape. Next steps were done in Latvia by CastPrint and all of them were explained and discussed with the author of this work. Second after scanning was modeling of the scan with the scanning software. Modeling took around 2 hours. In the course of modeling the noise and outlying areas were reduced and not necessary areas were erased. After modeling the data from the native file format was exported into OBJ. format and designing of the final version of AFO was made. Designing was done by taking into account the specifications of the anatomical position of the model ankle. Last step was printing by the Ultimaker 2+ Extended 3D printer. A total number of 2 orthoses were printed, for the left and right leg. Material used was PLA and it took 8 hours to print one orthosis. Printed AFO was light, easy to use and the shape was correct. It is important that the neutral position of the ankle can be achieved by the orthosis. Modeling and printing were done by CastPrint team members, who are qualified professionals in this field. Usually, scanning and measuring of the body part can take around 5-30 minutes, depends on the problem and the anatomical area to be scanned and measured. However, it is important to remember that times of scanning, modeling and designing can vary depending on the computers used, user's skill level and experience. The overall process of the AFO manufacturing can be repeated, if needed, as the data remains in the used software. It allows to produce AFO faster, cheaper and without causing discomfort to the patient. 3D printed orthoses from PLA material were quite rigid, which is an essential factor for the night splints. Therefore, it can be concluded, in order to achieve more flexible AFO some of the modeling and printing specifications have to be modified. For example, another material can be used, or the joint part can be movable, so the walking can be achieved. In general, the feasibility of AFO manufacturing with 3D printing technique was once again proven by practical experiment as well. Moreover, it also shows that this method should be further investigated, so that the most suitable materials and techniques can be introduced to the orthosis manufacturing field. In addition, 3D printing company team members as well as traditional technique orthotist have to be experienced and qualified. This experiment was successful because of the experience and knowledge the CastPrint team have.

Below is the description of all steps used in the data interpretation, reconstruction and fabrication of a custom-made AFO. Four processes were passed in order to manufacture a custom-made AFO with the 3D technique:

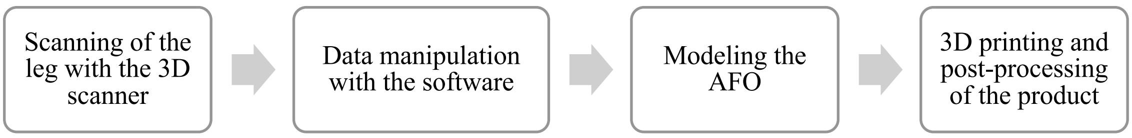

Figure 6. 3D printing processes. Source: the author.

1) To manufacture AFO using 3D printing technique, scanning of the patient’s 3D geometry of the lower leg and foot was done with a 3D scanner- Structure Sensor attached to the iPad (Figure 7). The measures of the lower leg and foot were taken manually with the measuring tape (Appendix).

Before the scanning process, the patient was asked to go prone and to hold knee in flexion on the 90 degrees. The longitudinal, transverse, and metatarsal arches must be considered when designing the AFO. If needed, in the standing position, the scanning procedure can be repeated [32].

Figure 7. Structure Sensor scanner attached to the iPad. Source: the author.

Scanning was made by the author and took around 1,5h. All scanning processes were supervised and if needed changed by CastPrint company. Several scans of a model lower leg and foot were taken from 360 degrees perspective. It was important to capture all neccessary regions of the anatomy to produce a suitable AFO. The most important parts are- Achilleus area (both sides) and foot (base).

2) Generic Structure Scanner app was used to process the data acquired from the Structure Sensor laser scanner. This scanning software was used to reduce the noise and outlying areas, while keeping the important scan details. All points or areas, which were belonging to the background were manually erased.

3) The modified geometry was exported into a OBJ. file and another software was used. In order to model and modify the orthosis were used three programs- Rhino 3D, Meshmixer, Cura. The following steps were performed at Rhino 3D and Meshmixer softwares:

- Importing of 3D model in Rhino 3D from Structure Sensor and increasing the size x1000 – 1v1 to real life size
- Fixing of all model errors in Meshmixer, making a solid model – correcting the anatomical position
- Creating a new copy of 3D model and offset it to 3mm (to make it fit)

- Cutting the unnecessary structures, adding holding mechanisms and preparing for slicing

Cura was used for slicing and creating .gcode file that allows the 3D printer to execute the order. Modeling took around 1-2 hours. Modeling was done in three steps: inner surface modeling, outer surface modeling and shaping.

4) Next step was the AFO printing with the Ultimaker 2+ Extended 3D printer. Printing took 8 hours for each leg and used 192 grams of filaments for one AFO with support structures (removed later). The AFO was printed in PLA (Poly-Lactic Acid), which is biocompatible and non-toxic material. One spool (1 kg) of the filament costs approximately 20 EUR (excl.VAT), which is making the cost of the material used to produce AFOs around 4 EUR.

Figure 8. 3D printed custom-made AFOs. Source: the author.

5) Last step was testing on the model. Fitting to the model was done in the beginning of May 2020 in Tallinn Children's Hospital. Both AFOs were suitable and model was able to try them. However, because of the rigid material the model was not able to walk with them in the room.

5. DISCUSSION

Development of additive manufacturing and 3D technology gave to the healthcare sector and medical field overall a lot of positive opportunities. Using a 3D printing technique in medicine open up an unlimited possibility in order to make the treatment quality better, effective and faster. There are different 3D printing companies in the market offering several types of medical devices, which can be used in patient treatment. These devices can be used in several medical fields and orthosis manufacturing is no exception. Usage of 3D printing in custom-made orthosis manufacturing is trending around the world. It has shown many of the beneficial points and possibilities to introduce this technique in orthosis manufacturing field. This technique has been used mostly in producing wrist and ankle foot orthosis. However, the quality and evidence-based of this technique is still not well-studied. There are studies that describe the processes of AFO manufacturing with the additive manufacturing technique and describe the most suitable materials. In addition, there is a description of 3D printed AFO assessment, which points to pay attention to.

This thesis explored the feasibility of custom-made AFOs manufactured with 3D printing technique. In order to achieve this aim, work include the two main parts- comparement and description of the both processes used nowadays and practical printing of one pair of orthoses. Three different methods were used. The first method was literature research and composed review was bases on it. The second method was a questionnaire, which included 4 different companies to have practical experience in addition to theoretical overview. The third method was practical experience by printing one pair of AFOs to the model, in order to assess the feasibility of AFO manufacturing with 3D technique.

AFO is widely used to improve walking ability and pattern, to support the lower part of the leg and foot. They are designed this way so the gait can be improved and, also, energy costs of walking are reduced. Moreover, a definite connection has been found between AFO stiffness and gastrocnemius muscle and Achilles tendon functions. These two structures are very important in order to achieve an efficient gait, especially for children with the CP [5], [38]. AFO can be used for different medical conditions, but mainly for neurological conditions (cerebral palsy, neuromuscular disorders), limb injuries and congenital deformities. AFOs have to be lightweight, strong and stiff enough to support the lower part of the leg while walking and doing activities of daily living (ADLs) [12]. Nowadays, the mostly used technique is the traditional plastic mold. Traditional AFO fabrication technique is commonly used among orthotist worldwide. However, it has different challenges, which have to be improved or changed. First of all, this technique is labor intensive. Secondly, it is time consuming as it requires long fabrication time. Delivery time is usually higher than 10 days [36]. Thirdly, there are limited variations of materials, which can be used. Lastly, this technique is dependent on the technician skill. It means, that in order to produce product in a good quality the orthotist have to be experienced and well educated in this field [5]. The traditional manufacturing processes for orthotic devices are still mostly achieved manually by orthotist hard hand work. Traditional manufacturing of AFO consists of manual plaster casting to get the negative and positive molds, molding of thermoplastic materials, and cutting them as a form of AFO [12], [32]. This kind of technique requires delicate skill, experience and time. In some cases (e.g paediatric patient) these processes can be unpleasant to the patient or final product can cause the skin abrasions by pressure points. Furthermore, the whole process of this manufacturing must be repeated if the AFO is destroyed or a patient's condition is changed (growth, new deformities) [32]. It was found that the only way to evaluate the comfort and suitability to the patient is to have the patient try it on and test it (walking, sleeping) [16].

Usage of 3D printing technology in orthosis manufacturing has a potential and many advantages. First of all, time of production and costs. In most cases production of orthoses is much cheaper than with the traditional technique. As some of the processes are automated then manufacturing time can be reduced. Based on the literature review the most suitable techniques are FDM, SLA, SLS and 3DP [7], [8], [20]. This type of 3D printed orthosis was the most similar to the traditionally made AFO. Moreover, patient was satisfied as the product was comfortable and the weight was smaller if compared to traditional AFO. In addition, it was easy to use and adjust the orthosis. However, in some cases compared to the traditional custom-made AFO the 3D printed AFO can be less functional and less effective. For example, due to some material or design shortcomings the 3D printed AFO can't prevent some limitations (excessive foot drop) [32], [39]. One of the suitable 3D printing techniques is FDM. The best suitable material for FDM is PLA and Nylon [2], [16]. Totah *et al.*, also brought out that the most suitable techniques to produce custom-made AFOs are FDM and SLS. According to their findings, the most optimal materials are PP and PE. Same materials and techniques were also pointed out by other authors as well [7], [8], [23]. In addition, as suitable materials were mentioned PLA and PETG [8]. These materials can be combined with the natural soft polymers (hydrogels). Soft polymers are used to absorb moisture, reduce skin irritation and friction, so the patient feels comfortable [40]. Therefore, it is important to remember that different techniques can be used for different purposes. In preparation for scanning, the patient has to keep the ankle stable. For an adult it can be easy, but for child there can be some issues. Ankle has to be in neutral position (90 degrees) if possible, without any eversion, inversion, pronation or supination. If it is impossible or hard to hold the necessary position, additional aid can be used. Walbran *et al*, proposed to use a fixture, which helps to hold the patient leg at approximately neutral position during the scanning [8]. This shows that the methods in use can be constantly developed and improved if needed according to the needs and specifications of the patient and orthosis maker. 3D printed AFOs are cheaper, more eco-friendly, user-friendly and lighter than traditionally manufactured AFOs [23]. Nowadays, all over the world people are trying to keep the environment cleaner. They are trying to find solutions and materials, which can be recycled and are eco-friendly for everyone. This also applies to different products, which are produced these days and orthoses are no exception. Traditionally manufactured AFOs can't be reused and materials are not reusable. However, the 3D printing technologies are developing and different attempts are done in order to make this technique environmentally friendly. For example, novel methods and systems are developed so the recycled polymer materials can be utilized [41].

Additionally, it is important to test the durability of the 3D printed AFO as it has to last until the patient has grown (child) or medical condition has changed. According to Maso *et al*, a FEM stimulation can be one possibility to test the FDM AFO. In the FEM stimulation different loads can be applied based on the device specifications [16]. Furthermore, to assess the durability of the 3D printed AFO a mechanical stress test can be used as well [32]. In addition, it is necessary to evaluate the gait function with the 3D printed AFO, traditionally manufactured AFO and without. Main parameters, which can be measured: gait pattern, speed, stride length and stride width. 3D gait analysis can be used as well [32], [39]. Comparison of these parameters is crucial so the clinical usefulness and efficiency of the 3D printed AFO can be proven or rejected. Patient satisfaction is also an important factor, which should be taken into account. QUEST test can be used to assess the patient satisfaction [32]. Moreover, it is suggested to use developed computer modeling algorithms together with the 3D printing techniques in order to improve the manufacturing process of the AFOs. Assessment of the mechanical behavior and stress test before manufacturing can prevent unnecessary waste, time and errors. In this case, 3D printing technologies can be used together with the construction of finite element (FE) models to produce patient specific products [42].

The majority of the 3D printed devices have been clinically trialed in order to reach the medical market. However, only few articles assessed effectiveness of clinical 3D printed devices. Most of the clinical studies were carried out in a narrow field (surgical training, oral or maxillofacial surgery). Moreover, only a few papers assessed the long-term outcomes, which is also an important factor when it comes to medical field. Therapeutic devices such as orthotics offers a perspective opportunity in the patient rehabilitation and in medicine overall. It should be mentioned that despite their big promise, most of these devices are still at early stage of development and there is no much research into their efficacy in a clinical environment. 3D printed medical devices, and in this case, orthoses are a great possibility to make a patient specific products, but as with any other device, that alone is not enough. There should be correct legal aspects and proven clinical efficiency and effectiveness. Moreover, there were not enough of these medical devices tested against sufficient control group. In addition, a lot of the studies were in poor quality and did not had a control group at all. 3D printing technique will continue to develop and available techniques and materials will increase. More and more of medical devices will be produced and brought into the medical market. However, the demonstration of clinical efficacy, effectiveness, correct legal aspects and device safety is very important part in this development. Clinicians, who are using the 3D printing in their field, have to make a long-term assessments of their medical devices with the control group, in order to determine that their medical device is clinically relevant [8]. Clinical trials have been done mostly in the USA, and in some European countries. Despite small population one of the clinical trials was made in Estonia as well. The previous implementation of clinical trials shows that it is possible to make more thorough research on this topic.

Currently, main advantages of 3D printing have been found on overall medical costs. Advantage of use of 3D printers in customized medical devices production shows cost-saving. Especially, for small production runs, like small-sized implants and prosthetics.

Moreover, increased productivity would help to reduce the cost of the final product. Although, despite that in the future there will be benefits, the implementation of the 3D printing technologies can be quite expensive in the beginning for the hospitals or organizations. Besides, there is a need for close cooperation between 3D printer provider and the client (hospital, organization) [43]. Next important factor to keep in mind is the legal aspect of the medical device. All of the 3D products are medical devices. It means that these devices have to comply the Medical Devices Act and be clinically assessed. In addition, these devices must compliant with the laws of the production and selling countries. However, according to the Regulation (EU) 2017/745 3D printed custom-made devices do not have to bear the CE mark [25], [26].

In order to support literature review findings, the author carried out a clarifying questionnaire. According to questionnaire answers, both of the techniques can be used to produce custom-made AFOs. However, in Estonian clinical practice traditional technique is mainly used, because so far it has been proven to be an effective technique to manufacture high quality orthoses for the patients. If to compare traditional and 3D printing technique, then the biggest difference is working time. Traditionally manufactured AFOs can be done in a few days. Although, because of the big workflow and big amount of orders AFOs are produced usually in a few weeks or even months. In this case 3D printing can be a good opportunity to speed up the process of production. 3D printed AFOs can be usually done in one or two days. Modeling is taking few hours, whereas printing can take 10-15 hours for one orthosis. Moreover, to capture the shape of the lower leg within traditional technique plaster casting is used. This process is time consuming, and in some cases unpleasant to the patient (especially pediatric). If patient needs new orthosis, then the same process must be repeated as previously made negative mold or cast can’t be used again. 3D scanning is a good opportunity to capture the shape of the lower leg and foot fast and without unpleasant feelings to the patient. In addition, usage of 3D scanner for this purpose is only a one-time expense, as one scanner can be used with different devices (phone or iPad) and for years. For comparison, both techniques are using manual measurements of the lower leg and foot with the measuring tape. This is an essential part to make orthosis in the right size. For both techniques almost all of the parts are hand-made or made by the developer (in case of 3D printing). However, for traditional technique in order to produce articulated AFOs the metal joints are already prefabricated. These kind of orthoses are widely used, whereby the dorsiflexion in the ankle can be achieved during the walking. If orthoses are planned to be used at a daytime then 3D printed AFOs have to be elastic and flexible during the walking as well. In this case choosing the right material is crucial. Therefore, in order to get a more flexible orthosis a good option can be a PP. Nevertheless, there is a need for further research, so that the best suitable materials can be found out via additional clinical trials. Duration of usage is quite similar for both techniques, around one year for pediatric patient. Next comparable factor is the price. For both techniques, prices may vary, as it depends on different factors. For the price influencing factors may be- amount of material used, time of production, type of orthosis, production severity and labor taxes. However, in this part 3D printed AFOs are also ahead of the traditionally manufactured AFOs as price for them is cheaper. Difference is not very big (around 100 to 200 euros), but when bigger amount of production is considered then it is definitely much more reasonable. Both of the 3D printing companies brought out, that if the patient condition is more complex then usage of traditional technique is more appropriate as the shape of the leg is captured more precisely. For example, if there are already existing deformities in the skeletal structures of the ankle and the neutral position of the ankle can't be achieved by the therapist or orthotist. In general, based on the questionnaire usage of 3D printing in orthosis manufacturing can be a good competitor to the traditional AFO manufacturing technique.

Additionally, to assess the feasibility of AFO manufacturing with 3D printing technique there has been carried out a practical experiment. Experimental printing was necessary in order to support literature review and knowledge gained from the questionnaire. Moreover, it was important part of the work as the author had to be able to describe processes passed when custom-made AFO is produced with the 3D printing technique. 3D printing was done together with the Latvian company CastPrint. For the equipment, work instructions were provided by CastPrint. Furthermore, all of the activities were supervised by them as well. Based on the practical experience the time of the production was reduced and cost for the 3D printed AFO was cheaper compared to the traditionally manufactured AFO. According to calculations, material used to produce AFOs was around 4 EUR, which is an important factor. However, the biggest costs in the 3D manufacturing process are printing hours and the labour costs. In addition, the 3D printing processes are faster and more easily feasible. These processes can be introduced to the healthcare specialist, who can perform some of the steps in the process independently. For example, in the beginning the 3D scanning can be done by the 3D printing company representative. After some training and practice the specialist can do the 3D scanning itself. Based on the practical experience, main idea is to teach the healthcare specialist if needed, so they can easily perform the 3D scanning himself according to the guidelines. It will decrease costs and manufacturing time as well. As 3D printing requires special equipment (3D scanner, 3D printer itself) and digital softwares, the manufacturing fully depends on the hospital/healthcare specialist financial capabilities. However, the healthcare specialist can have only 3D scanner attached to the phone or iPad and other steps in process can be done by 3D printing company engineers. Possibility to make the 3D scanning by the healthcare specialist in some cases can improve the quality of the product, as the doctor usually have the best overall picture of his patient health condition. Furthermore, compared to the traditional technique it will reduce labour time and costs related to it. Despite that there is a need in a high investment in a 3D equipment, materials and training, the implementation of this technology in the orthoprosthetic industry can have many positive aspects, which in turn will improve the quality of the treatment [30].

3D printing can be widely used in different medical fields. There has been already proven that this novel method is usable, and it has a lot of potential so the customized medical applications can be produced in a good quality. Printing techniques and materials are rapidly developing and therefore, interest of research is increasing as well [44]. The most important question in this thesis was, if the 3D manufacturing of custom-made AFO is feasible. Therefore, the main finding of this thesis is that 3D printing technique can be used in order to produce custom-made AFOs. Moreover, 3D printed custom-made AFOs can be compared with the traditionally manufactured custom-made AFOs. The feasibility of using 3D printing technique in orthosis manufacturing is seen and proven based on the literature review and personal practical experiment. In addition, there can be used different 3D printing techniques- SLS, SLA and FDM. According to the literature review, 3D printing methods and materials differed between the studies. However, in different studies were highlighted the benefits and disadvantages of various techniques and materials used. These findings were also confirmed by Wojciechowski *et al.* [33]. It is important that 3D printed AFO production is well thought out, and suitable materials and techniques are selected, so the walking ability, durability, long-term benefits and patient satisfaction can be improved. Different mechanical, physical and technical properties have to be taken into account in order to produce device with a good quality. Although, additional clinical research is playing an important role before the 3D printed AFOs can be actively used in a clinical practice.

Additionally, when comparing the literature review findings and the questionnaire, it was found out that 3D printed AFOs can be a reality. It is also proven by trial project, which is conducted by HNRK and Custom 3DTech WIDE via ProVaHealth. Moreover, personal practical experience is essential in order to prove the feasibility of this technique. It can be concluded that this technique can be well used for the paediatric population, spastic patients with CP, for the patients with the neuromuscular disorders and after acute trauma. For example, for intensive care unit patients, as they need AFOs immediately, so the deformities in ankle will not occur. In this case patient need passive rigid orthosis, so that the neutral position of the ankle is ensured. This technique is more suitable in these cases as it cheaper and faster than traditional technique. However, so as to produce quality product for spastic independent patient it is important to choose the right material, so the patient will be able to stand and walk safely. In spite of all previous findings, in order to make more specific conclusions about target group and suitable products there is a need to make a thorough and clinical research on this topic.

5.1 Limitations

Despite the fact that the aim has been achieved, there are some limitations in this study. Firstly, the novelty of the topic. Literature research was quite limited due to the specific topic. There were only few articles, which studied exactly the feasibility of AFO's manufactured with 3D printing technique. Majority were describing processes and technical part (materials, software used, modeling) of 3D printing in this field.

Secondly, the questionnaire was not based on the previous ones, because there was not any of the studies that have used similar questionnaires. In order to get the correct and practical answers there was a need to conduct a specific questionnaire, based on the author own experience and literature review. Moreover, though the response rate was 100%, due to the Estonian and Latvian small market the number of participants was limited. In addition, as the focus of the thesis were custom-made AFO's, then companies, which are selling prefabricated AFO's were not involved as the participants.

Finally, this thesis was not intended to highlight nowadays used technique to produce custom-made AFO’s in a bad sides, but instead to study possibilities how to improve existing technique together with the 3D printing technique.

5.2 Suggestions, further studies and developments

The methodology used in this thesis can be used as a basis for future research, as the innovative development of 3D printed technologies and methods will continue worldwide. In addition, need for faster and cheaper technology in orthosis manufacturing will only grow. Therefore, it is recommended to conduct a thorough and complete research on this topic. Moreover, research with the clinical trials, which if possible funded and supervised by the Health Insurance Fund and Ministry of Social Affairs will be the best option.

During the further study it is important to see, who would be the main target group in the Estonian market, and how many people will actually need these 3D printed orthoses. Similarly, to previously conducted clinical trial it would be necessary to compare 3D printed and traditionally manufactured orthoses to. Different aspects can be compared in order to find the best solution: price, time of production, materials used, technical and physical properties, durability, comfort and patient satisfaction. Assessment of these aspects is crucial, so that innovative method can compete with the already existing method.

Conclusion

3D printing as AM in medical field is becoming increasingly popular. Assessments and research on this technique has shown a good potential, so as to cheaper and faster production of medical devices in a good quality can be achieved. Especially, concerning these products, which are crucial in patient's treatment. For example, custom-made orthoses, which are playing an essential role in a patient rehabilitation.

Based on the findings of the research the following conclusions can be made:

1. There are few limitations of the nowadays used custom-made AFO manufacturing technique: cost, time of the production and the whole process of this technique is labor-intensive. Moreover, orthotist has to be well qualified and have special skills and experience.
2. 3D printing technique is feasible in order to produce custom-made AFOs. This technique is fast, comfortable, cheap and repeatable. Additionally, 3D printed custom-made AFOs can be compared with the traditionally manufactured custom-made AFOs.
3. The 3D printing could easily replace traditional producing method in orthotic industry due to it feasibility. Nevertheless, it is important to select suitable 3D printing techniques with the best materials, so the medical device will be produced in a good quality.
4. Manufacturing of custom-made AFOs with the 3D printing technique is more comfortable to the patient and to the maker as well.
5. Despite that 3D printing technique can be widely used in different medical fields, according to the literature review there is still not enough evidence-based support for the benefits of this method and the legal aspects have to be clear as well.

Development of 3D printed orthoses is as important as the development of traditional techniques used nowadays. Therefore, thorough knowledge and future research are still needed to achieve the best possible result for the patient, which should be safe, comfortable, readily available, easy to use and not very expensive. This study is really important to initiate bigger and more comprehensive research in the future, as nowadays used techniques need to be improved and updated with the innovative additive techniques.

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APPENDICES

Appendix 1. Consent.

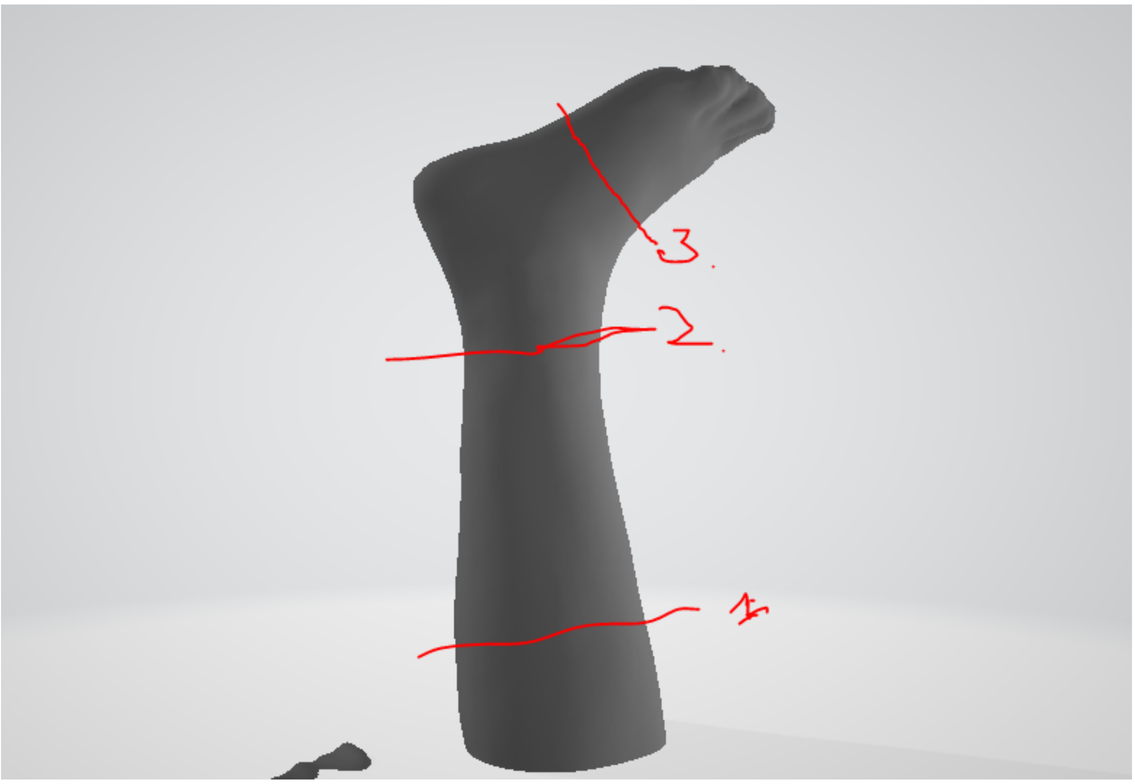
Consent

The aim of my master thesis is to investigate the feasibility of custom-made AFO's manufactured with 3D printing technique. As practical experiment sees using a child as a model for the AFO manufacturing there is a need for your approval. Therefore, me, Anna Dudkina, as author of this work certify that none of the personalized or medical data of the child will be used, and there will be no change in the treatment process because of the custom-made 3D printed ankle-foot orthoses.

Anna Dudkina	Valentin Sander
Author of the work	Tallinn Children's Hospital

01.03.2020

Appendix 2. Manual measurements with the measuring tape of the lower part of the leg.



Appendix 3- Questionnaire

Questionnaire about custom-made ankle-foot orthosis (AFO) manufacturing

1) General information about custom-made AFO’s

- What is custom-made AFO?
- Can you produce a custom-made AFO?
- Are there any alternatives to custom-made AFOs? For example, prefabricated foot orthosis. Do you have them?

2) Manufacturing of custom-made AFO’s

- What kind of manufacturing techniques do you use to produce custom-made AFO’s?
- How do you make the measurement of lower part of the leg?
- How is the shape of the feet captured?
- Do you make all of the parts yourself or are some of them already prefabricated?
- How long are the casts stored for?
- What are the technical challenges, which can occur with AFO manufacturing?
- How long does it take to produce one pair of custom-made AFO’s?
- What is the price (approximately) for one pair of AFO’s?
- How long do you expect an orthotic to last?

3) Materials used

- What kind of materials do you use?
- Can you reuse the materials?

4) **3D printing as additive manufacturing (AM)**

- Do you or can you use 3D scanning or printing to manufacture custom-made AFO's?

    - **If yes**, then what kind of scanner do you use?

    - What kind of software do you use to process the data acquired from the scanner?

    - What kind of program do you use to model the custom-made AFO?

    - What kind of 3D printer do you have?

    - What are the technical challenges, which can occur with AFO manufacturing ?

    - How long does it take to produce one pair of custom-made AFO's?

    - What is the price (approximately) for one pair of AFO's?

    - How long do you expect an orthotic to last?

- **If not**, do you or can you use 3D printing as AM technique to produce any other kind of orthosis or brace?

- Do you think that this technique can replace the currently used handmade manufacturing technique?