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3D Prototyping of Medical Devices for Non-Invasive Glucose Monitoring

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ABSTRACT

In recent years, as global diabetes rates have increased, a growing number of individuals have been experiencing pain and infections due to the invasive nature of conventional commercial glucose meters. Non-invasive blood glucose monitoring technology has emerged as a prominent international research subject and is a potential solution that could alleviate the suffering of numerous patients.

The sensor unit for which a housing is designed in this paper uses one of the many solutions for non-invasive glucose measurement, near-infrared reflectance spectroscopy (NIRS).

The designing of the housing is done with the CAD software Autodesk Inventor Professional (Autodesk, Inc., San Rafael, CA).

The finished prototype is ready to print and should enable better and more convenient measurements for one thing and secondly have a smooth look as a standalone device.

Various non-invasive technologies can be customized to meet the requirements of diabetic patients depending on the specific body target used for detection. Further research may be necessary to improve the precision and sensitivity of selected technologies.

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Introduction

Prototyping of Medical Devices

As technology evolves, the desire for customized products grows, and alternative manufacturing methods must be used. Additive manufacturing (AM) is the development of physical models by the deposition of layer-by-layer material following a virtual three-dimensional model. This technology is also known as rapid prototyping or, more commonly, 3D printing.

More specifically, Fused Deposition Modeling (FDM), a technology where the material used gets extruded threw a nozzle, is a 3D printing technique which is also used frequently by the most known 3D printers [1]. Medical devices need to have multifaceted forms often, to fit the complex form of the human body. As not every shoe fits every foot, 3D printing makes minor changes possible and affordable [2].

The process of AM can be separated in 6 steps: the first step is creating a 3D Model with Computer-Aid Design (CAD) Software or use a 3D Scanner to create the model. There are several software solutions for CAD available, like, for instance, Solidworks, Autocad, or even freeware such as Blender or Freecad. The next step is the conversion of the model into a standard format, where the faces are converted to unstructured triangulated surfaces to approximate the model. A commonly used file format is called STL (Standard Tecelation Language). Thirdly, the STL file must be converted to machine readable code, which is done by a so-called slicing software. The file is called a g-file, which contains all the instructions for the 3D printer. The material, called the filament or resin, is then extruded through a heated nozzle as the print head moves in specific directions.

The disadvantages of 3D printing are that the resolution is limited due to the diameter of the nozzle and that it is limited in speed and the size of the build plate.

The advantages are simplicity, the low cost of building functional models, and minimum material waste [1]. Rising international competition forces companies to reduce their time-to-market while maintaining high quality and to be able to do minor changes quickly to ensure the competitiveness on the market. AM could reduce the cost of product development by building the model layer by layer instead of traditional machining methods where material is removed or subtracted [3]. 3D printing can be outsourced to external companies, but small companiesand startups could also print their own prototypes usually without professional skills.

Non-Invasive Glucose Measurement

Diabetes is a widespread and persistent medical condition with global implications due to its potential to cause heart attacks, strokes, vision loss, kidney failure, and lower extremity amputation. Managing diabetes and its associated complications involves regular monitoring of blood glucose levels.

However, the process of self-measurement of blood glucose through finger pricks is uncomfortable, painful, and involves the potential for infection. Moreover, repetitive finger pricking can lead to substantial scarring and the formation of calluses, culminating in diminished sensitivity or impaired perception [4].

The prevalence of diabetic patients worldwide has almost doubled since 2010 to more than 400 million people. In 2009, there were estimated 290 million people affected by diabetes, and this number is projected to increase to 690 million by 2045 [5]. Type 1 Diabetics maintain their blood glucose with insulin injections, Type 2 Diabetics must watch their nutrition, need to burn fat and eventually take medicine, too. Either way, diabetic patients need to monitor their blood glucose level, thus, a method for continuous measurement would be desirable. On the one hand, to relieve diabetes patients from daily finger pricking, and on the other hand, to ease possible at home testing and improve the rate of early detection as the awareness of people for their blood glucose level would increase [6].

Current state of the Art of Non-Invasive Blood Glucose Measurement

These continuous measurements would be desirable to be non-invasive, which means without causing damage to the skin. Methods for non-invasive blood glucose measurement can be divided in optical methods, electrochemical and microwave methods. Optical methods are for instance near-infrared reflectance spectroscopy (NIRS), Raman spectroscopy, fluorescence, or optical coherence tomography. But blood glucose can not only be measured in blood, but also in saliva, tears and sweat.

Each measurement method has advantages and disadvantages, as well as different accuracy in different applications. The linear range of measurement values by optical or microwave methods and the actual blood glucose value is narrow, but machine learning algorithms can improve accuracy. As skin can vary in color, age, or overall condition, calibration before measurement is essential [7]. Figure 1 gives an overview of most of the current available measurement methods for blood glucose measurement.

If the measurement conditions are good, the calibration is good, the noise is low, and the patient follows the instructions, the accuracies of all techniques are quite good. Nevertheless, for a medical device to get placed on the market, it must meet required regulations and standards. In 2013, the International Organization for Standardization (ISO) introduced ISO 15197, a standard aimed at guaranteeing the safety and appropriateness of in-vitro glucose monitoring instruments and self-monitoring glucometers for human usage. Today, various tools are employed to assess the precision of non-invasive glucose monitors. These include metrics such as the mean average relative difference, the Clarke error grid (CEG), and the consensus error grid, also referred to a s the Parkes error grid (PEG). Among these, the mean average relative difference (MARD) is the preferred choice for assessing accuracy in most advanced glucose meters due to its straightforward nature. Examples for CEG and PEG are illustrated in Figure 2.

The US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) require different minimal accuracy in specific zones, which means that a specific number of values of the predicted concentration must be in definite zones. The Reference Concentration is usually measured with invasive measurement method that is still considered as the gold standard [5].

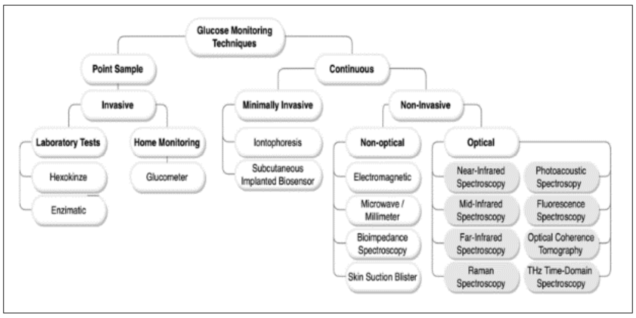

Figure 1: Overview over Glucose Measurement Techniques

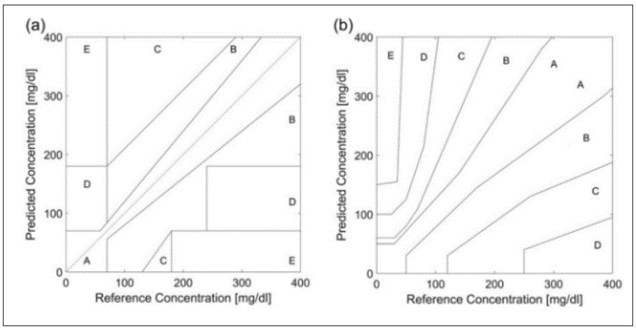

Figure 2: Error Grid Analyses a) CEG and b) PEG

The following model is a housing for a spectroscopic sensor unit, which additionally uses a motor to apply light pressure on the fingertip, varying the reflection signal strength of the four different wavelengths.

Methods

In this work, a housing for a noninvasive glucose sensor should be modeled using CAD softwa re. The sensor unit is provided by a company named SIATLAB GmbH and consists of four LEDs in different wavelengths, a photodiode, and a belt, which exerts with a motor pressure on the index finger placed on the sensor. The photodiodesignalgives, along with a regression model, a blood sugar value. The a im of redesigning the housing was to fit the existing sensor unit but have a more convenient palm-fitting form and allow relaxed finger during measurement.

This should allow for more convenient and more accurate measurements. The design should be for a standalone device supplementary to the already existing portable device housing.

For modeling, the software Autodesk Inventor Professional (Autodesk, Inc., San Rafael, CA), which is a very user-friendly sketch-based interfaces for modeling (SBIM), is used. The sensor unit part from the company is imported from a STL-file.

Here, a 2D sketch of an ellipse should be the bottom plate and beginning of the housing. With the revolve tool a half ellipse is then built and hollowed out afterwards. After editing and separating the different parts of the housing, the finished model is printed with an Creality Ender 3 printer (Shenzhen Creality 3D Technology Co, Ltd) and for simplicity, PLA as material. The three different parts are a removable bottom plate, the housing of the sensor and a removable cover which is magnetically attached.

Results

The finished model is shown in Figure 3, without the cover and Figure 4 with the attached cover. The three parts, namely the bottom plate, the housing, and the cover, can be exported from Autodesk Inventor Professional (Autodesk Inc., San Rafael, CA) separately as STL-files which are then ready to be sliced and printed.

The model fulfills all requirements as it fits the sensor unit, has enough space inside the housing for the battery, the motor, the communication module (BLE) and the PCB, and enables a relaxed position of the finger on the sensor. The circular recesses in figure 1 are for the magnets to hold the cover in place.

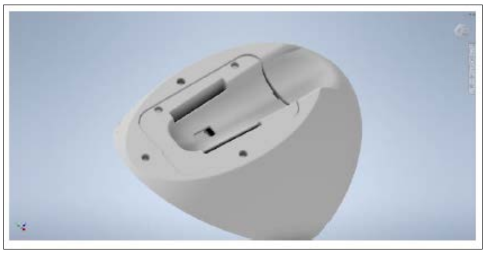

Figure 3: Finished Model without Cover

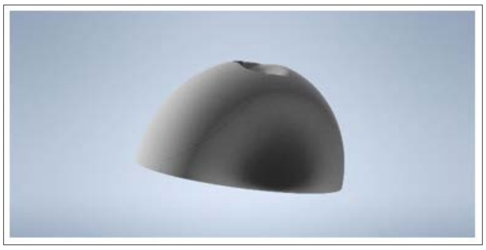

Figure 4: Rendered Model with Cover Attached

Figure 5 shows a picture of a printed version of the model. This print is post-treatment, which gives it a shinier and smooth surface.

Figure 5: Picture of the Printed Model

For a technical drawing of the 3D Model, see Figure 6. In addition to the views from the top, the side, and the front, there are also slices (Section C and Section D) added.

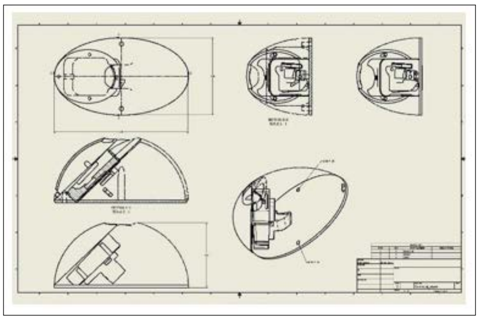

Figure 6: Technical Sketch of the Model

Discussion

Rapid prototyping or 3D printing offers numerous benefits against traditional manufacturing methods, like lower costs and time consumption for prototyping. As every piece is printed layer by layer, minor or even mayor changes in the design do not produce as high costs as they would in mass producing. Additiona ly, there is not as much material waste as in traditional methods; in fact, if no support structure is necessary, zero material is wasted. Although mass production has obvious benefits over rapid prototyping for bigger amounts of devices, for prototyping new devices with possible minor design changes, it is the better option [8].

Especially for small companies or startups that are unable or unwilling to pay an external company for producing every prototype they are having, 3D printing is an ideal and cost-effective choice.

Modern and simple user interfaces of CAD software makes modeling already easy to learn, but artificial intelligence could find more applications in CAD software and make modeling even easier.

For medical device design, innovation will bring a lot of new opportunities, like better and faster 3D Scans which can in combination with a 3D printer guarantee fast and personalized devices.

Especially prostheses and implants benefit already from personalized rapid prototyping [9].

The modelling in this paper is done with the software Autodesk Inventor Professional (Autodesk Inc., San Rafael, CA), which has a very user-friendly interface and a lot of tools.

In this paper, two methods are used to hollow out a body, and it was found that the Shell tool has the advantage over subtracting a smaller profile in that a minimum thickness can be set.

The finished model housing that is produced in this work is still a prototype; therefore, minor changes may occur. Especially on tolerances should be a focus, as 3D printers have a finite resolution, and some parts may not be correct dimensioned. It does not yet meet the standards of a medical device, which would require it, according to EU Directive 2017/745 class IIa medical device, to consist of a bio-compatible material, for example.

Non-invasive glucose measurement would ease the life of the many diabetes patients and would also improve early detection as it would facilitate the measurement process which would motivate more people for a measurement. The upsides of noninvasive glucose measurement, because of the omitted finger pricking, are the possible continuous measurement, which improves therapy, no required needle which could be feared, no possible infection without the needle, and financial issues because of the disposable needles would also be nonexistent [10].

The methods for noninvasive glucose measurement differ from optical to electrochemical and microwave techniques, and despite the research on this topic going on for so many years already, no technique has really been withdrawn so far.

There were countless attempts with different solutions for noninvasive glucose measurement, but until today none really made it, having an accuracy high enough for certification, to the market.

With the recent trend of smart wearable devices like smartwatches and rings, the market seems to get even bigger, as more and more people are willing to wear a health monitor every day. This could be another reason why researchers and developers will not stop to seek for the breakthrough; thus, it seems so daunting. Until we get to the breakthrough, which can be possible achieved by combining different techniques and improved machine learning algorithms as well as big datasets, invasive blood glucose monitors will stay the gold standard [10].

Conclusion

This paper gave an overview over rapid prototyping and non-invasive glucose measurement methods. Also, the task of designing a housing for a non-invasive glucose sensor was performed.

With sketches and primarily with the extrusion and the revolving tool, the creation of the model or subtraction of parts was straight forward. The Fillet tool makes the creation of smooth edges easy. Overall, the user interface of Autodesk Inventor Professional (Autodesk Inc., San Rafael, CA) makes modelling possible for everyone.

Using rapid prototyping, the design and fabrication process could be accelerated on the one hand, and on the other hand, the research could be accelerated as well, as different shapes or features of the prototype could lead to better measurement results. 3D printing makes prototypes available faster, but also cheaper and adaptable [2].

The interest in inventing a noninvasive glucose measuring device is, in addition to its importance, also because of the huge potential market, very high. Nevertheless, no certified medical device for non- invasive glucose measurement is on the market yet. Notwithstanding, attempts won't stop, and some techniques made considerable progress in the recent years [11].

It is to be hoped that noninvasive glucose measuring devices will replace minimal invasive solutions, primarily to relieve the many patients with diabetes and to facilitate early detection of diabetes.

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