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ARTIFICIAL INTELLIGENCE–BASED AUTONOMOUS SOCKET PROPOSAL PROGRAM: A PRELIMINARY STUDY FOR CLINICAL DECISION SUPPORT SYSTEM

ORIGINAL ARTICLE

ABSTRACT

Purpose: The aim of this study is to develop artificial intelligence-based interfaces that can be used by professionals (clinicians and/or academics) working with disabled individuals who need prosthetics and to create a sample data set for professionals working in this field.

Methods: 101 patients who had undergone amputation were enrolled. The residual limbs of all patients were scanned using a three-dimensional (3D) scanner and saved on the computer. The prosthetic sockets, fabricated using traditional methods, were also scanned with the same scanner and saved as a 3D model. Residual limb–prosthetic socket matches were obtained using data points and a deep neural network (DNN)-based decision support system was developed.

Results: Simulation studies conducted with the point cloud data sets of 101 patients yielded a training success rate of 86%. The DNN model exhibited a generalization success rate of 78%.

Conclusion: The artificial intelligence–based software interface has potential and could assist professionals by suggesting a suitable 3D socket model for patients in need of a prosthesis. Further studies will benefit from additional sample data to enhance the accuracy of the model.

Keywords: Amputation, Artificial Intelligence, Decision Support System.

YAPAY ZEKA TABANLI OTONOM SOKET ÖNERME PROGRAMI: KLİNİK KARAR DESTEK SİSTEMİ İÇİN ÖN ÇALIŞMA

ARAŞTIRMA MAKALESİ

ÖZ

Amaç: Bu çalışmanın amacı, protez ihtiyacı olan engelli bireylerle çalışan profesyonellerin (klinisyenler ve/veya akademisyenler) kullanabileceği yapay zeka tabanlı arayüzler geliştirmek ve bu alanda çalışan profesyoneller için örnek bir veri seti oluşturmaktır.

Yöntem: Amputasyon cerrahisi geçiren toplam 101 hasta çalışmaya dahil edildi. Tüm hastaların güdükleri üç boyutlu tarayıcı kullanılarak tarandı ve bilgisayara kaydedildi. Çalışmaya dahil edilen hastaların geleneksel yöntemlerle üretilen protez soketleri de aynı tarayıcıyla taranarak elde edilen üç boyutlu modelleri de bilgisayara kaydedildi. Üç boyutlu tarayıcılarla elde edilen nokta bulutu verileri kullanılarak güdük-protez soket eşleşmeleri elde edildi ve derin sinir ağı (DNN) tabanlı bir karar destek sistemi geliştirildi.

Sonuçlar: 101 hastaya ait nokta bulutu veri setleri ile yapılan simülasyon çalışmalarında %86 oranında eğitim başarı oranı elde edildi. DNN modeli %78'lik bir genelleme başarı oranı sergiledi.

Tartışma: Bu çalışma ile geliştirilen yapay zeka tabanlı otonom soket önerme ara yüzü protez ihtiyacı olan hastalar için uygun 3 boyutlu soket modeli önererek profesyonellere yardımcı olabilir. Daha sonraki çalışmalarda modelin doğruluğunu artırmak için daha fazla hastanın verilerinin kullanılması planlanmaktadır.

Anahtar Kelimeler: Amputasyon, Yapay Zeka, Karar Destek Sistemi

INTRODUCTION

Prosthetic rehabilitation is the most effective method for increasing the functional levels of patients who have undergone amputation of their extremities. Traditional methods for socket fabrication can be expensive, particularly in developing countries with poor accessibility to materials, such as epoxy resins, fiberglass, or carbon fiber. According to the World Health Organization, only 5%–15% of patients who have undergone amputation in low-income countries have received an appropriate prosthesis (1-4). This can be attributed to high costs, difficulty accessing prosthetic materials, a lack of trained personnel, a lack of information regarding prostheses, and difficulty accessing well-equipped hospitals or health centers (1-4).

Advancements in the industrial sector have positively influenced prosthesis manufacturing processes. Recently, the use of three-dimensional (3D) scanners and printer systems for prosthesis fabrication and related studies has grown in popularity. With the rapid development of 3D systems (scanner and printer), prosthesis fabrication has become simpler and more accessible (4,5). The 3D printing systems shorten the prosthesis manufacturing processes and allow for the fabrication of patient-specific socket and prosthetic components at lower costs (4,5). However, appropriate software and computer systems utilizing 3D technology are required to fabricate prostheses suitable for each patient. Although 3D systems seem a viable option for prosthesis fabrication in developing countries, the lack of access to appropriate software and computer systems is a roadblock. Even though they are more efficient in terms of time and cost effectiveness compared to traditional methods, research in developing countries is insufficient to apply 3D technology in prosthesis fabrication as a long-term solution (4,5).

It is considered that the development of an artificial intelligence-based software can help to overcome some of these shortcomings. Thus, intelligent approaches can make significant contributions to healthcare professionals by helping them the creating socket process.

The primary objective of the study was to utilize artificial intelligence to create a recommendation program for the fabrication of prosthetic sockets. This program will be based on data points derived from the residual limbs and socket shapes of previous patients. Furthermore, another aim of the study was to generate a sample set for the clinical decision support system.

METHODS

From January 2020 to June 2021, eligible patients who had undergone amputation at the Faculty of Health Sciences, Department of Physiotherapy and Rehabilitatio, Hasan Kalyoncu University and expressed willingness were enrolled in this study. The inclusion criteria were as follows: 1) age > 18 years; 2) no intellectual disability; 3) have a transfemoral or transtibial amputation and used the prosthesis for at least a year. The exclusion criteria were as follows: 1) severe visual or perceptual impairment; 2) postoperative functional sequelae in the extremities; 3) pain that would prevent the study procedures from being performed; and 4) neurological diseases, e.g., stroke and multiple sclerosis.

Ethical approval was obtained from the Faculty of Health Sciences Research Ethics Committee, Hasan Kalyoncu University (Clinical Trial Registration Number: NCT05341674). Written informed consent was obtained from all participants. Patients were made aware of their right to withdraw from the study at any time.

Data collection

Participants' residual limbs, while wearing the silicone liner, were scanned in a sitting position above the stool (Figure 1) and recorded on a computer using the Artec Eva Lite (Artec Group 2013, Luxembourg) 3D scanner with 0.1-mm sensitivity, 0.2-mm resolution, and a 16-frames/s frame rate (6,7). In the literature, it is stated that the Artec Eva 3D scanner is a reliable device capable of capturing even the smallest details of the human body with point cloud data, and therefore, it has been decided to use this device in this study (6,7). While the patients held their residual limbs in this position, scans were taken 5 times and

from different angles to minimize the effect of gravity. All scanning procedures were completed within 3 minutes to avoid fatigue in the patients. All these scanning operations were saved on the computer. After completing the residual limb scanning procedures, we used the same scanner to scan the prosthetic sockets that patients had used for at least 1 year without any complaints. During the scanning procedures, the prosthesis was placed on a stable surface (Figure 1) (8). The residual limb 3D models of all patients were matched with the 3D model of the prosthetic socket of the same patient and saved to the computer.

Developing an artificial intelligence model

Artificial intelligence is the ability of computers to replicate the working structure of human intelligence and perform tasks that require logic, such as drawing conclusions, finding solutions, making generalizations, understanding problems, and learning by using past experiences (9). It aims to replicate or imitate human intelligence within a computer system, encompassing the subfield of machine learning.

Deep learning is a machine learning technique recognized by artificial neural networks based on the working principle of brain neurons. In recent years, it has been widely used in both research and industry. DNN, a basic architecture in deep learning, was used in this study.

The interface obtained using the data in the study (using DNN) is a preliminary study for a

clinical decision support system. In this study, in which the deep learning model was developed, a classical statistical analysis was not performed, but artificial intelligence was used to determine the accuracy of the desired interface.

We processed the data through various stages before developing the artificial intelligence model. Scanned residual limb and socket models were converted into solid models by a professional computer engineer through the Artec studio program (Artec Group 2013, Luxembourg) (6,7) and were saved to the computer (Figure 2). Along with the residual limb and socket images converted into a solid model, information about the patients such as age, gender, amputation level, amputation side and dominant limb were recorded on the computer.

The artificial intelligence model was developed on the Anaconda data science platform using the Python (Python 3.0,2020, Python Software Foundation License, designed by Guido van Rossum) programming language and the Tensor-Flow deep learning library. The point cloud dataset was divided into training and test sets at a ratio of 9:1 to create the best DNN model. The most appropriate DNN model was determined based on the trials to create the most accurate decision support system. Seven layers were used in the obtained model, with the first being the input layer and the last being the output layer. The "ReLu" function served as the activation function for the input and intermediate layers, while the "linear" function served as the activation

Figure 1. Scanning processes with 3D scanner. A: Scanning residual limb (8), B: scanning prosthetic socket (permission was taken from the patient for the image)

function for the output layer. As the optimizer, "Adam" was chosen as the most successful algorithm for model training. Within the scope of the study, a new interface was designed using the Python (Python 3.0,2020, Python Software Foundation License, designed by Guido van Rossum).

 programming language to develop the program that would run the decision support system. The most suitable DNN models and weights were obtained and integrated into the newly developed decision support system. The software that recommended the most suitable prosthetic socket for the end user was utilized.

RESULTS

101 patients who fulfilled the eligibility criteria, including 68 men and 33 women were enrolled. Using point cloud data consisting of residual limb and socket matches of these participants, a preliminary study of an artificial intelligence model that can recommend autonomous sockets was completed.

The "batch size" of the model trained with a total of 500 "epochs" was determined to be 64. Table 1 summarizes the hyperparameter values.

90% of the point cloud dataset is reserved for training and 10% for testing. The training performance of the DNN model was 86%. Testing the model with the point cloud test data yielded a success rate of 78%.

Figure 3 shows a 3D model of the prosthetic socket suggested by the artificial intelligence– based DNN model. This 3D socket model was prepared using Plotly's This 3D socket model was prepared using Plotly's Python (Python 3.0,2020, Python Software Foundation License, designed by Guido van Rossum) graphics library and found to be able to use as a decision support system.

DISCUSSION

In this study, a recommendation program for prosthetic socket production was created using artificial intelligence. The sample set obtained from our study may contribute to the development of a clinical decision support system for prosthesis production with 3D systems (3D printer and scanner) in future studies.

Point cloud; It is a data type that allows representing the geometry of objects and/or anatomical structures with a large number of points

Figure 2. Example images of the process of converting 3D models into solid models with the Artec eva studio program *(*Artec Group 2013, Luxembourg). A: Three-dimensional scanning raw image, B: Cleaning of artifacts from the raw image, C: Final image of the solid model after all operations

Figure 3. Example of a 3D model of the prosthetic socket suggested by the proposed deep neural network model for a patient with transtibial amputation.

sampled on their external surfaces, and is used for 3D modeling in healthcare fields (10-12). In the literature, studies in which point cloud data are obtained by scanning the residual limbs of amputees are quite limited (13,14). In our study, point cloud data was obtained by scanning the residual limbs of the patients with a 3D scanner and these point cloud data were used in the developed program. This study, which includes the use of point cloud data obtained from amputees, can serve as an example for future studies. Studies on processing and analyzing point cloud data with the help of artificial intelligence are limited in the literature (15). In this study, point cloud data obtained from amputee patients were processed and analyzed with the help of artificial intelligence. It is believed that these results obtained from our study will make significant contributions and guide researchers working in the field.

Three-dimensional modeling methods provide a better understanding of anatomy beyond traditional imaging (16). When studies are examined, it can be seen that computerized tomography (CT) and magnetic resonance imaging (MRI) systems are generally used to visualize the anatomical structure of an organ or tissue in detail in a non-invasive manner (12,17). These are software available in the literature that use these MRI or CT images to make three-dimensional modeling of organs or any anatomical part (17). The most widely used one of these software is the software called MIMICS (The Materialize Group, Leuven, Belgium) (17). MIMICS can make three-dimensional modeling with CT images of patients in DICOM format (17). Organ modeling is generally done with this software, and the images obtained contain only the point cloud data of that organ (18-20). It is not a software that recommends any prosthesis or similar device suitable for the resulting three-dimensional model. The software obtained from our study recommends a socket that may be suitable for the patient using the residual limb point cloud data scanned with any 3D scanner. Healthcare professionals using this software can make the necessary changes via this recommended socket (3D model). This feature of the software may facilitate the work of healthcare professionals who want to design sockets suitable for amputees applying to the clinic.

Sockets in lower extremity prostheses are one of the most important prosthetic components when evaluated in terms of mobility (21). Sockets are generally handmade according to the morphology of the patient's anatomical region (21). However, there are also software in the literature that produces sockets with computer-aided systems (21). Software such as The Canfit™ computer-aided design (CAD) software application and rodin4d can be given as examples (21). These are known as software that helps design prostheses and orthoses that work with CAD/CAM technology (21). While designing prostheses or orthoses (such as scoliosis orthoses) with this software, the point cloud data obtained from the patients are matched with the patient's x-ray images. In order to design prosthesis with this software, the professional using the software must be experienced and be able to use his/her own skills for the resulting models. Therefore, design in this way, it is important that the person using the software is as knowledgeable and skilled as an engineer. In the software we obtained in our study, when the point cloud data of the amputee patient is entered into the system, a sample socket is suggested by the software. The healthcare professional can make the necessary changes on this recommended socket. With this feature, the software obtained from the study may be easier to use than software such as The Canfit™ computer-aided design (CAD) software application rodin4d.

In order to produce a prototype of any product with three-dimensional printers, a three-dimensional model of that product must first be designed/drawn. Programs such as Solidworks and Meshmixer are frequently used for these designs or drawings (7,22-26). It requires advanced software and engineering knowledge to make such designs or drawings. The drawings/designs made depend on the abilities of the person using the software. The software obtained in our study provides both drawing/design opportunities to professionals who want to produce sockets and suggests a socket model according to the shape of the patient's stump (according to point cloud data). This model (3D socket model) recommended by the system can be printed with three-dimensional printers if desired. If it is thought that the proposed socket is not suitable for the patient, drawings can be made based on the proposed model and the model can be revised. It is believed that this software obtained from our study is easier to use than other software (Solidworks, Meshmixer) due to this feature. In addition, since this software uses the deep learning method within artificial intelligence models, the

software continues to learn and increase its socket recommendation success (deep learning). As a healthcare professional who uses the software in our study in his own clinic uploads the three-dimensional models (point cloud data) of the residual limbs of the patients coming to his clinic to this software system and continues to produce sockets suitable for that patient, the software will be able to increase its success by continuing to learn from these processes. In this aspect of the study, it can make significant contributions to the literature.

According to the World Health Organization, patients in low-income countries cannot easily access prostheses due to high costs and lack of equipped personnel and institutions (1-4). It has been emphasized that prosthesis production using 3D technologies may be a good option for patients in low-income countries (4,5). It is stated in the literature that for production with 3D systems to be successful, appropriate software must be available (4,5,7). Studies have shown that the lack of adequately suitable software is a problem (4,5,7). The software in our study is a recommendation program that can produce sockets with the help of artificial intelligence. Thanks to this feature, it can help produce sockets that are more compatible with patients and make faster designs.

This software obtained as a result of our study was created with data obtained from real patients, and the success of the software was tested in a computer environment. It has not been tested on a real patient. Our work continues to test it on patients.

With this work we have done, an artificial intelligence-supported software has been developed with a success rate of more than 80%. It is believed that this artificial intelligence-based autonomous socket recommendation program may be preferred by healthcare professionals interested in prosthetic manufacturing processes compared to other 3D modeling software. The sample data set obtained from this study also enabled the development of a clinical decision support system that can be used in prosthesis production processes with 3D systems. We think that these results support the literature.

Furthermore, the AI-supported interface developed in this study can provide significant contributions by assisting physiotherapists, prosthetists and prosthetic orthosis technicians in the socket creation process. The point cloud data used in this study will offer valuable contributions to the effective clinical implementation of this interface. The resulting software has only been tested and verified in a virtual environment. One of the limitations of the research is that it has not been tested on patients. Future studies should focus on developing additional software to enhance the accuracy of the model and validate it using a larger sample of patients.

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