



The Need for a Software To Remotely Monitor VAD Patients and the Designing, Planning and Project Support Phases of PASA VAD

VAD Hastalarının Uzaktan Takibi İçin Geliştirilen Bir Yazılım İhtiyacı ve PASA VAD Yazılımının Tasarım, Planlama ve Destekleme Süreci

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Received \ Geliş tarihi : 17.06.2020
Accepted \ Kabul tarihi : 04.08.2020
Online published : 04.03.2021
Elektronik yayın tarihi

Cite this article as:
Bu makaleye yapılacak atf:
Özçobanoğlu S, Aşık MD. The need for
a software to remotely monitor VAD
patients and the designing, planning and
project support phases of PASA VAD.
Akd Med J 2021; 7(1):125-33.

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ABSTRACT

Objective: The aim of this study is to discuss the need, and the designing, planning and support phases of a remote monitoring software that supports the physicians and coordinators in the follow-up and treatment of patients by combining the features of smartphones with the software for the ventricular assist device patients.

Material and Methods: The highlights and the content that should be in the software, and the engineering, workspace and foundation requirements of this study, were determined by the physicians and ventricular assist device (VAD) coordinators, who were working together in an experienced clinic in the field.

Results: Project engineers who work on the development, design, testing and control of the mobile and desktop device's software in addition to image processing and an expert with a PhD in biostatistics and medical informatics for the identification, adaptation, and integration of the necessary analysis methods to the software started to work with the support of TÜBİTAK. Antalya Technopark provided the workspace for the engineers. Vestel Electronics Industry and Trade Company provided a preliminary study for the support plan of the hardware that will work with software. Software will be developed for the Android, iOS and desktop platforms with these elements.

Conclusion: It can be predicted that the variations of the PASA VAD software can support both the patient and the healthcare professionals for many different diseases that require remote monitoring. Moreover, it is foreseen that the data and data classes that will be obtained can create new data and data analysis clusters in the field of patient health through scientific studies.

Keywords: Ventricular Assist Device, Remote Monitoring, Software, Image Processing, Data Processing

ÖZ

Amaç: Bu çalışmanın amacı, akıllı telefonların özelliklerini uygun bir yazılım altyapısı ile birleştirerek ventriküler destek cihazı hastalarının uzaktan takibi ve tedavisinde doktor ve koordinatörleri destekleyebilecek bir yazılımın ihtiyaç, tasarım, planlama ve destek aşamalarını tartışmaktır.

Gereç ve Yöntemler: Kalp yetmezliği ve VAD implantasyonu konusunda oldukça deneyimli bir klinikte çalışan doktorlar ve ventriküler destek cihazı (VAD) koordinatörleri ile birlikte, bu çalışmanın konusu olan yazılımın mühendislik, çalışma alanı ve temel gereksinimlerinde bulunması gereken başlıklar ve içerikleri belirlenmiştir.

Bulgular: Proje mühendisleri mobil ve masaüstü cihazların yazılımı, görüntü işleme yazılımı, yazılım görsellerinin tasarımı, yazılımın testi ve kontrolü için, bir biyoistatistik ve tıbbi informatik doktoru ise yazılımda kullanılacak istatistiksel yöntemlerin belirlenmesi, yazılıma adaptasyon ve entegrasyonu için TÜBİTAK tarafından karşılanan maddi destek ile çalışmaya başlamıştır. Takımın çalışacağı alan Antalya Teknokent tarafından sağlanmıştır. Vestel Elektronik Sanayi ve Ticaret Şirketi, yazılım için gerekli olan donanım için destek planının ön çalışmasını sağlamıştır. Yazılım android, IOS ve masaüstü platformlar için bu koşullar altında geliştirilmiştir.

Sonuç: Çalışma sonucunda ortaya çıkacak yazılımın varyasyonlarının uzaktan izlenmesi gereken birçok hastalıkta hem hastayı hem de sağlık uzmanlarını destekleyebileceği tahmin edilebilir. Ayrıca, bu yazılımla elde edilecek veri ve veri sınıflarının, birçok bilimsel çalışma ile hasta sağlığı alanında yeni veri ve analiz setleri oluşturabileceği düşünülebilir.

Anahtar Sözcükler: Ventriküler Destek Cihazı, Uzaktan Takip, Yazılım, Görüntü İşleme, Veri İşleme

DOI: 10.17954/amj.2021.2904

INTRODUCTION

Heart failure concerns about 23 million patients worldwide and the annual treatment expenditure for this disease is \$108 billion (1). As is known, heart transplantation is the gold standard treatment for end-stage heart failure patients. More than 30,000 patients are waiting for a heart transplant all over the world. According to 2018 data, approximately 8,000 patients have benefited from this treatment (2,3). For Turkey, 1089 patients were waiting in the heart transplant list in 2018; however, only 91 patients were able to undergo heart transplantation. The annual treatment cost of the patients who cannot be transplanted can reach 25,000 ₺ (4).

Long term ventricular mechanical support systems technology (Ventricular Assist Device - VAD), which is expanding its field of use by achieving better results for the end-stage heart failure patients, has been developing in the last 20 years. While this treatment has been applied to a limited number of patients in many centers in the early 2000s, it is now applied to about 20,000 patients every year in approximately 300 centers worldwide. The average 5-year survival rate for this treatment is 70% (5). In Turkey, 251 VAD implantations were accomplished in 2018. Nevertheless, VADs and patients have to be strictly monitored after the operation. There are many unintended consequences of both the device and the medical treatment. Special surgical teams and VAD coordinators are assigned to avoid unwanted results.

After a successful operation and hospitalization process for VAD patients, a new life begins. After discharge, they continue their daily lives with a mechanical support system in their bodies. The patient's device values, body characteristics, and medical treatments should be monitored daily from home and at intermittent hospital visits. The data obtained during daily and intermittent follow-ups should be classified, controlled, and monitored. Besides, recording this data regularly is very important in regulating the patient's treatments. VAD coordinators are responsible for recording, classifying, monitoring the patient and informing the relevant physicians. They take care of 50 patients on average (6-7). VAD coordinators and physicians provide their connections with the patients through daily telephone calls, one-on-one interviews during hospital visits, social media, and general messaging services (7). Apart from one-on-one interviews, the patients' driveline wounds are followed up by smartphone messaging applications.

Despite the close follow-up of physicians and VAD coordinators, it is not known how medical treatments, device values, and control cable wounds affect VAD-implanted heart failure patients' daily lives as well as the many problems requiring home monitoring. Even if VAD devices

provide the opportunity to store and examine the device data at very short intervals up to 30 days, there is no possibility to associate this data with the daily life of the patients. There are limited studies on VAD patients and disorders requiring home monitoring (8-9).

Patients share their immediate or short-term status during both daily and intermittent hospital follow-up. Physicians and VAD coordinators can only have immediate or short-term data of the patient's situation in physical or electronic communication platforms and they have to make their decisions with this limited information. An opportunity to continuously record patient data, classify recorded data, and instantly monitor data trends can facilitate patient follow-up by both VAD coordinators and physicians. It may also provide physicians with more long-term and detailed information about the patient in decision-making.

Today, the use of smartphones is very common in all ages and all segments of society. Smartphones; processors, geolocation and tracking, image, and data transmission competence, combined with an appropriate software infrastructure, can help physicians and VAD coordinators and enable the establishment of infrastructures that will allow patients to be monitored more safely. This study supports the physicians and VAD coordinators in the follow-up and treatment of VAD patients by combining the features of smartphones with appropriate software infrastructure. The planning, support, and manufacturing process of the PASA VAD (Patient and Attendant Smartphone Application for VAD) software is discussed.

For the usage of the patient data, local ethics committee approval was obtained (Akdeniz University Ethics Committee approval date and number: 06.11.2019/ 1048). The study was conducted in accordance with the principles of the Declaration of Helsinki.

METHODS

Together with physicians and VAD coordinators, who are working in a highly experienced clinic for heart failure and VAD implantation (More than 200 VAD implantations), the highlights and the contents that should be in the software were determined;

A- Data Requirements

1- Daily Data (Daily data should be entered into the software)

- Patient's daily weight measurement
- Device Flow value
- Device Watt value
- Device RPM value
- Device Pi value
- Driveline exit site gleet, Yes / No indication

2- Control Data (Data should be entered into the software after hospital control)

- INR Value
- White Blood Cell count value
- CRP Value
- Hematocrit value

3- Daily Activity Data (Location data and additional hardware data that can measure activity)

- Walking/running distance (Total walking distance, continuous duration, and speed of each walking activity, number of rest intervals taken during walking and resting time)
- Frequency and duration of inactivity
- Number of daily steps

4- Image Data (Storing images and displaying them sequentially by date)

- Surgical field view
- Driveline exit area display
- Laboratory and examination results image

5- Emergency Information (To be able to share emergency presence and current location along with the data of global positioning system with a physician, VAD coordinator, and predetermined patient relatives via the software and SMS)

- Emergency moment information
- Emergency localization information

6- Possibility of Special Communication (Between patient and related physician)

- Online messaging

7- Drug Use Support (Schedule, time and dose information alert for daily drug use via smartphone)

- Coumadin
- Other medical treatments

8- Follow-up Appointment Calendar (Calendar, pre-check and follow-up day alert via smartphone)

- General control
- INR control

9- Data Analysis (Time-based analysis and graphing of all data obtained from each patient - when a new data entry is perceived, analysis of the trends of the entered data and new statistical analysis of the relevant data for each new data entry - instant notification of statistical significance to the attendant)

- Analysis of daily data
- Analysis of control data

- Analysis of movement data
- Prediction of future data
- Cross-analysis of daily control and motion data

10- Image Analysis (Optical character analysis [OCR] scanning of test and examination reports with a smartphone camera and recording to the software database, processing of surgical field images and scanning for possible complications)

- Analysis of the images of the tests
- Analysis of surgical areas
- Driveline exit area analysis

B- Engineering Requirements

1- Software Engineering (The engineering required for the software to work on mobile, desktop devices in Android, Windows and iOS environments)

2- Biostatistics and Medical Informatics (Determination of formulas necessary for the processing of the data that obtained, statistical evaluation software that will work together with the formulas and integration with smartphone software)

3- Image Processing Engineering (Driveline cable exit area and surgical wound image analysis, with OCR for test results)

4- Industrial Product Design (Design of software interfaces and software icons to be used in mobile and desktop devices)

5- Test and Control Engineering (Testing of software related to mobile and desktop device)

C- Support Requirements

1- Financing support (Provision of necessary equipment and financing for required engineering service)

2- Hardware support (Integration of these devices with software, smart wristband, and scales with remote communication capability to work with software)

3- Workspace support (An area where the engineer and medical team benefit to form a software development)

An engineering team is formed for the specified data, engineering, hardware, financial support, and workspace requirements. Institutions and organizations that provide financial support, equipment, and working area were searched, and support applications were made to the organizations deemed appropriate. The software plan was presented to the VAD implantation centers in Turkey and a reference letter obtained from the responsible physicians of 7 centers.

C-Patient Data Requirements

Required patient DATA for the development of statistical data analysis methods were taken from the hospital database.

For the usage of the patient data, local ethics committee approval was obtained (Akdeniz University Ethics Committee approval date and number: 06.11.2019/ 1048). The study was conducted in accordance with the principles of the Declaration of Helsinki.

RESULTS

It is necessary to employ engineers and meet the engineering requirements to develop the software. For the finance and employment of engineers, TUBITAK incentives were assessed. It was decided that the TUBITAK 1512 program was the most appropriate support program for the recruitment of engineers. In 2018, an application was made with a project proposal. 820 project applications were accepted to 1512 program that has received more than 5,000 applications. As a result of the review, the PASA software received funding support as one of 147 projects (Project no: 2180656) that received TUBITAK 1512 program support.

National technology companies were contacted to claim the software required for hardware supply and also its integration into the PASA VAD software. Vestel Electronics Industry and Trade Company provided a preliminary study for the support plan of the hardware that will work with software.

For the PASA VAD software, two software engineers worked on the Android, Windows and iOS platforms for both mobile (Smartphone, tablet) and desktop devices; one software engineer for testing and control; a doctor of biostatistics and medical informatics for the identification, adaptation, and integration of the necessary analysis methods; an image processing engineer for processing wound images and OCR technology; and an industrial product engineer for software design and design of software icons, employed with the financial support provided by TUBITAK. Akdeniz University Antalya Technopark provided the workspace for the engineers.

After the infrastructure, hardware and financial support was provided, the preliminary work of the aforementioned requirements was made with the created team, and the production of the following software for the PASA VAD software was started;

1- PASA VAD Analysis, Tracking And Warning Software, And Attendant Interface (Figure 1).

The PASA VAD analysis, monitoring and alerting software, which was written in C Sharp language, is mainly

used to file, classify, and process the data on a “Dedicated server” and send the monitoring data, abnormal data, and the analysis of the abnormal data determined from the mobile patient smartphone application to the attendant smartphone application and WEB service as numeric, graphic, and warning notifications. In this database, data is entered according to the HL-7 format and stored with the necessary security measures. Access to the database is edited on Microsoft SQL or Azur with 128-bit encryption. With Android Studio, the structure for taking photos and GPS data on the mobile device is created. IOS versions of the software are written using SWIFT. Windows-based software is created on Visual Studio.

With the mobile application developed in the project, patients will record data in two ways: daily and after follow-up visits. For the VAD devices in use, the normal data is obtained from the relevant companies and the change rates of the data required for clinical follow-up is determined by the project team and added to the software (Table I). For this purpose, time series analysis is performed using the Python programming language and the findings are presented graphically. When users register data in the application interface, the Python modules run on the server side, and this module checks whether the data entered by the user and the estimated values calculated based on historical values are within safe ranges. ARIMA, Holt-Winters method, Holt’s Linear Trend method, Simple Exponential Smoothing, etc. are used. The estimation model that gives the best results among such methods will be used in the study. The Numpy, matplotlib, pandas, scikit-learn, statsmodels, seaborn and scipy libraries will be used in the development of the Python module.

In the project, Python is used as a programming language in the optical character definition section. As an image processing library, Opencv (Open source computer vision) is preferable because it is open source. The Tesseract library is preferred as the character identification library. In the driveline cable exit area and surgical field image processing, the Python software language and Open CV library are preferred. It was decided to use the open-source TensorFlow library to scan the driveline cable exit area with artificial intelligence. Also, it was planned to map the images of the surgical area and driveline cable exit areas with the smartphone camera to determine the homogenization and heterogenization, the color placement and distribution of the mapped images, the brightness ratios at the pixel level, to follow the trends on the sequential images, and to make sense of the trends using artificial intelligence. The planned method was accepted as a master’s thesis proposal at the Akdeniz University Electrical and Electronics Engineering Department in 2019 following the application of the relevant engineer.

Online messaging, calendaring, and drug use support are included in the main software. Data viewing, tracking, and analysis software can be accessed from the android, Windows, and iOS platforms with mobile and desktop devices. Patients are not able to access the screen where

the data is stored and analyzed. The software has institution-based authorization and the screens that healthcare professionals can access according to their authority are limited. The desktop software image of the PASA VAD attendant software is shown in Figure 1.

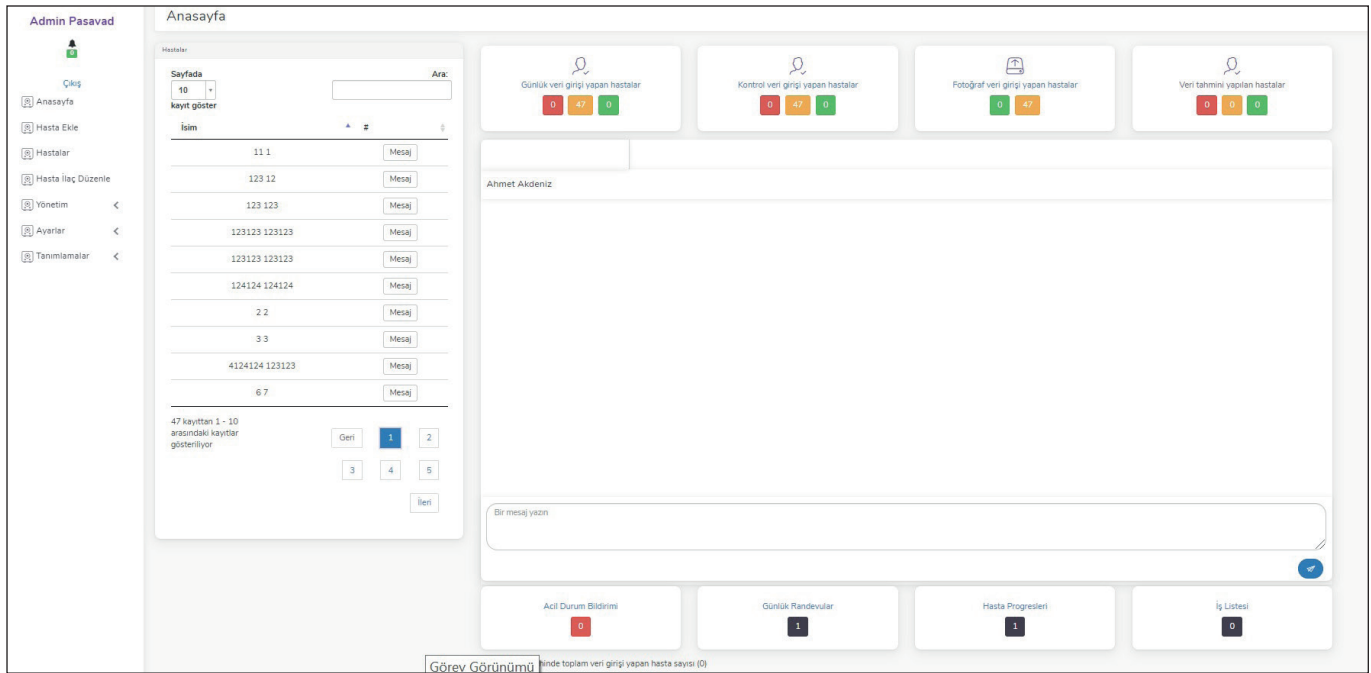


Figure 1: Attendant control panel for mobile and fixed devices.

Table I: Daily data parameters for follow-up.

Device	Heartware	Heartmate 2	Heartmate 3
*Watt¹	1- 1.7 < * < 2.5		
	2- 2.0 < * < 3.0		
	3- 2.3 < * < 3.3		
	4- 2.6 < * < 3.8	± 2 watt	± 2 watt
	5- 3.0 < * < 4.4	(Normal range 3.5 – 7.5 watt)	(Normal range 2.5 – 5.5 watt)
	6- 3.3 < * < 5.0		
	7- 3.8 < * < 5.6		
	8- 4.2 < * < 6.3		
*Flow²	± %20 *	± %20 *	± %20 *
*RPM	1- 2200 < * < 2300		
	2- 2300 < * < 2400		
	3- 2400 < * < 2500		
	4- 2500 < * < 2600	8000 – 10000	4000 – 7000
	5- 2600 < * < 2700		
	6- 2700 < * < 2800		
	7- 2800 < * < 2900		
*Weight³ /kg	± %2 * /kg	± %2 * /kg	± %2 * /kg
*Pi⁴	None	3.0 < * < 7.0	2.0 < * < 5.0

¹ Watt Value, saved at the discharge time, ² Flow Value, saved at the discharge time, ³ Patient weight, saved at the discharge time, ⁴ Pi value, saved at the discharge time (Only for Heartmate 2 and 3 devices)

2 - PASA VAD Patient Mobile Device Application (Figure 2)

Additional software developed for patients that will only work on mobile devices. The Java software language is used for Android and improvements are made on Android Studio. Furthermore, the Swift software language is used for iOS and improvements are made on Xcode. In this developed software, subtitles are created to allow patients not only to enter notes daily but also control data manually. In the meantime, they can take pictures of medical reports, the surgical area, and driveline cable exit area. A separate subtitle for online messaging is provided. Separate hoods for emergency and drug use support are also added. The industrial design engineer support increases patient compliance in order to make the patient's interface simple and easy to understand.

DISCUSSION

It is known that VAD patients' close follow-ups, which require daily control and frequent hospital visits, have a positive effect on long-term mortality and morbidity (6). In addition, face-to-face interviews, telephone, social media, and messaging applications are used for daily and intermittent follow-ups. However, a practice that provides a specific connection between VAD patients and medical attendants is not available today. In this study, it is assumed that a special platform should be created both for the connection of the patients and attendants, and for data sharing between them. It is thought that if a specific connection is provided, it can facilitate better communication between the patients and the medical attendants, and enable a more strict follow-up.

VAD Coordinators and physicians record a lot of information while monitoring patients. However, a patient's daily device data cannot be recorded (7). With this study, it will be possible to record the daily device data and store the device data information during the long-term follow-up, and also to associate the complications that may occur during the follow-up period with the daily device data. It is thought that daily monitoring of the patient's body weight might also be related to renal performance reflecting end-organ perfusion. With the follow-up of daily body weight changes, the circulatory performance of the device might be predicted. It is also possible to assess the change in the fluid load due to device performance or patient behavior (medication failure, excessive fluid or salt consumption, etc.) through daily weight monitoring. The necessity of indicating the presence or absence of any gleet at the outlet of the driveline cable daily will benefit physicians and VAD coordinators in the follow-up of driveline infections.

The results of the laboratory evaluations such as CRP and white blood cell counts during hospital follow-ups are

important for understanding the presence of an infection. The INR values for the detection of anticoagulation levels will be entered manually into the software. Patients who can perform INR tests at home will be able to manually enter INR values without entering other values. After OCR technology is integrated into the software during the development, liver and renal function tests will be added to the follow-up data as well. Without OCR technology, the manual entry screen was limited for critical items in terms of the data to be entered, since it was thought that manually recording many values into the software may impair patient compliance.

The normal limit ranges of the daily and follow-up data related to the device were determined according to the limit ranges obtained from the manufacturers of three commonly used VAD devices, and those related to the patient were determined by clinical observations (Table II). Boundary ranges of the patient-related data can be rearranged with the data and the data analysis to be obtained during the study.

In the literature, there is only one study showing that data transfer by smartphone can be used for VAD patients and there it is stated that data transfer is usable and beneficial (9). Moreover, the images of the surgical area and the driveline exit area that were sent to the attendants via the software can be very useful, and if required, they can be displayed on the software in order of date. It is planned to display multiple images side by side at the same time during the study period. The images that will be taken

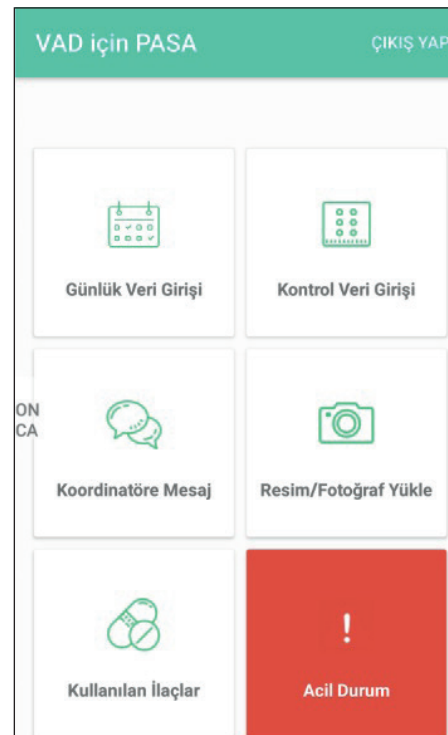


Figure 2: Patient control panel for mobile devices.

Table II: Control data parameters for follow-up.

*INR ¹	2.5 < * < 3.5	1.5 < * < 2.5	2 < * < 3
*WBC ² /mm³	4.8 < * < 10.8 /mm ³	4.8 < * < 10.8 /mm ³	4.8 < * < 10.8 /mm ³
*CRP ³ mg/dl	0.00 < * < 1.5 mg/dl	0.00 < * < 1.5 mg/dl	0.00 < * < 1.5 mg/dl
* Htc ⁴	± % 5 *	± % 5 *	± % 5 *

¹International normalized ratio (As an anticoagulation parameter), ²White blood cell, ³C Reactive Protein, ⁴Hematocrit value of the patient at the discharge time from hospital

with a smartphone camera through the application can be classified as a driveline site area picture or a medical report with OCR. Online messaging is structured for only the patient and the VAD coordinator. It is considered that the online messaging of patients with other patients or with the attending physicians are not necessary for the patients' follow-up and treatment.

The emergency notification will be designed as an additional button, and it will be necessary to press this button to reach the notification activation button. After the button is pressed, an additional button, which is easily accessible, will be placed on the screen and it is necessary to keep this button pressed for 5 seconds to activate the emergency notification. In this way, it is believed that false emergency notifications can be limited. The time required for notification might be rearranged according to the results obtained during the testing of the software. When the emergency notification is made, the patient's emergency notification and GPS coordinates will be sent to the VAD coordinator with the emergency warning on the application and as an SMS message to the mobile phone numbers to be entered while the patient is being recorded in the software.

The medicinal drug support page was specifically designed to adjust the anticoagulant doses of the patients and to improve patient's compliance with drug use. Incorrect, deficient, or excessive use of drugs, especially anticoagulants, is a problem frequently encountered by healthcare professionals and the consequences of this can be catastrophic. Therefore, it planned to record the drug treatments of the patients as daily used drug names, drug hours, and drug doses via the software. It was decided to add to the software a way to remind the recorded drug treatment plan according to the hours and dosages on a daily basis (drug information and dose on the smartphone screen both in written and visual form).

In order to obtain and use the data, images, or the location information of the patients, the users should be registered in the software and an online contract will be signed with the patients so that the software can work in the background. The

patient application will be downloaded to the smartphone by the patient as in many social media and online messaging applications. Likewise, in order to use the software, healthcare professionals will be asked to accept an online agreement. The Approval for the provision and transmission of data to the manufacturer organizations of the Android and iOS platforms will be obtained within the working process. The application for permission to the Device Ethics Committee of the Ministry of Health for the use of the software by patients and health professionals will be made before the software proceeds to the patient testing phase.

The numerical data obtained from the patients can be compared instantly with the normal value ranges. In the case of abnormal data detection, both the patient and the attendants are warned via the software. Besides, digital and image data will be evaluated by big data processing techniques and image processing artificial intelligence, which will be developed during the study period. Whenever a patient enters the data in the software, the total data are reprocessed with the specified statistical methods and the significant results will be shared with the healthcare professionals. Also, the neural network codes that will be produced during the study process will be able to select the most appropriate statistical method for each condition. Together with OCR technology, which provides data entry into the system by processing the medical report's images, the image processing for the images of the surgical field and the driveline cable outlet as taken by the smartphone camera will also be evaluated with artificial intelligence to be developed during the project process and monitored for infection development. There are several studies on this subject in the literature and in these studies, it is emphasized that it is possible to determine whether the driveline cable exit area is infected by image processing methods (9,10). However, the period between the healthy and infected phases of this area was not evaluated. Digital and image data will also be analyzed for data trends. Digital and image data as well as data trends will be divided into time series events (e.g., summer/winter period, home follow-up/hospital follow-up, etc.). In image processing



Figure 3: Driveline wound processing view.

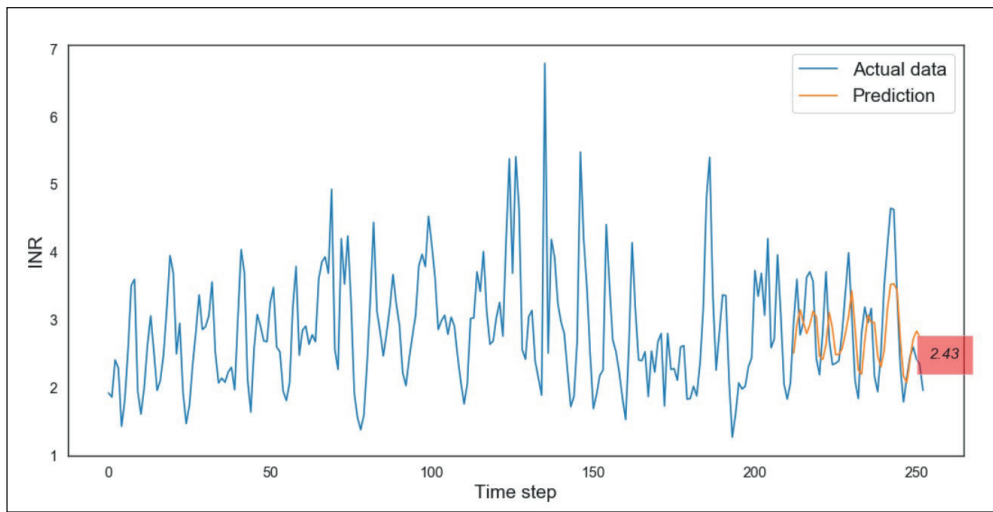


Figure 4: Data prediction graphic view.

technology, the control cable output area will be monitored from the first moment after the surgery, and the data trend monitoring of the area will be conducted according to the aforementioned parameters. A preliminary result of the surgical area image process was shown in Figure 3.

It is thought that the evaluation of both numerical and image data trend curves by time series can be used for future data estimation. The preliminary estimation graphic for the INR value was shown in Figure 4. Although the methods to be used as a result of preliminary statistical investigations on the subject have been determined, it will be possible to test the accuracy of future data prediction techniques when the software proceeds to the clinical testing phase and real patient data are obtained.

CONCLUSION

In addition to the widespread usage of smartphones with an advanced processor and data transmission capabilities, the novel artificial intelligence, and big data processing methods enable us to monitor and examine each disease with a patient-level approach. This also makes it possible

to share and process the data for future predictions. This study discusses the need, designing, planning, and support phases of remote monitoring software that supports the physicians and coordinators in the follow-up and treatment of patients by combining the features of smartphones with the software for ventricular assist device patients. It can be predicted that the variations of PASA VAD software can support both the patient and the healthcare professionals for many different diseases that require remote monitoring. Moreover, the data and data classes to be obtained with PASA software could create new data and analysis clusters in the field of patient health through many scientific studies.

Conflict of Interest: The authors declare that they have shares in Antkalp ARGE Danışmanlık San. ve Tic. LTD Şirketi Antalya/Türkiye.

Financial Disclosure: The study that was discussed in this paper was supported by TUBITAK (The Scientific And Technological Research Council of Turkey), Project no: 2180656)

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