Comparison of the Wound Area Assessment Methods in the Diabetic Foot Syndrome

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The paper presents results of comparison of the wound area assessment methods in the diabetic foot syndrome (DFS). Wound size is a basic parameter that is used to evaluate efficacy of the applied treatment. Four measurement methods were used: the rulers, the planimetric Visitrak (Smith & Nephew, England), the Silhouette (Aranz Medical, New Zealand) applying lasers, digital photography and planimetry as well as the patient's module of TeleDiaFoS telecare system with the foot scanning capabilities. Study group consisted of 18 DFS patients. Nineteen wounds were successfully measured with all 4 methods. The results of the Visitrak and the Silhouette can be used interchangeably ($r = 0.994$, slope = 1.01, intercept = 0.154 cm^2). For the other systems strong linear relationships exist that can be used to convert the wound area measured with one method to the corresponding value of another method. The correlation coefficients higher than 0.985 were obtained in case of 3 systems: Visitrak, Silhouette and TeleDiaFoS.
The TeleDiaFoS system can provide a physician with the patient-self-taken wound images that can be used for reliable assessment of the wound healing process during home tele-monitoring of the DFS patients.

K e y w o r d s: Diabetes mellitus, Diabetic Foot Syndrome, wound area assessment, wound healing

1. Introduction

Diabetes is a group of diseases in which the body either does not produce enough or does not properly respond to insulin. This causes a rise of glucose concentration in the blood, i.e. hyperglycemia, leading to many acute and late complications. Chronic hyperglycemia disturbs functions and damages structure of many organs, especially: eyes, kidneys, nerves, heart and blood vessels.

Diabetic foot syndrome (DFS) is one of the late complications of diabetes, which is related to neuropathy or angiopathy that deteriorate ability to sense stimuli, including pain and induce blood flow disorders in the feet. DFS lead to ulcers and wounds prone to infections, foot deformation which could in consequences lead to necrosis and necessity of an amputation. Occurrence of DSF is higher in patients with long-lasting poorly controlled diabetes. The DFS patients require intensive treatment of diabetes, antibiotic therapy of the infections and also local treatment.

Wound size in 3D or, most often, wound area in 2D is a basic parameter that is used to evaluate efficacy of the applied treatment and a progression of the wound healing. The wound volume and the wound area changes might be correlated with changes of physiological parameters resulting from the treatment being applied. According to the Wound Healing Society (WHS), if a wound area does not decrease significantly, i.e. at least by 40% during 4 weeks of the treatment, then probability of the complete recovery without changes of the treatment applied decreases significantly [1]. In such a case, WHS recommends to consider modification of the treatment. On the other hand, when a wound decreased remarkably during 4 weeks, then, most likely, it should heal completely in 12 weeks [1, 2]. Currently, a few wound volume and /or area measurement techniques are available:

In 3D a wound can be measured using Kundin gauge – this is a commercially available ruler used to calculate wound area and volume. Another 3D method uses moulds of the wound that are created by taking a cast of the wound cavity using a saline or alginate filling. Computerized stereophotogrammetry method that originated from land surveying uses two pictures of the same area taken from different known positions to produce a 3D image. A computerized matching algorithm searches for corresponding points in the two images and then computes the height of each point [3].

For 2D wound area measurements several other methods are applied. The simplest, cheapest and the most popular 2D method is the calculation of the wound area by measuring its linear dimensions with a tape measure or a ruler in two perpendicular directions. Then, in the simplest case, wound area is approximated by a surface of a rectangle. Alternative, usually more accurate, approximation methods are based on the formulas for circle or ellipse. Scaled photography is a method when a photograph is scanned together with a scaled ruler or a surface specimen of the known surface area. The ruler or specimen is used to calculate length and width or the wound area. This method is useful for comparison of the pictures but there is the

potential for magnification errors. Wound tracing (known also as acetate tracing) is another 2D wound measurement method, in which a pen is used to trace the outline of the wound directly onto sterile transparent foil. Then, a wound shape can be cut out with a scissors and weighted to obtain the area measure. In case of the planar images from a photograph or the wound tracing, planimetry can be applied to estimate the wound area. In this case, a checkered template is laid over the photograph or wound tracing contour, either manually as a sheet of transparent foil or virtually using a computer, and the number of complete graph squares or pixels within the boundaries of the wound are added up to produce an area calculation.

Recently, some of the above techniques have been combined with others or modified and implemented in original, innovative systems. For example, in a Silhouette system (Aranz Medical, New Zealand) wound photographs are scaled based on analysis of a laser beam traces. This system, like the wound tracing method, is also able to compute curvature of the photographed area. The wound tracing method and the computer-aided planimetry was combined in a Visitrak system (Smith & Nephew, Great Britain). Another example concerns TeleDiaFoS – a home telecare system that was designed and developed in Nałęcz Institute of Biocybernetics and Biomedical Engineering PAS [4, 5]. In this system, the ulcerated area of the foot is scanned using an originally designed Patient Module (PM) instead of being photographed. Thanks to this, images can be taken by the patients themselves and they are always in the same scale. Scanned images are automatically transmitted to the foot care unit where the wound areas are measured using a clinical module of the system that utilizes computer-aided planimetry.

The aim of the study was to assess conformity and comparability of the results of the wound area measurements in the DSF patients that were performed with the following methods and systems: the ruler, the Visitrak, the Silhouette and the TeleDiaFoS.

2. Materials and Methods

2.1. Methods and Systems for Wound Area Assessment

In the DFS patients most of the wounds are located on the sole of the foot [6]. Nevertheless, three of the systems examined can be used to measure size of the wounds located at any part of the foot. However, even in case of the simplest method of wound area assessment involving rulers a documentation of the wound is hardly done by the patients themselves. Among four systems tested only the TeleDiaFoS system allows for self-documentation of the wounds and it is dedicated to wounds located on the sole of the foot. Yet, laterally located wounds might be scanned as well.

Below the detailed description of the wound area measuring procedures that are used in all the systems tested have been provided.

2.1.1. Rulers

Disposable rulers were used to measure the wound maximum dimensions in two perpendicular directions. Then the wound area P was approximated by a surface of an ellipse according to the following well known formula:

$$P = \frac{\pi}{4}(a * b)$$ (1)

where a and b is the longest and shortest chord of ellipse respectively.

2.1.2. Visitrak System

The system consists of a transparent two-layered foil, a planimetric module in a form of a specialized pressure-sensitive tablet and a scriber (Fig. 1). Two layers of the foil are initially glued together. The foil is put over the wound and then the wound boundary is traced with the scriber. Then, one layer of the foil, i.e. the layer, which was in contact with the skin, is removed and the other layer (the one with the drawn contour) is put on the surface of the tablet and the contour of the wound, which is visible on the foil, is retraced once again using the scriber. When the contour is closed a measured wound area is shown on a small LCD display.
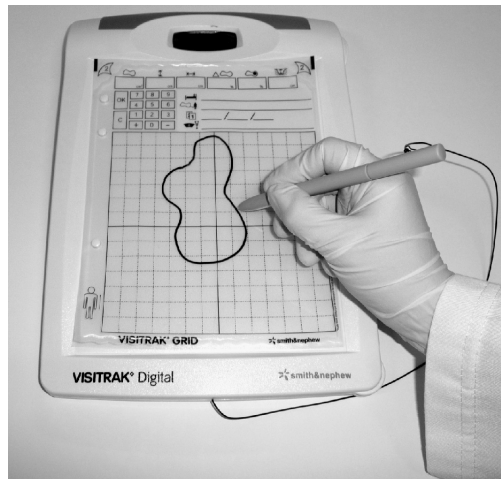

Fig. 1. Tracing of the wound contour on the Visitrak system

In addition to the wound area, the Visitrak system is able to display height and width of the wound. Moreover, two contours can be traced one after another to display the relative change of the wound area. Unfortunately, when the module is switched off all data are lost.

2.1.3. Silhouette System

The system consists of an iPAQ palmtop PDA (Hewlett Packard, USA) and a digital medical camera with class 1M laser attached to it (Fig. 2).

Fig. 2. Silhouette system during assessment of wound area (source: Aranz Medical)

To take a picture the system is brought close to the wound. The picture can be taken when a clear, sharp image of the wound positioned between two laser generated lines is seen on the screen of PDA. The laser's rays are used to estimate a distance between the wound and the camera. After the picture has been taken, a contour of the wound can be traced directly on the touch-sensitive screen of PDA using a stylus. The drawn contour can be corrected if necessary. Then, an area of the wound is automatically calculated. Thanks to the application of the laser technology the Silhouette system is able to estimate depths of the wounds being documented. In this case, only one laser generated line is visible, which should be positioned over a center of the wound. This line is bent on the unevenness of the wound surface that allows to calculate depth and height of the wound. Some additional data analysis can be made using the system, e.g. changes of the wound area can be plotted over time.

2.1.4. TeleDiaFoS System

A Patient's Module of the TeleDiaFoS system that is used by the patient to scan the sole of the foot is operated with a simple two-button remote controller (Fig. 3a).

The scanned images are temporally saved on a hard disk of PM and are transferred automatically as files using ftp protocol to the Central Clinical Server (CCS) for a permanent storage. Then physicians can access these files and other patient's data that are stored in a database of the system using local workstations. The data in the workstations are synchronized with the data in CCS, so that the local data are always up-to-date.
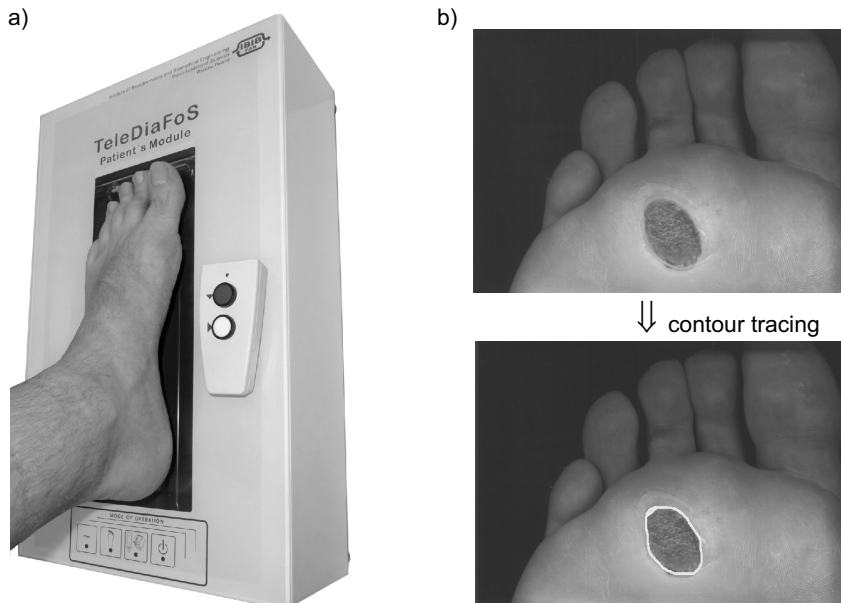
Fig. 3. The TeleDiaFoS system: a) a patient's module and a remote controller, b) the contour tracing of the wound

Using a software of the TeleDiaFoS system the physician displays the foot image on the workstation and traces the wound boundary with a pointing device (Fig. 3b). Resolution of the scanned images is constant just as an area of the scanned surface. Thus, every pixel of the image covers a constant area of 0.00016129 mm^2 and the area of the wound is calculated applying a simple formula:

$$P = n * P_{pix} \qquad (2)$$

where: n – number of pixel inside the traced area including border,

      P_{pix} – area covered by a single pixel.

The TeleDiaFoS software calculates also relative change of the wound area in comparison with the first image being available for the particular patient.

Currently, TeleDiaFoS together with other home and mobile telecare solutions developed in the IBBE PAS are being integrated in a system called the Model Center of the Diabetes Treatment.

2.2. Research Protocol and Study Group

Patients were enrolled into the study group according to an open, prospective protocol, i.e. all the patients who fulfilled the inclusion criteria and signed the written

consent for participation where qualified into the study group. The study group consisted of the in-clinic patients hospitalized in the Clinic of Gastroenterology and Metabolic Diseases MUW and the ambulatory patients visiting the DFS Outpatient Clinic operating in the same hospital. The inclusion criteria comprise type 1 or type 2 diabetes and location of the wound on the sole of the foot.

A medical doctor interviewed and examined all the patients before any measurements have been done. Then, a nurse cleaned the wound and measured maximum linear size of the wound in two perpendicular directions with the ruler. Next, she used the Visitrak foil to trace boundary of the wound. The Silhouette system was used afterwards to make a digital photograph of the wound. Finally, the sole of the foot was scanned using PM of the TeleDiaFoS system. After finishing the measurements in all the patients, the nurse contoured all the wounds on the pictures taken with the Silhouette system and on the scanned images produced by PM of the TeleDiaFoS system. The same nurse performed all the operations necessary to measure the wound area in all the patients using four systems tested. The study protocol has been approved by the Local Bioethical Committee of the MUW.

The study was carried out on the group of 18 DSF patients, including 3 women and 15 men. Average age of the study group (mean ± SD) was 55.4 ± 10.3 years, ranging from 34 to 75 years. Half of the study group (9 cases) had the neuropathic and 44% (8 cases) had mixed (i.e. neuro– and angiopathic) DFS diagnosed. In one case a Charcot Foot was identified.

2.3. Statistical Analysis

The linear correlation analysis was used to assess conformity and comparability of the wound areas obtained using the four methods tested. Determination coefficients, i.e. squared correlation coefficients, were employed to characterize strength of the interrelationship of the wound areas estimated applying each pair of the four methods tested. Slopes and intercepts of the regression lines were analyzed to check whether a direct comparison of the wound areas measured with any two of the methods tested is possible.

3. Results

The wound areas measured during the study are presented in Table 1. Twenty one wound examinations were performed, including 15 patients with wounds on one foot, 2 patients with wounds on both feet (no. 8 and 9 as well as no. 10 and 11) and 1 patient with a single unhealing wound, which was examined twice on two visits separated by a period of 2 months (no. 4 and 19).

Table 1. Wound areas in cm^2 measured in 18 DSF patients using 4 systems tested

Case no.	Ruler	Visitrak	Silhouette	TeleDiaFoS
1	0.11	0.1	0.1	0.04
2	16.49	14.1	15.9	12.47
3	0.61	0.4	1.4	0.17
4	6.79	5.4	6.2	6.12
5	25.13	19.1	18.6	14.07
6	0.12	0.0	0.2	0.37
7	0.44	0.2	0.4	0.43
8	0.079	0.0	0.1	0.10
9	0.79	0.7	1	0.85
10	0.38	0.3	0.4	0.56
11	6.28	4.2	3.4	3.60
12	0.39	0.2	0.2	0.22
13	2.36	1.6	1.6	1.78
14	6.28	6.8	7.3	4.94
15	1.18	0.9	0.8	0.85
16	5.89	5.8	5.6	5.11
18	3.53	1.7	2.2	2.10
19	7.85	7.6	7.9	7.90
21	1.70	1.9	1.7	1.54
Mean ± SD*	4.55 ± 6.48	3.7 ± 5.2	3.9 ± 5.3	3.33 ± 4.21
Median*	1.70	1.6	1.6	1.54

* Calculated after eliminating the data of patients 17 and 20.

In the majority of cases there were no problems encountered while measuring the wounds using four methods tested. However, there were few exceptions to this rule. It was not possible to take a proper photograph of the ulcerated foot of patient no. 17 using the Silhouette system. In this case the wound was located on the big toe and the laser generated lines refracted many times on the surface of the patient's foot and toes. The Silhouette system also failed to measure a large area wound covering almost the whole surface of the foot sole in patient no. 20. It was also difficult to trace contours of large wounds using the transparent foil of the Visitrak system because it was getting foggy from the evaporated moist from the wound very quickly and consequently, the visibility of the wound boundary was deteriorating significantly. Because of these problems, the wounds no. 17 and 20 were eliminated from the further analysis.

Mean and median areas of the wounds that were properly measured with all 4 methods (i.e. all wounds excluding no. 17 and 20) were the smallest in case of the TeleDiaFoS system (3.33 ± 4.21 cm^2 and 1.54 cm^2, respectively) and the largest in case of the rulers (4.55 ± 6.48 cm^2 and 1.70 cm^2, respectively). Noticeable differences between mean and median values were caused by uneven distribution of the area of the assessed wounds. Fifty percent of these wounds had area in the range of: 0.42 – 6.28 cm^2, 0.3 – 5.6 cm^2, 0.4 – 6.5 cm^2 and 0.4 – 4.98 cm^2 according to the rulers, Visitrak, Silhouette and TeleDiaFoS system, respectively.
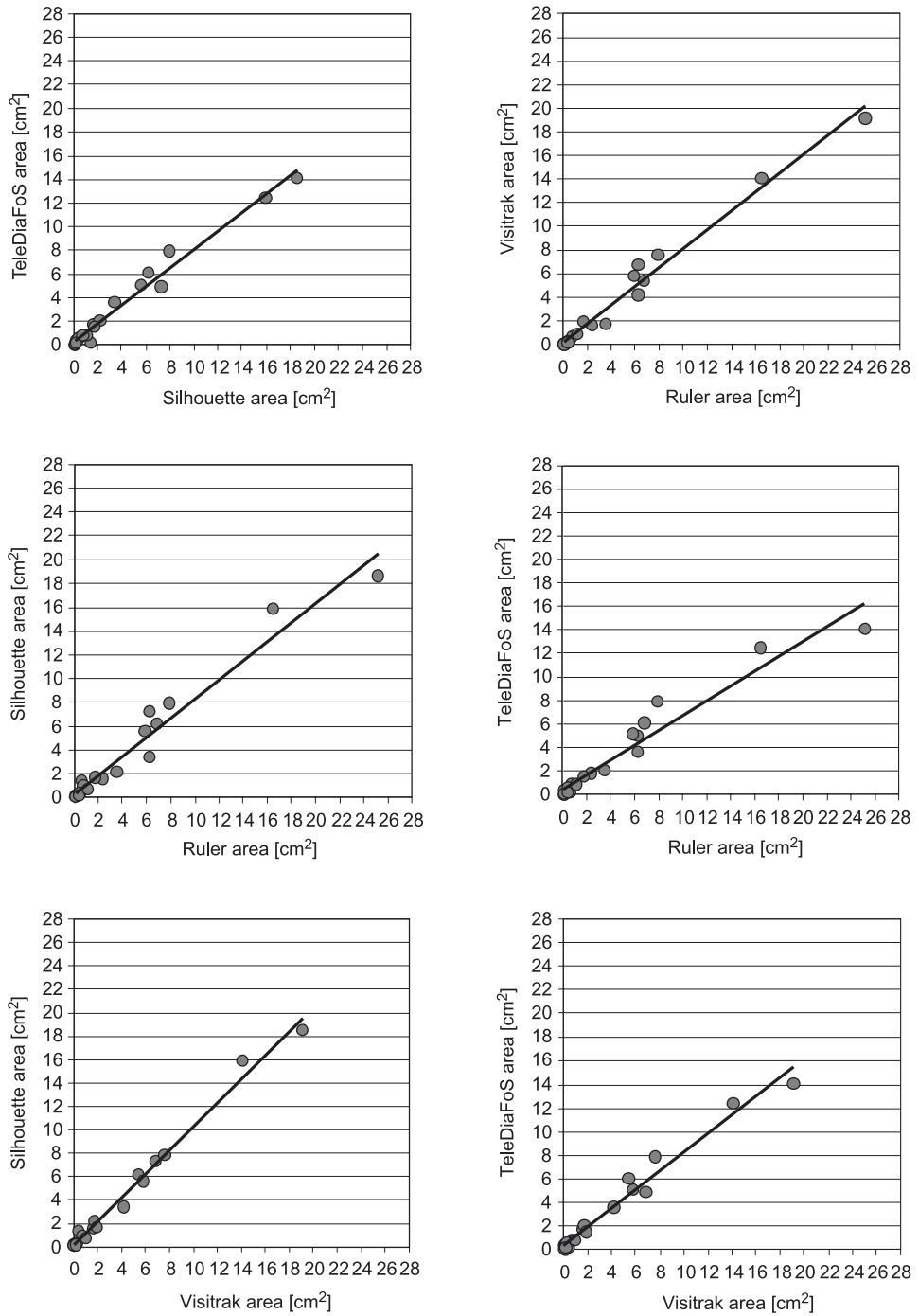
Fig. 4. Linear regression lines for 4 systems tested

Linear regression lines obtained for each pair of the methods assessed are il-lustrated in Figure 4. Parameters of the regression lines as well as the correlation and determination coefficients are summarized in Table 2.

All the correlation coefficients were equal to or higher than 0.969. The best correlation and the highest determination coefficient equal to 0.989 was registered in case of Visitrak and Silhouette systems and the lowest r^2 equal to 0.940 was noted in case of the ruler and TeleDiaFoS system. A slope of the regression line was the closest to the unity in case of Silhouette and Visitrak systems.

Table 2. Correlation and determination coefficients

System	Slope	Intercept	r	r^2
	–	cm	–	–
Visitrak *vs.* TeleDiaFoS	0.792	0.368	0.986	0.972
Silhouette *vs.* TeleDiaFoS	0.77	0.255	0.989	0.977
Ruler *vs.* TeleDiaFoS	0.63	0.466	0.969	0.940
Visitrak *vs.* Silhouette	1.01	0.154	0.994	0.989
Visitrak *vs.* Ruler	0.78	0.101	0.980	0.980
Silhouette *vs.* Ruler	0.81	0.275	0.979	0.959

4. Discussion

Measuring the wound size (i.e. surface area or volume) in general and the size of the ulcers developing on the feet in the course of DFS in particular is a complex problem. Wound's boundaries are not easy to define. Moreover, they may change significantly depending on the foot position and the natural curvature of the foot might influence a result of the measurement and the simples wound area assessment methods (e.g. ruler based methods) introduce some systematic error while calculat-ing a surface of the wound. Theoretically, the methods that trace wound boundaries directly on the foot and those, which are able to account for the curvature of the surface surrounding the wound should produce more reliable and more accurate results than methods based on 2D images. The later do not measure actual area of the wound but rather a projection of this area onto the plane of the image. However, the results obtained in the current study indicated that for the DFS ulcers located on the sole of the feet, the wound areas measured using different systems tested were highly correlated. For 3 pairs of the systems, i.e. Visitrak *vs.* Silhouette, Visitrak *vs.* TeleDiaFoS and Silhouette *vs.* TeleDiaFoS we obtained correlation coefficients of 0.994, 0.986 and 0.989, respectively, which were comparable to the value of 0.992 reported by G. Gethin and S. Cowman in a study comparing the use of acetate trac-ing and the Visitrak system [7]. However, it must be noted that the last mentioned

value was obtained for wounds measuring at least 10 cm^2 and that the acetate tracing and the Visitrak system use basically the same method of the area measurement, i.e. the manual wound contour tracing with a subsequent planimetrics of the wound, which is either "manual" or computer-aided. Based on the current results it can be stated that the wound area measured using Visitrak can be treated interchangeably with the area measured using the Silhouette system, particularly in case of larger wounds, since the slope of the regression line is close to the unity and the intercept is equal to 0.15 cm^2.

Several other authors conducted studies aiming at comparison of the wound area measurement methods too. Similarly to the current work, these studies were mainly devoted to assessment of precision, accuracy or conformity of the wound area or volume measured using some newly developed devices or systems in comparison with the results obtained applying widely used methods or devices, e.g. the rulers or the acetate tracing. P. Plassmann and T. D. Jones from University of Glamorgan, UK designed and developed a device called Measurement of Area and Volume Instrument System (MAVIS) in 1997. The MAVIS operation has been based on the principle of color coded structured light. Among other parameters, they assessed linear correlation between the wound areas measured using MAVIS, wound tracing, ruler and alginate casts. The wounds were located in different body regions. The best correlation coefficient equal to 0.9446 was obtained in MAVIS and transparency tracing [8]. In 2000, R. P. Wunderlich et al. from the University of Texas Health Science Center assessed linear correlation between the wound areas measured using digital videometry, i.e. combination of the scaled photography and planimetry, acetate tracing and the ruler. The best correlation coefficient of 0.944, which corresponded to r^2 value of 0.891 was obtained in the digital videometry and the acetate tracing methods. The authors concluded that those methods could be used interchangeably [9]. It must be noted, however, that only five wounds artificially created with a scalpel in cadaver specimens have been measured by 4 raters in this study. In 2008, F. L. Bowling and others developed a novel wound imaging system that used optical methods to create a 3D calibrated-color image of a diabetic foot ulcer and its surrounding. They compared wound areas measured in the DFS patients using this system with a traditional measure attained using a ruler and the formula for an ellipse obtaining the correlation coefficient of 0.961 [10].

Comparing the above-mentioned data with the results obtained in the current study it can be stated that the wound area estimates calculated using different methods and systems are highly comparable in general. In average, about 97% of the variability of the results measured with any given method can be explained by a linear relationship bounding them to the results measured with another method.

From the practical point of view, the main feature of the above mentioned systems as well as 3 out of 4 systems evaluated during the current study is that all of them require presence of the patient and the person measuring the wound in the same place at the same time to assess the area of the wound. In contrast, using the

TeleDiaFoS it is possible to conduct the wound area assessment on a distance applying a store-and-forward mode. The current study demonstrated clearly that such a telecare system can provide a physician with estimates of the surfaces of the DFS wounds, which are comparable with the wounds' area measured using both, the simplest and the most widely used method (i.e. rulers) and more sophisticated, more accurate but at the same time more troublesome methods.

5. Conclusions

The results of the study indicates that the wound areas measured with four systems tested are highly comparable. The highest level of conformity was obtained in case of the Visitrak and the Silhouette systems. For the other pairs of the systems strong linear relationships exist that can be used to convert the wound area measured with one method to the corresponding value of another method.

The TeleDiaFoS system can provide the physician with the patient-self-taken wound images that can be used for reliable assessment of the wound healing process during telemonitoring of the DFS patients.

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