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Validation of three-dimensional wound measurements using a novel 3D-WAM camera

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Abstract

In order to monitor wound healing it is essential to obtain accurate and reliable wound measurements. Various methods have been used to measure wound size including three-dimensional (3D) measurement devices enabling wound assessment from a volume perspective. However, the currently available methods are inaccurate, costly or complicated to use. As a consequence, we have developed a 3D-WAM camera (Wound Assessment Monitor camera), which is able to measure wound size in three-dimension and to assess wound characteristics.

The aim of the study was to assess the intrarater and interrater reliability of the 3D wound measurements using the 3D camera and to compare these with traditional measurement methods. Four raters measured 48 wounds using the 3D camera, digital imaging method (2D area) and gel injection into the wound cavity (volume). The data were analysed using linear mixed effect model. Intraclass and interclass correlation coefficient (ICC) and Bland-Altman plots were used to assess intrarater and interrater reliability for the 3D camera and agreement between the methods.

The Bland-Altman plots for intrarater reliability showed minor differences between the measurements, especially the 3D area and perimeter measurements. Moreover, ICCs were very high for both the intrarater and interrater reliability for the 2D area, 3D area and perimeter measurements (ICCs >0.99), although slightly lower for the volume measurements (ICC= 0.946-0.950). Finally, a high agreement was found between the 3D camera and the traditional methods (2D area and volume) assessed by narrow 95% prediction intervals and high ICCs above 0.97.

In conclusion, the 3D-WAM camera is an accurate and reliable method, which is useful for several types of wounds. However, the volume measurements were primarily useful in large, deep wounds. Moreover, the 3D images are based on digital technology and therefore carry the possibility for use in remote settings.

Introduction

Chronic wounds including diabetic foot ulcers constitute a huge burden on the health care system [1]. Diabetic foot ulcers affect 15% of people with diabetes mellitus during their lifetime [2]. The healing of diabetic foot ulcers is usually delayed and treatment is complicated due to vascular disease, neuropathy and infection. As a consequence, the risk of amputation and subsequent disability is increased [3]. Furthermore, diabetic foot ulcers impose an economic burden to society; the annual cost of treating people with diabetic foot ulcers in Denmark (5.5 million inhabitants) is estimated to be around $130 million [4].

In the treatment of wounds, it is essential to have an accurate and reliable measurement method for monitoring wound healing. Various approaches have been used to measure the wound size including two-dimensional (2D) and three-dimensional (3D) methods [5].

In a hospital setting, 2D measurement methods are the most commonly used including the simple ruler method (length x width), planimetric method and digital imaging method [6, 7]. Recently, several 3D techniques have been developed including structured light techniques, stereophotogrammetry and digital imaging [8-10]. The 3D measurement technique allows assessment of wound healing from a volume perspective, but the methods currently available are inaccurate, expensive or complex to handle [5].

To address these issues, a 3D Wound Assessment Monitor (WAM) camera was developed, which is able to measure wound size and to assess wound characteristics. A pilot study by Rasmussen *et al.* [11] investigated wound characteristics in 36 wounds in 30 patients using the 3D-WAM camera and found a better correlation to clinical assessment (gold standard) compared to 2D images used in telemedical care. However, the wound measurements were not validated in this study. The aim of this study was therefore to estimate the intrarater and interrater reliability of three-dimensional measurements using the 3D-WAM camera and compare these with traditional measurement methods.

Material and methods

The study was conducted from August 2015 to February 2017 at the University Centre of Wound Healing at Odense University Hospital, Odense, Denmark. Four raters including three doctors and a medical student performed the wound measurements using the 3D-WAM camera, digital imaging method and gel injection into wound cavity.

Patients aged 18 or older were eligible for enrolment in the study if they had a wound with an area of at least 0.5x0.5 cm^2. Forty-eight wounds were selected in various sizes including deep and superficial wounds and different shapes. Each wound was measured by two different raters. The combination of raters is as described in Table 1 to ensure the largest variability of pairings. The wounds were measured twice using the 3D-WAM camera, once with the digital imaging method and once with gel injection into the wound cavity by each rater assigned to the task.

Between each wound measurement, the raters had a break of at least ten minutes in which they were performing other clinical tasks to avoid bias in the repeated measurements.

Moreover, data were collected on age, gender, type of wound and location of wound. The first author collected all data using the electronic REDCap database. The study was conducted according to Good Clinical Practice (GCP) standards and was monitored by the local GCP-unit at Odense University Hospital.

3D-WAM camera

The 3D-WAM camera used for this study is a prototype comprising three cameras and a projector. A pattern consisting of many points creates a mesh and is projected on the surface of the wound. Two of the cameras recognise the pattern and create the 3D geometry. The third camera creates a colour photo for texture, which is adjusted to the 3D geometry [11].

The raters were trained to perform standardized measurements. They were instructed to take three photos from different angles including one photo parallel to the wound. Furthermore, the photos were taken approximately within the same distance from the wound supported by two red laser spots projected at the wound base from the 3D camera (Figure 1). The photos were merged to a 3D image by corresponding points in the photos accordingly. The wound margin was outlined by a pointing device on a computer monitor. Immediately afterwards, the software calculated four different wound measurements: *2D area*, *3D area*, *perimeter* and *volume*. The definitions of the wound measurements are as follows: the *2D area* is the wound surface area, the *3D area* is the area of the wound bed (taking into account the body curvature and unevenness in the wound), the *perimeter* is the circumference of the wound, and the *volume* is a measure of tissue loss from the wound (Table 2).

Information about the collaborating company is available at http://www.teccluster.com.

Digital imaging method (2D area)

An image of the wounds was provided using an iPhone 5s. A ruler was placed close to the wound on the image to calibrate the software and to assess distance. The raters were instructed to place the smartphone parallel to the wound surface and the wound in centre of the image. The images were transferred to a computer and opened with ImageJ, which is an imaging processing program (NIH, USA) [7, 12]. The wound edges were traced using the computer mouse, and the wound area (2D area) was calculated by the software accordingly.

Gel injection into wound cavity (volume)

The volume measurements from the 3D camera were compared to gel injection into the wound cavity, which represents the tissue loss/volume. The wound was covered with a transparent adhesive film (Tegaderm™, 3M, Copenhagen, Denmark) and the gel was injected into the wound cavity with a 5 ml syringe (Figure 2). In order to avoid extension of the film and reduce leakage of the gel, the raters were instructed to inject the gel flat until horizontal to the wound edges.

The gel used for the study was Purilon® gel (Coloplast, Humlebæk, Denmark), which had a adequate viscosity permitting less gel leakage [13].

Approvals

The study was approved by the Regional Committees on Health Research Ethics for Southern Denmark and the Danish Health and Medicines Authority. The study was registered in ClinicalTrials.gov identifier: NCT03063138. The study participants provided written informed consent.

Statistical analysis

The following linear mixed effect model was used for the analysis of the single method:

$Y_{pri} = \mu + P_p + R_r + PR_{pr} + \varepsilon_{pri}$ (p = 1-48 patient ID, r= 1-4 raters and i= 1,2 replicate measurements), where the P_p is the random patient effect, R_r is the rater effect, PR_{pr} is the random effect due to the raters could be affected more by some patients than others and the ε_{pri} is the measurement error. It was assumed that P, R, PR and ε were independently and normally distributed with the variance components σ_P^2, σ_R^2, σ_{PR}^2 and σ_ε^2 [14]. Non-normal measurements were transformed to normality using the natural logarithm for the 2D area, 3D area and perimeter measurements and cubic root of the volume measurements. The data were then transformed back to the original scale for the Bland-Altman plots (rater included as a fixed variable) [15].

Using the variance components from the model, an intraclass and interclass correlation coefficient value (abbreviated ICC_1 and ICC_2) was calculated for estimating intrarater and interrater reliability (rater included as a random variable). ICC_1 was calculated using the formula 1- $(\sigma_{\varepsilon}^2/\sigma_{\text{total}}^2)$ and ICC_2 was calculated using 1- $(\sigma_R^2 + \sigma_{PR}^2 + \sigma_{\varepsilon}^2)/\sigma_{\text{total}}^2$ with $\sigma_{\text{total}}^2 = \sigma_P^2 + \sigma_R^2 + \sigma_{PR}^2 + \sigma_{\varepsilon}^2$[14]. In the calculation of the interclass correlation coefficient an additional variance component of interaction between rater-patient was included. ICC values less than 0.5 indicate poor reliability, those ranging from 0.5 to 0.75 indicate moderate reliability, values between 0.75 and 0.9 indicate good reliability and values greater than 0.9 indicate excellent reliability [16].

Finally, the different methods were compared using this model

$Y_{mpri} = \mu_M + P_p + R_r + PR_{pr} + MP_{mp} + RMP_{rmp} + \varepsilon_{mpri}$ (m= 1,2 methods). P_p is the random patient effect, R_r is the rater effect, PR_{pr} is the random patient-rater effect, MP_{mp} is the random method-patient effect, RMP is the random rater-method-patient effect and the ε_{mpri} is the measurement error. Bland-Altman plots with 95% prediction interval were used for comparing the different methods (rater included as a fixed variable). Additionally, an intraclass and interclass correlation coefficients (ICC_3 and ICC_4) were estimated for intrarater and interrater reliability using the formulas

ICC_3= 1- $(\sigma_{MP}^2 + \sigma_{RMP}^2 + \sigma_{\varepsilon}^2)/\sigma_{\text{total}}^2$ and

ICC_4= 1- $(\sigma_R^2 + \sigma_{PR}^2 + \sigma_{MP}^2 + \sigma_{RMP}^2 + \sigma_{\varepsilon}^2)/\sigma_{\text{total}}^2$ with $\sigma_{\text{total}}^2 = \sigma_P^2 + \sigma_R^2 + \sigma_{PR}^2 + \sigma_{MP}^2 + \sigma_{RMP}^2 + \sigma_{\varepsilon}^2$ (rater included as a random variable). Statistical analyses were carried out using the STATA Statistical Software (STATA 15.0 software).

Results

Demographics

In the study 48 wounds in 47 patients, 7 women and 40 men, were included. The wounds were of various sizes and etiology: 42 diabetic foot ulcers, 3 surgical wounds, 2 traumatic wounds, and 1 pressure wound. The wound area ranged from 0.3 to 36.1 cm^2 (mean 9.06 cm^2).

Figure 3 illustrates the distribution of the 3D area wound measurements. Thirty-two wounds had a 3D area below 10 cm^2 and 16 wounds above 10 cm^2. The wounds were located on the toe (2%), forefoot (46%), midfoot (25%), heel (19%), ankle (4%), and lower leg (4%). Due to technical problems two 3D images were lost.

Intrarater and interrater reliability

The intrarater reliability was assessed by the Bland-Altman plots (Figure 4). The figures illustrate the difference between repeating wound measurements performed by the same rater on the same patient (the dots). The figures show minor differences between the repeating measurements particularly with wounds below 20 cm^2. It is also apparent from the figure that only a few measurements differ more than five cm^2. Additionally, the 95% prediction intervals (the lines) illustrate the most likely difference between two measurements performed by the same rater on the same patient. In all four figures it can be seen that the prediction interval increases with wound size. The most narrow prediction interval is seen for the 3D area and perimeter measurements (Figure 4B and 4C). Supplemental Tables 1-4 provide more detailed information of the 95% prediction interval adjusted for mean wound size (see Appendix). Furthermore, no significant difference was found between the wound measurements performed by the four raters on the same patient ($P > 0.05$). Table 3 presents an overview of the intraclass and interclass correlation coefficients (ICC). The intrarater and interrater reliability were excellent for all four wound measurements assessed by an ICC_1 and ICC_2 above 0.99 for the 2D area, 3D area and perimeter measurements, however somewhat lower for the volume measurements ($ICC_1 = 0.971$, $ICC_2 = 0.946$).

Method comparison

We compared the 3D-WAM camera and the traditional measurement methods by estimating ICC values. As shown from Table 4, the ICC values were very high for both intrarater and interrater reliability, which show a strong correlation between the different methods. Figure 5 and 6 are Bland-Altman plots of the agreement between the methods, which illustrate the difference between the wound measurements (2D area and volume) using the different methods on the same patient by the same rater. More detailed information about the 95% prediction intervals is displayed in Supplemental Tables 5-6 (see Appendix).

Discussion

In evaluating the wound healing process, an accurate and reliable measurement method is essential both in a hospital setting and in clinical studies comparing different wound treatments. Furthermore, the ideal measurement method should be useful for measuring different types of wounds, practical in clinical settings, easy to learn, and cost efficient [5].

Recently, several 3D techniques have been developed, which enable clinicians to assess wound healing from a volume perspective [10]. Interestingly, it has been hypothesized that changes in wound volume is a more sensitive predictor of wound healing compared to wound area and perimeter by reflecting development of granulation tissue [9, 17]. However, only a few 3D measurement techniques are commercially available including Silhouette® (Aranz, New Zealand), Eykona® 3D camera (Fuel 3D, UK), LifeViz® 3D system (Quantificare S.A., France) and inSight® (eKare Inc, VA, USA) [8-10]. A new study compared the Eykona® and Silhouette® camera with a digital planimetric method (2D area) and water displacement (volume) by measuring artificial wound models [9]. The results indicated satisfactory correlation regarding wound area, but both methods overestimated wound volume compared to water displacement.

The main findings emerging from our study were as follows: 1) the 3D camera provided four different wound measurements (2D area, 3D area, perimeter and volume) with excellent intrarater and interrater reliability; 2) no significant difference was found between the wound measurements performed by different raters (user independence); 3) the 3D measurements are highly correlated with digital imaging method (2D area) and gel injection into wound cavity (volume).

Major strengths of this study include the sample size of 48 wounds, which is large compared to similar validation studies [5, 8, 9, 18-21]. In addition, wounds in different sizes and etiology were measured in this study, which demonstrates a wide range of applications of the 3D camera. Further, the 3D-WAM camera was not limited by the size of the wound compared to the 3D systems by Davis *et al.* and Kecelj-Leskovec *et al.*, which were not able to measure wounds with a diameter above 6 and 10 cm [10, 17]. However, the prediction interval increased with wound size.

To the best of our knowledge, the 3D-WAM camera is the first wound measurement method that is able to measure 3D areas [5]. For that reason, it was not possible to compare the 3D area measurements with other methods. However, the results show particularly low intrarater and interrater variability indicating that the 3D area measurement can detect small changes in wound bed size. Compared to the other measurements, the 3D area was especially accurate in measuring wound size of wounds located on the heel, toes, and curved part of the body.

Additionally, the advantages of the camera included reduced risk of infection because the method is non-invasive. Furthermore, the 3D images are digital and therefore has potential for use in telemedicine [22].

A limitation of the study was that the 3D camera was incapable of measuring volume of shallow, flat wounds and some wounds located on toes. Instead, the 3D camera was more accurate in estimating 3D area in these types of wounds. Unfortunately, two images were lost due to a technical problem, however it is unlikely that this has affected the results due to the large sample size with repeating measurements. In addition, we measured real wounds in our study, which can be a limitation because we do not know the exact wound size. Several validation studies are using artificial wound models, which have the advantage that the exact size of the wound model is known [8, 9, 19, 21, 23-25]. However, the results of these studies must be interpreted with caution because real wounds in clinical practice are often much more complex.

Furthermore, the 3D camera was not able to measure undermined parts of wounds. However, this is a general problem with all wound measurement methods [9, 10]. Blood and other fluids in the wound could potentially affect the 3D area and volume measurements. However, this could also affect the wound measurements using other 3D methods [10]. It is therefore recommended to clean the wound before capturing the image. Finally, the method is user-dependent in outlining the margin of the wound.

To summarize, the 3D-WAM camera provides four different wound measurements by each 3D image, which are accurate and reliable. The 3D camera can be used for several types of wounds but the volume measurements are primarily useful in large, deep wounds. The 3D images are digital and therefore has the potential for use in remote settings. Future perspectives include development of a handheld, portable device as well as faster software applicable for clinical use.

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Disclosures

GBJ is a member of the Advisory Board for Coloplast. The other authors have no disclosures to report.

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Tables

Table 1: Experimental design displaying the combinations of raters and patients.

Patient ID no.	Rater A	Rater B	Rater C	Rater D
1-8	X	X	-	-
9-16	X	-	X	-
17-24	X	-	-	X
25-32	-	X	X	-
33-40	-	X	-	X
41-48	-	-	X	X

Rater A-D: the four raters who performed the wound measurements using the three methods. Each wound was measured twice using the 3D camera, once by digital imaging method and once by gel injection into wound cavity by two different raters according to the table (marked with an X).

Table 2: Definitions of the four wound measurements

Definitions of the four wound measurements calculated by the 3D-WAM camera	
2D area	Wound surface area
3D area	Area of the wound bed taking into account the unevenness and curvatures of the wound bed
Perimeter	Circumference of the wound
Volume	Measurement of the tissue loss from the wound

Table 3: Overview of intraclass (ICC_1) and interclass correlation coefficients (ICC_2) for each wound measurement using the 3D-WAM camera

Measure	Intraclass correlation coefficient (ICC_1)	Interclass correlation coefficient (ICC_2)
2D area	0.997	0.997
3D area	0.999	0.999
Perimeter	0.998	0.998
Volume	0.971	0.946

Table 4. Intraclass (ICC_3) and interclass correlation coefficients (ICC_4) for comparison of wound measurements using the 3D-WAM camera and the traditional measurement methods (2D area and volume).

Method comparison	Intraclass correlation coefficient (ICC_3)	Interclass correlation coefficient (ICC_4)
2D area: 3D camera vs. digital imaging method	0.997	0.996
Volume: 3D camera vs. gel injection	0.975	0.973

Figure Legends

Figure 1. The 3D-WAM camera taking a 3D image of a wound supported by two red laser spots projected at the wound base

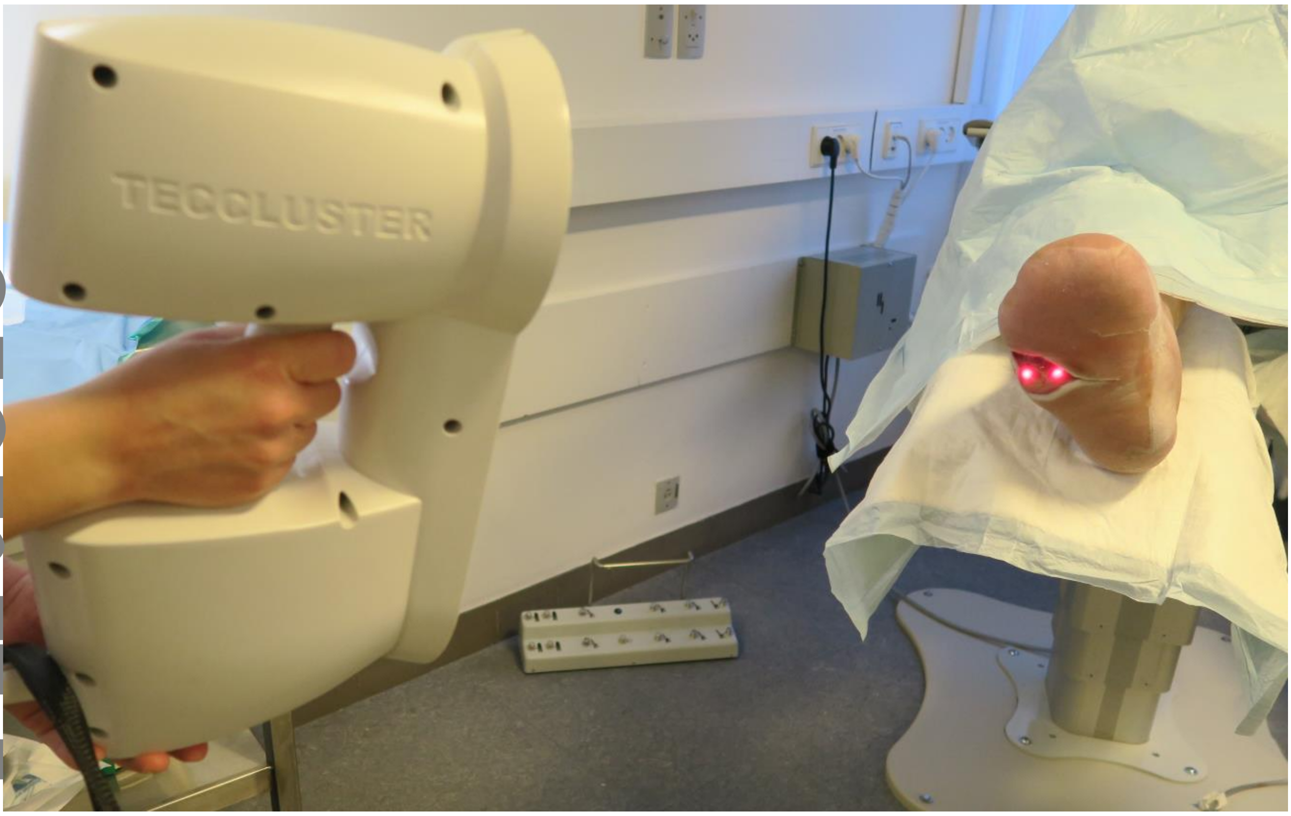
Figure 2. Gel injection into wound cavity using a syringe and a film covering the wound in order to measure wound volume

Figure 3. Overview of all the 3D area wound measurements in performed by the four raters. Each wound was measured twice using the 3D camera by two different raters. The y-axis is the 3D area measurements in cm^2 and the x-axis is the Patient ID. Each rater is marked by a circle or triangle

Figure 4. Bland-Altman plots of differences between the 2D area (A), 3D area (B), perimeter (C) and volume (D) measurements plotted against each individual mean per rater (the dots). The lines represent the 95% prediction intervals

Figure 5. Bland-Altman plot of agreement between the 2D area measurements using the 3D-WAM camera and digital imaging method. The dots represent the difference between the 2D area measurements by the two methods. The lines represent the 95% prediction intervals

Figure 6. Bland-Altman plots of agreement between volume measurements using the 3D-WAM camera and gel injection into wound cavity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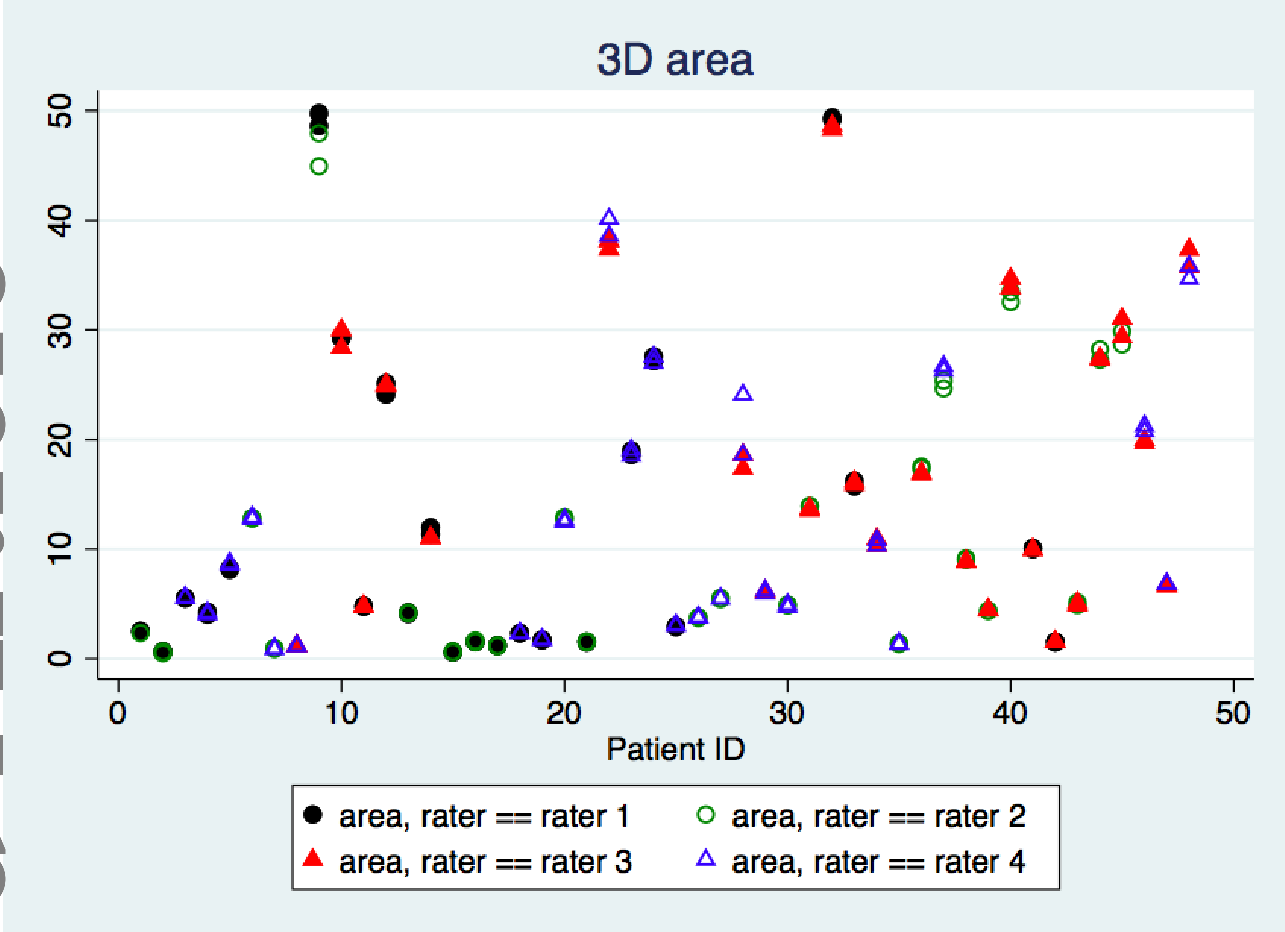
3D area
0
10
20
30
40
50
0
10
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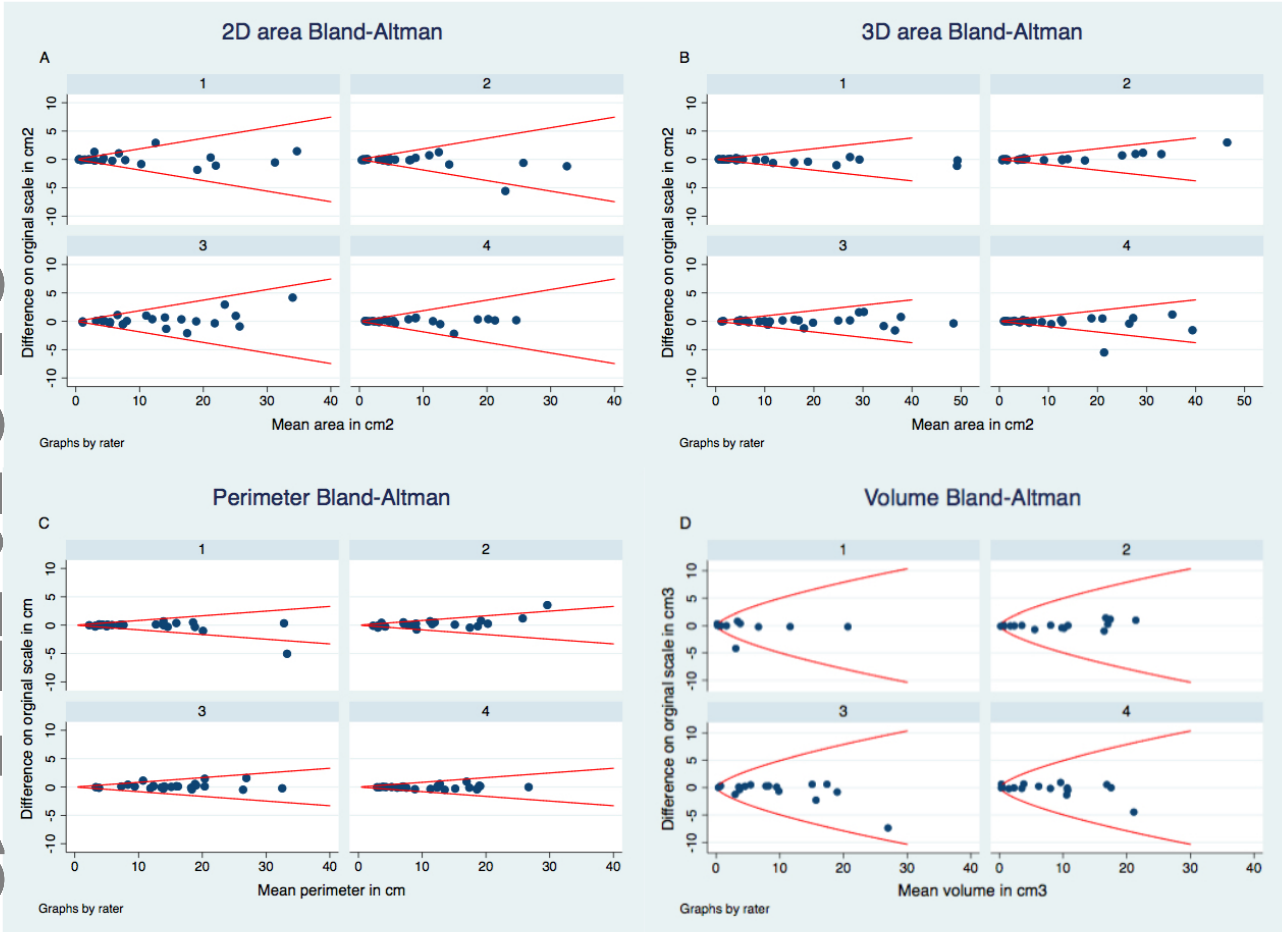
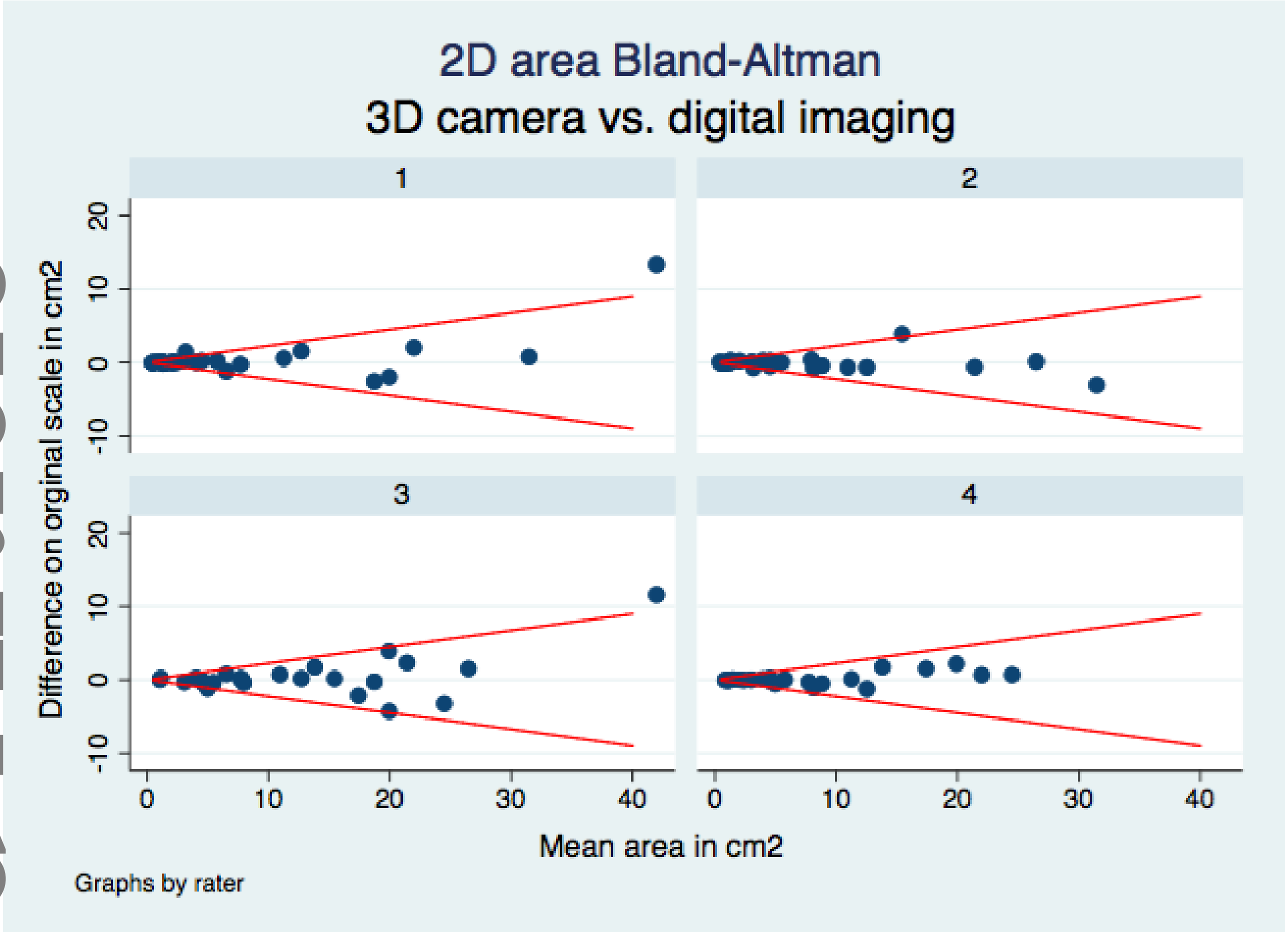
30
40
50
Patient ID
area, rater == rater 1
area, rater == rater 2
area, rater == rater 3
area, rater == rater 4



2D area Bland-Altman
A
Difference on orginal scale in cm2
Mean area in cm2
Graphs by rater
3D area Bland-Altman
B
Difference on orginal scale in cm2
Mean area in cm2
Graphs by rater
Perimeter Bland-Altman
C
Difference on orginal scale in cm
Mean perimeter in cm
Graphs by rater
Volume Bland-Altman
D
Difference on orginal scale in cm3
Mean volume in cm3
Graphs by rater


2D area Bland-Altman
3D camera vs. digital imaging
1
2
3
4
Difference on orginal scale in cm2
20
10
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-10
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10
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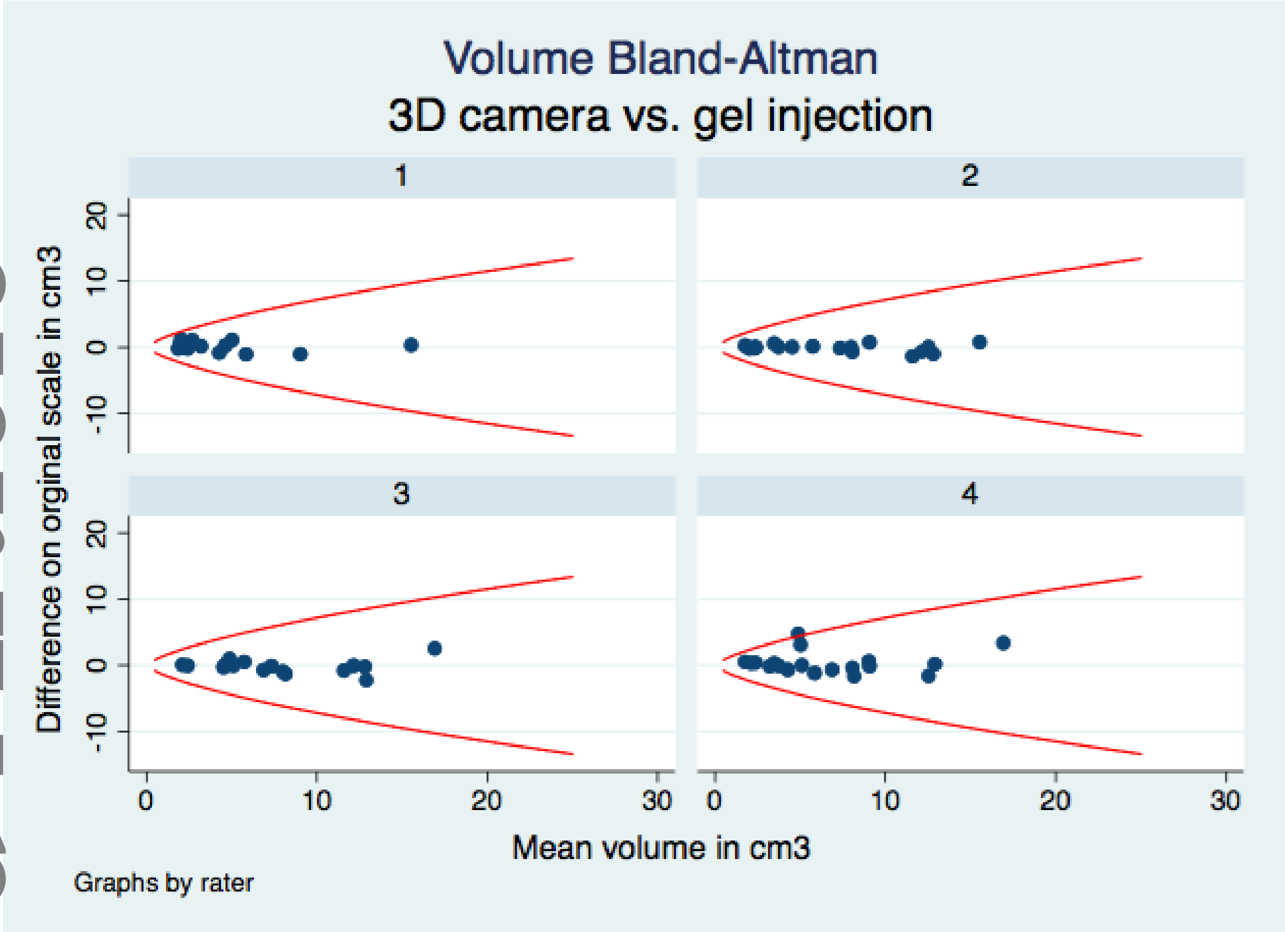
30
40
Mean area in cm2
Graphs by rater


Volume Bland-Altman
3D camera vs. gel injection
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2
3
4
Difference on orginal scale in cm3
-10
0
10
20
0
10
20
30
Mean volume in cm3
Graphs by rater