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Portable three-dimensional imaging to monitor small volume enhancement in face, vulva, and hand: A comparative study

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3D imaging;

3D technology;

3D laser scan;

Structured light;

Stereophotogrammetry

Summary Multiple handheld three-dimensional (3D) systems are available on the market, but data regarding their use in detecting small volumes are limited. The aim of this study was to compare different portable 3D technologies in detecting small volumetric enhancement on a mannequin model and a series of patients.

Five portable 3D systems (Artec Eva, Crisalix, Go!Scan, LifeViz Mini, and Vectra H1) were tested in a controlled environment with standardised volumes and in a clinical setting with patients undergoing small volume fat grafting to face, vulva, and hand. Accuracy was assessed with absolute and relative technical error measurement (TEM and rTEM); precision with intra- and inter-observer reliability (r_p and ICC); and usability in clinical practice with the following parameters: portability, suitability of use in operating theatre/clinic, ease of use of hardware and software, speed of capture, image quality, patient comfort, and cost. All tested devices presented overall good accuracy in detecting small volumetric changes ranging from 0.5 to 4 cc.

Abbreviations: CT, computed tomography; FG, fat grafting; MRI, magnetic resonance imaging; 3D, three-dimensional; TEM, absolute technical error of measurement; rTEM, relative technical error of measurement; r_p , Pearson's correlation coefficient; ICC, intraclass correlation coefficient; SPSS, Statistical Package for the Social Sciences.

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Structured-light laser scanners (Artec Eva and Go!Scan) showed high accuracy, but their use in clinical practice was limited by longer capture time, multiple wiring, and complex software for analysis. Crisalix was considered the most user-friendly, less bothering for patients, and truly portable, but its use was limited to the face because the software does not include vulva and hand. Three-dimensional technologies exploiting the principle of passive stereophotogrammetry such as LifeViz Mini and Vectra H1 were the most versatile for assessing accurately multiple body areas, representing overall the best long-term value for money.

Therefore, 3D portable technology is a non-invasive, accurate, and reproducible method to assess the volumetric outcome after facial, vulval, and hand injectables. The choice of the 3D system should be based on the clinical need and resources available.

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Introduction

Three-dimensional (3D) imaging is being used progressively in plastic surgery for surgical planning, outcome assessment, and research. Advantages of 3D imaging include high accuracy, quick acquisition, non-invasiveness, and more contained costs compared to other methods such as MRI, CT scan, or anthropometric estimation. ²

Three-dimensional imaging technologies include structured light and stereophotogrammetry. Structured-light technology estimates the 3D surface of an object by the deformation of a projected full structured-light pattern (stripes, grid, dots, etc.) onto a subject.^{3,4} With the knowledge of the geometry of a projected pattern and perception of the deformation by the 3D surface of the object, it is possible to estimate the 3D surface of the object and generate a 3D surface image. 5 Stereophotogrammetry is a technique used to reconstruct a digital model of the subject's surface from multiple 2D images taken from different angles. 6 This procedure may be passive, where the images taken by two or more cameras determine 3D surfaces via triangulation^{3,6}; active, where incorporated structured-light projects a pattern onto the surface and two or more cameras capture the deformation of the pattern by the objects' surface⁶; or hybrid, where both active and passive are combined to achieve higher accuracy and quality in 3D surface imaging.⁵

Most 3D technologies currently available on the market are static devices involving large stationary rigs with cameras at multiple angles, with the disadvantage of requiring a designated room, being expensive, bulky set-ups that require frequent calibration, and limited mobility without effort.^{5,7} In addition to that, these static systems are unsuitable to monitor body areas such as genitalia or hand because they require a specific positioning of the patient.³

In recent years, new handheld technologies have entered the market, providing surgeons with valuable tools for outcome evaluation as valid alternative to the static systems.² Amongst the advantages of using handheld devices, the scanning process can be performed without any specific positioning of the patient and are easily transportable in different consultation rooms, without the need of a designated room. The ideal porD imaging device should be accurate to detect small volumetric variations; able to acquire good quality images in a short time frame; easy to handle and safe in a medical environment; include an easy-

to-use and not-time-consuming software for the measurements; the overall cost should be contained.

Volume enhancement is one of the procedures most frequently performed either with fat grafting (FG) or injectables. Multiple studies are available on the use of 3D portable technologies to monitor volume change, focussing mainly on the facial region. ^{1,2,8-10} No data are available on small volume change in vulva or hand, although volumetric enhancement in these areas is becoming increasingly popular. ¹¹⁻¹³

In this study, we investigated accuracy, reproducibility, and usability of different handheld 3D imaging systems currently available on the market to assess small volume changes after FG in face, vulva, and hand. For this purpose, we compared five 3D systems in a sample of adult participants and mannequins.

Materials and methods

The study obtained favourable ethical opinion (16/SC/0669 and 16/LO/1980). Written informed consent was obtained from all study subjects prior to data acquisition.

The following previously validated handheld devices were included: **Artec Eva** (Artec 3D, Luxembourg), ^{1,14} **Clisalix 3D Sensor** (Virtual Aesthetic, Crisalix, Switzerland), ^{5,15} **Go!Scan** (Creaform, Germany), ¹⁶ **LifeViz Mini** (QuantifiCare, France), ¹⁷ and **Vectra H1** (Canfield Scientific, NJ USA), ^{7,18} in alphabetical order. The static **3dMD Torso System** (3dMD LLC, GA USA) was also included as reference against which the other methods were compared because its reliability and accuracy have been extensively tested in previous validation studies, which have shown an accuracy of within 1 mm. ^{2,19-22} Characteristics of each technology are summarised in **Table 1**.

Artec Eva (Artec 3D, Luxembourg) and Go!Scan (Creaform, Germany) are structured-light laser scanners. The scanning process takes place by moving the scanner manually around the patient and projecting a white light to recognise an object's shape. This projection changes the image of the laser stripe according to its surface. The 3D data are then retrieved by triangulation of those correspondences. Clisalix 3D Sensor (Virtual Aesthetic, Crisalix, Switzerland) is a portable device to be plugged into a tablet. It produces 3D images by moving the sensor around the patient. The 3D reconstruction is automatically created on a

Table 1 Technical specifications of the included porD surface imaging systems.

Name	Artec Eva	Crisalix	GO! Scan 20	LifeViz Mini	Vectra H1	3dMD
		200	0	LING		
Company	Artec 3D	Crisalix SA	Creaform Inc.	Quantificare SA	Canfield scientific Inc.	3dMDvultus Inc.
Country	Luxembourg	Switzerland	Canada	France	USA	USA
Realisation	Structured-light	3D reconstruction from	Structured-light laser	Passive	Passive	Hybrid (active and
of 3D image	laser scan	2D image analysis	scan	stereophotogrammetry	stereophotogrammetry	passive) stereophotogrammetry
Price	~ 19k€	Membership-based: ~ €300-400 / month	£ 34,500 (incl.VAT)	~ 10-20k€	~ 13k€	~ 20k€
Size (cm)	26 x 16 x 6	Sensor (ST01):	15 x 17 x 25	15 x 15 x 11	28.29 x 14.34 x 13.26	-
		11.92 x 2.8 x 2.9				
		iPad mini:				
		19.54 x 13.48 x 0.63				
Weight (kg)	0.9	0.095	1.25	0.800	1	-
View Field	30 x 21 cm		38 x 38 cm	25cm(H) x 19cm(W)	270mm (H) x 165mm	-
view i leiu	30 X 21 CIII		36 X 36 Cm	x 20cm(D)	(W) x 100mm (D)	
				X 20cm(D)		
					capture volume	
3D point	0.1 mm	0.5 mm	0.1 mm	-	they do not have a	-
accuracy					specification for this	
3D	0.2 mm	VGA 640 x 480	0.5 mm	0.5-2 mm	0.95 mm	-
resolution		QVGA 320 x 240			geometry resolution	
		QV6/1020 X 2 10				
					(triangle edge length)	
Working	0.4-1	Face 0.5	0.3 – 3.0	0.75	Face 0.475	-
Distance (m)					Body 1.055	
Texture	1.3 mp	1024x1024 pixels	50 to 150 DP	Image resolution:	24.2MP sensor	-
resolution				13.5-24 Million pixels		
				x3		
Colours	24 bpp		24 bits	-	they do not have a	
Colours	24 upp	-	24 Dits	-		
					specification for this	
Capture time	-	± 20 seconds	-	5 ms	2 ms	-
Data	18 mln points/s	30-45 seconds on a	1.5 mln nointe/s	<1min	they do not have a	-
	10 mm points/s		1.5 mln points/s	< 1111111		
acquisition		good internet			specification for this	
speed (up to)		connection				
	Artec Studio	Crisalix	VXelements	DermaPix (for body)	Sculptor	Vultus
Software	Artec Studio	STIGUTIA		, ,,		

Volume (cc)	Artec Eva	Crisalix	GO!Scan	LifeViz Mini	Vectra H1	3dMD
Standardised vo	olume - flat surface					
0.5	$\textbf{0.18} \pm \textbf{0.02}$	-	$\textbf{0.17} \pm \textbf{0.04}$	$\textbf{1.22} \pm \textbf{0.04}$	$\textbf{0.25} \pm \textbf{0.06}$	-
	0.35%	-	0.32%	2.43%	0.5%	-
1	$\textbf{0.05} \pm \textbf{0.04}$	-	$\textbf{0.03} \pm \textbf{0.04}$	$\textbf{6.85} \pm \textbf{0.08}$	$\textbf{0.09} \pm \textbf{0.08}$	-
	0.05%	-	0.03%	6.85%	0.09%	-
2	$\textbf{0.35} \pm \textbf{0.11}$	-	$\textbf{0.27} \pm \textbf{0.09}$	$\textbf{0.68} \!\pm \textbf{0.01}$	$\textbf{0.53} \pm \textbf{0.10}$	-
	0.17%	-	0.13%	0.34%	0.26%	-
4	$\textbf{0.34} \pm \textbf{0.15}$	-	$\textbf{0.02} \pm \textbf{0.36}$	$\textbf{0.13} \pm \textbf{0.01}$	$\textbf{0.09} \pm \textbf{0.29}$	-
	0.08%	-	0.005%	0.03%	0.02%	-
Mean	0.20 ± 0.18	-	0.12	1.81 ± 3.05	0.19 ± 0.27	-
	0.14%	-	0.10%	2.22%	0.21%	-
Ranking	2nd	-	1st	4th	3rd	-
Standardised vo	olume - breast					
0.5	$\textbf{0.25} \pm \textbf{0.16}$	-	$\textbf{0.17} \pm \textbf{0.04}$	$\textbf{1.22} \pm \textbf{0.37}$	$\textbf{0.91} \pm \textbf{0.01}$	-
	0.49%	-	0.35%	2.43%	0.18%	-
1	$\textbf{0.07} \pm \textbf{0.04}$	-	$\textbf{0.07} \pm \textbf{0.06}$	$\textbf{0.21} \pm \textbf{0.01}$	$\textbf{0.04} \pm \textbf{0.01}$	-
	0.07%	-	0.07%	0.21%	0.04%	-
2	$\textbf{0.54} \pm \textbf{0.09}$	-	$\textbf{0.26} \pm \textbf{0.07}$	$\textbf{0.68} \pm \textbf{0.01}$	$\textbf{0.39} \pm \textbf{0.01}$	-
	0.27%	-	0.13%	0.34%	0.19%	-
4	$\textbf{0.32} \pm \textbf{0.03}$	-	$\textbf{0.25} \pm \textbf{0.33}$	$\textbf{0.13} \pm \textbf{0.01}$	$\textbf{0.41} \pm \textbf{0.02}$	-
	0.08%	-	0.06%	0.03%	0.10%	-
Mean	0.29 ± 0.18	-	0.20 ± 0.17	0.56 ± 0.44	0.23 ± 0.17	-
	0.23%	-	0.16%	0.75%	0.13%	-
Ranking	3rd	-	1st	4th	2nd	-
Standardised vo	olume - face					
0.5	$\textbf{0.23} \pm \textbf{0.03}$	-	$\textbf{0.17} \pm \textbf{0.05}$	$\textbf{0.16} \pm \textbf{0.04}$	$\textbf{0.14} \pm \textbf{0.07}$	$\textbf{0.02} \pm \textbf{0.06}$
	0.45%	-	0.34%	32%	0.27%	0.03%
1	$\textbf{0.13} \pm \textbf{0.12}$	-	$\textbf{0.15} \pm \textbf{0.10}$	$\textbf{0.18} \pm \textbf{0.02}$	$\textbf{0.02} \pm \textbf{0.01}$	0.02 ± 0.13
	0.13%	-	0.15%	0.18%	0.02%	0.02%
2	$\textbf{0.30} \pm \textbf{0.16}$	-	$\textbf{0.35} \pm \textbf{0.03}$	$\textbf{0.35} \pm \textbf{0.01}$	$\textbf{0.35} \pm \textbf{0.12}$	0.00 ± 0.09
	0.15%	-	0.17%	0.18%	0.17%	0%
4	$\textbf{0.23} \pm \textbf{0.23}$	-	$\textbf{0.23} \pm \textbf{0.03}$	$\textbf{0.94} \pm \textbf{0.01}$	$\textbf{0.30} \pm \textbf{0.07}$	0.11 ± 0.29
	0.06%	-	0.06%	0.23%	0.07%	0.03%
Mean	0.22 ± 0.15	-	$\textbf{0.22} \pm 0.10$	$\textbf{0.15} \pm 0.50$	$\textbf{0.05} \pm 0.24$	0.05 ± 0.17
	0.20%	-	0.18%	0.02%	0.10%	0%
Ranking	4th	_	3rd	1st	2nd	Control

The table illustrates the difference between the absolute volume of the standardised volumes (deconstructed cubes) and the value detected by each device in the three different settings (flat surface, breast mannequin, and human face). Data are reported as absolute technical error measurement TEM (cc mean \pm SD) and relative technical error measurement rTEM (%). Based on TEM and rTEM values, the devices are ranked from the most accurate (1st) to the least (4th).

cloud-based 3D imaging software (Crisalix, Switzerland).²⁴ **LifeViz Mini** (QuantifiCare, France) and **Vectra H1** (Canfield Scientific, NJ USA) are compact 3D cameras based on the principle of passive stereophotogrammetry. Three images are acquired from different perspectives and are then stitched into a single 3D image. Both cameras include a flash system and a dual-beam pointer to standardise photographing distance. The use of LifeViz Mini and Vectra H1 has been validated in multiple studies involving facial assessment.^{7,18}

The static system 3dMD is a hybrid stereophotogrammetry system composed of four fixed modular units for a total of twelve cameras²³ with the software algorithms using both projected random patterns and texture of the skin (pores, freckles, etc.) to stereo-triangulate and generate a 3D surface image.⁵ The 3dMD is a fixed device widely used and validated for volume assessment; therefore, it was included

as reference to compare the performance of portable technologies with the more established static one.

Study design

Experimental section with standardised small volumes: A set of plasticine cubes of known volume (CassArts, UK) was used. The cube volumes were 0.5 cc, 1 cc, 2 cc, and 4 cc. They have been deconstructed to mimic volumetric changes more accurately (Supplementary Figure 1). The same operator captured the objects with each device on a flat smooth black surface; on a mannequin representing the breast (Supplementary Figure 2); and glued on a human face (Supplementary Figure 3) to test accuracy and precision of each de-

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Aesthetic unit	racy - clinical sec	Artec Eva	Crisalix	GO! Scan	LifeViz Mini	Vectra H1	3dMD
	. ,	AI LEC EVA	Crisalix	GO: Scall	LITEVIZ MITTI	vectiani	JUMD
Fat grafting - fa Upper	2.5	0.90 ± 0.25	0.5	$\textbf{0.36} \pm \textbf{0.68}$	$\textbf{1.41} \pm \textbf{0.06}$	$\textbf{0.32} \pm \textbf{0.05}$	0.23 ± 0.93
	2.3	$0.36\% \pm 0.23$	0.20%	0.30 ± 0.08 0.14%	0.56%	0.32 ± 0.03 0.13%	0.23 ± 0.93 0.09%
lip Lower	3	1.37 ± 0.59	0.20%	0.14% 0.32 ± 0.14	0.70 ± 0.12	0.13% 0.03 ± 0.47	0.07% 0.27 ± 0.48
lip	3	1.37 ± 0.39	0.20%	0.11%	0.70 ± 0.12	0.03 ± 0.47	0.27 ± 0.40
Chin	1	0.44 ± 0.18	1	0.11% 0.18 ± 0.28	0.23% 0.01 ± 0.11	0.65 ± 0.10	0.03% 0.33 ± 0.17
Cilii	'	0.44 ± 0.18 0.44%	1%	0.18 ± 0.28	0.01%	0.65%	0.33 ± 0.17
Right	2	1.62 ± 0.32	0.5	0.35 ± 0.21	0.60 ± 0.19	0.55 ± 0.06	0.35% 0.16 ± 0.65
cheek	_	0.81%	0.25%	0.18%	0.30%	0.27%	0.08%
Left	2	0.59 ± 0.29	0.5	0.10% 0.14 ± 0.60	0.53 ± 0.14	0.69 ± 0.09	0.40 ± 0.34
cheek	_	0.30%	0.25%	0.07%	0.27%	0.35%	0,20%
Nose	2	0.70 ± 0.18	1	0.66 ± 0.22	0.11 ± 0.24	0.07 ± 0.09	0.10 ± 0.20
11050	_	0.21%	0.5%	0.33%	0.05%	0.04%	0.05%
Right	1	0.66 ± 0.09	0.5	0.68 ± 0.33	0.92 ± 0.04	0.36 ± 0.25	0.13 ± 0.30
NLF	•	0.40%	0.5%	0.68%	0.92%	0.36%	0.13%
Left	1	0.62 ± 0.27	0.5	0.33 ± 0.48	0.70 ± 0.05	0.43 ± 0.22	0.03 ± 0.54
NLF	•	0.37%	0.5%	0.33	0.70%	0.43%	0.03%
Total	14.5	4.78 ± 0.53	3	0.49 ± 1.02	4.25 ± 0.33	0.95 ± 0.58	1.43 ± 1.23
		0.20%	0.21%	0.03%	0.33%	0.07%	0.10%
	Mean	1.06 ± 1.52	0.67 ± 1.03	0.11 ± 0.63	1.06 ± 1.4	0.20 ± 0.51	0.30 ± 0.72
		0.30%	0.29%	0.05%	0.36%	0.08%	0.10%
	Ranking	4th	3rd	1st	5th	2nd	Control
Fat grafting - v							
Right	3	_	-	$\textbf{0.65} \pm \textbf{0.13}$	1.17 ± 0.52	$\textbf{0.46} \pm \textbf{0.21}$	-
labia		_	_	0.22%	0.39%	0.15%	-
Left	2.5	_	_	$\textbf{1.18} \pm \textbf{0.43}$	$\textbf{0.59} \pm \textbf{1.73}$	$\textbf{1.33} \pm \textbf{0.49}$	-
labia		-	-	0.47%	0.24%	0.53%	-
Posterior	1.5	-	-	$\textbf{0.91} \pm \textbf{0.23}$	$\textbf{5.19} \pm \textbf{0.11}$	$\textbf{1.32} \pm \textbf{0.11}$	-
fourchette		-	-	0.61%	3.46%	0.88%	-
Clitoral	1.5	-	-	$\textbf{0.22} \pm \textbf{0.49}$	$\textbf{3.51} \pm \textbf{1.71}$	$\textbf{0.68} \pm \textbf{0.26}$	-
area		-	-	0.15%	2.34%	0.45%	-
Total	8.5	-	-	$\textbf{0.85} \pm \textbf{0.79}$	$\textbf{7.28} \pm \textbf{4.30}$	$\textbf{0.85} \pm \textbf{0.54}$	-
		-	-	0.08%	0.68%	0.08%	-
	Mean	-	-	$\textbf{0.06} \pm \textbf{0.95}$	$\textbf{3.31} \pm \textbf{3.70}$	$\textbf{0.06} \pm \textbf{1.06}$	-
		-	-	0.04%	1.33%	0.04%	-
	Ranking	-	-	1st	3rd	1st	-
Fat grafting - h	ands						
Right	2	-	-	$\textbf{0.76} \pm \textbf{0.50}$	-	$\textbf{1.48} \pm \textbf{0.30}$	-
dorsum		-	-	0.38%	-	0.74%	-
Left	3	-	-	$\textbf{0.51} \pm \textbf{0.24}$	-	$\textbf{0.41} \pm \textbf{0.14}$	-
dorsum		-	-	0.17%	-	0.14	-
	Mean	-	-	$\textbf{0.15} \pm \textbf{0.72}$	-	$\textbf{0.94} \pm \textbf{0.60}$	-
		-	-	0.11%	-	0.44%	-
	Ranking	-	-	1st	-	2nd	-

The table illustrates the difference between the absolute volume of lipoaspirate injected and the volumetric change detected in multiple aesthetic units of three body areas (face, vulva, and hand). Data are reported as absolute technical error measurement TEM (cc mean \pm SD) and relative technical error measurement rTEM (%). Based on TEM and rTEM values, the devices are ranked from the most accurate (1st) to the least (5th).

Abbreviation: NLF, nasolabial fold.

vice in detecting the standardised small volumes in a clinical model simulation.

Clinical section with fat grafting in real patients: Each device was used to capture 3D images of the face, vulva, and hand from 2 patients undergoing fat transfer. Subjects' incapable of giving written informed consent in English was considered not eligible. All the patients included were women, with average age 47 years (\pm 0.3) and BMI 24. The facial images were captured before and 6-8 h after the procedure. The vulval and hand images were captured before and after FG in the operating table.

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Outcome assessment

The present study aimed to evaluate the accuracy, precision, and usability of the tested 3D systems in detecting the known small volume changes. Accuracy was defined as the ability of each device to capture the volume difference in comparison with the reference volume. In the experimental section, the reference values were known as provided by the manufacturer. In the clinical section, the reference values were the amount of fat injected during the operation as reported in the surgical notes. Precision was defined as follows: (a) repeatability, which is the degree of similarity of multiple measurements performed by the same operator using the same method and (b) reproducibility, which is the magnitude of the differences between repeated measurements by different operators who are using the same technique. 2,21,25 Usability was assessed by evaluating the following parameters (Table 5): image quality (illumination and sharpness), ease of use & manoeuvrability of the device, ease of use software, speed of image acquisition, time and effort for analysis, patient comfort during acquisition, and cost. For each parameter, a ranking was assigned to each device from the highest (5 stars) to the lowest (1 star). The first two parameters were graded by two professional medical photographers who scanned the objects and subjects; ease of use of the software was graded by the operators performing the volumetric analysis; the speed of acquisition and time for analysis were ranked based on the average time recorded for each device; patient comfort was ranked by the scanned patients. The cost was graded considering the purchase price of each device and the overall cost over a period of 5 years, which has been considered a reasonable amount of time to complete a follow-up assessment in a clinical trial. The final score was based on the average overall scores obtained for each device, ranking them from the one with the highest score (5 stars) to the lowest (1 star).

Volumetric analysis

Three-dimensional images were acquired with all devices in the same setting and standard lighting by a professional medical photographer trained on the use of each technology. Data processing and analysis were performed on a desktop or laptop provided with the capture device using the following software: Artec Studio (Artec Eva), Crisalix (Crisalix), VXelements (GO! Scan 20), Lifeviz App for face and DermaPix for body (LifeViz Mini), Sculptor (Vectra H1), and Vultus (3dMD).

Two images were selected and designated as a pre-(before adding the known volume) and post-surface. The superimposition of the two surfaces was performed with a landmark-based registration. Superimposed images require precise 3D alignment to be free from registration artefacts; therefore, when superimposing two surfaces, the software performing volumetric analysis generates a quantitative measure of variation or error called root mean square (RMS) error value, which is calculated as the square root of the sum of squared deviation in all 3 spatial directions and is an analogue to the target registration error as described in different articles. In previous studies, RMS cut-off values equal or less than 0.5 mm have been described as clinically acceptable to indicate the minimal level of variation. ¹⁸ Therefore, in this study, alignment was repeated until reaching such value of RMS. ^{29,30} Once the images were correctly superimposed, volumetric analyses were performed via subtraction analysis by two operators who received training from the software providers or manufacturers.

Statistical analysis

Accuracy was determined by calculating the absolute and relative technical error of measurement (TEM and rTEM). TEM is the absolute value of the difference between the actual value and the measured value, showing how far or close a measurement is from the value it should have; rTEM is a measure of how close a measured value is to the true value expressed in percentage of deviation.³¹ Repeatability or intra-observer reliability was analysed by comparing repeated measurements of each operator individually using the Pearson's correlation coefficient (r_p) . Reproducibility or inter-observer reliability is the magnitude of the differences between repeated measurements by different operators who are using the same technique. It was calculated using the intraclass correlation coefficient (ICC) between the two operators overall volumes in all subsections.^{2,21,32} Statistical analysis was performed with Statistical Package for the Social Sciences (SPSS, Version 27.0, IBM, New York, NY).

Results

Overall, all the tested devices presented small variation in the absolute volumes (Table 2 and Table 3). The error between known and detected volumes was as follows: 1.06 ml for Artec Eva, 0.67 for Crisalix, 0.11 for GO! Scan, 1.06 for LifeViz Mini, 0.20 for Vectra H1, and 0.30 for 3dMD in real patient after facial FG; 0.06 for GO! Scan, 3.31 for LifeViz Mini, and 0.06 for Vectra H1 after vulval FG; 0.15 for GO! Scan, and 0.94 for Vectra H1 after FG to the hand (Table 3). In both experimental models and clinical cases, average repeatability was considered high to very high: $r_p=0.986$ for Artec Eva, $r_p=0.770$ for GO! Scan, $r_p=0.719$ for LifeViz Mini, $r_p=0.982$ Vectra H1, and $r_p=0.995$ for 3dMD (Table 4). Reproducibility was considered high to very high: ICC=0.995 for Artec Eva, ICC=0.708 for GO! Scan, ICC=0.984 for Life-Viz Mini, ICC=0.995 Vectra H1, and ICC=0.993 for 3dMD (Table 4). Both measures of precision demonstrated similarities to the r_p and ICC values obtained with the control (3dMD). Crisalix could not be tested in the experimental section because the software did not recognise the plasticine volumes (Supplementary Figure 4), and both $r_{\rm p}$ and ICC values were not quantifiable because the volumetric analysis is performed automatically by the software and not by operators.

The overall ranking is illustrated in Table 5. While Crisalix, LifeViz Mini, and Vectra H1 are truly freestanding, Artec Eva and Go!Scan required to be connected to a laptop during the entire scan; therefore, their true portability is limited. Crisalix was the lightest device (95 gr plus 300 gr iPad), followed by LifeViz Mini and Vectra H1. Go!Scan was

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p-value < 0.001 Precision: intra- and inter-observer reliabilities. The agreement between the repeated measurement performed by each operator individually over all volumes wass tested with Pearson's correlation coefficient (rp). The agreement between the two operators performing the volumetric analysis was calculated using the intraclass correlation 0.752 -0.7080.989 Fat grafting - hands p-value <0.001 0.36 -0.291< 0.001 -< 0.001 0.980 ٩ p-value < 0.001 0.922 0.991 2 Fat grafting - vulva p-value <0.001 <0.001 <0.001 0.966 0.837 0.956 ٥ A 0.001 p-value < 0.001 0.993 p-value ICC Fat grafting - face <0.001 <0.001 < 0.001 0.988 < 0.001 0.974 0.992 ٩ ^ 0.001 ^ 0.001 0.0010.001 p-value Standardised volume - face 0.660 1.000 <u>ပ</u> p-value <0.001 <0.001 <0.001 <0.001 0.988 0.990 ے p-value < 0.001 0.0010.001 < 0.001 Standardised volume - breast 0.986 0.999 1.000 p-value ICC <0.001 <0.001 <0.001 <0.001 0.988 0.850 0.989 < 0.001 0.992 ٩ ^ 0.001 ^ 0.001 p-value < 0.001 Standardised volume - flat 0.998 0.991 1.000 0.991 ပ္ပ p-value <0.001 <0.001 <0.001 surface -0.0600.990 0.989 0.985 coefficient (ICC) LifeViz Mini Table 4 Artec Eva Vectra H1 GO!Scan Crisalix

heavier (1.25 kg) and less ergonomic than Artec Eva (850 gr). The quickest device considering image acquisition and time to import the images into the software was the LifeViz Mini with an average time of 30 ± 19.3 s, followed by Vectra H1 (36 ±24.5 s), Crisalix (62 s), Artec Eva (64.4 \pm 67.3 s), and Go!Scan (132.2 \pm 107.4 s). LifeViz Mini presented the best illumination and sharpness features, followed by Vectra H1, Crisalix, Go!Scan, and Artec Eva (Figures 1-3).

The easiest-to-use software for facial analysis was Crisalix, with the analysis performed in just few clicks on a tablet or computer. The second was the Lifeviz Facial App, followed by Sculptor, both utilising the subtraction analysis tool. Instead, in the vulval and hand analyses, the easiest-to-use software was the Sculptor, followed by Dermapix Pro. With the latter, the analysis has to be done in 2 passages calculating the discrete volumes of the preoperative and postoperative images, and then the subtraction has to be done manually. The software ranked as fourth was the VX-elements, followed by Artec Studio in fifth.

According to patients, Crisalix was considered the less bothering, followed by Lifeviz Mini and Vectra H1, which were both ranked as second. Artec Eva and Go!Scan were graded as the least comfortable because they strobe and the scanning process takes a long time.

Discussion

In recent years, new handheld technologies have entered the market at substantially lower price, providing surgeons with valuable tools for outcome evaluation as valid alternative to the static systems. In this study, the authors investigated accuracy, reproducibility, and usability of different handheld 3D imaging systems. To the best of our knowledge, this is the first comparison of portable 3D technologies to detect small volumes in different clinical applications, including vulval FG.

Accuracy data from our study are in line with the literature previously published. With Artec Eva, we found that accuracy in facial assessment was on average 0.47 ml, similarly to other studies that ranged between 0.26¹ and 0.65.³³ In addition to that, the same device presented a mean variation of 0.21 cc in our experimental section with plasticine blob attached to a human cheek, similarly to a previous experimental study involving a Lego brick attached to a patient's cheek where the average variation was 0.30.34 With Crisalix the variation was 0.35 cc, in line with a previous report showing a variation below 2 cc. 5 With Vectra H1, we detected an error of 0.20 ml in facial FG, which was even higher than the reference technology, the 3dMD, which had an accuracy error of 0.30 ml. Vectra H1's accuracy in previous studies ranged between 0.15¹ and 0.84.⁷ With Life-Viz Mini, the variation between detected and absolute volumes was 0.35 in facial FG; therefore, the error value was lower than previously reported deviations that ranged between 0.5^{35} and $0.85.^{36}$ Conversely, with Go!Scan, we detected an average variation of 0.29 ml, while a previous study reported a variation of 0.085.16

This study also investigated the precision of the different 3D imaging systems. Artec Eva and Vectra H1 showed the highest reliabilities (0.990 \pm 0.007 and 0.988 \pm 0.011, respectively). LifeViz Mini showed an average reliability of

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 Table 5
 Comparative table illustrating the individual ranking for each parameter and the overall score.

PARAMETERS FOR COMPARISON	Artec Eva	Crisalix	Go!Scan	LifeViz Mini	Vectra H1
Accuracy					
(TEM ±SD)	*****	****	*****	****	****
(rTEM)	0.44 (±0.41)	0.67 (±NA)	0.14 (±0.06)	1.38 (±1.24)	0.35 (±0.32)
	0.22%	0.29%	0.11%	0.94%	0.17%
Reliability					
(average correlation coefficient ±SD)	****		****	***	****
	0.990 (±0.007)	NA	0.740 (±0.560)	0.851 (±0.309)	0.988 (±0.011
Image quality					
	****	****	****	****	****
Speed of image acquisition, seconds					
(average ±SD)	****	****	****	****	****
	64.4 (±67.3)	62	132.2 (±107.4)	30 (±19.3)	36 (±24.5)
Ease of use & Manoeuvrability					
	****	****	****	****	****
Portability					
	****	****	****	****	****
Ease of use software					
	****	****	****	***	****
Time and effort for analysis					
	****	****	****	****	****
Patient comfort					
	****	****	****	****	****
Cost over 5 years-time*					
	****		****	****	****
	12,000 £		36,000 £	14,000 £	13,000£

		15,000-			
		35,000£			
Overall ranking					
Mean score rating	****	***	****	****	****
	1.2	3.3	2	3.8	3.9

The table summarises the ranking assigned to the multiple technologies for each parameter.

Abbreviations: TEM, absolute technical error of measurement; SD, standard deviation; rTEM, relative technical error of measurement. *The cost was calculated for a 5-year period, which has been considered a reasonable time required to complete the follow-up evaluation in a clinical trial.

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[m6+;May 31, 2022;13:44]

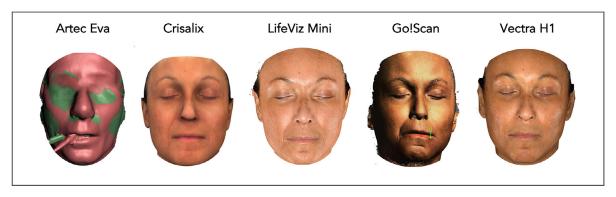


Figure 1 The panel shows the facial images produced with each 3D technology.



Figure 2 The panel shows the vulval images produced with the three 3D technologies that were able to perform the capture.

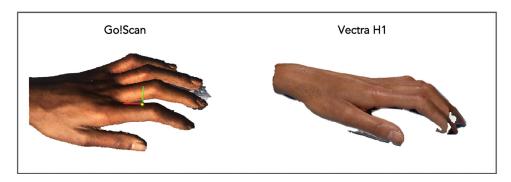


Figure 3 The panel shows the hand images produced with the three 3D technologies that were able to perform the capture.

0.851 \pm 0.309, followed by the Go!Scan with 0.740 \pm 0.560. Therefore, our results suggest that the tested 3D technologies present not only high accuracy but also high to very high repeatability and reproducibility, particularly for facial FG application. The clinical implication of this observation is that the included devices can be implemented simultaneously in multi-centre trials as results are similar in the facial area, and fat survival rate measured with these tools can be compared in meta-analysis without including substantial bias.

Overall, we found structured-light laser scanners such as Artec Eva or Go!Scan were overall accurate, but their use is not feasible in a dynamic clinical setting. They require longer acquisition time and therefore are more prone to movement artefacts (even breathing movements can invalidate the scan). They strobe during the capture, therefore, are uncomfortable for patients and might not be suitable for facial scanning in case of photosensitive epilepsy, and the analysis with the software is complex and time-consuming. Artec's software calculates the volume on a flat surface but not on curved surfaces; therefore, sagittal planes need to be created to allow measurements (Supplementary Figure 5) making the analysis more complex. Finally, they are considered portable but require wiring to be connected to an

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electric source during the entire process, thus making their use unpractical and even dangerous in the operating theatre.

The iPad device Crisalix showed good accuracy in the facial area, quick and easy image capture, automatised volumetric analysis, and user-friendly system requiring little time to complete the measurements. In addition to that, it is entirely online-based; therefore, no office space is required, and physicians are not limited to a single location to acquire or review patient data.³⁷ However, it produces lesser quality images; it does not include all the body areas; data are uploaded to the cloud (Crisalix is hosted in the Amazon Private Cloud³⁸) and stored in a database located in Germany, with data accessible to the 'Crisalix' Affiliate' that is located in the Philippines,³⁹ creating potentially data handling issues with patients from public health systems.

Compact 3D cameras based on the principle of passive stereophotogrammetry such as LifeViz Mini and Vectra H1 presented high accuracy and precision; true portability (low weight and acceptable size); short acquisition time and fast acquisition of images into the software; patients were comfortable during the scan. With LifeViz Mini calibration cannot be self-performed; therefore, if it accidentally drops, it needs to be sent to the manufacturer (France) for recalibration. With Vectra H1, we have been able to produce a colour map representing clearly the volumetric variation between the preoperative and postoperative scan (Supplementary Figure 6).

Overall, the Vectra H1 received the highest ranking and represented the most versatile device to assess multiple body areas, with the best long-term value for money.

When choosing a 3D handheld system, the advantages and limitations of each technology should be considered to select the most appropriate device based on the clinical need.

Limitations

One of the main limitations of the study is that the accuracy of vulval and hand quantitative assessments was calculated considering only their variation with the known volume changes (amount of fat injected) and not compared with the reference device (3dMD). This could not be avoided because static systems, such as 3dMD, are not suitable for vulval or hand assessment, which is the reason why this study investigates the usage of handheld technologies in the first place.

Conclusions

All tested technologies are accurate in detecting small volume enhancement and therefore can be implemented in clinical practice to monitor the volumetric outcome after FG or other injectables.

Overall, we found that compact 3D cameras based on the principle of passive stereophotogrammetry such as LifeViz Mini and Vectra H1 are easier to adopt in a clinical environment. With Vectra H1, we have been able to assess multiple body areas and produce a colour map. Therefore, based on

the data obtained, Vectra H1 represented the best value for money.

The choice of the 3D system should be based on the clinical need and resources available. Doctors should define their requirements before making the final decision for purchase.

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Declaration of Competing Interest

The authors have no conflict of interest or financial disclosures.

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Ethics

The study conformed to UK Medicines Research Council Guidelines for Good Clinical Practice in Clinical Trials and adhered to the World Medical Association Declaration of Helsinki. It was conducted after obtaining ethics approval from both the relevant regional and institutional ethics committee responsible for human experimentation (references 16/SC/0669 and 16/LO/1980).

The patients included gave written informed consent before participation in the study and provided written consent for the release of their clinical photographs for publication.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.bjps.2022.04.042.

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