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Original article

IODA-shoulder[®], a 3-dimensional automated software for glenoid bone loss quantification in shoulder instability. A validation study

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ABSTRACT

Background: Glenoid bone loss (GBL) calculation in patients with shoulder instability has a wide variability in methods and their reliability. The purpose of this study was to describe and validate a new semi-automated software developed to improve GBL calculation using a 3D imaging modeling (IODA-shoulder) and to compare the method to the PICO area method.

Patients and methods: A semi-automated software to assess GBL was preliminarily developed and validated on 7 fresh frozen specimens (scapulae with artificially created glenoid defect), using water displacement method. Afterwards, the software was retrospectively used on CT images of 20 patients affected by recurrent shoulder dislocation. Inclusion criteria were: unilateral dislocation, minimum 2 dislocation episodes. Exclusion criteria were bone reconstruction of the glenoid, failed shoulder stabilization, bilateral dislocation, shoulder arthritis. Three-dimensional computed tomography images of bilateral shoulder were retrieved for each patient. Two methods to determine GBL were compared. The PICO surface area method and the new IODA method. We assessed the intra- and inter-rater reliability of the two methods with the Intraclass Correlation Coefficient (ICC), the Bland-Alman analysis, and Lin's concordance correlation coefficient (CCC).

Results: We did not find a statistically significant difference between the mean volumes calculated with PICO and IODA methods, respectively 914 vs. 815 mm³, $p = 0.155$. The analysis carried out by using the traditional PICO method showed a lower concordance rate among four observers than the higher concordance found using IODA method, regardless of the size and the location of the defect. The ICC agreement with PICO was significantly lower than with IODA (0.76 vs. 0.97). We found a poor CCC with PICO (from 0.65 to 0.81) and a substantial one with IODA (from 0.96 to 0.98).

Discussion: The intra- and inter-rater reliability using IODA method is significantly better than PICO method. The assessment of GBL using IODA method is time saving, avoiding significant inter- and intra-observer variation, mainly due to individual skill and experience in the method.

Level of evidence: IV, experimental study.

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1. Introduction

Recurrent anterior shoulder dislocations often result in glenoid bone loss, which has been demonstrated to be a risk factor for poor results following an arthroscopic soft tissue repair [1]. From the

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original description of the “inverted pear” glenoid to newer reports that demonstrate a “sub-critical value” of glenoid bone loss (GBL) that can still affect outcomes, much attention has been placed on an accurate measurement of glenoid bone loss when determining the most suitable surgical intervention for the patient with recurrent instability [2,3]. Anterior GBL has been noted in up to 41% of patients after an initial dislocation and in 90% of patients with recurrent instability [4,5].

Traditional thresholds of 20% of GBL have given way to less acceptable amounts of bone loss with even 13%–10% GBL [4], now being utilized as a potential cut-off in the decisional process of surgeons, to advocate a bony reconstructive procedure instead of a soft tissue repair alone. The incidence of Hill-Sachs lesions is associated with up to 100% in recurrence of dislocation [6,7].

In the last ten years, a shift in surgical planning paradigm has recognized the importance of bipolar bone loss and recent studies introduced the concept of the glenoid track which defines “on-track” and “off-track” lesions, based on combined imaging measurements of the GBL and the humeral head bone loss [8]. However, the current glenoid track paradigm is inaccurate to actually understand the bipolar bone loss and relative clinical implications [9,10].

Many different measurement methods have been advocated in the literature, although no proposed technique is recognized to be superior to others and acceptable in a daily practice [11–15].

To date, no consensus has been reached in the surgical community regarding an accepted method to quantify GBL [10]. In current clinical practice computed tomography represents the most reliable imaging modality, on which two types of calculation can be carried out, including linear or surface-based methods.

The linear methods have been reported to globally overestimate the GBL with a low accuracy, as they do not consider the exact site of the defect (upper or lower location) [1,5,11]. The surface area methods are considered more reliable but still inaccurate, due to lack of precision of the best fit circle positioning and still have a large inter-observer and intra-observer variability [10]. Furthermore, in some cases it is substantial enough to impair preoperative planning and the selection of the correct surgical procedure, because of individual skill of the surgeon in assessing the defect size.

The purpose of this study was to validate a semi-automated software properly developed to improve glenoid bone loss calculation (IODA-shoulder) using a 3D approach. The method was compared to the validated handmade PICO area method; our hypothesis is that the software drastically reduces the calculation time and provides reliable results to modeled an optimal 3D artifact of GBL.

2. Patients and methods

2.1. Study settings

The first study phase was implemented at ICLO Research and Teaching Center laboratory, where the developed software was preliminary tested on 7 cadaveric specimens. A second study phase for software validation was carried out on DICOM images (bilateral shoulder CT scan) acquired from patients referred to shoulder surgery consultations of the authors (M.M. and M.O.G.) between July 2020 and November 2022. All patients have given their informed consent to participate to the study with data collection and pseudonymization and processing. For the experimental (laboratory-controlled and software processing) nature of the study, approval by the local Ethical Committee was waived.

2.2. Inclusion and exclusion criteria

Following inclusion criteria were considered: patients with traumatic, unilateral, recurrent shoulder instability with more than 2 episodes of shoulder dislocation. Exclusion criteria were: patients with previous bone reconstruction of the glenoid, failed stabilization procedure, bilateral involvement, glenohumeral arthritis or previous shoulder fractures.

2.3. Software development

A semi-automatic software prototype was developed using C++ programming language, Qt library (for the development of user interface) and VTK library (for the DICOM images processing). To calculate the GBL using the IODA-Shoulder prototype v1.0, an algorithm that involves the following steps has been implemented:

1. input: the algorithm started by uploading the DICOM images set as input, from CT scans with both shoulders acquired (the injured and intact sides);
2. 3D reconstruction: the algorithm proceeded to create a 3D representation of the input DICOM set. In this phase an automated segmentation is performed with the running cubes algorithm, then the phase ends with the cleaning of the small objects and the smoothing of the surface of the 3D model;
3. automatic splitting (segmentation): the algorithm automatically separate bone volumes to allow the following semantics assignment (Fig. 1);

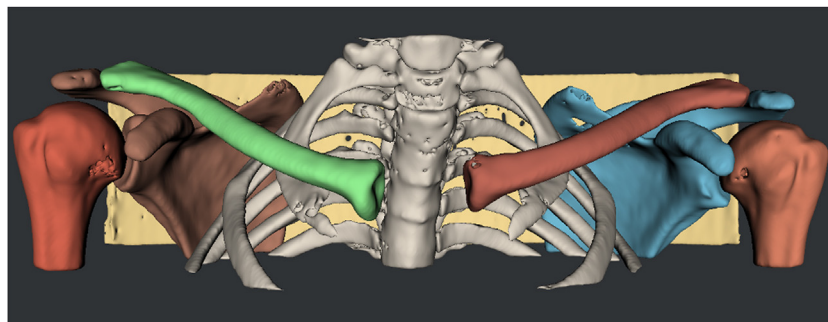


Fig. 1. Three-dimensional reconstruction of bilateral shoulder region, before semantics assignment and subtraction.

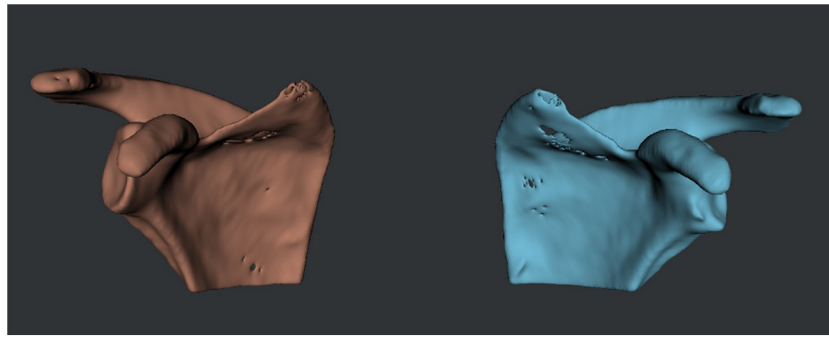


Fig. 2. Selection of scapulae as a region of interest.

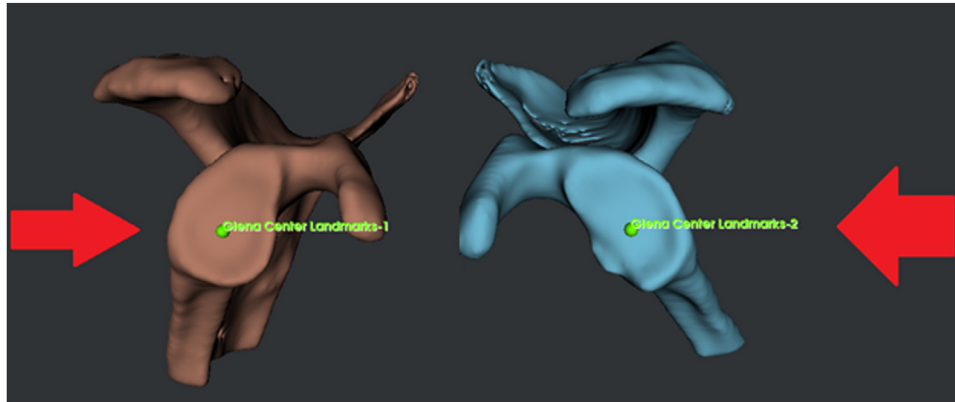


Fig. 3. Landmarking of glenoid center on bilateral 3D image.

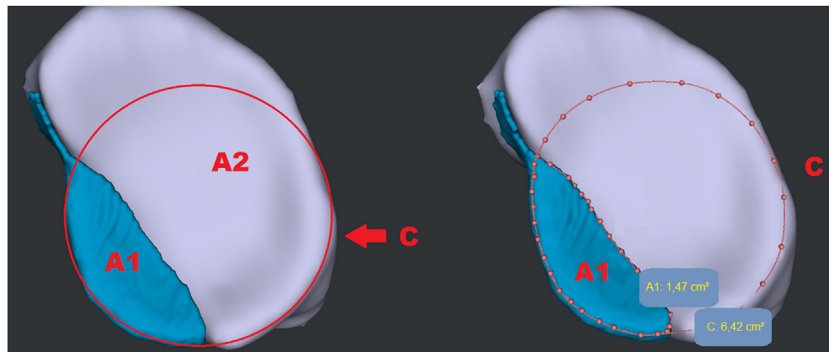


Fig. 4. Three-dimensional landmarking of A1 and C surfaces. C represents the surface subtended by the three-dimensional closed curve obtained from the landmarks of the ideal circumference projected onto the healthy glenoid and matching with the lower lateral edges of the healthy glenoid surface. A1 represents the part of the glenoid surface subtended by the 3D closed curve relative to the GBL artifact.

4. semantics assignment: the identification of the scapulae was done manually by the operator, who selected the right and left scapulae from a list of labels proposed by the software (Fig. 2);
5. landmarking: the operator use picking tools provided by the software to manually position the center of the glenoid concavity. This landmarking task is aimed at detecting the glenoid surface, to achieve an optimal matching between the glenoids of both sides (Fig. 3);
6. glenoid bone loss calculation: in the final steps of the algorithm, the software performed automated steps to reconstruct the GBL as 3D object and calculate its volume.

The output of the described algorithm is a 3D artifact representing the reconstruction of the GBL. Once the three-dimensional reconstruction of the GBL was obtained, the glenoid best fit circle and the limit between the GBL and the native glenoid was

manually determined. Once the closed curves have been defined with manual landmarking, the prototype was able to automatically provide the areas of the surfaces of C and A1 delimited by the closed curves. This allowed us to calculate the percentage of GBL using the same approach as the PICO (Fig. 4) using the analogous formula $GBL = A1/C$. Using this approach, we were able to obtain an accurate measurement of GBL in a 3D environment. This step reflects, analogously to the PICO method, the positioning of the ideal circle in the oblique sagittal plane of the healthy contralateral glenoid in the PICO method.

These surfaces were used to calculate GBL in percentage of the global surface, similarly to the classical handmade PICO method. In Fig. 5 is shown the added value of using 3D assessment and the more comfortable way to perform landmarking with respect to the 2D vision and approach of the PICO shown in Fig. 6.

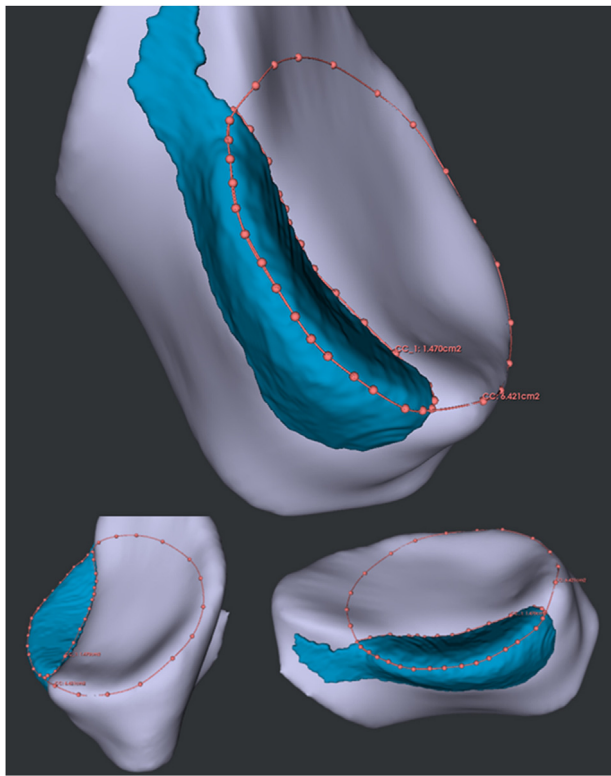


Fig. 5. Multiplanar placement of the ideal circle in the healthy contralateral glenoid.

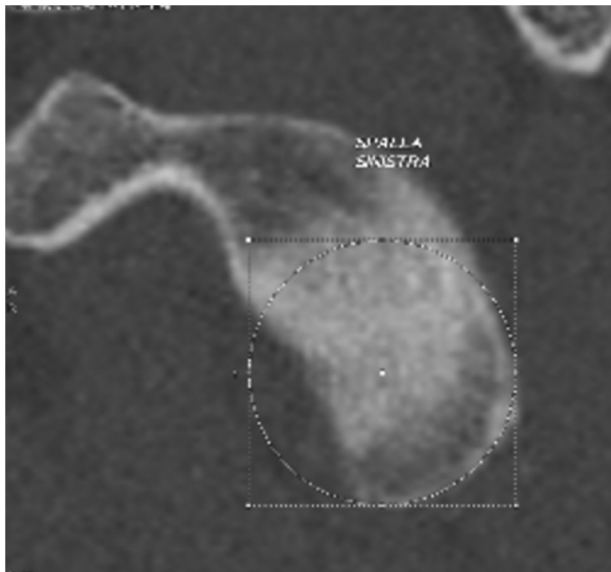


Fig. 6. Selection of the region of interest in the two-dimensional PICO area method.

2.4. Software validation

2.4.1. In vitro validation

In the first study phase, the GBL calculation algorithm has been verified *ex vivo*. DICOM images of 7 healthy shoulder specimens were acquired using a 3D Cone-Beam CT, using a Newton 5G device, by means of conical beam volumetric scans with field of view 18×16 cm and 0.5 mm slice thickness.

A dissection was performed of the 7 glenoid cavities which were freed from the labrum and capsular tissue so that the mere joint could be analyzed. The short and long axes of the glenoid pear

surface were identified in such a way as to identify the bare spot of the glenoid and therefore an ideal circle with a blue marker (Fig. 7A).

After a first acquisition on intact specimens, an artificial bone defect was created at the level of the inferior-anterior face of the glenoid, making a cut along the middle of the radius (R) corresponding to the segment (D) starting from the bare spot and reaching the middle of the edge of the anterior lower border at 6–9 o'clock (Fig. 7B). Considering the ideal circle depicted with the blue marker on the glenoid vault and making use of the following formula for calculating the area of the circular segment relative to the GBL area:

$$R^2 \arccos \left(1 - \frac{D}{R} \right) - (R - D) \sqrt{R^2 - (R - D)^2}$$

we obtained the percentage of the created bone loss starting from the linear deficit D. The cuts therefore produced an average bone loss of 14.5%.

Also in this case a CT acquisition was performed, to obtain a scan before (CTB) and after (CTA) the creation of the bone defect. DICOM files were imported on a dedicated workstation and analyzed with core software prototype algorithm. Comparing the 3D reconstruction of CTB and CTA the software could reconstruct the GBL as shown in Fig. 8.

To validate the volume returned by the software we compared each GBL volume calculation with the volume of the true bone defect obtained by the water displacement method. For this purpose, a set of glass graduated cylinders was used (Fig. 7C).

2.4.2. Clinical validation

Afterwards, in a second study phase, the prototype was reengineered and fine tuned with a different technology implementation using Python and Slicer 3D platform (IODA-Shoulder, prototype version 2.0). In this version, the algorithm remained the same, but the user interface was improved, and automation process has been executed on 20 clinical cases. DICOM images obtained by patients affected by recurrent shoulder dislocation were examined and a clinical setting validation study was carried out. All included patients performed a bilateral shoulder CT scan with the same facility: 3D CT scan Newton 5G device, using 1.25 mm slice thickness.

According to the study by De Wilde et al. [16], it was suggested that the glenoids of the same patient would not differ substantially in surface area and bone volume. Therefore, contralateral, healthy shoulder images were used to compare images of the involved side. Two methods to determine GBL were then used on each image set (The Pico Surface area method and the IODA-shoulder) and results of multiple observations were compared. In order to compare measurements, the DICOM images of the included patients were used as input to the software prototype (full algorithm) and the GBL was calculated. Furthermore, the PICO area method was used on the same images, according to previous description of the method by all the measurements were independently carried out by four independent investigators, orthopedic surgeons and radiologists who were experienced in this field, blinded to each other measurements.

2.5. Statistical analysis

We used the paired *t*-test to assess differences between the measures of PICO and IODA methods for each individual observer. Continuous variables were described as mean $\pm$ standard deviation (SD). Statistical significance was set at $p < 0.05$. Intra-rater reliability of the two measurement methods was assessed through the Intra-class Correlation Coefficient (ICC) [17] and 95% Confidence Intervals (95%CI). The strength of the agreement was classified as excellent ($ICC > 0.75$), good ($0.40 < ICC < 0.75$), or poor ($ICC < 0.40$). To assess the inter-rater reliability of the four observers for each of the two measurement methods, Bland-Altman analysis was computed.

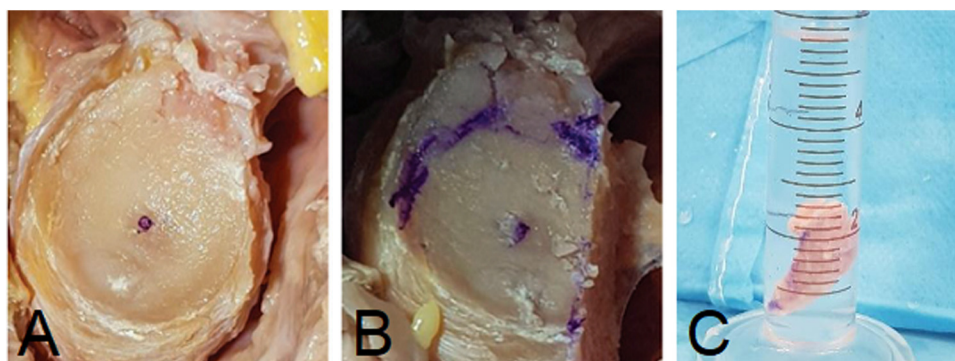


Fig. 7. Three-dimensional evaluation of the whole construct showing healthy, pathological and fusion constructs.

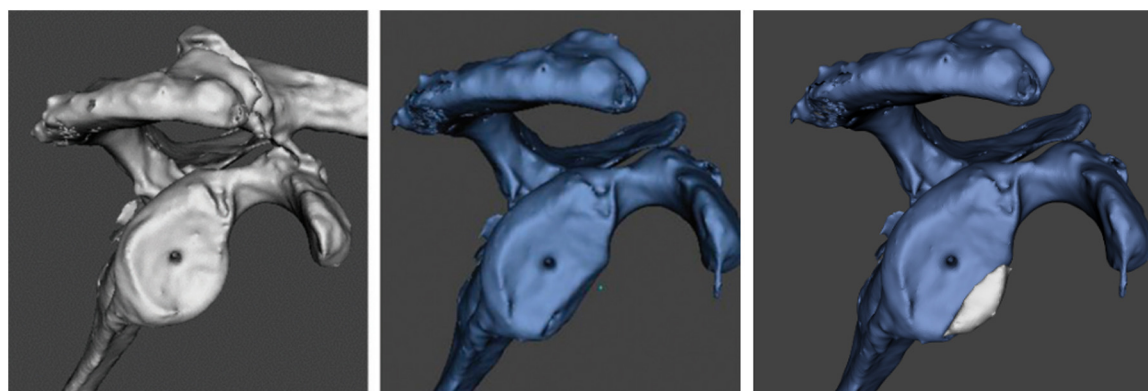


Fig. 8. Cadaver preparation was carried out by isolating the glenoid from surrounding tissue (A), creating a defect at the antero-inferior edge of the glenoid between 15% and 25% in diameter (B), and assessing the cut volume by means of the water displacement method (C).

The same analysis was used to assess the inter-method variability during the first study phase (water displacement compared to software). As far as a high correlation does not necessarily imply there is good agreement between the two methods, also Lin's concordance correlation coefficient [18] was calculated to investigate the inter-observer concordance. The strength of the Lin's coefficient was classified, following the guidelines for interpreting Lin's concordance correlation coefficient [18] as poor (< 0.90); moderate (0.90 to 0.95), substantial (0.95 to 0.99), almost perfect (> 0.99). We used Jamovi (version 2.3.21) to perform the statistical analyses.

3. Results

3.1. In vitro validation

In the first study phase, we did not find a statistically significant difference between the mean volumes calculated with PICO and IODA methods, respectively 914 ± 279 vs 815 ± 223 mm³, $p = 0.155$. Fig. 9 reports the concerned Bland-Altman plot.

3.2. Clinical validation

Twenty patients participated in the second study phase. Four independent observers used IODA-Shoulder and PICO method for GBL estimation. Table 1 reports mean and SD of GBL measures according to PICO and IODA methods and the four observers. Only one observer shows a statistically significant difference when assessing the GBL with different methods.

The ICC agreement among the four observers with PICO method is at the lower limit of excellence (0.76), whereas we found a statistically significantly higher agreement (0.97) with IODA method (Table 2). Moreover, the width of 95%CI of ICC were consistently

Table 1
Mean and SD of GBL measures according to PICO and IODA methods and the four observers.

Observer	PICO method	IODA method	<i>p</i>
	Mean $\pm$ SD	Mean $\pm$ SD	
Observer 1	13.5 $\pm$ 7.4%	12.0 $\pm$ 6.9%	0.223
Observer 2	13.9 $\pm$ 5.9%	11.8 $\pm$ 6.7%	0.038
Observer 3	13.0 $\pm$ 4.4%	12.1 $\pm$ 6.6%	0.394
Observer 4	11.8 $\pm$ 6.6%	11.5 $\pm$ 6.6%	0.767

GBL: glenoid bone loss; SD: standard deviation; *p* of paired *t*-test.

Table 2
ICC agreement for PICO and IODA methods.

Method	Consistency	Agreement	95%CI
PICO	0.77	0.76	0.54–0.85
IODA	0.97	0.97	0.94–0.98

ICC: intraclass correlation coefficient.

higher with PICO method than with IODA method (respectively from 0.54 to 0.85 vs from 0.94 to 0.98).

Table 3 shows that the inter-rater reliability of the four observers is better for IODA method than for PICO one, when considering the Bland-Altman limits of agreement of each pair of observers. The width of the 95%CI limits of agreement is two/three times lower with IODA method (from 4.8% to 8.1%) than with PICO method (from 14.3% to 18.8%).

The inter-rater reliability of the four observers confirmed to be significantly higher with IODA method than with PICO method. The concordance correlation coefficient showed a substantial concordance correlation for all the pair of observers with IODA method

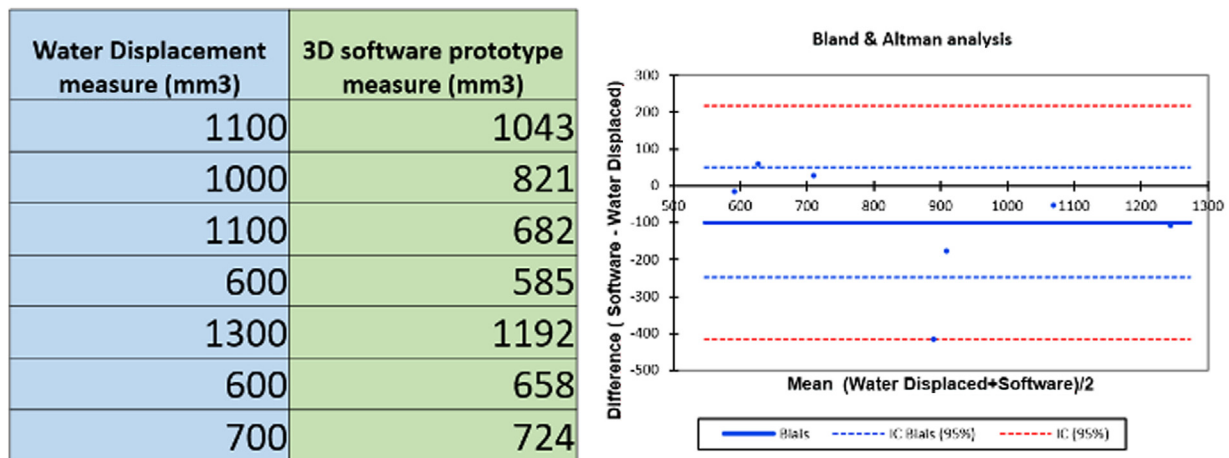


Fig. 9. Bland-Altman plot of water displacement compared to software method.

Table 3

Bland-Altman analysis (including 95%CI limits of agreement) for PICO or IODA methods for each pair of observers.

	PICO method			IODA method		
	Lower (%)	Upper (%)	Width (%)	Lower (%)	Upper (%)	Width (%)
Obs1 vs. Obs2	-8.5	7.7	16.7	-3.8	4.2	8.1
Obs1 vs. Obs3	-8.9	9.9	18.8	-3.0	2.8	5.9
Obs1 vs. Obs4	-6.2	9.5	15.7	-1.9	2.9	4.8
Obs2 vs. Obs3	-6.2	8.1	14.3	-2.8	2.2	5.0
Obs2 vs. Obs4	-5.5	9.7	15.1	-3.1	3.7	6.8
Obs3 vs. Obs4	-7.8	10	17.8	-2.2	3.4	5.7

Table 4

Lin's concordance correlation coefficient (including 95CI) for PICO and IODA methods for each pair of observers.

	PICO method		IODA method	
	Value	95CI	Value	95CI
Obs1 vs. Obs2	0.81	0.60–0.91	0.96	0.89–0.98
Obs1 vs. Obs3	0.69	0.46–0.83	0.98	0.94–0.99
Obs1 vs. Obs4	0.81	0.60–0.92	0.98	0.93–0.99
Obs2 vs. Obs3	0.74	0.49–0.87	0.98	0.95–0.99
Obs2 vs. Obs4	0.76	0.52–0.89	0.97	0.91–0.99
Obs3 vs. Obs4	0.65	0.38–0.82	0.97	0.91–0.99

(Lin's coefficient from 0.96 to 0.98), and a poor concordance with PICO method (Lin's coefficient from 0.65 to 0.81) (Table 4).

The reliability of the semi-automated software method IODA are shown in Figs. 10 and 11, reporting the graphical differences between the two methods for each pair of observers.

Moreover, the processing time to obtain the GBL calculation from the DICOM input is approximately 2 minutes, whereas using the traditional PICO it takes about 20 minutes.

4. Discussion

Main findings of the present investigation suggest that the IODA software achieves a better estimation of the GBL in either ex vivo or in clinical setting (compared to PICO method). The intra-rater reliability of the new IODA software is significantly higher than the one found adopting the classical PICO Surface area method (ICC respectively 0.97 vs 0.76). When considering the excellent ICC with PICO method, we must stress that all the four observers had a satisfactory skill and expertise of such method, which is, now, the golden standard for GBL measurement. Even the inter-rater reliability with the IODA software is statistically significantly higher than with PICO method in all pair of observers. The concordance plot on all the

IODA method shows a minimal deviation from the line of perfect concordance and this makes us assert that with such method there is greater concordance among observers.

Furthermore, the time expense of the PICO method is considerably reduced. These results confirmed the study hypothesis, that the IODA automation highly reduces dependencies of GBL estimation due to user individual ability and expertise and drastically reduces timing of measurement. Using IODA a high visualization quality is available for the operator and, at the same time, the possibility of evaluating the GBL in 3D from various angles and the possibility of analyzing the 3D medial extension of the defect (Fig. 5), otherwise not possible using the 2D PICO method (Fig. 6). Surgical treatment of traumatic instability should be carefully planned, taking into account concomitantly soft tissue and bony defect, in order to provide a full stability both caring of joint congruence and ligamentous balance [15,19]. Bankart procedures alone, in the presence of a misdiagnosed or mistreated relevant bone loss, lead to detrimental outcomes, with up to 67% recurrence of instability [4,20–23]. Moreover, in the last ten years, soft tissue procedures augmenting the Bankart repair like remplissage or ASA have been demonstrated to be effective in restoring joint stability drastically reducing the recurrence rate of the Bankart repair alone in patients with a GBL 15% and an ISI score > 3 [23]. According to these results, in presence of critical GBL an anterior glenoid reconstruction is required. This technique consists in a coracoid transfer (Latarjet) or bone graft transfer (Bone Block technique) [24–27]. Several bone-focused procedures have been developed [1,4,10,28], although high complications rate have been reported for Bristow-Latarjet-Patte procedure and for bone block augmentation and Eden-Hybinette technique [27,29], inescapably leading to the development of glenohumeral osteoarthritis [30]. The Latarjet procedure provides satisfactory outcomes with its triple effect, however, this procedure is not anatomical and is often associated with a high rate of complications [29]. The bone block needs an autograft or an allograft [26].

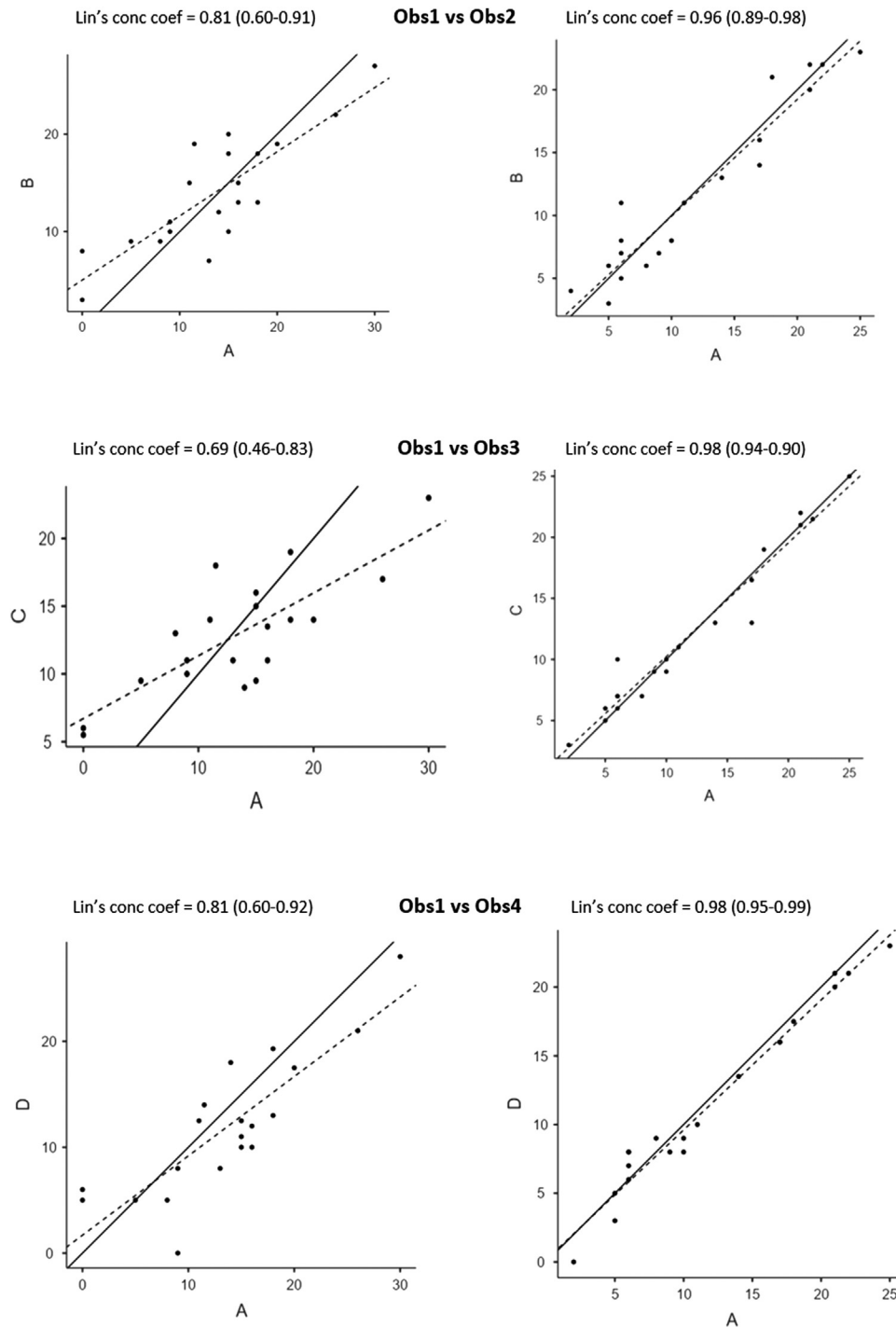


Fig. 10. Concordance of the first 3 pair of observers with PICO system (left) and IODA system (right).

The main issue at present is that a consensus concerning the critical GBL value still lacks, with suggested values ranging between 13.5% [31] and 25% [32], according to literature, with even 13.5% now being an end decision point to decide for glenoid reconstruction procedure instead of soft tissue repair alone. Moreover, following the doubt of an underestimate of the defect, the surgeon could force the indication of a bony procedure specially if an open Latarjet is planned, where it is not possible to perform a double check of the GBL arthroscopically. This inconsistency often misleads the surgeon from an appropriate surgical planning, in the decisional process about the need of a bony procedure in association to soft tissue repair. To achieve this result, improve decisional algorithm

and avoid an overtreatment, there is a need for an accurate and reproducible method for estimation of GBL. In the actual scenario, the tools developed are often inaccurate and complex to be used by inexperienced surgeons or radiologists, outside from specialized centers [33].

Several methods have been advocated for estimation of bony defect, although results of concordance and usability were not satisfying [10]. In the cadaveric study by Arenas-Miquelez et al. [34], the highest consistency coefficient (ICC) reported for experienced observers was 0.87 using 2D Barchilon method (0.809 for PICO method), with less than 2% overestimation of the defect. However, no 2D or 3D method achieved an ICC over 0.9. For less

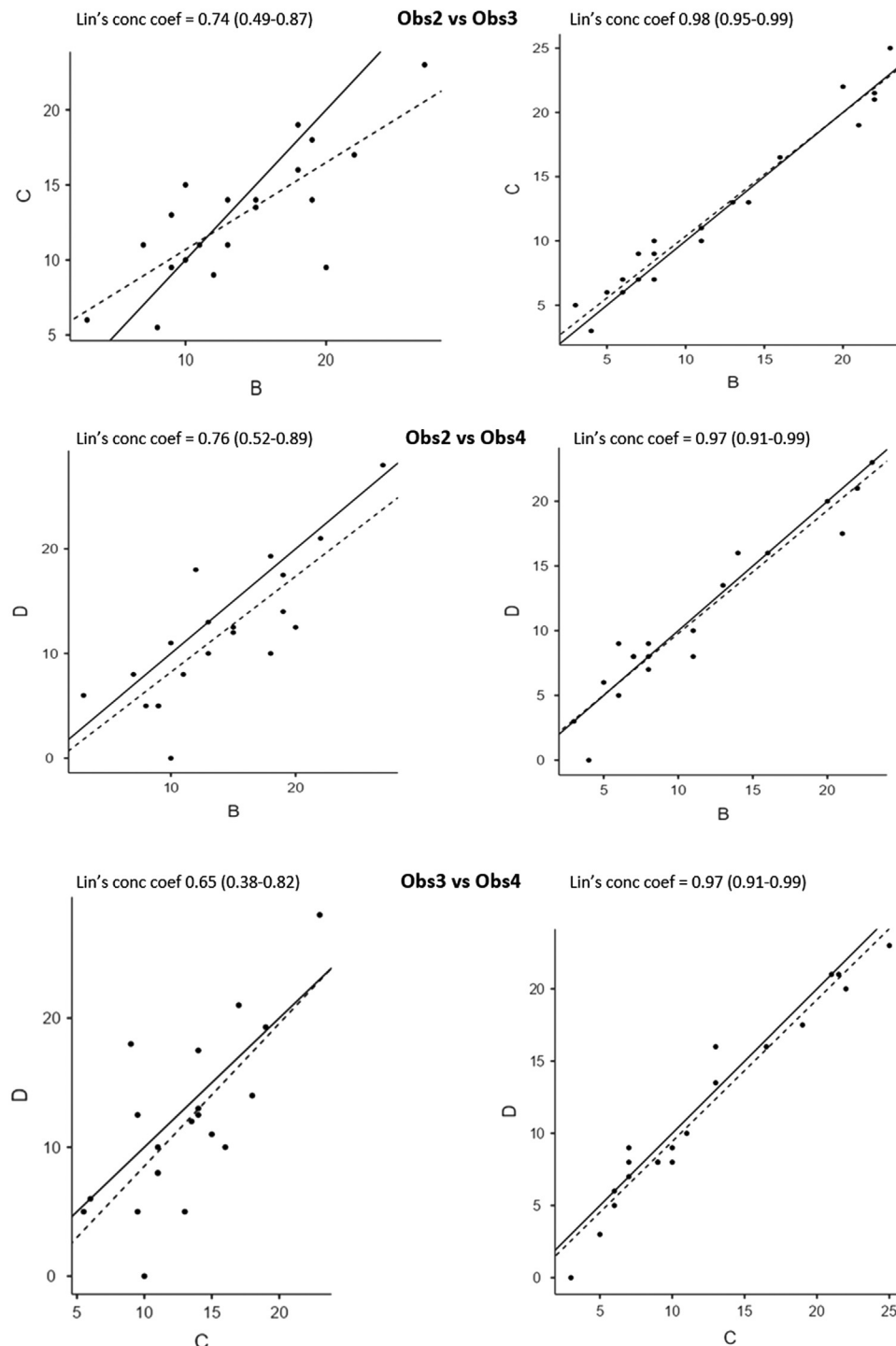


Fig. 11. Concordance of the last 3 pair of observers with PICO system (left) and IODA system (right).

experienced observers, the 2D Barchilon method achieved an ICC of 0.394 and PICO method achieved an ICC of 0.76 [10]. However, the low sample size did not allow to achieve statistical significance in the evaluation of the different methods. A comparison of the linear and surface-based methods in a clinical setting have been carried out in the study by Bakshi et al. [11]. On 29 adult subjects results showed an inter-rater agreement of 0.97 using PICO method and of 0.95 using linear method ($p < 0.001$), with linear methods leading to a 5% to 10% overestimation of GBL, in comparison to PICO method. More recent methods, caring about glenoid natural concavity were advocated [35]. In the report, authors found

a 0.95 ICC for Anatomic Concave Surface Area (ACSA) method, in comparison to best fit circle (ICC 0.71) and of glenoid height/width method (ICC 0.79), with a difference in mean estimation reported to be up to 8.2% (9.4% using ACSA vs. 17.6% using glenoid H/W, $p < 0.001$) [35]. It seems clear that glenoid concavity plays a major role in estimating the defect and can not be neglected, a key point already focused in preceding studies [3,36]. Furthermore, recent studies suggested that taking the contralateral glenoid as a reference improved the GBL estimation, with an ICC of 0.98 vs. 0.91 using contralateral area comparison or best fit circle, respectively [37]. This highlights that contralateral glenoid comparison is another

fundamental spot proposed in the tool developed in the current study.

Area method is more reliable than Linear method [13] which overestimates deficit [2,11]. Area method is not issues free, in fact Scapula tilt in enface view is a problem and best fit circle positioning is a problem [36].

Besides, even if PICO is the overall most accepted area method to estimate GBL, different observers landmark in different way, due to their different skill, hence correct estimation can be affected and therefore clinical decisions. In our study the new procedure proposed improves inter-observer reliability in the glenoid deficit percentage estimation. The reduced presence of lacks is mainly brought by the glenoid bone automated reconstruction coming within the prototype. Besides, leveraging on the 3D artifact we have been able to operate straightly on a reconstructed deficit, putting the best fitting ideal circle and landmarking on a single artifact instead of 2, like in PICO (injured and contralateral glenoid). As a further added value, operating in a 3D environment gives feedback in assessing morphological assets and render easy manage landmarking respect to the sagittal oblique plans used in the PICO. Some limitations affect the results of our investigation, which is however preliminary as for its design. The study has been conducted in an experimental setting; thus no clinical assessment is available on patients which allowed for images processing. This will be the focus of future investigations using IODA software. Furthermore, the authors acknowledge the narrow sample size, in the absence of a prospective quantification and power analysis; however, as a pilot study, the data provided by this investigation will be used for a more accurate estimation of sample size in future clinical studies. Moreover, there is a lack of an intraoperative measurement of GBL, to compare radiologic estimation with in vivo measurement. Furthermore, in those cases where contralateral glenoid presents other defects (previous trauma or surgery, bone dysplasia) the IODA calculation could be more difficult or at times impossible to carry out. For those cases, further development of the software is ongoing, with possible unilateral (index) glenoid rendering at maximum likelihood. Eventually, the GBL calculation has been carried out by only highly-skilled observers, without assessing the effect of a calculation performed by a low-skilled surgeon. However, to our knowledge this study represents the first attempt at estimating GBL with an automated 3D-based software, that resulted highly performant in comparison to PICO method and with an excellent inter-observer reliability.

5. Conclusion

The intra- and inter-rater reliability using IODA method is significantly better than PICO method. The assessment of GBL using IODA method is time saving, avoiding significant inter- and intra-observer variation, mainly due to individual skill and experience in the method.

Ethics approval

Only experimental data were collected, without the active involvement of patients. All patients have given their informed consent to participate to the use of DICOM images and their processing. For the experimental (laboratory-controlled and software processing) nature of the study, approval by the local Ethical Committee was waived. The investigation was carried out with the respect of the Declaration of Helsinki and according to the standards of Good Clinical Practice.

Patient confidentiality and consent for publication

Written consent was obtained from all the patients for publication of aggregated data and any accompanying image for research purpose. A copy of written consent is available for review.

Disclosure of interest

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Author's contributions

MM and SDN conceived and developed the software and carried out preliminary validation procedures. MM, MOG, AA and SB performed the validation assessment. MC performed formal analysis of data. GT wrote and edited the manuscript. MM, SDN and MOG edited the manuscript. MM and MOG supervised the work and performed a final review. All the authors read and approved the final manuscript.

Artificial intelligence statement

No artificial intelligence was used for the writing of the submitted work.

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