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Adjustment method for mechanical Boston scientific corporation 30 MHz intravascular ultrasound catheters connected to a Clearview® console

Mechanical 30 MHz IVUS Catheter Adjustment

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Abstract

Intracoronary ultrasound (ICUS) is often used in studies evaluating new interventional techniques. It is important that quantitative measurements performed with various ICUS imaging equipment and materials are comparable. During evaluation of quantitative coronary ultrasound (QCU) software, it appeared that Boston Scientific Corporation (BSC) 30 MHz catheters connected to a Clearview® ultrasound console showed smaller dimensions of an in vitro phantom model than expected. In cooperation with the manufacturer the cause of this underestimation was determined, which is described in this paper, and the QCU software was extended with an adjustment. Evaluation was performed by performing in vitro measurements on a phantom model consisting of four highly accurate steel rings (perfect reflectors) with diameters of 2, 3, 4 and 5 mm. Relative differences (unadjusted) of the phantom were respectively: 15.92, 13.01, 10.10 and 12.23%. After applying the adjustment: −0.96, −1.84, −1.35 and −1.43%. In vivo measurements were performed on 24 randomly selected ICUS studies. These showed differences for not adjusted vs. adjusted measurements of lumen-, vessel- and plaque volumes of −10.1 ± 1.5, −6.7 ± 0.9 and −4.4 ± 0.6%. An off-line adjustment formula was derived and applied on previous numerical QCU output data showing relative differences for lumen- and vessel volumes of 0.36 ± 0.51 and 0.13 ± 0.31%. 30 MHz BSC catheters connected to a Clearview® ultrasound console underestimate vessel dimensions. This can retrospectively be adjusted within QCU software as well as retrospectively on numerical QCU data using a mathematical model.

Introduction

Intravascular ultrasound (IVUS) and intracoronory ultrasound (ICUS) allow transmural, highly detailed tomographic imaging of blood vessels providing insights into the pathology of vessel wall disease by defining its geometry and showing major components of atherosclerotic plaques. The advantages of this technology have been described in many publications [1–3]. The ability of ICUS to detect and show small amounts of intima hyperplasia has made this technique popular to visualize and quantify results of new interventional techniques such as for example, the revolutionary new drug-eluting stents. The results of the first drug-eluting stent studies are showing extremely good results [4]. However, it is possible that small amounts of intima will grow into these stents over time. To monitor this process, ICUS, followed by quantitative coronary ultrasound analysis (QCU), is being applied in most of these ongoing studies. The quantification of small amounts of plaque requires accurate and reliable QCU measurements.

Recently, we started a validation project of a new QCU package CURAD (CURAD, Wijk bij Duurstede, Netherlands) [5]. Since in our institution multiple different ICUS catheters and consoles are used, it was decided to perform an in vitro study to validate the whole measurement 'chain' from catheter until final analysis. During this validation, an underestimation of dimensional measurements was found when using 30 MHz mechanical rotating ICUS catheters from the Boston Scientific Corporation (BSC, IVUS Technology Center, Fremont, CA, USA), formerly known as Cardiovascular Imaging Systems (CVIS), connected to a BSC Clearview® console. We report our findings of this validation study, identify the found problem and describe solutions developed in cooperation with BSC, the manufacturer.

Methods

ICUS equipment

For the in vitro validation study we used two ultrasound consoles: (1) a BSC Clearview® console and (2) a Jomed In-Vision Gold console. Two different catheters were connected to the Clearview® console: (1) a 30 MHz mechanical rotating element [6] catheter and (2) a 40 MHz mechanical rotating element catheter, both manufactured by BSC. To the In-Vision Gold system we connected a 20 MHz electrical phased array catheter [7] (Figure 1).

In vitro ICUS imaging

A phantom model consisting of four steel rings with diameters of 2, 3, 4 and 5 mm (deviation <1%) was constructed for the validation study. The rings were mounted in a transparent synthetic housing (Figure 1). A special construction allowed the outer sheath of the mechanical BSC catheters to be straightened in the opening of the phantom and the ultrasound element positioned in the center of the steel rings. Unfortunately, such catheter

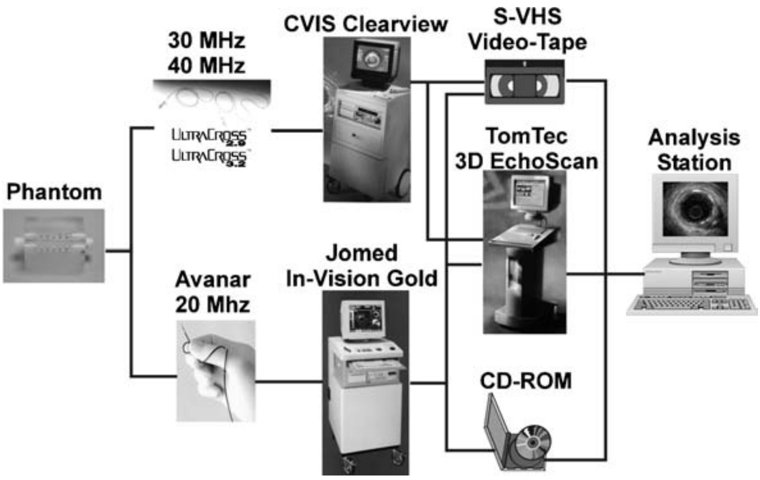

Figure 1. In this figure the measurement 'chain' is presented. At the left side the phantom is visible. Then there are two ultrasound consoles, (1) a BSC Clearview® and (2) a Jomed In-Vision Gold. One 30 MHz Ultracross® and one Atlantis™ 40 MHz catheter were connected to the Clearview®. To the In-Vision Gold console an Avanar® 20 MHz catheter was connected. Image data were stored on S-VHS video-tape, digitally on a 3D workstation (EchoScan, TomTec GmbH) and for the In-Vision Gold console also on CD-ROM. On the far right is the analysis station.

guidance could not be applied with the design of the phased array catheters; those do not have an outer sheath.

To transport the ultrasound waves, we used a fluids mixture containing 90% degassed water and 10% ethanol as the in vitro replacement for blood. The room temperature was 22°. This resulted in an ultrasound propagation speed of approximately 1.548 mm/μs [8]. The ultrasound propagation speed used to perform calculations in the BSC Clearview® console was 1.563 mm/μs. The speed used in the In-Vision Gold system was unknown.

The catheters were inserted into the phantom and pulled back using a device that pulled the catheters with a continuous speed of 0.5 mm/s [9]. The images were recorded for both systems on S-VHS videotape and simultaneously digitized using a three-dimensional (3D) workstation (EchoScan, TomTec GmbH, Unterschleissheim, Germany) [10]. On the In-Vision Gold system, the images were also stored on CD-ROM in the DICOM image format [11].

Patient population

For the in vivo measurements, we used 24 randomly selected ICUS image data sets, e.g. pullback sequences, previously acquired in patients participating in different interventional studies and were selected for analysis in this study since they were imaged with 30 MHz BSC mechanical rotating element catheters connected to a BSC Clearview® ultrasound console. All patients, except one, were imaged post-stent implantation.

In vivo ICUS imaging

All patients received 250 mg aspirin and 10,000 U heparin IV. If the duration of the entire catheterization procedure exceeded 1 h, the activated clotting time was measured, and intravenous heparin was administered to maintain an activated clotting time of >300 s. The 30 MHz catheter used was equipped with a 2.9F 15-cm-long sonolucent distal sheath with a lumen that alternatively houses the guide-wire (during catheter introduction) or the ultrasound transducer (during imaging, after retraction of the guide-wire). This design avoids direct contact of the ICUS imaging element to the vessel wall. The ICUS transducer was withdrawn with a pullback device operating with a continuous speed of 0.5 mm/s.

ICUS analysis protocol

The in vitro and in vivo ICUS image data sets were analyzed with an off-line semi-automated QCU software package, CURAD [5]. The pullback sequences recorded on S-VHS videotapes were digitized with a frame-grabber. The software translated them into the DICOM imaging standard [11]. Calibration of the videotaped images is performed using the calibrated grid on the images provided by the manufacturer. It also imported already digitized data recorded on Magneto-Optical disk from the 3D EchoScan workstation or imports any other DICOM image sequence, such as stored on CD-ROM from the In-Vision Gold system (Figure 1). The acquired in vitro ICUS images from the phantom with the 30 MHz BSC catheter were also analyzed on the 3D EchoScan workstation and on the Clearview® console itself (Figure 2).

Adjustment of BSC 30 MHz catheter measurement underestimation

During the validation of the QCU software, it became apparent that the 30 MHz BSC catheters showed considerably different measurement results than the other two catheter types (results in Table 1), and from what could be expected theoretically. After consulting with the research and development department of BSC the following explanation was given for this underestimation: The catheter configuration of the BSC catheters contains an outer sheath to prevent direct contact of the ultrasound element to the vessel wall. For the Ultracross® 30 MHz catheters this sheath has a wall thickness of 127 μm. This thickness will delay the ultrasound signal (Figure 3). This issue was not taken into account with previous software versions on the BSC ultrasound consoles. The speed of sound in the sheath material is 2.38 mm/μs. The temperature dependence of this speed is negligible for the sheath material used over the

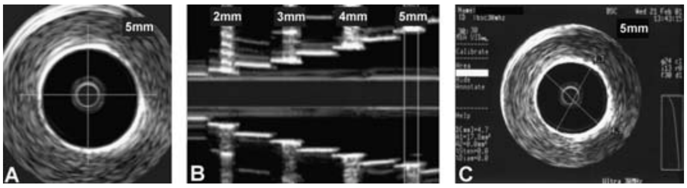

Figure 2. Images of the phantom. Panel A shows a cross-sectional ultrasound image of the 5 mm steel ring acquired with a 30 MHz Ultracross® catheter. In panel B, a 2D reconstructed longitudinal reconstruction of the 2, 3, 4 and 5 mm steel rings from the phantom is shown. In panel C, a screen dump of the measurements on the BSC Clearview® ultrasound console itself is presented.

Table 1. In vitro validation.

	BSC 30 MHz					BSC 40 MHz		Jomed 20 MHz	
Phantom Ring	Area ($\pi * r^2$)	Area Unadjusted	Δ% C2 vs. C1	Area Adjusted	Δ% C4 vs. C1	Area	Δ% C6 vs. C1	Area	Δ% C8 vs. C1
2	3.14	2.64	15.92	3.11	−0.96	3.11	−0.96	3.11	−0.96
3	7.07	6.15	13.01	6.94	−1.87	7.14	0.98	7.13	0.84
4	12.57	11.3	10.10	12.4	−1.37	12.33	−1.95	12.44	−1.05
5	19.63	17.23	12.23	19.35	−1.45	19.6	−0.15	19.96	1.65
	C1	C2	C3	C4	C5	C6	C7	C8	C9

In column 1 (C1) the theoretical areas are given. In C2, C6 and C8 the measured areas are presented. In C4 the area results from the adjusted quantitative coronary ultrasound software are presented. In C3, C5, C7 and C9 the relative differences between the measured and the theoretical areas are given.

Figure 3. The increased propagation speed of the ultrasound signal crossing the catheter sheath was neglected in the BSC 30 MHz Ultracross® software in the Clearview® instrument. This must be taken into account for accurate radial, and thus also area measurements. Applying Equation 1 can retrospectively do this.

range of temperatures of interest. The transducer is tilted 5° from the normal to the sheath. The curvature of the sheath is not taken into account. The Clearview® instrument assumes a 1.563 mm/μs propagation speed. The two-way transit through the sheath in pulsed-echo mode therefore introduces a radial adjustment term (RAT) that can be calculated as

$$\mathrm{RAT} = 2 * \frac{1.5625\left(\frac{0.127}{1.5625} - \frac{0.127}{2.38}\right)}{\cos\left(5 * \frac{\pi}{180}\right)} = 87.6\,\mu\mathrm{m} \quad (1)$$

The factor of two accounts for the pulsed echo two-way transit and the numerator accounts for the difference in transit time due to the sheath and what the machine assumes. The cosine factor corrects for the tilt angle.

The adjustment term applies to any radial measurements, thus also influences area measurements. Any diameter measurement made with Ultracross® 30 MHz catheters on a Clearview® console with software version 4.11, 4.12 and 4.22 should add $2 * 87.6 = 175.2$ μm to bring their results in line with Atlantis™ 40 MHz catheters or 20 MHz Jomed phased array catheters or all BSC catheters operated on the BSC Galaxy™ ultrasound console.

For an accurate adjustment, the RAT needs to be applied to the raw contour data. Therefore, it has been implemented in the core of the QCU software.

BSC 30 MHz mathematical model based adjustment

Besides the integrated QCU solution to adjust for the underestimation of measurements, as described above, a mathematical model was developed to be applied to numerical QCU result data (areas and volumes), avoiding the necessity to perform a time consuming complete re-analysis of previously measured data.

The model is based on two output parameters incorporated in the QCU software, namely the projected maximum and projected minimum diameter of each contour [12]. In the model, an adjustment factor to be applied to the measured cross-sectional area, is calculated as the ratio of adjusted and not adjusted areas of a mathematical ellipse described by the maximum and minimum projected diameters as its long and short axis respectively:

$$\text{Adjusted area} = \text{Unadjusted area} * \left(1 + 2 * \mathrm{RAT} * \left(\frac{d+D}{d*D}\right) + \frac{4*\mathrm{RAT}^2}{d*D}\right) \tag{2a}$$

where d is the projected minimum diameter and D the projected maximum diameter and $\mathrm{RAT} = 87.6\ \mu\mathrm{m}$ (Figure 4A and C). The last term, $(\frac{4*\mathrm{RAT}^2}{d*D})$, is a very small contributing component to the final adjusted area (<0.5%) and was therefore neglected. The applied formula is thus:

$$\text{Adjusted area} = \text{Unadjusted area} * \left(1 + 2 * \mathrm{RAT} * \left(\frac{d+D}{d*D}\right)\right) \tag{2b}$$

This formula (Equation 2b) was also applied for adjustment of the total measured volume (mean area times segment length) of the analyzed segment, with d and D in this case taken as the mean projected diameters of the analyzed segment. This was done to investigate if a time-consuming re-calculation per frame could be avoided.

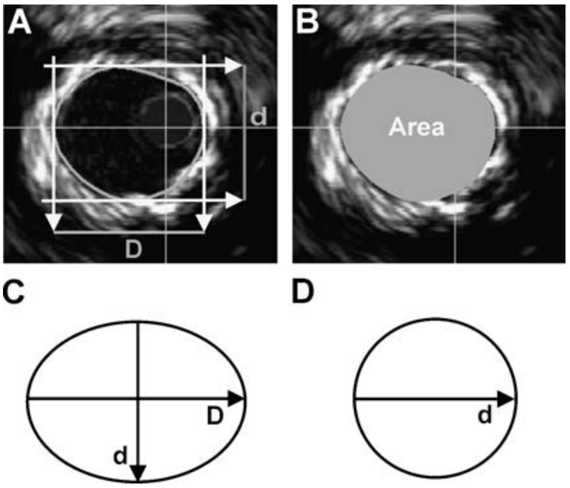

Figure 4. In panels A and C, the elliptical model based on the projected contour diameters is presented. The ellipse is defined by the projected minimum contour diameter (*d*) and the projected maximum contour diameter (*D*) (Equation 2). In panels B and D, the circular model is presented. From the detected contour, the enclosed area is calculated. This area defines the circle to which the radial adjustment factor can be applied (Equation 3).

There are other QCU software packages that do not calculate the projected contour diameters in their analyses. Therefore, we investigated if a circular model could also be applied for retrospective adjustment to area measurements:

$$\text{Adjusted area} = \text{Unadjusted area} * \left(1 + \frac{2*\mathrm{RAT}}{d}\right)^2 \tag{3}$$

Where d is the mean contour diameter in a single cross-sectional frame as derived from the measured area $d = \sqrt{\frac{2A}{\pi}}$, $\mathrm{RAT} = 87.6\ \mu\mathrm{m}$ (Figure 4B and D).

Statistical analysis

Quantitative data are presented as mean ± standard deviation (SD). All results are plotted in diagrams according to Bland and Altman [13].

Results

In vitro validation

In Table 1, the results of the in vitro phantom measurements, additional adjustment and recalculations are presented. Area measurements for the BSC 40 MHz (C6 and C7) and the Jomed 20 MHz (C8 and C9) were within a maximum relative range of 2% difference. However, the BSC 30 MHz catheter showed a relative difference up to 15.92% (C2 and C3). After applying the RAT within the QCU software, the recalculated results of the 30 MHz catheters came into the same accuracy range as compared to the other two catheters (C4 and C5).

In vivo measurements

In Table 2, all in vivo results are presented. The relative differences between the actual and the adjusted volumetric results were quite large (C1–C3).

Applying the mathematical models, operating retrospectively on the numerical output, the relative differences found were for area adjustment per frame and subsequent recalculation of the volumes for the lumen 0.31 ± 0.53% (C7). It was for adjustment on the total volume 0.36 ± 0.51% (C5) and finally for the circular model 0.66 ± 0.52% (C9). Similar results were found for the total vessel and plaque measurements. Bland–Altman results for these measurements are presented in results plot 1 (Figure 5).

Discussion

The present study demonstrates that measurements performed with BSC 30 MHz catheters connected to a Clearview® console underestimate true dimensions. Such findings have been previously reported [14, 15]. With the explanation of the cause of the problem as supplied by BSC, the manufacturer, an adjustment was integrated into the QCU analysis software.

After verification that this method of adjustment brought dimensional measurements for BSC 30 MHz catheters well into range with the other investigated catheters and consoles, the adjusted results could be used to test a mathematical model working retrospectively on previously calculated numerical QCU data. From the derived mathematical models (Equations 2b and 3) it was surprising to see that of all three different methods of recalculating the volumes, even the worst relative difference was, on average, well below 1% in comparison to adjusted re-analysis within the QCU software. Even the simple circular model, resulting in a relative difference of 0.66 ± 0.52% for lumen and 0.26 ± 0.32% for the total vessel volumes, appeared to be a valid method for retrospective adjustment.

Table 2. In vivo measurements.

	Volume	Volume adjusted	%Δ C1 vs. C2	Model	%Δ C4 vs. C2	Analysis per frame	%Δ C6 vs. C2	Circular analysis PF	%Δ C8 vs. C2
Lumen	177.87 ± 62.58	197.49 ± 69.32	−10.01 ± −7.04	198.24 ± 69.64	0.36 ± 0.51	198.10 ± 69.49	0.31 ± 0.53	198.79 ± 69.73	0.66 ± 0.52
Vessel	475.83 ± 289.97	508.66 ± 307.59	−6.71 ± 0.92	509.23 ± 307.28	0.13 ± 0.31	509.13 ± 307.2	0.12 ± 0.32	509.78 ± 307.49	0.26 ± 0.32
Plaque	297.96 ± 241.35	311.17 ± 251.59	−4.38 ± 0.59	310.99 ± 251.37	−0.06 ± 0.26	311.03 ± 251.50	−0.06 ± 0.29	310.99 ± 251.52	−0.08 ± 0.27
	C1	C2	C3	C4	C5	C6	C7	C8	C9

In column 1 (C1) the measured volumes are presented. In C2 the results from the adjustment quantitative coronary ultrasound (QCU) software are given. In C3 the relative differences between the actual and the adjusted results are given. In C4 the results of the mathematical model applied to the total measured volume of the coronary segment are presented. C5 shows the relative differences between the model output and the adjusted results. In C6 the mathematical model is applied to each individual frame followed by recalculation of the volumes, relative differences are shown in C7. In C8 the volumes are recalculated assuming a circular model for each individual frame. C9 shows the accompanying relative differences against the model QCU output.

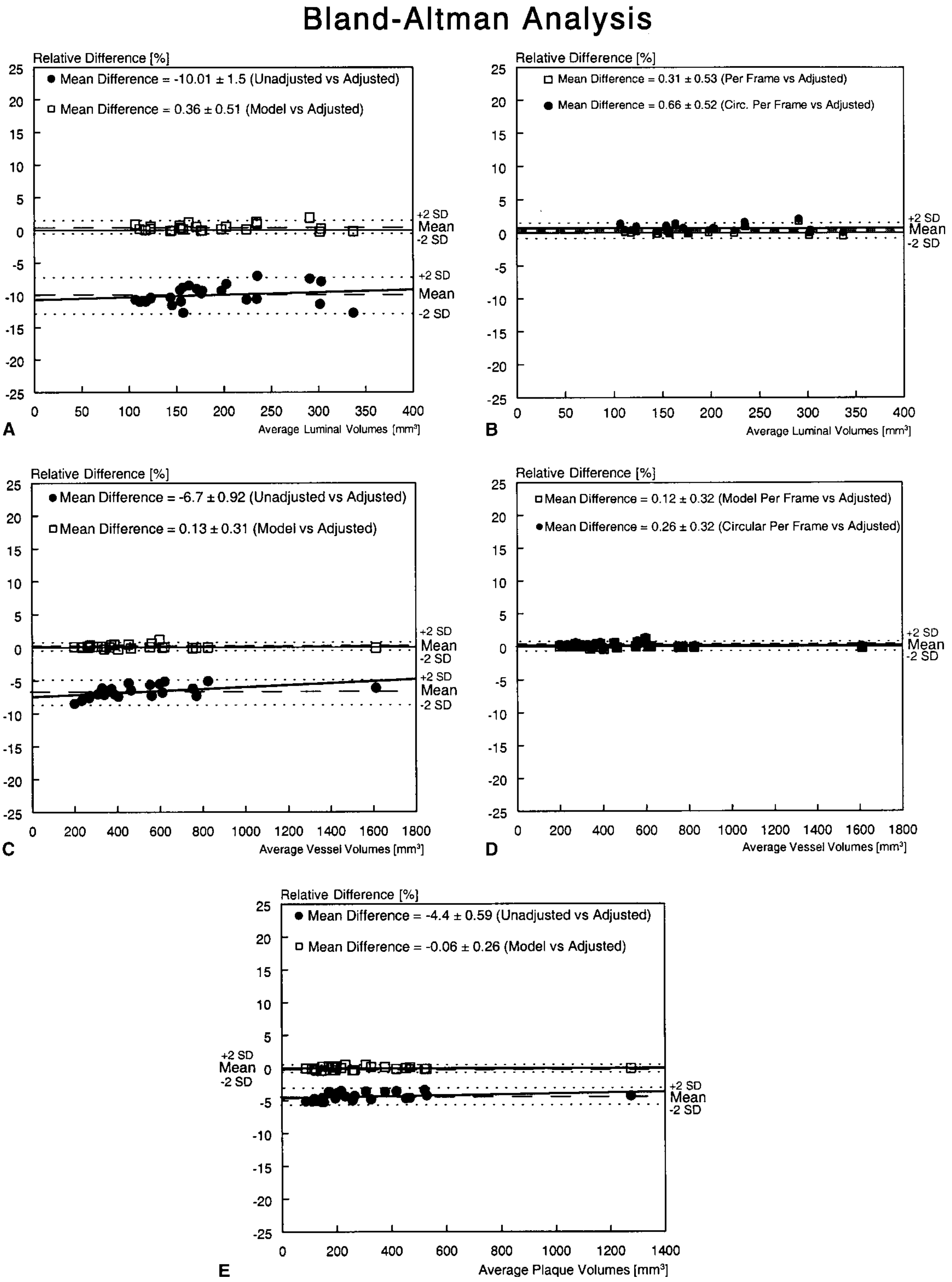

Figure 5. The results plot. In the top two graphs (A and B) the Bland–Altman analysis of the luminal volumetric measurements is presented. At the left side is the before and after adjustment within the QCU software. At the right side are the relative difference results of the two mathematical models compared to the QCU adjustment. In panels C and D the results of the vessel volumetric measurements are presented in a similar fashion as for the lumen results. In panel E, finally the plaque results are shown.

BSC states a diameter accuracy claim of ± 300 μm or ± 10%, whichever is greater and that the underestimation found is within this accuracy claim. The newly developed 40 MHz catheters on the Clearview® console, as well as catheters on the Galaxy™ console utilize an algorithm that further improves accuracy.

It is important to note that the adjustment is not cancelled in the plaque calculation. This results in a mean underestimation of plaque volume of 4.4% (Table 2). The adjusted plaque volume is the difference of the adjusted vessel and lumen volumes.

Clinical implications

In some baseline and follow-up studies we encountered that patients have been imaged using various catheters at different times. For example, at baseline with a 30 MHz catheter and at follow-up with a 40 MHz catheter, or *vice versa*. From the analysis provided in this paper, comparison between these two data sets would not be appropriate as the plaque volume; for example, from the 30 MHz catheter would yield a 4.4% underestimation. We recommend that the adjustment factor provided in this paper be applied according to the methods described in this paper. Some previously published results such as the choice of balloon size based on QCU measurements [16], clinical decision making of stenting in small vessel using ICUS based measurements [17, 18] or comparison papers of QCU vs. QCA [12, 19], may benefit from applying the adjustment factor retrospectively.

Potential sources of error and study limitations

The liquid solution used with the reported room temperature did not exactly match the ultrasound propagation speed implemented by BSC, although the difference is rather small, 1.548 vs. 1.563 mm/μs [8], leading to an area measurement inaccuracy of about 1.5%. The steel rings used in the phantom cause 'hard' reflections, which can lead to a 'blurred' effect on the ICUS images causing inaccurate measurements. Other researchers suggested using soft reflectors [20]. However, many of these materials are more temperature dependent, which can cause shrinkage or enlargement when put in a water bath.

Conclusion

30 MHz mechanical element catheters from BSC connected to BSC Clearview® ultrasound consoles underestimate true dimensions. This can be solved prospectively within QCU software as well retrospectively with a simple mathematical model on already analyzed ICUS image data sets.

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