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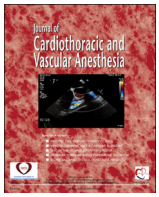

Original Article

Electrical Cardiometry: A Reliable Solution to Cardiac Output Estimation in Children With Structural Heart Disease

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Objective: Comparison of cardiac output (CO) obtained using electric cardiometry (EC) and pulmonary artery catheterization (PAC) in pediatric patients with congenital structural heart disease.

Design: Prospective, observational study.

Setting: A tertiary hospital.

Participants: The study comprised 50 patients scheduled to undergo cardiac catheterization.

Interventions: CO data triplets were obtained simultaneously from the cardiometry device ICON (Osypka Medical, Berlin, Germany) and PAC at the following predefined time points—(1) T1: 5 minutes after arterial and venous cannulation and (2) T2: 5 minutes postprocedure; the average of the 3 readings was calculated. Reliability analysis and Bland-Altman analysis were performed to determine the limits of agreement, mean bias, and accuracy of the CO measured with EC.

Measurements and Main Results: The measured EC-cardiac index 4.22 (3.84-4.60) L/min/m^2 and PAC-cardiac index 4.26 (3.67-4.67) L/min/m^2 were statistically insignificant (p value > 0.05) at T1. Bland-Altman analysis revealed a mean bias of 0.0051 L/min/m^2 and precision limits of $\pm$ 0.4927 L/min/m^2. The intraclass correlation coefficient was 0.789 and Cronbach's alpha was 0.652, indicating good reproducibility and internal consistency between the two techniques. Postcatheterization analysis also revealed strong agreement and reliability between the two techniques.

Conclusions: This study demonstrated that cardiac indices measured in children with a variety of structural heart diseases using EC reliably represent absolute values obtained using PAC. EC technology is simple and easy to use and offers noninvasive beat-to-beat tracking of CO and other hemodynamic parameters in children with structurally abnormal hearts.

Key Words: pediatric cardiac output monitoring; congenital heart disease; noninvasive; electric velocimetry; thoracic electrical bioimpedance; pulmonary artery catheter

CARDIAC FUNCTION ASSESSMENT in the pediatric age group is difficult to perform, and pediatric intensivists and anesthesiologists mostly have relied on indirect assessment of cardiac performance (heart rate, blood pressure, pulse volume, central venous pressure) and end-organ perfusion (urine output, capillary refill, core-peripheral temperature difference, mental state, serum lactate concentration, and base excess). This reliance on surrogate markers of cardiac function is attributed to the existing deficiency of technology in pediatric cardiac output (CO) estimation and the belief that CO can be estimated clinically in children.[1–3] In the era of advancing

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technologies, reliance on nonspecific markers cannot be justified while administering treatment regimens in critically ill children because these markers have shown to be inaccurate[4] and may promote suboptimal or even inappropriate interventions.[5] Pulmonary artery catheterization (PAC), which still continues to be the gold standard technique for CO estimation in both children and adults, has limited scope in pediatric patients due to difficulty in venous cannulation, lack of availability of age-appropriate catheters,[6,7] and an inherent significant complication rate of this traditionally used method.[8] This also has made the validation of newer techniques of CO estimation in the pediatric population extremely difficult. As a result, CO estimation techniques designed so far, which have been evaluated thoroughly in the adult population under various clinical conditions, are yet to be validated for use in the pediatric age group.

Thoracic electrical bioimpedance (TEB)–based electrical cardiometry (EC) has an important role to play in addressing the unmet need for improved methods/devices to measure pediatric CO and hemodynamic function assessment. The technique is based on the maximum changes in the TEB as the ohmic equivalent of the mean aortic blood flow acceleration.[9–11] Orientation of the erythrocytes in the aorta changes quickly from random to alignment in the direction of blood flow on opening of the aortic valve. This alignment of erythrocytes during early systole produces a pulsatile change in electrical conductivity that is reflected in a decrease in electrical velocimetry during early systole and an increase later (Fig 1). CO then is calculated using the mathematical algorithms formulated by Bernstein and Lemmens in 2005.[12]

EC has been evaluated previously in the pediatric subset of the population (including low and very low birth weight infants) under various clinical scenarios and has shown comparable results with invasive technologies.[9,13–19] However, research is limited in patients with structural congenital heart disease, including shunts and obstructive lesions. Many children with long standing cardiac diseases are scheduled to undergo cardiac catheterization for detailed cardiac evaluation. The authors therefore seized this opportunity to compare CO values obtained noninvasively via the EC device ICON (Osypka Medical, Berlin, Germany) with those derived from the PAC to evaluate the efficacy and reliability of the EC device and to validate the device for use in the pediatric population with structural heart disease.

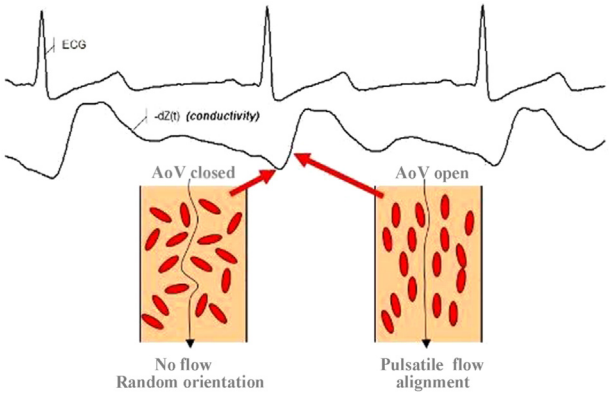

Fig 1. EC analysis of the rate of change in conductivity before and after aortic valve opening, which is based on how fast the red blood cells are aligning. The technology derives the peak aortic acceleration of blood and the left ventricular ejection time (flow time). The velocity of the blood flow then is derived from the peak aortic acceleration and used to derive stroke volume. AoV, aortic valve; dZ(t), conductivity; ECG, electrocardiogram.

Material and Methods

After obtaining written informed consent from parents of patients, the prospective, observational clinical study included 50 children scheduled to undergo elective cardiac catheterization procedures for various conditions under monitored anesthesia care/general anesthesia at a tertiary center for pediatric cardiology. Patients with hemodynamic instability requiring inotropic support, renal disease, hepatic disease, peripheral vascular disease (suggested by claudication or varicose veins or documented by previous Doppler studies), coagulopathies, and age $>$ 18 years were excluded from the study. All cardiac medications except diuretics and angiotensin-converting enzyme inhibitors were continued until the morning of the procedure. All children were premedicated with syrup chloral hydrate, 0.5 mL/kg, 30 minutes before the scheduled procedure. Intraoperative sedation was administered in the form of intravenous midazolam, 0.02 mg/kg. Twenty-two children required general anesthesia either due to lack of compliance or due to the need for transesophageal echocardiography during the procedure. Anesthesia was induced using inhalation induction with sevoflurane, and tracheal intubation was facilitated with injection of rocuronium, 1 mg/kg. Anesthesia subsequently was maintained using an oxygen, air and sevoflurane mixture at 1 minimum alveolar concentration. The airways of all children requiring general anesthesia were extubated successfully at the end of the procedure.

Cardiac Monitoring

The ICON EC device was connected, and patient demographic and anthropometric data (age, weight, height) were entered. Four skin electrodes (iSense Electrical Cardiometry Skin Sensors; Osypka Medical) were applied on the neck and thorax per manufacturer recommendations (Figs 2 and 3). Utmost attention was paid to the best signal quality, electrocardiogram, and dZ/dt curve as assessed using the signal quality indicator on the ICON monitor, which is similar to a cell phone reception bar. A balloon-tipped, flow-directed PAC (Edwards Lifesciences, Irvine, CA) was placed via the femoral vein up to the wedge position, and the correct position was confirmed radiographically and from pressure tracings. The femoral artery was cannulated for hemodynamic monitoring and obtaining blood samples for oximetry to calculate the CO using the direct Fick oxygen principle.

Data Acquisition

CO data triplets (3 serial measurements separated by an interval of 60 seconds each) were obtained simultaneously from both techniques at the following predefined time points—(1) baseline: 5 minutes after arterial and venous cannulation

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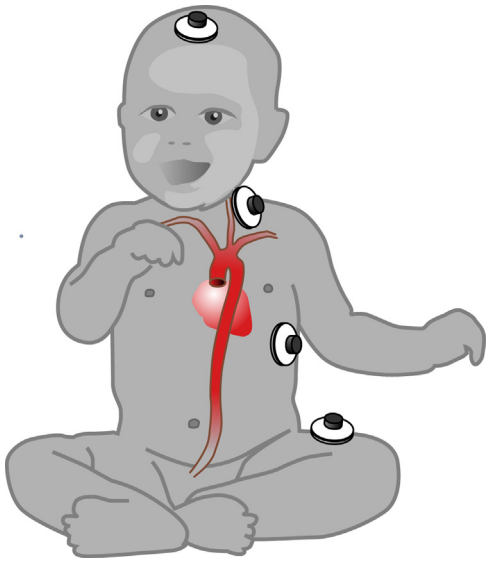

Fig 2. Placement sites for electrodes per recommendations from manufacturer.

and (2) T2: 5 minutes postprocedure. One hundred data triplets were generated for each parameter for both techniques and the average of the 3 readings was taken for analysis. None of the measurements were recorded during a hemodynamically unstable phase or during arrhythmias.

Statistics

Reliability of EC for assessing various hemodynamic parameters compared with PAC was examined using the reliability analysis. Reproducibility and internal consistency are different aspects of reliability and hence were estimated separately by calculating the intraclass correlation coefficient (ICC) and Cronbach's alpha, respectively. ICC is used to assess rating reliability by comparing the variability of different ratings of the same subject to the total variation across all ratings and all subjects. It has the advantage over correlation coefficient in that it is adjusted for the effects of the scale of measurements and that it will represent agreements from more than two raters or measuring methods. Cronbach's alpha is a measure of internal consistency, that is, how closely related a set of items are as a group. It is considered to be a measure of scale reliability and is written as a function of the number of test items and the average intercorrelation among the items.

The calculation also involved an initial two-way analysis of variance. Accuracy of the noninvasive device was defined as the agreement between the two methods of CO measurement using the Bland-Altman method. Bias was defined as the mean difference between COs derived from two sites or methods. Limits of agreement were calculated arbitrarily as ± 1.96 standard deviation of the bias.

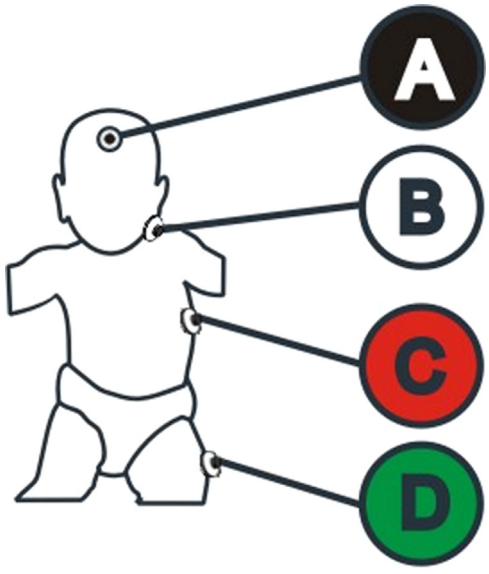

Fig 3. Placement sites for electrodes (specific to each letter) per recommendations from manufacturer.

Results

The study was performed in 50 children (28 males, 22 females) undergoing cardiac catheterization for various reasons, with a mean age of 6.4 ± 4.8 years, body surface area of 0.694 ± 0.24 m^2, and a hemoglobin concentration of 13.79 ± 2.07 g/dL. Demographic details of the patients and the procedures performed are given in Table 1. CO and stroke volume and their respective indices obtained using EC at baseline and after cardiac catheterization were not significantly different from those derived invasively from the PAC using the direct Fick oxygen method (Tables 2 and 3).

EC at baseline showed a cardiac index of 4.22 (3.84-4.60) L/min/m^2, which was similar to that obtained with cardiac catheterization, 4.26 (3.67-4.67) L/min/m^2 (p value > 0.05) (Fig 4). Bland-Altman analysis showed that EC measured the indexed CO, compared with PAC at baseline, with a mean bias of 0.0051 L/min/m^2 and with limits of agreement (± 2 standard deviation) of ± 0.49 L/min/m^2 (Fig 5). Reliability analysis revealed an ICC of 0.789 (average of raters), indicating a strong agreement between the 2 techniques of CO estimation. The Cronbach's alpha was 0.752, showing good internal consistency in CO estimation using EC.

Analysis at T2 revealed statistically insignificant CI values derived using EC (4.29 [3.99-4.73 L/min/m^2] and PAC (4.38 [3.95-4.76 L/min/m^2] (p value > 0.05), a mean bias of –0.015

Table 1
Patient Demographics

Procedure	Age Range (Years)	Number of Cases
ASD device closure	11-16	14
PDA device closure	02-07	13
PVBD	02-03	07
AVBD	01-03	08
MAPCA coil embolization	04-09	08

Abbreviations: ASD, atrial septal defect; AVBD, aortic valve balloon dilation; MAPCA, major aorto-pulmonary collateral arteries; PDA, patent ductus arteriosus; PVBD, pulmonary valve balloon dilation.

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Table 2
Hemodynamic Parameters Measured at Baseline Using EC and PAC

	EC	PAC	p Value
CO (L/min)	2.60 (2.10-3.92)	2.88 (2.20-3.72)	> 0.05
CI (L/min/m^2)	4.22 (3.84-4.60)	4.26 (3.67-4.67)	> 0.05
SV (mL/min)	26.00 (18.75-49.75)	25.38 (20.68-44.05)	> 0.05
SI (mL/min/m^2)	45.68 (38.36-51.26)	44.54 (38.03-47.67)	> 0.05

NOTE. Values are expressed as median (interquartile range). A p value < 0.05 is considered as statistically significant.
Abbreviations: CI, cardiac index; CO, cardiac output; EC, electric cardiometry; PAC, pulmonary artery catheterization; SI, stroke index; SV, stroke volume.

L/min/m^2, and precision limits of ± 0.49 L/min/m^2 (Fig 6) with an ICC of 0.907 (average of raters) and Cronbach's alpha of 0.866. The Bland-Altman analysis also was performed for stroke volume index measured during the study, and the results are shown in Table 4. Raw data in the form of the average of 3 readings are available as Supplemental Tables S1 and S2.

Discussion

Thermodilution and the direct Fick oxygen method are established, but invasive, gold-standard methods of measuring CO. Reluctance on the part of pediatric intensivists and pediatricians to measure CI in children using these traditional methods results from an inherent complication rate associated with them, difficulty in obtaining an adequate venous access (especially in the very young), or lack of availability of age-appropriate catheters.

The development of simple, safe, and noninvasive techniques for hemodynamic monitoring in children is highly desirable for optimal management in pediatric cardiac surgery and intensive care units because CO estimation is quintessential for diagnosing and monitoring children in shock and for the titration of cardiovascular drugs and fluids. EC is a noninvasive, easy to perform, and simple technique for CO measurement. According to the theory of EC, erythrocytes change their random orientation in the descending aorta during diastole to linear alignment as the heart begins to eject in systole.

Bioimpedance-based previous studies have shown mixed results when comparing impedance cardiography with PAC-derived CO.[10,20–22] Using the earliest versions of electrical impedance cardiography, Braden et al[20] and Miles et al[21] found good correlation between impedance cardiography and PAC-derived CO in young children with a variety of congenital heart diseases. Heringlake et al[22] and Tomasaki et al,[23] on the other hand, demonstrated a disagreement between these two methods before and after elective cardiac surgery, indicating a percentage error of 34% to 67%. With upgradation of the computer technology used and refinement of algorithms to calculate CO, the various problems with previous models now have been overcome and the technique now is referred to as "EC".

Most of the previous studies examining the utility of EC in estimating CO in the pediatric population have demonstrated a good degree of correlation with CO derived using aortic flow-based transthoracic echocardiography.[9,24] However, its performance against the gold-standard PAC seldom has been tested, primarily due to a very limited possibility of cardiac catheterization and PAC Fick CO assessment in noncardiac patients.

Table 3
Hemodynamic Parameters Obtained From EC and PAC After Cardiac Catheterization

	EC	PAC	p Value
CO (L/min)	2.60 (2.20-4.00)	2.60 (2.30-3.73)	> 0.05
CI (L/min/m^2)	4.29 (3.99-4.73)	4.38 (3.95-4.76)	> 0.05
SV (mL/min)	26.83 (20.47-44.56)	25.63 (21.05-43.41)	> 0.05
SI (mL/min/m^2)	45.72 (40.19-49.35)	44.73 (38.57-48.02)	> 0.05

NOTE. Values are expressed as median (interquartile range). A p value < 0.05 is considered as statistically significant.
Abbreviations: CI, cardiac index; CO, cardiac output; EC, electric cardiometry; PAC, pulmonary artery catheterization; SI, stroke index; SV, stroke volume.

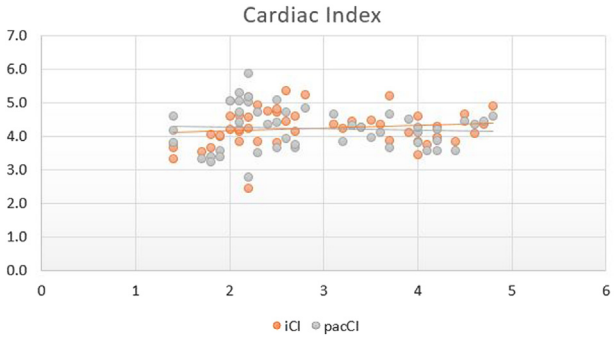

Fig 4. Scatter plot with points representing pairs of EC and PAC values at baseline. EC, electric cardiometry; iCI, ICON (EC) derived cardiac index; PAC, pulmonary artery catheterization; pacCI, PAC derived cardiac index.

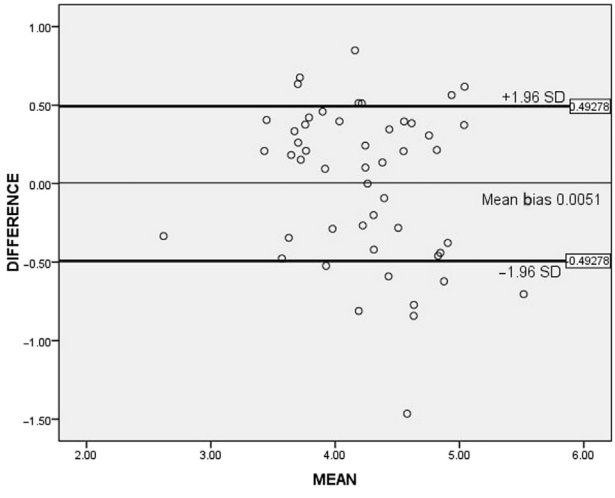

Fig 5. Bland-Altman analysis of cardiac index measured by electrical velocimetry and the direct Fick oxygen method at baseline. X axis: mean CI from EC and PAC ([EC–CI] + [PAC–CI])/2; Y axis: CI difference ([EC–CI] – [PAC–CI]). Mean bias = 0.0051 L/min/m^2, limits of agreement (± 2 standard deviation) ± 0.49 L/min/m^2. CI, confidence interval; EC, electric cardiometry; PAC, pulmonary artery catheterization; SD, standard deviation.

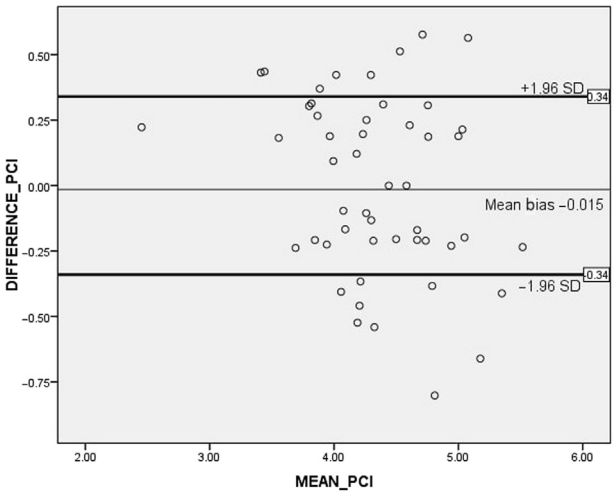

Fig 6. Bland-Altman analysis of cardiac index measured by electrical velocimetry and the direct Fick oxygen method after cardiac catheterization. X-axis (MEAN_PCI): mean CI from EC and PAC ([EC–CI] + [PAC–CI])/2; Y axis (DIFFERENCE_PCI): CI difference ([EC–CI] – [PAC–CI]). Mean bias = –0.015 L/min/m^2, limits of agreement ($\pm$2 standard deviation) $\pm$ 0.34 L/min/m^2. CI, confidence interval; EC, electric cardiometry; PAC, pulmonary artery catheterization; SD, standard deviation.

Moreover, CO assessment using transthoracic echocardiography is operator-dependent and requires round-the-clock presence of a trained cardiologist/sonographer.

This study demonstrated that the completely noninvasive EC-derived CI using the ICON monitoring system produced strong agreement and a good internal consistency to that estimated using PAC both before (Cronbach's alpha 0.752, ICC 0.789) and after (Cronbach's alpha 0.830, ICC 0.907) the procedure. Bland-Altman analysis revealed a mean bias of 0.0051 L/min/m^2 and limits of agreement of $\pm$ 0.49 L/min/m^2 before the cardiac catheterization and a mean bias of –0.015 L/min/m^2 and limits of agreement of $\pm$ 0.34 L/min/m^2 at the end of the catheterization. These results were in agreement with the work done by Norozi et al[17] in pediatric patients with structural heart disease. In their study of 32 children with heart defects that used the AESCULON monitor (Osypka Medical), they demonstrated that CO estimated via electrical velocimetry showed excellent correlation (r = 0.97) with that derived using the Fick technique.

In addition to stroke volume and CO, EC using ICON also provides other real-time cardiovascular information regarding developing hemodynamic events (eg, systemic vascular resistance, stroke volume variation, thoracic fluid content, left ventricular ejection time, index of contractility, systolic time ratio) and readily can track the response to any therapeutic intervention performed.[25] The device is handy, easy to use, and does not require any calibration/operator assistance once the electrodes have been attached appropriately and anthropometric data entered correctly. Hemodynamic information provided by EC then can be used to supplement the combined data from all monitors and the clinical situation to guide therapy in children with structural heart disease.

Limitations

The fact that no patients with normal cardiac anatomy were included in this study may be considered a limitation. However, cardiac catheterization with the possibility of PAC Fick CO assessment in noncardiac patients is very rare and limits this type of investigation to pediatric cardiac patients. Another potential source of error was the measurement performed irrespective of the respiratory phases because they may induce CO variations over the respiratory cycle. Hemodynamically unstable patients with cardiac defects or those on inotropic therapy also were excluded from the trial, so the performance of this device in children with low CO states still needs to be verified. The cohorts enrolled in the study were heterogenous, and the study was not powered sufficiently to assess CO based on the presence of intracardiac/extracardiac shunts and left/right ventricular outflow tract obstruction or the effect of general anesthesia.

Conclusion

These preliminary data demonstrated that CO measurement in children with congenital heart disease using the EC-based ICON reliably represented absolute CO values obtained via PAC. Spot measurement of CO ranging from 1.4 L/min-to-4.7 L/min and CI ranging from 2.5 L/min/m^2-to-5.2 L/min/m^2, under a steady-state clinical situation, using electric velocimetry agreed well with the gold standard (PAC-derived) values. EC thus can make available a reliably, noninvasive, beat-to-beat estimation of CO and other hemodynamic data in children with a variety of structural heart defects. Additional validation trials are recommended for children with abnormal hemodynamics (inotrope therapy) and presence of complex cardiac anatomy (right aortic arch, transposition of the great arteries, univentricular physiology) and in patients after corrective surgery.

Table 4
The Bland-Altman Analysis and Reliability Analysis for Parameters Derived From EC and PAC at Baseline and After the Procedure

	Before Catheterization				After Catheterization			
	Mean Bias	Limits of Agreement	Cronbach's Alpha	ICC	Mean Bias	Limits of Agreement	Cronbach's Alpha	ICC
Cardiac index (L/min/m^2)	0.0051	$\pm$ 0.49278	0.752	0.789	–0.015	$\pm$ 0.340	0.830	0.907
Stroke index (mL/m^2)	2.801	$\pm$ 6.82744	0.722	0.776	0.6248	$\pm$ 4.3661	0.866	0.939

Abbreviation: ICC, intraclass correlation coefficient.

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Appendix A. Supplementary material

Supplementary data associated with this article can be found in the online version at http://dx.doi.org/10.1053/j.jvca.2016.12.009.

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