The impact of bowl size, program setup, and blood hematocrit on the performance of a discontinuous autotransfusion system

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BACKGROUND: Cell salvage is an essential element in the concept of blood management. Modern devices provide different bowl sizes and sensor-directed programs to optimally adjust to varying clinical situations.
STUDY DESIGN AND METHODS: In an experimental performance study, the discontinuous autotransfusion device XTRA (LivaNova/Sorin) was evaluated using fresh donor blood anticoagulated with heparin 5 U/mL and adjusted to a hematocrit of 10% or 25%, representing orthopedic or cardiac surgery. Test blood was processed with the autotransfusion device XTRA in four different bowls (55 mL, 125 mL, 175 mL, and 225 mL) and in three different program modes (a standard program, an optimized program, and an emergency program).
RESULTS: Processing speed increased with bowl size and with the emergency program (range, 6.4-29.8 mL red blood cells [RBCs]/min). The RBC recovery rate exceeded 90% for all bowls and programs except the 55-mL bowl with the emergency program. Plasma elimination exceeded 95% for all bowls and programs except the 225-mL bowl with the emergency and standard programs. Maximal RBC recovery (range, 94.7%-97.6%) and plasma elimination (range, 98.7%-99.5%) were obtained with the medium-sized bowls (125 mL and 175 mL) and the optimized program. Elimination rates for potassium or plasma free hemoglobin were consistently lower than for protein or albumin and were highest for heparin.
CONCLUSIONS: Increased hematocrit and RBC recovery rates are obtained with the optimized program Popt with the discontinuous autotransfusion device. The emergency program Pem speeds up the process but leads to RBC loss and reduced plasma elimination rates; therefore, it should be restricted to emergency situations. All four different sized bowls have high performance. Plasma elimination is represented best by protein or albumin elimination rates.

The transfusion of allogeneic blood is still associated with various side effects, such as immune modulation, infections, or transfusion-associated lung injury (TRALI).[1-3] To ensure the safety of banked blood, extensive testing is required, causing a steady increase in costs.[4] Autotransfusion has been one of the key elements in blood conservation during surgical procedures for many years.[5,6] Various autotransfusion devices have been used with high efficiency, especially in cardiac and orthopedic surgery.[7,8] These applications are evidence-based and recommended by guidelines for blood conservation.[9,10] To meet various clinical situations and produce autologous blood of high quality, different bowl sizes and improved process programs have been developed. One improvement, for example, has been the development of a smaller bowl for pediatric use; another is the addition of a new program for better fat removal.[11,12] Thus, for Latham bowl-based systems, different bowl sizes are available to process a large variety of blood volumes. Small

ABBREVIATIONS: Pem = emergency program; PFH = plasma free hemoglobin; Popt = optimized program; Pstd = standard program.

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TABLE 1. Process parameters of the programs (according to the manufacturer)

Bowl size, mL	Program wash phases	Volume flow, mL/min					Wash volume, mL
		Fill	Wash	Empty	Return	Concentration	
55	Pem	350	400	200	200	200	300
55	Pstd	300	100	150	150	200	300
55	Popt	300	100	150	150	200	200
125	Pem	500	800	500	300	350	800
125	Pstd	300	250	250	250	350	900
125	Popt	450	250	300	250	350	800
175	Pem	450	800	450	300	450	900
175	Pstd	350	350	250	250	450	1000
175	Popt	550	450	400	250	450	1000
225	Pem	400	800	500	300	300	1000
225	Pstd	350	800	450	250	300	800
225	Popt	400	500	400	250	300	1000

bowls (e.g., 55 mL) were designed to process small volumes in pediatric and neonatal surgery.[13] For extensive and rapid blood losses, as in trauma or transplant surgery, larger bowls and effective emergency program modes are available. Some experimental studies have tested the impact of various process parameters, like wash volume or pump rate, during filling and washing on both plasma elimination and red blood cell (RBC) recovery—the main quality parameters of cell salvage.[14] These insights, together with modern sensor technologies, allow for the design of specific program modes meant to optimize performance of the cell-separation and washing process. However, the resulting improvements in efficiency and product quality using these new programs and different bowl sizes have yet to be determined. In addition, autotransfusion devices usually are tested with one specific test blood; whereas, in clinical practice, there is wide variation in wound blood hematocrit (Hct).

The objective of this study was to characterize the performance of a new-generation autotransfusion device with regard to plasma elimination, RBC recovery, product Hct, and RBC processing speed under various conditions of input blood Hct. The autotransfusion device XTRA (LivaNova/Sorin), which was introduced to the market in 2010,[15] has four disposable Latham bowls, ranging in size from 55 mL to 225 mL. Along with a standard program (Pstd) and an emergency program (Pem), an additional program is available that has been optimized to achieve higher processing speed, plasma washout, and product Hct (Popt). The intention of this study was to test the hypothesis that bowl size, program mode, and input blood Hct are interacting parameters that influence product quality and device performance.

MATERIALS AND METHODS

Test blood

After obtaining institutional ethics committee approval (University of Regensburg, Regensburg, Germany; protocol no. 08-133) and informed consent from the donors, blood group–matched donations from healthy volunteers, anticoagulated with 5 IU/mL heparin (Heparin-Natrium 25000; Ratiopharm) were mixed and adjusted with saline solution (0.9% Careflex; Fresenius, Bad Homburg), to an Hct of 25% to represent test blood from cardiac surgery (TBcardio) and to an Hct of 10% to represent blood from orthopedic surgery (TBortho), with continuous stirring thereafter.

Blood processing by XTRA

An experimental study was carried out on the autotransfusion device XTRA (LivaNova/Sorin), with software version 1.01a, using the 55-mL bowl (X55), the 125-mL bowl (X125), the 175-mL bowl (X175), and the 225-mL bowl (X225). After a prerinse with 30 to 50 mL of test blood to compensate for initial blood loss during the first filling of bowl and tubings (filling of 50 mL with bowls X175 and X225 and filling of 30 mL with bowls X55 and X125, respectively, followed by emptying), each bowl was tested with the three programs (Pem, Pstd, and Popt). Performance was tested with both "TBcardio" (Hct 25%) and "TBortho" (Hct 10%) test blood. The programs were used as set up by the manufacturer (Table 1) in the following sequence: prefilling, Pem with TBcardio, Pstd with TBcardio, Popt with TBcardio, Pem with TBortho, Pstd with TBortho, and Popt with TBortho. The experiment was repeated six times, with the same bowl testing the various programs.

No reservoir was used to avoid RBC loss and determine the exact blood volume. Instead, a defined volume of 1000 mL test blood was offered in a beaker for bowls X175 and X225, and a volume of 500 mL was offered for the bowls X55 and X125. No transfusion bag was used; instead, the lines were cut, and product volumes were collected and measured in a graduated cylinder. Twenty-milliliter samples were taken from test blood and from the graduated collecting cylinder after an entire bowl had been processed. The amount of processed blood was calculated as the difference between the product volume and the offered

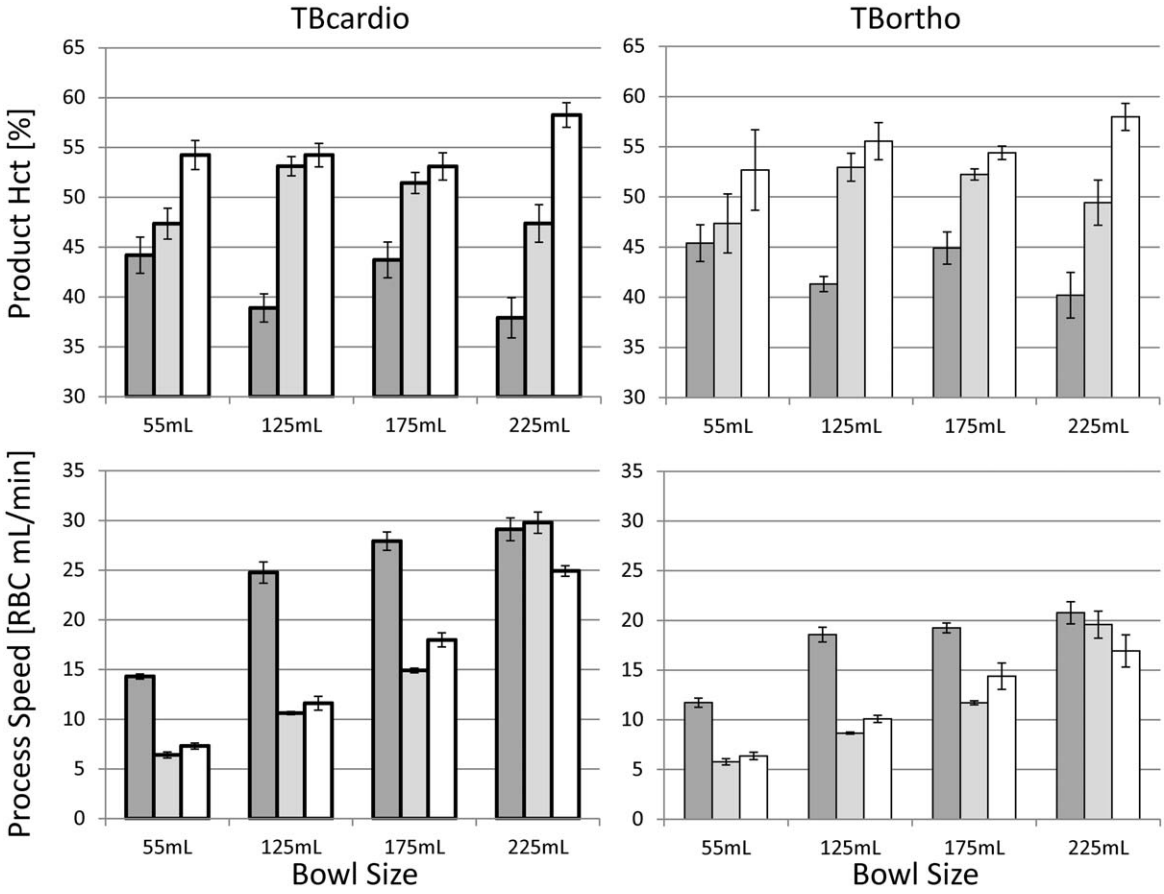

Fig. 1. Product hematocrit (%) and process speed (RBCs mL/min) for all four bowl sizes and tested programs (N = 6). Dark gray columns indicate the emergency program Pem; light gray columns, the standard program Pstd; white columns, the optimized program Popt. Test blood (TB) with an Hct of 25% (TBcardio; bold outlined columns) or 10% (TBortho) was used, representing cardiac or orthopedic surgery, respectively.

test blood volume. The time from starting the washing procedure to the final stop of the roller pump was recorded as the processing time. For comparison of the different bowls, processing time was converted to process speed by dividing the produced volume of RBCs (product volume × Hct) by the respective processing time.

Measurement of hematologic parameters

The Hct of blood samples was determined by blood gas analysis (Rapid Point 405; Bayer Healthcare) and a cell counter (Sysmex XE-5000; Sysmex Corporation). For the soluble substances, potassium was quantified on a clinical analysis system using an ion-selective electrode. Immune nephelometry in a plasma protein analysis system (BN ProSpec; Siemens Healthcare Diagnostics) was used to measure plasma free hemoglobin (PFH). Albumin in the supernatant was analyzed with a chemistry analyzer (ADVIA 1800; Siemens Healthcare Diagnostics). Heparin was measured using the Siemens BCS automated hemostasis testing system (Siemens Healthcare Diagnostics) with the COAMATIC heparin test (Chromogenix).

Calculation of quality parameters

Process speeds (RBCs mL/min) were calculated from the produced RBC volumes, that is, blood volume × Hct (%)/100%, divided by the time necessary for the process in minutes. RBC recovery rates were calculated by comparison of the amounts of input and output RBCs, as described elsewhere.[16,17] The elimination rates of the soluble substances were calculated according to the following equation:

$$\text{Elimination rate } (\%) = 100 - 100 \times ((V_{WRBC} \times (1 - Hct_{WRBC}/100) \times C_{WRBC})/(V_{TB} \times (1 - Hct_{TB}/100) \times C_{TB})),$$

where $V_{TB} \times (1 - Hct_{TB}/100)$ is the volume of the supernatant in the test blood, and $V_{WRBC} \times (1 - Hct_{WRBC}/100)$ represents the volume of the supernatant in the product of the washed RBCs (in milliliters). C_{WRBC} and C_{TB} are the

TABLE 2. Significant intragroup and pairwise differences in the comparison of bowl sizes

			p value*					
			Kruskal-Wallis			Mann-Whitney U		
Test blood Hct	Program	Bowl size, mL	Product Hct	RBC recovery	Protein elimination	Product Hct	RBC recovery	Protein elimination
25%	Popt	225/175/125/55	0.008	NS	0.001			
		225 vs.175				0.009		0.008
		225 vs. 125				0.008		0.008
		225 vs. 55				0.008		NS
		175 vs. 125				NS		NS
		175 vs. 55				NS		0.008
		125 vs. 55				NS		0.008
25%	Pstd	225/175/125/55	0.001	0.002	0.001			
		225 vs.175				0.008	0.008	0.008
		225 vs. 125				0.008	0.008	0.008
		225 vs. 55				NS	0.008	0.008
		175 vs. 125				NS	NS	NS
		175 vs. 55				0.008	NS	0.008
		125 vs. 55				0.008	0.008	0.008
25%	Pem	225/175/125/55	0.002	NS	NS			
		225 vs.175				0.009		
		225 vs. 125				NS		
		225 vs. 55				0.008		
		175 vs. 125				0.009		
		175 vs. 55				NS		
		125 vs. 55				0.008		
10%	Popt	225/175/125/55	0.006	NS	0.001			
		225 vs.175				0.009		0.006
		225 vs. 125				NS		0.006
		225 vs. 55				0.002		NS
		175 vs. 125				NS		NS
		175 vs. 55				NS		0.004
		125 vs. 55				NS		0.006
10%	Pstd	225/175/125/55	0.001	0,008	0.001			
		225 vs.175				0.004	NS	0.004
		225 vs. 125				0.009	0.004	0.004
		225 vs. 55				NS	NS	0.004
		175 vs. 125				NS	0.008	NS
		175 vs. 55				0.008	NS	0.008
		125 vs. 55				0.008	NS	0.008
10%	Pem	225/175/125/55	0.003	NS	0.002			
		225 vs.175				0.010		0.004
		225 vs. 125				NS		0.004
		225 vs. 55				0.010		NS
		175 vs. 125				0.008		NS
		175 vs. 55				NS		0.008
		125 vs. 55				0.012		0.008

* Intragroup comparison was conducted according to Kruskal-Wallis and followed by pairwise testing according to Mann-Whitney with Bonferroni-Holms correction.
NS = not significant.

concentrations of the substance in the supernatant of the product of washed RBCs and the used test blood, respectively.

Statistics

Mean values and standard deviations are given throughout. Data were processed using Excel 10.0 (Microsoft Corporation). Statistical analyses were performed with the statistical software program SPSS (version 19.0; SPSS, Inc., Chicago, IL). The Kruskal-Wallis test was applied for intergroup comparisons, with significance assumed as $p < 0.01$, followed by the post-hoc Mann-Whitney U test with Bonferroni-Holms correction in case of significant differences.

RESULTS

Product Hct

The Hct ranged from 37.9% (bowl X225, Pem) to 58.3% (bowl X225, Popt) when tested with TBcardio and from 40.2% to 58.0%, respectively, when tested with TBortho (Fig. 1). There were significant differences between the different bowls and the different programs, as shown in Tables 2, 3, and 4. With all bowls, Popt produced higher

TABLE 3. Significant intragroup and pairwise differences in the comparison of program modes

			p value*					
			Kruskal-Wallis			Mann-Whitney U		
Test blood Hct	Program	Bowl size, mL	Product Hct	RBC recovery	Protein elimination	Product Hct	RBC recovery	Protein elimination
25%	Popt/Pstd/Pem	225	0.002	NS	0.002			
	Popt vs. Pstd					0.008		0.008
	Popt vs. Pem					0.008		0.008
	Pstd vs. Pem					0.008		0.008
25%	Popt/Pstd/Pem	175	0.004	NS	0.005			
	Popt vs. Pstd					NS		NS
	Popt vs. Pem					0.008		0.008
	Pstd vs. Pem					0.008		0.008
25%	Popt/Pstd/Pem	125	0.005	0.009	0.007			
	Popt vs. Pstd					NS	NS	NS
	Popt vs. Pem					0.008	0.008	0.008
	Pstd vs. Pem					0.008	0.008	0.008
25%	Popt/Pstd/Pem	55	0.002	NS	NS			
	Popt vs. Pstd					0.008		
	Popt vs. Pem					0.008		
	Pstd vs. Pem					0.008		
10%	Popt/Pstd/Pem	225	0.001	0.008	0.003			
	Popt vs. Pstd					0.002	NS	0.002
	Popt vs. Pem					0.003	0.009	0.009
	Pstd vs. Pem					0.003	NS	NS
10%	Popt/Pstd/Pem	175	0.002	0.005	0.006			
	Popt vs. Pstd					0.008	0.008	NS
	Popt vs. Pem					0.008	0.008	0.008
	Pstd vs. Pem					0.008	NS	0.008
10%	Popt/Pstd/Pem	125	0.003	NS	NS			
	Popt vs. Pstd					NS		
	Popt vs. Pem					0.008		
	Pstd vs. Pem					0.008		
10%	Popt/Pstd/Pem	55	NS	NS	NS			
	Popt vs. Pstd							
	Popt vs. Pem							
	Pstd vs. Pem							

* Intragroup comparisons were conducted according to Kruskal-Wallis, followed by pairwise testing according to Mann-Whitney with Bonferroni-Holms correction.
NS = not significant.

Hcts than Pstd. With Pem (dark gray columns in Fig. 1), Hcts were markedly lower than with Pstd, and all were below 46%. The product Hct was highest with bowls X55 and X175 and lowest with bowl X225 when Pem was tested on test blood with lower or higher Hct. With Pstd (light gray columns in Fig. 1), the Hct was highest with bowls X125 and X175 and was significantly lower with bowls X55 and X225. With Popt (white columns in Fig. 1), the highest Hct was achieved with the largest bowl (X225).

Process speed

The processing time increased with bowl size, but so did the processed volume of RBCs. The resulting process speed was significantly higher with TBcardio than with the more diluted test blood (Fig. 1). The production rate of washed RBCs ranged from 6.4 to 29.8 mL RBCs mL/min with TBcardio and from 5.8 to 20.8 mL RBCs mL/min with TBortho. Pem (dark gray columns in Fig. 1) markedly enhanced the process speed compared with Pstd and Popt in most cases, but not with the 225-mL bowl. Results were higher for Popt than for Pstd, except for bowl X225. (It is noteworthy that, since this report, LivaNova/Sorin has introduced a software upgrade [SWv1.02] with modified processing parameters of Pstd for bowl X225 for faster processing, i.e., with a lower wash flow of 450 mL/min and a wash volume of 600 mL.)

All of these differences reached statistical significance with the exception of bowl sizes 175 versus 225 mL and 125 versus 225 mL. RBC processing speed significantly increased with increasing bowl size for both test blood preparations. Although, with Pem (dark gray columns in Fig. 1), the process rates nearly doubled from X55 to X125 and then stayed high for X175 and X225, there was a steady increase from X55 to X255 with Popt and a marked increase from X175 to X225 with Pstd (Fig. 1).

RBC recovery

RBC recovery was slightly lower with TBortho than with TBcardio, except for the smallest bowl (X55), which showed a marked loss of RBCs when processing TBcardio

TABLE 4. Significant intragroup and pairwise differences in the comparison of markers for plasma elimination rates of soluble substances

				p value*	
Test blood Hct	Program	Bowl size, mL	Plasma marker	Kruskal-Wallis	Mann-Whitney U
25%	Popt	175	Protein/albumin/K^+/PFH	0.002	
			Protein vs. albumin		NS
			Protein vs. K^+		0.008
			Protein vs. PFH		0.008
			Albumin vs. K^+		0.008
			Albumin vs. PFH		0.008
			K^+ vs. PFH		NS
10%	Popt	175	Protein/albumin/K^+/PFH	0.002	
			Protein vs. albumin		NS
			Protein vs. K^+		0.008
			Protein vs. PFH		0.008
			Albumin vs. K^+		0.008
			Albumin vs. PFH		0.008
			K^+ vs. PFH		NS

* Intragroup comparisons were conducted according to Kruskal-Wallis, followed by pairwise testing according to Mann-Whitney with Bonferroni-Holms correction.
K^+ = potassium; NS = not significant.

with Pem (Fig. 2). Otherwise, RBC recovery ranged from 89.9 to 97.6%. Significant differences between bowls were observed only for Pstd, and significant differences between programs were observed only for the larger bowls (see Table 2). Pem (dark gray columns in Fig. 2) consistently showed higher RBC loss than the other programs. Higher RBC recovery was achieved with Popt compared with Pstd, especially with bowl X225 except for the small bowl (X55). With Pstd and Popt, RBC recovery decreased from X125 to X225 with increasing bowl size, whereas performance was also somewhat lower with X55.

Plasma elimination rates of soluble substances

Plasma elimination, as determined by washout of total protein, was high under all conditions, ranging from 92.1 to 98.9% when tested with TBcardio (Fig. 2). With TBortho, the results were consistently higher for all comparisons, ranging from 97.1 to 99.6%. Significant differences were observed in the comparison of bowls, except in Pem tested with TBcardio (see Table 2); between programs for all bowls; and between bowls for all programs (see Tables 2 and 3). Protein washout was highest with bowls X125 and X175 and lower with bowls X55 or X225 (Fig. 2). In the comparison of program modes, differences were significant except for bowl X55 when tested with TBcardio and except for bowls X125 and X55 when tested with TBortho (see Table 3). Pem had lower performance than the other programs throughout, except for the largest bowl (X225). Pstd and Popt had very similar results, with the exception of bowl X225, with which the elimination rate was significantly improved by Popt.

Significant differences were observed between different soluble substances to reflect plasma elimination (shown only for X175 and Popt in Table 4). Determination of plasma elimination rates using albumin yielded results equivalent to total protein (Fig. 3). In contrast, potassium and PFH measurements resulted in significantly lower values, whereas heparin showed significantly higher elimination rates of 99.8% for TBcardio and 99.9% for TBortho.

DISCUSSION

Autotransfusion has been successfully established in many surgical fields.[5,7] A new generation of autotransfusion devices offers new possibilities to improve the efficiency of cell salvage and to adapt to different clinical situations.[18] A study by Salaria and colleagues has demonstrated a higher deformability of autologous blood compared with allogeneic blood, underlining the high quality of autologous salvaged blood.[19] To maintain a safe product of high quality, the implementation of a quality-management system is necessary, using plasma elimination rates of soluble substances and RBC recovery as the main quality parameters.[16,17] In addition to quality control, basic knowledge about the parameters that influence performance is essential to optimally accommodate various clinical situations and challenges. Thus, whereas other studies on the new-generation autotransfusion device XTRA have focused on user interface, data collection and management, and the built-in Hct indicator,[18] the objective of the current study was to clarify the role of the Hct, of the processed blood, of the bowl size, and of specific program modes in performance.

The role of the input Hct

A slight, nonsignificant increase in product Hct is observed when blood with lower Hct is processed (see Fig. 1) because of a longer phase of centrifugation. Processing

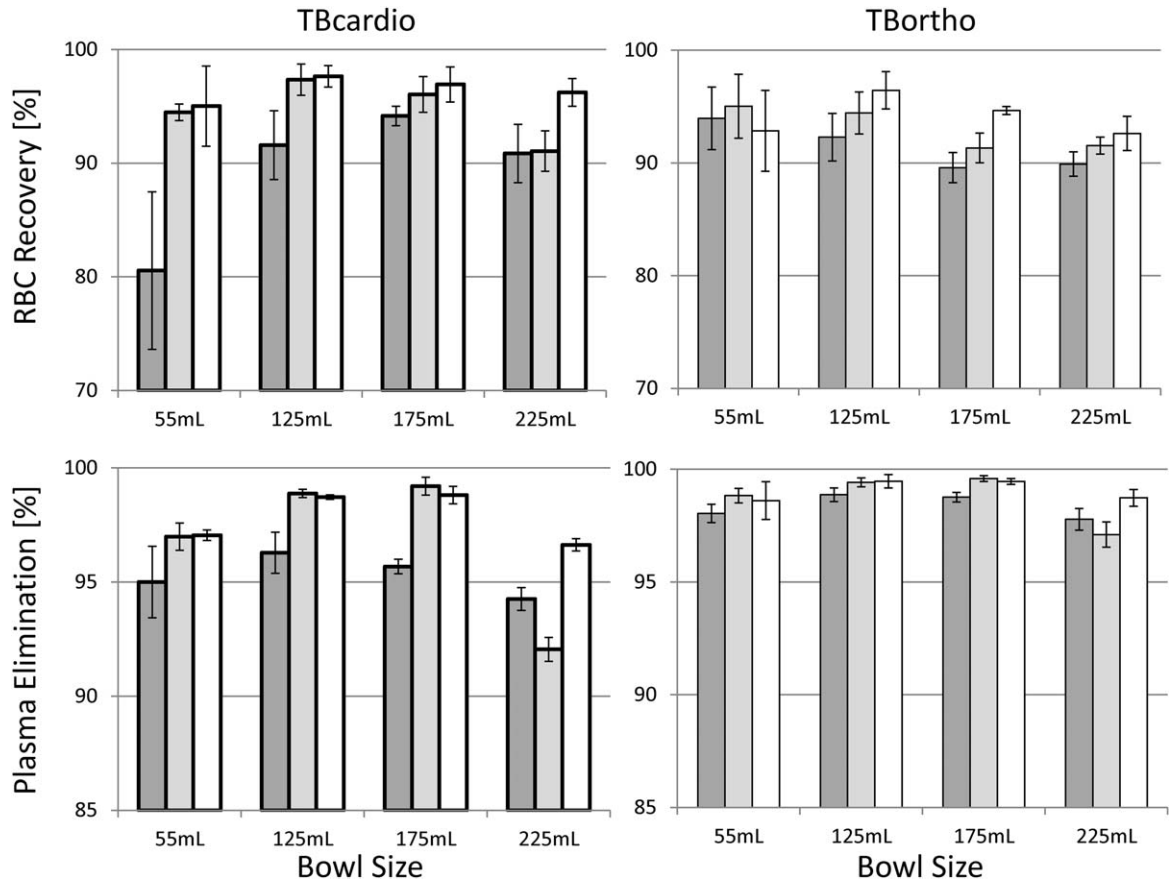

Fig. 2. RBC recovery (%) and plasma elimination rate (%) as measured by protein determinations for all four bowl sizes and tested programs (N = 6). Dark gray columns indicate the emergency program Pem; light gray columns, the standard program Pstd; white columns, the optimized program Popt. Test blood (TB) with an Hct of 25% (TBcardio; bold outlined columns) or 10% (TBortho) was used, representing cardiac or orthopedic surgery, respectively.

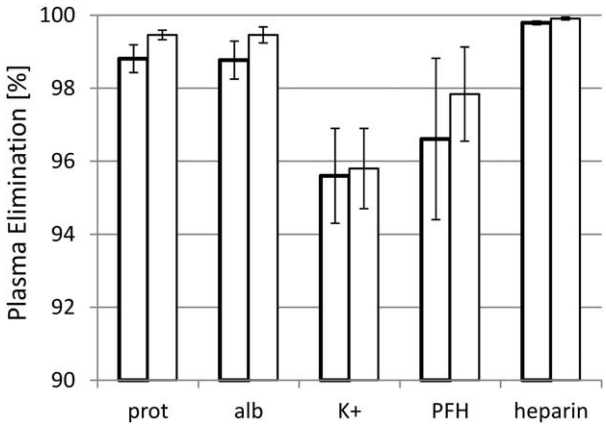

Fig. 3. Elimination rates for protein (prot), albumin (alb), potassium (K+), PFH, and heparin (for the 175-mL bowl with the optimized program Popt; N = 6) Test blood (TB) with an Hct of 25% (TBcardio; bold outlined columns) or 10% (TBortho) was used, representing cardiac or orthopedic surgery, respectively.

time increases with the dilution of wound blood, because more blood volume is needed to fill the bowl with RBCs. Nevertheless, on average, the process speed is reduced by only 25%, for example, from 18.0 to 14.4 RBCs mL/min (for bowl X175 with Popt) when the input Hct is cut to less than one-half. RBC recovery decreases slightly with more diluted blood, because more RBCs are lost with more supernatant removed during bowl filling. However, plasma elimination significantly increases with lower wound blood Hct for the same reason (see Fig. 2). This confirms results from a current study, in which albumin elimination rates increased from 96.6 to 98.5%, and up to 99.5% when tested in blood with an Hct of 30%, 20%, or 10%, respectively; whereas the product Hct increased from 52 to 55%.[20] In another study (which tested a fat-elimination program), increased product Hct and plasma elimination were observed with lower Hct of input blood; however, a decrease in RBC recovery was also observed.[11] In conclusion, RBC recovery is slightly reduced and plasma elimination is increased with more diluted wound blood.

The role of bowl size

With the Pstd, product Hct is highest with bowls X125 and X175 and is lower with the smallest and largest bowls. In contrast, with Popt, product Hcts are rather constant at about 55% for all bowl sizes, and even increased for bowl X225 (see Fig. 1). Process speed increases with bowl size, as expected. Both RBC recovery and plasma elimination are highest with bowls X125 and X175 and are lower with the smaller and larger bowl. This difference is more pronounced when blood with a higher Hct is processed. In clinical practice, process speed is rarely limiting. Usually, it is of no clinical impact whether the production of the equivalent to a unit of allogeneic blood (about 180 mL of RBCs at Hct 100%) takes 10 minutes (bowl X175; one cycle, 5.0 minutes) or 7.2 minutes (bowl X225; one cycle, 5.6 minutes), especially compared with ordering another unit of banked blood from the blood bank. Therefore, this limited saving of time with bowl X225 has to be weighed against the better performance with regard to plasma elimination and RBC recovery of the medium-sized bowls. With the small bowl (X55), efficient processing of small blood volumes has been demonstrated with both the Electa device[13] and the XTRA device,[21] and the results were comparable to those obtained using the continuous autotransfusion system (CATS). This study confirms the high performance of bowl X55. In a clinical study, Overdevest and colleagues[15] evaluated the XTRA autotransfusion device in cardiac surgery using the Popt program and the three larger bowls. In their study, process speed was related to the volume of product per minute. Because the product Hct can vary, our process speeds are given as the volume of RBCs (at an Hct of 100%) per minute for better comparison. The values that can be calculated from their data are comparable to ours. The RBC recovery rates reported by Overdevest and colleagues under their clinical conditions are lower (all below 92%) and show higher variability, probably due to a reservoir used and the inclusion of the first filling into the calculation. Their reported plasma elimination rates were similar to our results. In another study in which all four bowls were evaluated, optimal RBC recovery and plasma elimination rates also were observed with the medium-sized bowls.[11] In conclusion, the medium-sized bowls provide the lowest RBC loss and the highest plasma elimination rates.

The role of program mode

Comparisons of different program modes reflect the impact of variations mainly in wash flow rate and wash volume (see Table 1). Emergency programs have been developed to speed up processing in case of sudden high blood loss. Generally, these program modes are based on increasing the filling and washing pump rates and reducing the wash volumes. This usually leads to decreased plasma elimination and loss of RBCs,[20,22] for example, with BRAT2 (Cobe), from an albumin elimination rate of 93 to 63%, and, with Sequestra (Medtronic) using a Latham bowl, from 98 to 58%.[20] The program Pem tested here has been designed to counteract these disadvantages, among others, by reduced bowl filling. The test results verify this reduced Hct of the washed RBCs (Fig. 2). Despite the lower product Hct, the emergency program almost doubles the process speed, that is, the production rate of washed RBCs compared with Pstd and Popt (see Fig. 1). This advantage is diminished in the large bowl (X225). According to the lower bowl filling, RBC recovery is only moderately reduced compared with the other program modes (see Fig. 2), with the exception of the smallest bowl when processing blood with a high Hct. Plasma elimination is significantly reduced with Pem, although it consistently exceeds 95%, with the exception of bowl X225 when processing blood with an Hct of 25%. In summary, for the specific emergency program Pem of XTRA, our study confirms the accomplishment of an increased RBC processing in emergency situations with only moderate concession to RBC recovery and the plasma elimination rate. Still, the use of emergency programs should be strictly restricted to emergency situations. The largest bowl (X225) does not benefit from Pem, because the deterioration of quality parameters outweighs the minimal increase in process speed compared with Popt.

Pstd, the default mode, produces excellent results in terms of product Hct, process speed, RBC recovery, and plasma elimination, meeting all agreed quality standards.[14,16] A study by Melo and colleagues evaluated the Electa autotransfusion device (Sorin), which was the predecessor to the XTRA, using Pstd and the 125-mL bowl.[23] The RBC recovery rate was 87 $\pm$10%, compared with 97.3 $\pm$1.4% reported for XTRA here. Also, their reported potassium elimination rate of 91 $\pm$4% increased to 95.6 $\pm$1.5% in our study using XTRA. Thus, the development of a new-generation device has contributed to improvements in quality and performance.

The Popt program is optimized for higher Hct and shorter processing time. Both objectives are confirmed by this study. Popt had a higher product Hct under all conditions compared with Pem and Pstd and a higher process speed compared with the default program Pstd, except for bowl X225. However, the clinical impact of these measures is questionable. Although, in Latham bowls, the Hct produced can be considered a meaningful measure to prevent partially filled bowls, it is not a quality parameter per se. There is no medical advantage from the transfusion of blood with a high Hct; instead, RBC loss in dead spaces is increased, and the flow rate is decreased because of higher viscosity. Process speed, on the other hand, is rarely a limiting factor in clinical cell salvage. The increase by 9 to 20% compared with Pstd is of no clinical impact; because, under all conditions and with all programs, a single unit of autologous blood is produced within 10 minutes. However, Popt improves RBC recovery for all programs and bowl

sizes (see Fig. 2). With Popt, plasma elimination is similar to that achieved with Pstd for the smaller bowls but is increased for bowl X225; that is, Popt compensates for the lower process quality of that bowl. In conclusion, Popt should replace Pstd as the default mode of XTRA, and the use of Pem should be restricted to emergency cases.

Often, reductions in the concentration of plasma components have been used to describe the performance of autotransfusion devices.[22] This does not address the two phases of processing, that is, cell separation with supernatant elimination without change in concentration, and washing with dilution of supernatant. In this study, elimination rates were calculated from comparisons of input and output volumes and concentrations. In addition, total protein and albumin again confirmed their pivotal role in determining plasma elimination, whereas potassium or PFH measurements were obscured by release of both with hemolysis, and heparin elimination was overestimated because of surface and cell adsorption.[17]

This was an in vitro study and cannot completely reflect all clinical situations. However, in clinical situations, the variability is so high that usually no general conclusions can be drawn. One limitation of the study is the lack of a reservoir; however, only by eliminating this source of RBC loss and masking of the exact volume of processed blood can reliable and reproducible results be obtained.

The new-generation autotransfusion device XTRA offers not only improved handling but also different program modes and bowl sizes to cope with various clinical situations and challenges. Based on our results, use of the optimized program Popt leads to increased product Hct and RBC recovery rates and thus should be used in the daily routine. Use of the emergency program Pem results in faster RBC processing but should be restricted to emergency situations because of increased RBC loss and reduced plasma elimination. All four different sized bowls show high performance regarding plasma elimination. The results from this study may help clinicians use these options for optimal performance and product quality in cell salvage.

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CONFLICT OF INTEREST

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REFERENCES

1. Engels GE, van Klarenbosch J, Gu YJ, van Oeveren W, de Vries AJ. Intraoperative cell salvage during cardiac surgery is associated with reduced postoperative lung injury. Interact Cardiovasc Thorac Surg 2016;22:298-304.
2. Muszynski J, Nateri J, Nicol K, et al. Immunosuppressive effects of red blood cells on monocytes are related to both storage time and storage solution. Transfusion 2012;52:794-802.
3. Ikuta S, Miki C, Hatada T, et al. Allogenic blood transfusion is an independent risk factor for infective complications after less invasive gastrointestinal surgery. Am J Surg 2003; 185:188-93.
4. Shander A, Hofmann A, Gombotz H, et al. Estimating the cost of blood: past, present, and future directions. Best Pract Res Clin Anaesthesiol 2007;21:271-89.
5. Ashworth A, Klein AA. Cell salvage as part of a blood conservation strategy in anaesthesia. Br J Anaesth 2010;105:401-16.
6. Waters JH. Intraoperative blood recovery. ASAIO J 2013;59: 11-7.
7. Vonk AB, Meesters MI, Garnier RP, et al. Intraoperative cell salvage is associated with reduced postoperative blood loss and transfusion requirements in cardiac surgery: a cohort study. Transfusion 2013;53:2782-9.
8. Herd JM, Joseph JJ, McGarvey M, et al. Intraoperative cell salvage in revision hip surgery. Ann Med Surg (Lond) 2014;3:8-12.
9. Muñoz M, Garcia-Erce JA, Villar I, et al. Blood conservation strategies in major orthopaedic surgery: efficacy, safety and European regulations. Vox Sang 2009;96:1-13.
10. Society of Thoracic Surgeons Blood Conservation Task Force, Ferraris VA, Brown JR, et al. 2011 update to the Society of Thoracic Surgeons and the Society of Cardiovascular Anesthesiologists blood conservation clinical practice guidelines. Ann Thorac Surg 2011;91:944-82.
11. Seyfried TF, Gruber M, Breu A, et al. Fat removal during cell salvage: an optimized program for a discontinuous autotransfusion device. Transfusion 2016;56:153-9.
12. Seyfried TF, Haas L, Gruber M, et al. Fat removal during cell salvage: an optimized program for a discontinuous autotransfusion device. Transfusion 2015;55:1637-43.
13. Seyfried T, Breu A, Gruber M, et al. Processing of small volumes in blood salvage devices. Transfusion 2014;54:2775-81.
14. Hansen E, Bechmann V, Altmeppen J, et al. Quality management in blood salvage: implementation of quality assurance and variables affecting product quality. Transfus Med Hemother 2004;31:221-7.
15. Overdevest EP, Lanen PW, Feron JC, et al. Clinical evaluation of the Sorin Xtra(R) autotransfusion system. Perfusion 2012; 27:278-83.
16. Hansen E, Altmeppen J. Proposal for internal quality management in intra- and postoperative blood salvage. Infus Ther Transfus Med 2002;29:147-50.
17. Gruber M, Breu A, Frauendorf M, et al. Washing of banked blood by three different blood salvage devices. Transfusion 2013;53:1001-9.

18. Yarham G, Clements A, Oliver M, et al. Evaluating the 'next generation' of cell salvage—will it make a difference? Perfusion 2011;26:263-70.
19. Salaria ON, Barodka VM, Hogue CW, et al. Impaired red blood cell deformability after transfusion of stored allogeneic blood but not autologous salvaged blood in cardiac surgery patients. Anesth Analg 2014;118: 1179-87.
20. Shulman G. Quality of processed blood for autotransfusion. J Extra Corpor Technol 2000;32:11-9.
21. Baumann C, Lamesic G, Weiss M, et al. Evaluation of the minimum volume of salvage blood required for the successful use of two different autotransfusion devices. Paediatr Anaesth 2015;25:258-64.
22. Yoon C, Noh S, Lee JC, et al. Influence of the washing program on the blood processing performance of a continuous autotransfusion device. J Artif Organs 2014;17:118-22.
23. Melo A, Serrick CJ, Scholz M, et al. Quality of red blood cells using the Dideco Electa autotransfusion device. J Extra Corpor Technol 2005;37:58-9.