

REVIEW

Automation of blood component preparation from whole blood collections

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Vox Sanguinis

Background and objectives Automation of blood component preparation (BCP) from whole blood (WB) collections is increasingly being widespread implemented. This review summarizes the quality of blood components obtained with new automated devices.

Materials and methods We reviewed available literature on the quality of blood components obtained with new automated devices developed in the 2000s.

Results Blood components obtained with the new devices met European standards. Of note, compared with platelet concentrates obtained with manual methods, automation of BCP improved the consistency of the final products.

Conclusion The complete automation of BCP from WB collections is still in development and it represents a huge change in paradigm.

Key words: automation, blood components, efficiency.

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Introduction

Automation means to convert a process to operation by automatic equipment, and the original Greek word 'automatos' means 'acting of itself' [1].

There are two main reasons to introduce automation in the blood component preparation (BCP) laboratory. First, BCP laboratory includes a large number of repetitive actions that can be done manually or can (partly) be automated by a device. Second, the automation of a process might increase its efficiency.

The efficiency of the BCP laboratory has been only rarely studied [2]. However, the analysis of efficiency has become the focus of studies not only in other health-care fields [3], but also in other departments of the blood bank [4]. Data envelopment analysis (DEA) is one method to assess the efficiency in the production of blood components [5]. DEA is based on the concept of a production frontier, which is a description of the technically most efficient combination of inputs to produce a given output [6].

Two efficiency studies found that the majority of BCP laboratories were technically inefficient [7, 8]. Some

authors recommended improving efficiency through the reallocation and rescaling of input because output is generally based on external demand in blood banking, and blood centres cannot regulate demand [6].

The development of sterile connecting devices and semi-automatic instruments in the 1980s, such as Compomat (Fresenius kabi AG, Bad Homburg, Germany) and Optipress (Fenwal Inc, Lake Zurich, IL, USA), comprised the first generation of automating the separation of blood components from whole blood (WB) collections [9–13]. An excellent comparative analysis of different methods for routine BCP with those devices was published elsewhere [2, 14] and the present review will focus in the automation of BCP from WB collections with devices developed in the 21st century by Caridian BCT Corp. (Lakewood, CO) and by Terumo Corp. (Shibuya-ku, Tokyo, Japan). However, today, Terumo BCT (Lakewood, CO) is currently the sole supplier of these devices because this company appeared in March 7, 2011, after the acquisition of Caridian BCT Corp. by Terumo Corp [15].

Automation. Second generation

It comprised the development of devices to automate the preparation of pooled platelet concentrates (PC) from buffy-coat (BC) platelets, and plasma or platelet additive

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solutions (PAS) [16, 17], such as the OrbiSac system (Terumo BCT) and the Terumo Automated Centrifuge & Separator Integration system (TACSI); Terumo BCT).

OrbiSac BC system

The OrbiSac system was formed by the OrbiSac Standard BC Set and the OrbiSac device (Fig. 1). The set consisted of a number of lines to sterilely dock the BCs and plasma or PAS, a round bag that served as the pooling/separation bag, a Pall LRP6 filter (Pall Corp., Port Washington, NY, USA) and a platelet storage bag. The system performed a pooling procedure and continued on automatically by centrifugation, in-line filtration, transferred of the platelet-rich supernatant into the storage bag and sealing. The OrbiSac system produces one pooled PC in a single process in 10–12 min [12].

After first description of the OrbiSac system in 2003 [18], several authors described *in vitro* characteristics of the obtained platelets [19–22] and the organizational impact after introducing the OrbiSac system in the blood centre [23]. Taking together the results of previous articles, the OrbiSac system allowed an improved platelet yield without affecting platelet *in vitro* characteristics and improved consistency in product volume and yield (Table 1) [12].



Fig. 1 The OrbiSac device.

However, some authors found an elevated expression of CD62P in platelets obtained with the OrbiSac system when compared with the manual system [19, 22, 24].

Cid *et al.* [25] analyzed the platelet characteristics of 150 PCs prepared with the OrbiSac system in routine use and compared them with 97 PCs prepared manually. They found an improvement of the platelet content of PCs prepared with OrbiSac when compared with the manual pooling of BCs and a high consistency of the final product because the coefficient of variation (CV) of the platelet content and the platelet volume of the PCs changed from 31% to 20% and 17% to 11%, respectively (Table 1) [12, 25].

A retrospective study analyzed the efficacy of transfusing PCs prepared either with OrbiSac or manually. Cid *et al.* [26] collected data from 36 patients who received 205 platelet transfusions prepared with the manual method and compared with 36 patients who received 219 platelet transfusions prepared with OrbiSac. The platelet transfusion outcome was assessed with 1-hour count increment (1 h-CI), 1-hour corrected count increment (1 h-CCI) and transfusion interval. Cid *et al.* found that the use of the automated OrbiSac system led to significantly higher mean platelet content in the final PC when compared with the standard manual BC method ($2.4 \pm 0.6 \times 10^{11}$ vs. $3.9 \pm 1 \times 10^{11}$; $P < 0.05$). In that study, the 1-h CI was significantly higher in the OrbiSac system group when compared with the manual group, but the 1-h CCI and the transfusion interval were not. Cid *et al.* investigated the impact of 16 patient- and platelet concentrate-related variables on transfusion efficacy by multiple regression analysis. This analysis resulted in the model explaining 13% of the variance of 1-h CI ($R^2 = 0.13$; $P < 0.05$). Five factors were entered in the model, and the platelet preparation method accounted for most of the 13% of the variance of 1 h-CI ($R^2 = 0.50$; $P = 0.001$). In conclusion, there were no significant differences between the two preparation methods regarding clinical outcome, as the difference in 1-h CI was explained by differences in platelet content.

TACSI system

Terumo Automated Centrifuge & Separator Integration system processes six leucoreduced PCs in a single process, and the leucoreduction is achieved with a Imugard III-PL filter (Terumo BCT) [12]. The TACSI system is designed for the separation of cells from up to six units of pooled BCs (Fig. 2). Each processing unit contains a system box (fixed on the rotor) and an insert that can be removed for the mounting of the TACSI kit. Each system box is provided with a press system, controlled and monitored by an individual microprocessor. In a first sequence, after sterile docking of the BC and plasma or PAS, the BCs are sedimented in a vertical position. In the following step, the

Table 1 Platelet content of pooled PCs prepared either manually or with OrbiSac system

First author, year	Manual			OrbiSac					
	<i>n</i> ^a	BC ^b	PAS	Platelet content ($\times 10^{11}$)	CV (%) ^c	<i>n</i>	BC	Platelet content ($\times 10^{11}$)	CV (%)
Gulliksson, 2003 [18]	NA ^d	NA	T-Sol	NA	NA	6	NA	3.4 \pm 0.4	12
Janetzko, 2004 [19]	20	4	T-Sol	5.0 \pm 1.1	22	20	4	4.2 \pm 0.5	12
Larrea, 2005 [20]	18	5	Not reported	3.24 \pm 0.63	20	18	4	3.37 \pm 0.51	15
Larsson, 2005 [21]	6	6	T-Sol	4.1 \pm 0.65	16	6	6	3.9 \pm 0.65	17
Vetlesen, 2007 [22]	21	5	T-Sol	3.15 (3.0–3.3)	NA	21	5	3.43 (3.3–3.6)	NA
Cid, 2007 [25]	97	5	T-Sol	2.6 \pm 0.8	31	150	5	3.5 \pm 0.7	20

Values are mean \pm SD or median (range).

^a*n*, Number of pooled PCs analyzed.

^bBC, number of buffy coats included in the pooled PC.

^cCV (%), coefficient of variation.

^dNA, not available.



Fig. 2 The Terumo Automated Centrifuge & Separator Integration system (TACSI) device.

platelet-rich supernatant is transferred into a storage container by the activation of the press system in each box.

The TACSI system was validated in 2007 [27], other authors confirmed the previous results [28, 29] and Cid *et al.* [30] published an abstract comparing TACSI and OrbiSac systems.

Two published studies compared platelet characteristics of PCs obtained with TACSI and OrbiSac systems [31, 32]. First, Sandgren *et al.* [31] performed a non-paired study. Sandgren *et al.* found no significant differences in platelet counts, lactate dehydrogenase (LDH), mean platelet volume (MPV) and adenosine triphosphate (ATP) between groups, and they concluded that PCs prepared by the TACSI system were equivalent to PCs prepared by the OrbiSac system with regard to *in vitro* characteristics during 7 days of storage. Second, Plaza *et al.* [32] performed a two-paired study because authors pooled 10 ABO-matched BCs with PAS and split it into two identical aliquots. One aliquot was used to prepare PCs with the TACSI system, and the other aliquot was used to prepare PCs with the OrbiSac system. Regarding qualitative results, Plaza *et al.* found a transient increase in platelet activation and release of proinflammatory substances in PCs prepared with OrbiSac on the day of PC preparation. However, we agree with Plaza *et al.* that both type of devices prepared PCs that maintained similar cell content, platelet function and metabolism during standard storage.

Automation. Third generation

It comprised the introduction of devices to automate almost all the necessary steps for preparing RBCs, plasma, and platelets from WB collections [12]. The TACSI system has just adapted to work with WB collections to prepare blood components, and there is some preliminary data published as abstracts (Fig. 2) [33, 34]. However, we will discuss Atreus and Reveos systems because there are full manuscripts published about the quality of blood components obtained using these two devices.



Fig. 3 The Atreus device.

Atreus system

The Atreus system (Terumo BCT) is a self-contained, automated manufacturing system that processes WB up to 24 h after collection. The complete Atreus Whole Blood Processing System comprised of the Atreus device, Atreus System Manager (ASM) and disposable sets (Fig. 3) [12].

The Atreus system can be configured in three protocols. First, protocol 2C obtained one RBC unit and one plasma unit. The obtained plasma was leucoreduced by the centrifugation step, whereas the RBC unit could be leucoreduced manually after the centrifugation step. In this protocol, one unit of residual leucocytes was obtained and it could be used for research or waste. Second, protocol 2C+ obtained one RBC unit, one plasma unit, and one BC unit. The BC bag could be processed manually or with the OrbiSac or TACSI systems. Third, the protocol 3C obtained one RBC unit, one plasma unit and one platelet unit. This protocol also obtained one unit of residual leucocytes, and the platelet unit was ready to be transfused to the patient or could be pooled manually [12].

In the following paragraphs, we will show the results of published studies regarding the quality of blood components obtained with Atreus 2C+ and 3C, because we did not find any study regarding the quality of blood components obtained with Atreus 2C.

Atreus 2C+ system

Three published studies analyzed the quality of blood components obtained with the Atreus 2C+ system [35–37]. First, Sandgren *et al.* [35] investigated the effects of holding either WB or BC overnight before preparation of platelets by use of the Atreus system. WB units were separated into BC, RBC and plasma units and transferred into individual containers. Either the BC or the WB units rested overnight at $22 \pm 2^\circ\text{C}$. Six ABO-identical BCs and 300 ml of T-Sol (Fenwal Inc.) were pooled and processed with the OrbiSac system to obtain leucoreduced PCs (Table 2). Sandgren *et al.* did not find significant differences in pH, glucose consumption, lactate production, MPV, LDH activity, bicarbonate, ATP, RANTES and the expression of CD62p and CD42b between groups. The authors concluded that PCs obtained from BCs, obtained from either fresh or overnight-stored WB processed with the Atreus 2C+ system, were equivalent to control platelets with regard to platelet *in vitro* characteristics during 7 days of storage.

Second, Thomas *et al.* [36] compared the quality of RBC units, fresh frozen plasma (FFP) and BCs made from WB units held with or without active cooling. Active cooling was performed using Compocool II devices (Fresenius-Kabi, Bad Homburg, Germany), and WB collections were placed in containers in contact with the cooling element. The authors found that RBC units obtained met UK specifications for volume, haemoglobin content and haematocrit. Haemolysis, ATP, 2,3-DPG, potassium, glucose and lactate throughout storage and were all within expected ranges. FFP units also met UK specifications for volume, total protein, cellular contamination and coagulation factors. No differences were seen in RBCs or in FFP produced from WB held with or without active cooling. Authors found that the haematocrit of BCs produced from WB held without active cooling was lower than in BCs from WB held with active cooling. However, they did not find differences in platelet activation measured with the expression of cell surface P-selectin by flow cytometry. The authors concluded that blood components produced using the Atreus 2C+ system appeared suitable for clinical use, with no clinically significant difference in the quality of components from WB held at ambient temperature overnight with or without active cooling.

Third, Thomas *et al.* [37] compared the quality of PCs made from BCs using the Atreus 2C+ system or a manual method. BCs were obtained either with Atreus 2C+ or manually from WB collections following overnight hold of WB at ambient temperature without active cooling. BCs were then rested for 3 h and then 4 ABO-matched BCs were manually pooled with one unit of plasma to prepare a PC (Table 2). The PCs were analyzed for quality markers to day 9 of storage. The authors found that the platelet quality was good in both Atreus-derived PCs and

Table 2 Platelet content and platelet volume of pooled PC prepared with different configurations of the Atreus and Reveos devices

First author, year	Device configuration	Platelet pooling	<i>n</i> ^a	BC/IPU ^b	PAS ^c Type	Platelet concentration			Platelet volume	
						Volume (ml)	Concentration ($\times 10^9/l$)	CV (%)	Volume (ml)	CV (%)
Sandgren, 2008 [35]	Atreus 2C+, fresh	OrbiSac	10	6	T-Sol	300	896 \pm 136	15	357 \pm 27	8
	Atreus 2C+, stored	OrbiSac	10	6	T-Sol	300	988 \pm 122	12	365 \pm 10	3
Thomas, 2009 [37]	Atreus 2C+	Manual	8	4	Plasma	NA ^d	1023 (813–1142)	NA	294 (242–350)	NA
Cid, 2007 [38]	Atreus 2C+	OrbiSac	15	5	T-Sol	300	3.6 \pm 0.5 ^e	14	350 \pm 12	3
Sandgren, 2011 [39]	Atreus 3C, fresh	Manual	10	5	SSP	200	942 \pm 81	8	364 \pm 4	1
	Atreus 3C, stored	Manual	10	5	SSP	200	940 \pm 90	10	362 \pm 4	1
Jurado, 2012 [40]	Atreus 3C	Manual	30	4	Composol	200	1214 \pm 249	21	284 \pm 20	7
Cid, 2013 [41]	Atreus 2C+, PASII	OrbiSac	8	5	SSP	300	740 \pm 106	14	444 \pm 12	3
	Atreus 3C, PASII	Manual	8	4	SSP	200	1014 \pm 270	27	352 \pm 12	3
	Atreus 3C, PASIIIM	Manual	8	4	SSP+	200	1116 \pm 266	24	360 \pm 12	3
Lagerberg, 2013 [43]	Reveos 3C, fresh	Manual	15	5	SSP+	200	3.07 \pm 0.43 ^e	14	NA	NA
	Reveos 3C, stored	Manual	15	4	SSP+	200	3.06 \pm 0.35 ^e	11	NA	NA
Johnson, 2013 [44]	Reveos 3C	Manual	10	4	SSP+	200	1110.1 \pm 112.6	10	NA	NA

Values are mean \pm SD or median (range).

^a*n*, Number of pooled PCs analyzed.

^bBC/IPU, number of buffy coats/interim platelet units included in the pooled PC.

^cPAS, Platelet additive solution.

^dNA, Not available.

^eValues are platelet content ($\times 10^{11}$).

control units throughout storage. Metabolic markers, such as pH, ATP and hypotonic shock response, and activation markers, such as CD62P, annexin V binding, microparticles and GP IIb/IIIa, did not differ between the Atreus and control units. However, the authors found that Atreus-derived PCs contained fewer platelets than control units ($3.02 \pm 0.59 \times 10^{11}$ vs. $4.11 \pm 0.76 \times 10^{11}$; $P < 0.01$). The authors concluded that PCs prepared from BCs using the Atreus 2C+ system appeared suitable for clinical use, and WB may be held at ambient temperature overnight without the use of active cooling devices.

One study, published as an abstract, analyzed the characteristics of blood components obtained with the Atreus system in a preroutine environment. In that study, Cid *et al.* [38] used active cooling with butane-1,4-diol plates to store WB donation bags at $22 \pm 2^\circ\text{C}$ from the donation day until processing them with the Atreus system in the morning of the day after the blood donation. Working with these conditions, the authors found that the Atreus system allowed automated processing of WB rested overnight with active cooling in routine use, because the obtained blood components met European standards.

Atreus 3C system

It produces three components from WB collections: one RBC unit, one plasma unit and one interim platelet unit (IPU) that can be pooled with other IPUs to form a platelet dose for transfusion. The Atreus 3C system also

includes a platelet yield indicator (PYI), which is an advanced algorithm that provides an index that is shown to correlate well with the amount of platelets that finally end up in the IPU bag. Without being a cell counter, the PYI provides an estimate of the platelet content in the IPU, and this indicator may be a helpful tool to increase and/or standardize platelet content either by removal of low-yield IPUs from inclusion in the pooling process or by offering the possibility to combine low- and high-yield IPUs in a more consistent manner or by both.

Two published studies analyzed the quality of blood components obtained with the Atreus 3C system [39, 40]. First, Sandgren *et al.* [39] published an *in vitro* study where authors focused on platelet quality obtained with Atreus 3C system. Authors compared the effects of holding WB collections overnight versus processing WB collections fresh (2–8 h), both with 18- to 24-hour storage of the IPUs before pooling into a transfusable platelet dose. PCs were prepared pooling 5 IPUs and 200 ml of SSP (Macopharma, Tourcoing, France). The authors concluded that platelets prepared from either fresh or overnight-stored WB and pooled after a subsequent resting time of 18 to 24 h met necessary *in vitro* criteria without any relevant differences between platelet units in the two groups (Table 2). By using the PYI feature as a predictor of the platelet yield in the final unit, platelet yield from WB processed within 2 to 8 h could be improved to the same level as that of WB stored overnight.

Second, Jurado *et al.* [40] compared the Atreus 3C system (test group) and the routine method (control group) used in the blood centre with regards to product quality and operational value. Authors processed 810 WB collections over a 5-week period with the Atreus 3C system and compared with 19 512 WB collections processed with the conventional method. PCs were prepared pooling 4 IPU's and 200 ml of Composol (Fresenius kabi AG). Regarding product quality of the blood components, RBC units obtained with the Atreus 3C system had higher volume (276 ± 18 ml vs. 263 ± 21 ml; $P < 0.01$) and slight higher haemoglobin content (52.3 ± 5.4 g/unit vs. 50.1 ± 5.9 g/unit; $P = 0.06$) when compared with control group. PCs obtained with Atreus 3C system showed lower volume (284 ± 20 ml vs. 350 ± 12 ml; $P < 0.01$) and higher platelet yield ($3.44 \pm 0.68 \times 10^{11}$ vs. $3.11 \pm 0.47 \times 10^{11}$; $P < 0.05$) when compared with control group (Table 2). Finally, plasma units obtained with Atreus 3C system showed lower plasma volume (253 ± 20 ml vs. 265 ± 26 ml; $P < 0.05$) and higher fibrinogen content (316 ± 70 mg/dl vs. 284 ± 60 mg/dl; $P < 0.05$) when compared with control group. Regarding operational value, the study assessed productivity, space, equipment and staffing requirements, and they found that the Atreus 3C system enabled higher throughput while requiring less space and employee time, by decreasing the amount of equipment and processing time per unit of WB bag processed when compared with control group (40.03 min vs. 58.81 min).

Comparison of Atreus 2C+ versus Atreus 3C

Our group published one study showing that PCs obtained with Atreus 3C had lower volume when compared with PCs obtained from Atreus 2C+ and OrbiSac (352 ± 12 ml versus. 444 ± 12 ml; $P < 0.01$) [41]. In contrast, the platelet concentration was 37% higher when the PCs were prepared with the Atreus 3C in comparison with the Atreus 2C+ and the OrbiSac ($P < 0.01$). The resulting platelet yield was 9% higher in PCs prepared with the Atreus 3C when compared with PCs prepared from the Atreus 2C+ and the OrbiSac, although the difference was not significant (Table 2).

Regarding metabolic assays, Cid *et al.* showed a slightly stronger decrease in glucose concentration and increase in lactate concentration in PCs prepared with the Atreus 3C, when compared with PCs prepared with the Atreus 2C+ and OrbiSac, and both variables were significant on Day 5 and Day 7 ($P < 0.05$). However, the glucose consumption rate (calculated using glucose consumption between day 1 and 7 corrected by platelet concentration) was similar for both systems. This observation could be related to the fact that PCs prepared with the Atreus 3C resulted in a lower volume and higher

platelet concentration when compared with PCs prepared with the Atreus 2C+ and OrbiSac.

Regarding flow cytometry analysis, there were no differences between PCs obtained with both systems. We observed better results when PCs prepared with Atreus 3C were suspended in PAS-IIIM (SSP+, Macopharma) in comparison with PCs prepared with Atreus 3C and suspended in PAS-II (SSP, Macopharma). The authors concluded that PCs prepared with the Atreus 3C and suspended in PAS-IIIM preserved satisfactorily the *in vitro* platelet quality during 7-day storage. Platelet activation during a 7-day storage period was lower when the storage solution was PAS-IIIM, in comparison with PAS-II.

Reveos system

The Atreus system had a limited capacity of processing 1 WB bag per run, and the centrifuge was not refrigerated [42]. To overcome the previous drawbacks, the Reveos system (Terumo BCT) processed simultaneously 4 units of WB collections per procedure, and the centrifuge was refrigerated (Fig. 4). The system consists of a



Fig. 4 The Reveos device.

computer-controlled centrifuge equipped with a rotor with four fixed buckets, in which the quadruple WB collection system can be placed. Each bucket contains a hydraulic-driven expressor to press the different fractions of the centrifuged blood from the top to the satellite bags. Moreover, there is a temperature control system that manages the basin temperature and supports up to six Reveos, and it can be placed in a remote location.

The Reveos 2C protocol produces 1 plasma unit and 1 RBC unit from the WB bag. An additional small product, the leucopack, contains most of the platelets and white blood cells (WBCs) and is not meant to be used for preparation of a platelet transfusion product. The Reveos 3C procedure, in addition to 1 plasma unit and 1 RBC unit, produces 1 IPU and 1 leucopack containing most of the WBCs (but not of the platelets). The IPUs can be manually pooled with other IPUs using a pooling kit with integrated leucoreduction filter to form a transfusable adult-size PC without the need of an additional centrifugation step for RBC removal. Similar to the Atreus 3C, the Reveos 3C system also includes a PYI, which provides an estimation of the platelet content in the IPU, making it possible to increase and/or standardize platelet content of the final PC by selecting the optimal IPUs.

Two recent published studies analyzed the quality of blood components obtained with Reveos [43, 44]. First, Lagerberg *et al.* [43] analyzed blood components obtained with a prototype of the Reveos 2C and 3C system from either fresh (2–8 h) or overnight-held WB collections. Regarding RBCs, all units showed haemolysis <0.8% and *in vivo* recovery >75% after 42-day storage period. The plasma units produced by the Reveos from both fresh and overnight-stored WB collections showed significantly lower numbers of contaminating RBCs and WBCs than routinely produced plasma units. All Reveos-produced plasma units contained <1 × 10⁶ WBCs and can therefore be considered leucoreduced. Finally, PCs obtained with both configurations of the Reveos system showed no significant differences and platelet quality was well maintained during the 7-day storage period (Table 2).

Second, Johnson *et al.* [44] determined the *in vitro* quality of blood components produced with the Reveos

3C system and compared with historical reference units produced using semi-automated methods (Optipress and manual pooling of BCs). *In vitro* quality parameters of RBC units were very similar when compared with reference units, and the volume of the RBC units was higher with Reveos, when compared with reference units (272 ± 4 vs. 249 ± 2; *P* < 0.05). All plasma units contained <1 × 10⁶ WBCs, and can therefore be considered leucoreduced. The platelet yield of PCs was higher with Reveos system when compared with reference units (3.31 ± 0.3 × 10¹¹ vs 2.97 × 10¹¹; *P* < 0.05; Table 2). Some *in vitro* quality parameters, such as pH, glucose and lactate metabolism, hypotonic shock response and phosphatidylserine expression, were very similar although platelet activation markers (CD62P and cytokine levels) were higher in the PCs obtained with the Reveos system.

Conclusion

The complete automation of BCP from WB collections is still in development, and we are living a time with a lot of changes in this field. Given the huge change in paradigm that it represents, we would have to follow closely the development of these new techniques. In summary, we are now living an exciting time to study automation of BCP from WB collections.

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Conflict of interests

Joan Cid has received lecture fees from Terumo BCT. Laura Magnano has no conflicts to disclose. Miguel Lozano has received lecture fees and research grants from Terumo BCT.

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