2009 Abstract Book

Selected Abstracts for the Spectra Optia Apheresis System

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Spectra Optia®

APHERESIS SYSTEM

Selected abstracts for the Spectra Optia Apheresis System 2009

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Abstracts

An Initial Single-Center Experience With Plasma Exchange on the Spectra Optia Cell Separator Machine: 106 Consecutive Optia Procedures Compared to 114 Consecutive COBE Spectra Procedures on the Same Patient Group

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Purpose: Our Unit purchased two Spectra Optia cell separators in June 2007, shortly after the Optia platform had received regulatory approval for Europe: we believe these to have been the first two Optia machines in routine clinical use in the world. We now present our initial experience with the first 106 consecutive plasma exchange procedures performed on 23 different patients at our Unit on the Spectra Optia cell separator (Gambro BCT, Inc.), which we have compared with 114 consecutive plasma exchange procedures on the same patient group performed on the older COBE Spectra cell separator.

Methods: Retrospective audit of procedure run sheets.

Results: All patients had at least one procedure on each machine. This was a relatively elderly patient group, with median age 65 years (range 25 – 89). Individual diagnoses were as follows: cryoglobulinaemia, five patients; autoimmune neuropathy, five patients; Waldenström's, four patients; myasthenia, three patients; limbic encephalitis, two patients; miscellaneous other conditions, four patients. Citrate was used as the anticoagulant for all procedures. The median plasma exchange efficiency of Optia was 86% (range 73 – 99%), which was significantly higher than that of Spectra at 77% (range 68 – 87%; $P<0.01$). This resulted in significantly lower anticoagulant infusion rates over the procedure as a whole on Optia (median 0.36 mls/min/Liter total blood volume) than on Spectra (median 0.49 mls/min/liter total blood volume; $P<0.01$). Total anticoagulant infused to the patient was also lower on Optia (median 67.9 mls) than on Spectra (median 116.3 mls). Spectra and Optia calculate total run time differently, with Optia including time for rinseback at the end of the procedure while Spectra does not: allowing for rinseback, Optia procedures were slightly faster overall (median run time 108.5 min including rinseback time) compared with Spectra (median run time 103 mins not including approximately 8 min rinseback). There was no significant difference in reported toxicities (citrate toxicity, vasovagal episodes, and other toxicities) between the two machines, with toxicities generally being low. In this outpatient-based patient group, 88% of procedures overall were performed using peripheral venous access, with the proportion being similar for Spectra and Optia procedures. It was noted that Optia was less tolerant than Spectra of high return pressures, with relatively frequent return pressure alarms, though it was generally possible to resolve this by reducing inlet flow rate or temporarily pausing the procedure rather than having to resite the return cannula. It is suspected that this problem is due to the return pump being discontinuous on Optia, with a transient spike in return pressure at the start of each revolution: we have informed Gambro BCT of this issue, which could potentially be correctable in second-generation Optia software. No problems were encountered with return pressure alarms in the relatively small group of patients having Optia procedures using central venous access.

Conclusions: Overall, our initial experience of plasma exchange using Optia has been positive, with the lower citrate exposure experienced by patients being particularly valuable.

Presented at the 29th Annual Meeting of the American Society for Apheresis (ASFA), April 2008, Galveston, TX, USA. Reprinted with permission from the *Journal of Clinical Apheresis* 2008; 23: 17-18. Published by John Wiley and Sons, Inc.

Therapeutic Plasma Exchange With the New Continuous Blood Flow Separator Spectra Optia®

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Purpose: Spectra Optia is a new apheresis system developed by Gambro BCT, based on the existing Trima automated blood component collection system and the COBE Spectra apheresis system. The Spectra Optia is a continuous blood flow centrifugal apheresis system currently CE marked for therapeutic plasma exchange (TPE). This study evaluates and reports performance of this new device in a routine use setting.

Methods: We have analyzed the operation and performance of Spectra Optia during the course of 26 TPE procedures. We analyzed: conditions of implementation, effectiveness of the plasma extraction and cell losses in the removed plasma, the tolerance of the treatments as well as the satisfaction of the patients and users. Finally, detailed attention was paid to the relevance of alarms and their impact on the safety of the patients.

Results: Twenty-six procedures were carried out for a total of eight patients treated for one thrombotic thrombocytopenic purpura, two myasthenia gravis, one myeloma, two cryoblobulinemia, one gammapathy, and one chronic neuropathy. The replacement fluid used was fresh plasma frozen for 12 procedures with the same patient and 4% human serum albumin for 14 procedures. The installation of the single use disposable is simple, intuitive, and particularly rapid. The on line help accessible from the touch screen is very relevant. Average (SD) plasma extraction efficiency was 87.9%±5.9%. The number of platelets in extracted plasma is particularly low, the median platelet count being 9.79×10^9/L (3×10^9/L – 36×10^9/L), median sequestration 0.3% (0.09 – 1.36%) of the total number of the circulating platelets. The overall tolerance of the procedures was excellent; three episodes of hypocalcaemia were rapidly resolved. The patients, accustomed to other separators with continuous blood flow particularly appreciated the low noise level of the system during use. Finally, the nurses responsible for apheresis did not face any difficulty of using this separator, reporting its ease of use, speed and simplicity of implementation as well as the relevance of alarms, factors that guarantee the absolute safety of the patient.

Conclusions: The new platform Spectra Optia takes into account the user's needs and combines the assets of platforms COBE Spectra and Trima. This represents a significant improvement as regards cell separation technology of which we appreciated user-friendliness, safety, and the performances in routine use testing. Some points deserve to be re-examined, in particular: capacity of the plasma waste bag, which in our practice is insufficient, the management of the remove and replace pumps in certain situations, the amount of information reported during the run and the format of export of the data.

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First Experience With the New Apheresis Platform Spectra Optia for Therapeutic Plasma Exchange

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Background: Since the introduction of automated cell separators in the 1970s, therapeutic plasma exchange (TPE) is an established procedure in the treatment of a diversity of diseases including neurological disorders (e.g. myasthenia gravis and Guillian-Barré syndrome). With the Spectra Optia (manufactured by Gambro BCT, Inc.), a new apheresis device has been developed based on the previous COBE Spectra and Trima systems. We report experience and processing data of the initial use under routine conditions.

Methods and Material: 50 procedures were performed in 19 patients (m/f=7/12). 6 patients with multiple sclerosis, 3 with myasthenia gravis, 3 with Guillain-Barré syndrome, 3 with chronic inflammatory demyelinating polyradiculoneuropathy, 3 with acute CNS inflammatory demyelinating disease and 1 with Stiff-person syndrome. Therapeutic target was the exchange of one plasma volume per session. Substitution was performed with cristalloide, colloide and human albumine solutions. Due to frequently present dehydration in these patients, 110% fluid balance was chosen. Practicability of the method was evaluated among the operators with a questionnaire.

Results: Instruction of the new system to the operators was faster and easier compared to previous apheresis systems. Furthermore, mobility, handling and operation were sensed as less intense and time consuming, including lighter weight, lower noise levels and higher feasability due to the graphic user surface. The average time per procedure was 109±17 min. 5555±1039 ml blood volume was processed in the average per run. 92.2±13.1% calculated plasma volume was exchanged. This standard procedure resulted in an efficiency of the plasma removal of 86.1±3.5%. Analysed laboratory blood parameters (before/after apheresis) were: 10.5±4.2/11.6±4.6×10e3/µl white blood cells, 224.4±94.4/206.5±81.7×10e3/µl platelet counts, 12.4±1.1/11.9±1.5 g/dl hemoglobin and 37.3±3.4/36.4±4.2% hematocrit. There were no serious adverse events with the Spectra Optia.

Conclusion: The Spectra Optia proved to be a safe and operator friendly device. Processed volume was comparable to previous apheresis systems with a marked improvement in the practicability of use and the duration of the treatment.

Presented at the Joint Annual Congress of the German Society for Transfusion Medicine and Immunohaematology (DGTI) and the Interdisciplinary European Society for Haemapheresis and Haemotherapy (ESFH) in cooperation with the Société Française de Transfusion Sanguine (SFTS), September 2008, Düsseldorf, Germany. Reprinted with permission from *Transfusion Medicine and Hemotherapy* 2008; 35 (Suppl.1): 2. Published by S. Kargar AG.

Therapeutic Plasma Exchange Employing the New Spectra Optia 1.0 Device. The Italian Experience

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Background: Considering the procedure risks and the economic costs still related to Therapeutic Plasmapheresis (TP), recently the American Society for Apheresis (ASFA) revised and restricted the category indications for TP with an evidence based approach.

Aims: In order to minimize the procedure risks related to plasma exchange, especially in critically ill patients, and to simplify the personnel working load, Gambro BCT, Inc., developed a new device specifically dedicated for TP, with a minimal extracorporeal volume (185 mL), able to guarantee in real time the control of the entire procedure parameters through a sophisticated software. We report our preliminary experience of 30 procedures on 14 pts.

Methods: The new Spectra Optia 1.0 cell separator device was employed to treat 14 pts affected with Waldenstrom disease (one), Cryoglobulinemia (four), Myasthenia gravis (two), Guillain-Barré syndrome (one), Chronic inflammatory demyelinating polyradiculoneuropathy (three), HELLP syndrome (one), Systemic lupus erithematosus (two). Data related to whole blood and total plasma volume processed, procedure time, plasma exchange efficiency and hemocytometric analysis on patient's peripheral blood before and after TP and on the waste bag were registered in order to evaluate a possible platelet loss and Rbc and Hb contamination in the waste bag. Volume exchanged/procedure was set between 1 and 1.2 plasma volumes, fluid balancement was set between 100% and 105%, replacement fluid used was saline solution with 5% albumin and fresh frozen plasma (in HELLP syndrome). Pts were monitored for blood pressure and heart rate during every procedure.

Results: From August to December 2007, 30 consecutive TP in 14 pts were performed in Apheresis Section of our Service with a mean of 2 procedure/pts. Mean whole blood processed/procedure was 6200 mL (range: 3500 – 7000) and mean total plasma volume/procedure (ACD corrected) was 3870 mL (3400 – 4100), mean procedure time was 135 minutes (105 – 150), mean plasma exchange efficiency was 85.8% (82.2 – 89.8) and hemocytomeric analysis pre and post procedure revealed non significative reduction in platelet value (1.1%). RBC count and Hb value in waste bag was always 0 and mean platelet contamination was 7.3×10e6/mL (1 – 58). All pts showed no significative change in blood pressure and heart rate except for one affected with cryoglobulinemia and one with Guillain Barré syndrome who suffered from important hypotension episode during the second part of TP and promptly responded to albumin infusion (bolus option).

Conclusion: Our preliminary experience on the new Spectra Optia device demonstrated the high efficiency of plasma removal (85.8%) paired with a slight platelet loss (1.1%). The dedicated software permitted an optimal monitoring of the large numbers of the procedure parameters, allowing in particular to manage precisely the fluid balance in all the pts treated thus avoiding relevant side effects in the wide majority of the critically ill pts treated.

Presented at the 30th annual meeting of the International Society of Blood Transfusion (ISBT), June 2008, Macao, China. Reprinted with permission from *Vox Sanguinis* 2008; 95 (Suppl. 1): 20-21. Published by Wiley Blackwell.

Patient and Operator Satisfaction With the Spectra Optia Cell Separator Machine for Plasma Exchange: An Initial Single-Center Experience

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Purpose: Our Unit recently purchased two Spectra Optia cell separators (Gambro BCT, Inc.) in addition to our existing 5 COBE Spectra machines. We wished to survey patient and operator satisfaction with the new machines during routine use for plasma exchange.

Methods: Patient telephone survey; staff questionnaire.

Results: Of 23 patients who had all received plasma exchange on both machine types within the past year, 13 were well enough to be contacted, and all were happy to undertake a phone survey. Three patients were unaware of having treatment on two different machine types, and were not questioned further. The remaining 10 patients were then asked whether they felt better, worse or the same during plasma exchange on Optia compared with Spectra: one patient felt better on Optia; none felt worse; nine patients felt the same. Because we are aware that many of our patients report fatigue immediately postexchange, patients were then asked if they felt better, worse or the same during the 12-h period immediately postexchange. Four patients felt better postprocedure with Optia; none felt worse; six felt the same with Optia and Spectra. When asked about any other advantages of Optia over Spectra, four patients felt Optia to be "quicker," and two patients felt it was "quieter." When asked about any disadvantages of Optia, two patients were aware of more frequent return pressure alarms than with Spectra. Our four Apheresis nurses were also surveyed for their views on operating the two machine types. Loading and priming of the disposables was felt to be harder on Optia by two nurses, and the same for both machines by two nurses. Data entry was felt to be easier on Optia by two nurses and the same for both machines by two nurses. Performing the actual procedure was felt to be easier on Optia by one nurse, easier on Spectra by one nurse, and the same for both machines by two nurses. Stripping the set was felt to be equally easy for both machines by all four nurses. On open-ended questioning, the most frequent perceived advantages of Optia over Spectra were, in order of frequency: lower citrate exposure (three responses); smaller and lighter machine (two responses); better control over fluid balance (two responses); easier troubleshooting of alarms (two responses); a better user interface (two responses); and a perception that it would be easier to train new staff on Optia (two responses). The only recurring perceived disadvantage of Optia compared with Spectra, mentioned by all four nurses, is that it appears less tolerant of high return pressure.

Comments: Initial experience with Optia appeared very positive with patients, with no patients reporting Optia to be worse than Spectra in any of the areas surveyed. It is notable that the four patients who reported feeling less tired post-procedure on Optia include the three patients who have had the most procedures on Optia overall, and who would therefore have the best basis for comparison. Citrate exposure is known to be less with Optia than with Spectra, which may be why patients feel less tired afterwards. Nursing staff found both machines acceptable to operate. Despite a perceived problem with relatively frequent return pressure alarms, all staffs were very positive about the introduction of Optia, despite the fact that all four nurses had previously had several years' experience performing plasma exchange exclusively on Spectra. Among a large number of perceived advantages suggested for Optia, lower citrate exposure for patients was the most frequent.

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Preliminary Experience Using the Spectra Optia Apheresis System for Therapeutic Plasma Exchange Procedures

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Purpose: The Spectra Optia is the next generation therapeutic apheresis system based on the Trima Automated Collection System and therapeutic functionality of the COBE Spectra. The new system incorporates an improved automated interface management system, a graphical user interface, better data management/processing options and simplified, ready to use tubing sets. Use of the Spectra Optia was evaluated in the routine clinical setting.

Methods: TPE procedures were performed on the Spectra Optia and compared with matched or retrospective procedures on the COBE Spectra. Outcome measures included set-up, prime and total processing times, total blood and plasma volume processed, plasma removed, platelet content of removed plasma, and platelet loss.

Results: Twenty-five TPE procedures were performed in five patients, two with TTP, one with Devic's Syndrome, one with Myasthenia gravis, and one with Waldenstrom's Macroglobulinaemia and von Willebrand's Disease. Adverse events were minor and included a single citrate reaction, one episode of hypotension and two reversible access related problems. Comparative data are presented in the Table.

Conclusions: Set-up and processing times were shorter using the Spectra Optia. Plasma was removed more efficiently using the Spectra Optia at 87% compared with 83% using the COBE Spectra. Similarly platelet content of the removed plasma was significantly less in Spectra Optia collected plasma compared to COBE Spectra derived plasma resulting in minimal platelet loss in the patient. Our preliminary evaluation suggests that the Spectra Optia is a highly mobile, more efficient user friendly device compared to the COBE Spectra.

	COBE Spectra (median)	Spectra Optia (median)
Set-up and prime time (min)	25	12
Process times (min)	145	128
Total blood volume processed (L)	6.3	5.4
Plasma volume processed (L)	3.5	3.1
Plasma volume removed (L)	2.9	2.7
Platelet content of removed plasma ($\times 10^9$/L)	13	2
Platelet loss (%)	7	1

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In Vivo Evaluation of the Spectra Optia Apheresis System for Therapeutic Plasma Exchange (TPEX)

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Purpose: Spectra Optia is a new apheresis device based on the COBE Spectra and Gambro BCT Trima systems. It is a lighter, more maneuverable device, with a user-friendly graphical user interface. We compared safety and efficacy of the Spectra Optia with that of the COBE Spectra during the performance of TPEX.

Methods: Twenty patients with medical conditions requiring at least two TPEX agreed to one procedure, each on the Spectra Optia and the COBE Spectra. The study was performed at Yale (n=13 pairs) and Johns-Hopkins (n=7 pairs). Procedures were determined using a random number generator program. Primary outcome measure was the efficiency of plasma removal of the two systems. Secondary outcome measures included the following: platelet content of the removed plasma, % hemolysis, coagulation and complement activation, fluid balance accuracy of the procedure, and adverse events.

Results: The efficiency of plasma removal of the Spectra Optia was 87% vs. 79% for COBE Spectra (P=1.36×10^{-8}). For every paired patient study, the Spectra Optia efficiency was always higher than the corresponding COBE Spectra efficiency. The study also looked at the platelet content of the removed plasma. Platelet loss for the Spectra Optia was lower than that of COBE Spectra in 16 of 20 paired procedures, with a median of 0.92×10^{10} platelets in the waste bag for Optia (95% CI, 0.5 – 2.3×10^{10}) vs. a median value of 3.3×10^{10} for Spectra (95% CI, 2.3 – 6.7×10^{10}). A Wilcoxon Signed Rank Test was applied (P<0.006). This corresponded with a median platelet loss from the patient of 1.0% for Spectra Optia vs. 3.6% for COBE Spectra. Accuracy of the anticoagulant, plasma removal, and replacement fluid pumps was 97%. Spectra Optia predicted fluid balance within 2% of that measured. If saline/albumin is used as replacement the Spectra Optia returns 44% less AC to the patient than does COBE Spectra. D-Dimer and PF1.2 assays showed no activation of the coagulation system. Measurements of C3a and C5a showed no significant activation of complement. Plasma-free hemoglobin in plasma from Spectra Optia was <0.5 çg/dL and did not differ from COBE Spectra. There were no Serious Adverse Events with the Spectra Optia, and one mild vaso-vagal event on the Optia, that responded to a bolus of saline.

Conclusions: The efficiency of plasma removal in this 20-patient crossover study was 87% for Spectra Optia compared with 79% for the COBE Spectra device, with less platelet loss in 16 of the 20 procedures. Spectra Optia removes plasma more efficiently, with less platelet loss than COBE Spectra, resulting in a decreased amount of whole blood that needs to be processed, and infusion of less anticoagulant to the patient. No serious adverse events were encountered. We conclude that the Spectra Optia is acceptable for use in clinical plasma exchange programs.

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Birth of a New Generation of Therapeutic Apheresis Platforms: Interim Analysis of a Routine Use Experience With the Spectra Optia

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Purpose: Gambro BCT, Inc., has developed the Spectra Optia apheresis system, the next generation of therapeutic apheresis processing systems. The platform is based on the Trima Automated Collection System design, with the therapeutic apheresis utility of the current COBE Spectra apheresis system. Optia was developed to provide a system for therapeutic apheresis, which is based on the most modern platform available today with a performance equal or better than COBE Spectra. Prior to this study, the device and disposable were CE marked for therapeutic Plasma Exchange (TPE), based on clinical studies for safety and efficacy.

Methods: The purpose of our trial was to obtain routine use experience with TPE procedures on the Spectra Optia. We report on the first 42 procedures performed, 19 with an initial version of software, and 23 with an upgraded version of software. Since this was not a comparative trial, we mainly looked at general routine performance of the platform. Of particular interest are the plasma removal efficiency and the extent of platelet removal. The occurrence of alarm conditions and adverse events were also regarded as important results, as well as the general perception of system use by the operators.

Results: The procedures were performed in 18 patients, 5 with myasthenia gravis, 4 with TTP, 4 with gammopathy, and 5 with other neurological disorders. During the first 19 runs, it was observed that the machine ran conservatively, which resulted in the generation of a lot of nuisance alarms. A software anomaly at the end of the 19th procedure (no adverse event occurred in the patient), prompted us to upgrade both software and hardware. This change appears to have addressed the majority of the nuisance alarms. No significant differences as far as performance outcome between the two software versions were seen. Therefore, the data were further analyzed as one single data set. Patient related adverse events included 10 mild citrate reactions (predominantly in FFP or repeat albumin procedures), 10 occurrences of reversible access alarms, and 2 cases of mild hypovolemia. Platelets found in the waste bag were in general very low, generating an average loss of 0.59% of the initial total platelet count in the patient. Moreover, the plasma exchange efficiency was very high, at an average of 84.6±3.6%. These data compare very favorable to historical data with the Spectra platform, averaging 1.6% of platelet loss in the waste bag (1) and 69% plasma exchange efficiency (2).

Conclusions: We conclude that the Spectra Optia is a safe, operator-friendly device with an intuitive software graphical user interface. The alarms occurring during the procedure were on the over conservative side (mostly in the initial version of software). Based on this limited experience and historical data, the performance of the Spectra Optia looks superior to the COBE Spectra platform.

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Presented at the 28th Annual Meeting of the American Society for Apheresis (ASFA), April 2007, Nashville, TN, USA. Reprinted with permission from the *Journal of Clinical Apheresis* 2007; 22: 69. Published by John Wiley and Sons, Inc.

Interim Analysis of a Routine Use Trial of TPE Using the Gambro Spectra Optia, a New Generation of Therapeutic Apheresis Platforms

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Background: Gambro BCT, Inc., has developed Spectra Optia, the next generation of therapeutic apheresis processing systems, based on the Trima Automated Collection System design, with the therapeutic apheresis utility of the current COBE Spectra apheresis system. Optia was developed to provide a system for therapeutic apheresis, that is based on the most modern platform available today with a performance equal or better than COBE Spectra. Prior to this study, the device and disposable were CE marked for therapeutic plasma exchange (TPE) based on clinical studies for safety and efficacy.

Methods: The purpose of our trial was to obtain routine use experience with TPE procedures on the Spectra Optia. We report on the first 96 procedures performed, 19 with an initial version of the software, and 77 with an upgraded version. Since this was not a comparative trial, we mainly looked at general routine performance. Of particular interest were the plasma removal efficiency and the extent of platelet removal. The occurrence of alarm conditions and adverse events were also regarded as important results, as well as the general perception of system use by the operators.

Results: The procedures were performed in 22 patients, 7 with myasthenia gravis, 5 with TTP, 4 with gammopathy and 6 with diverse neurological disorders. The exchange fluid was HSA in 47, and FFP in 49 procedures. The initial software version generated a lot of nuisance alarms, due to a rather conservative setup. This prompted an upgrade of both software and hardware. Patient related adverse events included 27 mild citrate reactions (predominantly in FFP procedures), 30 occurrences of reversible access or return alarms, and 2 case of mild hypovolemia. Platelets found in the waste bag were in general very low, representing 0% of the initial total platelet count in the patient (range 0 – 14,7%). This feature is a particular value in patients with low platelet counts. Moreover, the plasma exchange efficiency was very high, at a median of 85,4% (range: 71,9 – 92,8%). These data compare favorable to historical data with the Spectra platform averaging 1.6 % of platelet loss in the waste bag and 69% plasma exchange efficiency.

Conclusions: We conclude that the Spectra Optia is a safe, operator-friendly device with an intuitive graphical user interface. The alarms occurring were on the over-conservative side, but this issue was largely solved during the first software upgrade. Data on the second software upgrade are under analysis, but seem to have even further addressed this issue. Based on this trial and historical data, the performance of the Spectra Optia looks superior to the former COBE Spectra platform.

Disclosure of Conflict of Interest: Tom Bracke, Dirk Bermamns, Jeff Steward, Andreas Beck, Richard Smith: Nothing to Disclose; Koen Theunissen: Gambro BCT, Inc.—Travel Support of Honorarium, including this proposed educational program.

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