INTRODUCTION

TPE is a non-pharmacological treatment that removes a large volume of a patient’s plasma after separating it from the cellular components of the blood. The plasma removed is concomitantly replaced with appropriate fluids. For TPE to be an effective therapy, a disease or disorder must be induced and/or exacerbated by a pathological substance that can be effectively removed with the plasma in order to reduce symptoms. TPE is used to remove or decrease the level of circulating antibodies, antigen-antibody complexes, cytokines, abnormal plasma proteins, cholesterol, metabolic waste products, and plasma-bound toxins and drugs. Reducing the levels of pathological factors circulating in the patient’s plasma is the mechanism of action of TPE to eliminate symptoms or prevent further destruction of the involved organ or system. Alternatively, TPE can be used to replace a deficient factor, as in systemic thrombotic microangiopathy. It can be used as a standard treatment or as an adjunct therapy in combination with drugs and/or surgery.

TPE can be performed manually, where blood is extracted in repeated cycles and centrifuged ex vivo. The supernatant (plasma) is then discarded, and the remainder of the blood is returned with a replacement fluid. Alternatively, standard TPE can be performed by automated devices and is categorized into two distinct groups: centrifugal (cTPE) and membrane filtration (mTPE).

cTPE separates blood components based on the density of the individual elements. Exposing whole blood to a centrifugal field results in the separation of plasma from cellular components. A replacement fluid is mixed with the blood and returned to the patient.

With mTPE, the patient’s blood is pumped through a parallel-plate or hollow-fiber filter. The pores of the filter membranes have a specific diameter sufficient to allow passage of plasma, isolating it from the cellular components of the blood.

The Spectra Optia system, a next-generation therapeutic apheresis platform, has been available on the market for several years with an approved cTPE protocol. Since then, several researchers and physicians have published five papers and more than 20 abstracts regarding TPE. The following is a summary of these publications, including major outcomes.
PLASMA REMOVAL EFFICIENCY (PRE)

TPE is based on the premise that circulating disease mediators can be decreased more effectively than the body’s own mechanism to maintain homeostasis. Patients could benefit from the replacement fluid used and the removal of pathological substances, which in turn could regulate other immune mechanisms.11

GENERAL CONCEPT

PRE is an established metric to analyze the performance of an apheresis device during a TPE procedure.13,14,15 PRE can be simply stated as:

\[ \text{PRE} = \frac{\text{Vol}_{\text{rp}}}{\text{Vol}_{\text{pp}}} \times 100 \]

Vol_{rp}: Volume of plasma and anticoagulant (AC) that is removed
Vol_{pp}: Volume of plasma and AC that is processed

The Vol_{pp} is:

\[ \text{Vol}_{\text{pp}} = (V_{\text{in}} - V_{\text{ac}}) \times (1 - \text{Hct}) + V_{\text{ac}} \]

Hct: Venous hematocrit of the patient (ideally, an average of pre- and post-procedure values)
V_{in}: Volume of inlet blood processed
V_{ac}: Volume of AC used

The following complete formula was used by several authors both for the Spectra Optia system and the comparison to other cTPE devices:8,13,14,15

\[ \text{PRE} = \frac{\text{Vol}_{\text{rp}}}{[(V_{\text{in}} - V_{\text{ac}}) \times (1 - \text{Hct}) + V_{\text{ac}}]} \times 100 \]

Using this calculation, PRE shows the volume of plasma that can be removed per volume of plasma that is processed with a specific apheresis device; in other words, the fraction of the processed plasma that is actually removed. Logically, PRE should be rather independent of the amount of blood processed. However, short procedures tend to have lower PREs than longer procedures, as apheresis devices require time to build up the blood levels to the necessary requirements while replacing the priming fluid. During this starting phase, blood, and therefore plasma, is already being processed while there is no removal of plasma yet.

The Spectra Optia system is the only existing device using an Automated Interface Management (AIM) system, which continuously monitors and interprets the position of the interface (the distinguishable boundary between plasma and cells in centrifuged blood). It does this by evaluating the position of the interface on approximately every other rotation of the centrifuge, depending on the speed of the centrifuge. When the AIM system is enabled, it makes adjustments to the plasma pump flow rate to maintain the optimal position of the interface, when reliably identified (Spectra Optia system rarely might not ‘see’ the interface during a TPE procedure causing the interfaces not to be reliably identified during those occasional moments). Theoretically, this allows the Spectra Optia system to safely remove more plasma when compared to procedures that are based solely on a hematocrit algorithm.

Table 1: Summary of published average values for procedures performed on the Spectra Optia system. In the PRE/PE column, assume that PRE is used unless PE is indicated. When a parameter is not shown for a specific publication, the authors did not report it. Publication references in bold are peer-reviewed papers; the others are abstracts published at conferences and meetings. The last row shows the range for each parameter.

<table>
<thead>
<tr>
<th>Publication</th>
<th>Parameters (Average Values)</th>
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<tr>
<td></td>
<td>PRE/PE (%)</td>
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<tr>
<td>Balint, et al., 2013 a&amp;b21,22</td>
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<tr>
<td>Burgstaler and Winters, 2013 (ratio 13)23</td>
<td>86.6</td>
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<tr>
<td>Burgstaler and Winters, 2013 (ratio 26)23</td>
<td>83.2</td>
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<tr>
<td>Cid, et al., 2014a and Cid, et al., 2013a</td>
<td>82.9</td>
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<tr>
<td>Cole, et al., 2014a</td>
<td>116</td>
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<tr>
<td>Douglas, et al., 200816</td>
<td>86 (PE)</td>
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<tr>
<td>Golla, et al., 2011a and Hafer, et al., 201327</td>
<td>84</td>
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<tr>
<td>Hequet, et al., 20144</td>
<td>80-86</td>
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<td>Kim, et al., 201328</td>
<td>91</td>
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<tr>
<td>Lambert, et al., 2011a</td>
<td>83.2 (PE)</td>
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<td>Lefevre and Poullin, 200817</td>
<td>88 (PE)</td>
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<td>Opitz, et al., 200829</td>
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<td>Perotti, et al., 200830</td>
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<td>Puppe and Kindon, 201430</td>
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<td>Roxby, et al., 200831</td>
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<tr>
<td>Snyder, et al., 200722</td>
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<tr>
<td>Theunissen, et al., 2007 a&amp;b32,30</td>
<td>84.6 (PE)</td>
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<tr>
<td>Tormey, et al., 201032</td>
<td>87</td>
</tr>
<tr>
<td>Range</td>
<td>80–91</td>
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</table>
In general, cTPE devices significantly outperform mTPE devices in terms of PRE, as previously described.\textsuperscript{3,11} Published data show that flow rates for mTPE are typically much higher than for cTPE, which suggests that practitioners of mTPE devices counter the typically lower PRE by increasing the flow rate in order to reach similar procedure times for both device types.

**PRE VERSUS PLASMA EXCHANGE EFFICIENCY (PE)**

In addition to PRE, other names for efficiency of plasma removal exist, such as plasma exchange efficiency (PE). However, PE does not necessarily mean the same as PRE. Nevertheless, some authors use PE interchangeably with PRE with a similar formula as described above.\textsuperscript{8} Several abstracts describing the use of the Spectra Optia system in TPE also use the term PE instead of PRE, although the formula is not explained.\textsuperscript{16,17,18,19,20} It remains a question whether the authors really refer to one or the other. Therefore, this review will treat the PRE and PE in a similar way, although when PE is used instead of PRE, it will be clearly stated. Despite the apparent confusion in the literature, PRE is the preferred way to describe TPE performance.

**GENERAL VARIABLES**

**PRE AND PROCEDURE TIME**

Table 1 compiles the data for the main parameters described in the majority of the publications on the Spectra Optia system. The PRE on the Spectra Optia system ranges from 80 percent to 91 percent, and in 10 of the 15 publications, it is calculated above 85 percent. Comparisons with other devices will be discussed later in this review, but Ward summarizes that centrifugal apheresis devices in general have a PRE of 80 percent.\textsuperscript{3} As demonstrated in Table 1, the Spectra Optia system meets or exceeds 80% in every case but one in which PRE is measured.

Another important parameter reported in many publications is procedure time. The range of procedure times in the different abstracts and papers is wide. The reason is that procedure time depends on many factors, such as blood inlet flow rate, inlet:AC ratio used, AC infusion rate, total plasma volume (TPV) treated, type of replacement fluid used, pauses during the procedure and so on. Therefore, procedure time provides a standard basis for comparison when devices are compared for the same patients with similar conditions for the treatment. Additionally, it can be concluded that procedures can be finished quickly (within an hour) on the Spectra Optia system, especially when a high inlet:AC ratio is used.\textsuperscript{21} Conversely, with lower flow rates and/or higher TPVs treated, TPE procedures could take up to more than two hours, ranging from 55 to 135 minutes.\textsuperscript{18,31}

**PLATELET LOSS**

When performing TPE procedures, it is an important patient safety concern to have minimal cellular loss. Because platelets have the lowest specific gravity of all human blood cells, they have the highest probability of residing in the plasma fraction and can be the most affected in a TPE procedure. Furthermore, platelet activation and platelet aggregation mechanisms could contribute to an additional loss of platelets. In general, platelet loss is calculated using this formula:

\[
\text{Quantity of platelets in waste bag} \times 100
\]

\[
\frac{\text{Quantity of platelets initially in patient’s circulation}}{\text{(Pre-apheresis value – Post-apheresis value)}} \times 100
\]

Hequet and colleagues use a different calculation method:

\[
\frac{(\text{Pre-apheresis value} – \text{Post-apheresis value})}{\text{Pre-apheresis value}} \times 100
\]

It should be noted that many of the described publications do not explain how they calculate platelet loss, so Hafer, et al. may also have used some other method, but this remains unknown.\textsuperscript{21} In the publications where platelet loss is known to be calculated by the first formula shown above, it did not exceed 1.6 percent. Compared to other devices, these numbers are low (see the following sections).

**ANTICOAGULANT (AC)**

The validated AC used in the Spectra Optia system is ACD-A (Acid Citrate Dextrose formula A), which is known to potentially induce citrate toxicity. Therefore, it is important to control the AC infusion rate and the total amount of ACD-A used. Typically, total amounts of ACD-A used are much higher than the ACD-A that is actually infused (administered to the patient): only 44 mL to 71 mL of ACD-A is infused versus 414 mL to 687 mL used during the average TPE procedure. This allows citrate-induced adverse events (0.08 percent to 1.2 percent of procedures) to be mild and self-limiting.\textsuperscript{1} The low amount of ACD-A infused can be attributed to the high PRE result with the Spectra Optia system.

**INLET:AC RATIO COMPARISON**

Burgstaler and Winters used the Spectra Optia system when comparing an inlet:AC ratio of 13:1 with 7,000 units of heparin to an inlet:AC ratio of 26:1 in combination with 10,000 units of heparin.\textsuperscript{21} Each time, heparin was added to 1 L of ACD-A. However, for the procedures with an inlet:AC ratio of 13:1, the ACD-A was diluted with a saline solution to a 1:1 ratio, while for the 26:1 inlet:AC ratio procedures, non-diluted ACD-A was used (Terumo BCT does not recommend dilution of the ACD-A with the Spectra Optia system as this defeats the device’s ability to control the citrate infusion rate). Consequently, similar AC concentrations were used in both types of procedures in the extracorporeal circuit. Still, when using the higher ratio (26:1), the authors reported a similar PRE (the difference was not significant; p >0.05), but a shorter procedure time at a significantly higher blood flow rate (p <0.05) was used. Additionally, significantly less anticoagulant was infused to the patient (p <0.05). Due to dilution in the 13:1 inlet:AC ratio arm, the effective anticoagulation is unclear. No significant clotting was observed, and therefore no early termination of any procedure was reported.

**MISCELLANEOUS PARAMETERS**

Some publications also described different variables; one was pump accuracy of at least 97 percent.\textsuperscript{13,28} Three publications reported the volume of whole blood processed, which ranged from 5,555 mL to 6,796 mL.\textsuperscript{15,18,29} None of the published literature shows any serious adverse events (SAEs) experienced with procedures on the Spectra Optia system.

**PERFORMANCE IN COMPARISON TO THE COBE® SPECTRA APHERESIS SYSTEM**

The COBE Spectra system is the previous-generation apheresis device from Terumo BCT. Over 20 years of experience have been reported on this device, and it has been referred to as the “gold standard” in apheresis.\textsuperscript{33} It is, therefore, not surprising that many of the publications compare the Spectra Optia system to the COBE Spectra system. Table 2 summarizes the results of this comparison.
On the other hand, the lowest average platelet loss measured on the Spectra Optia system was 1.2 percent. Fewer platelets are lost in the Spectra Optia system than on the COBE Spectra system, as outlined in Table 2. In the abstracts of papers discussing the comparison of the two Terumo BCT systems, the inlet:AC ratio was 10:1 on the Spectra Optia system, while on the COBE Spectra system the inlet:AC ratio was 12:1. The lower inlet:AC ratio on the Spectra Optia system resulted in a lower flow rate.

In Table 3, two devices manufactured by other companies are compared to the Spectra Optia system. Two groups of papers discussing the comparison of the two Terumo BCT devices, the average platelet loss on the Spectra Optia system does not exceed 1.2 percent, with one exception of 3.4 percent. On the other hand, the lowest average platelet loss measured on the COBE Spectra system was 3 percent, and losses range up to 16.4 percent. This could be due to the fact that the Spectra Optia system uses a higher packing factor during the TPE procedures and, therefore, platelets are more likely to be found in theuffy coat layer. Furthermore, when reliably identified, the AIM system on the Spectra Optia system constantly controls the interface, which potentially leaves less room for operator errors.

### Anticoagulant

ACD-A is processed differently on the Spectra Optia system than on the COBE Spectra system. Both devices use comparable amounts of AC in the published data; however, as a result of the higher PRE on the Spectra Optia system, more ACD-A is also removed and thus less citrate is returned to the patient. This improves patient safety, as ACD-A can induce citrate toxicity.

### MISCELLANEOUS PARAMETERS

Some additional parameters were analyzed in several publications. Roxby, et al. describe the setup time on the Spectra Optia system to be 15 minutes, while on the COBE Spectra system the operator needed 25 minutes to prepare the device. As with the Spectra Optia system, no SAEs were observed on the COBE Spectra system.

### Comparing to Other Centrifugal Apheresis Devices

In Table 3, two devices manufactured by other companies are compared to the Spectra Optia system. Two groups compare it to the Amicus™ separator (Fresenius Kabi), while Lambert, et al. make the comparison to MCS+ platelet collection system (Haemonetics).
Tonev, et al. compare the Spectra Optia system to COM.TEC (Fresenius Kabi). This study comments only on the Spectra Optia system's higher mobility and lower platelet loss without showing any other results.24

**SPECTRA OPTIA SYSTEM VERSUS MCS+**

When the devices are analyzed side by side, the Spectra Optia system has a higher PRE than the MCS+. The procedure time is drastically higher on the MCS+, because this device works in a discontinuous way and uses only a single-needle procedure. Furthermore, the platelet loss is much higher in this study on MCS+ compared to the Spectra Optia system. The authors report a similar RBC loss post-procedure in both devices.

**SPECTRA OPTIA SYSTEM VERSUS AMICUS**

Amicus has been described by Cid and colleagues in both a peer-reviewed paper and an abstract as having comparable results to the Spectra Optia system.25,26 Although the PRE is superior in the Spectra Optia system, the authors measured longer procedure times on the Spectra Optia system than on Amicus. In the same publications, they also compare the COBE Spectra system to the Amicus and, as mentioned above, they used a lower inlet:AC ratio on the Spectra Optia system 10:1 versus 12:1 on both Amicus and the COBE Spectra system. Having more ACD-A per volume of blood processed implies that the overall blood flow rate goes down when the AC infusion rate remains the same; therefore, the procedure time logically increases. If similar blood flow rates had been used, a shorter procedure time could have been expected on the Spectra Optia system when processing the same amount of plasma, since the PRE was the highest on this device. Equivalent settings should be used to compare procedure times. This is the case for Cole et al., where the Spectra Optia system was the most efficient device in terms of procedure time in comparison to Amicus.25

In the article published by Cid, et al. in 2014, “anticoagulant infused” is used to mean “anticoagulant used” and not “anticoagulant administered to the patient”; therefore, it is put in the “anticoagulant used” column in Table 3. In this article, an average of 687 mL “anticoagulant infused” is reported, which is within the typical range used for a procedure—not all of that goes to the patient. (In contrast, for Ca<sup>2+</sup>–Mg<sup>2+</sup> solution “infused,” the authors do mean “administered to patients”).15 To compensate for the loss of Ca<sup>2+</sup> in the patients, more Ca<sup>2+</sup>–Mg<sup>2+</sup> solution was used in the Amicus procedures (81 mL with Amicus versus 56 mL with the Spectra Optia system; p <0.001), although anticoagulant used in the Spectra Optia system was the highest (which is to be expected with the lower inlet:AC ratio). The patient ionized Ca<sup>2+</sup> in the blood was not significantly different in the patients treated on both devices. Therefore, we can speculate that the infused volume of citrate used with the patients was significantly higher on Amicus than on the Spectra Optia system and COBE Spectra system during this study. This speculation is confirmed by Cole et al., who show an average 40 percent less infused volume of ACD-A when using the Spectra Optia system compared to Amicus.25

Finally, the comparison of the Spectra Optia system with Amicus shows a significantly higher plasma volume removed on the Spectra Optia system with a comparable volume of whole blood processed, probably due to a higher PRE on the Spectra Optia system.25 Additionally, a higher drop in ion Ca<sup>2+</sup> concentration in Amicus versus the Spectra Optia system is possibly due to a lower AC infusion rate on the Spectra Optia system versus Amicus.25

**PERFORMANCE OF THE SPECTRA OPTIA SYSTEM COMPARED TO mTPE DEVICES**

A last series of comparative studies between the Spectra Optia system and two mTPE devices is summarized in Table 4. Only two centers have reported on such a comparison. One discusses the performance of the Spectra Optia system against the Octo Nova® device (DIAMED) using a Plasmapheresis OP 05W filter (Asahi Kasei Medical, Japan) in two abstracts.26,27 The other group discusses the Spectra Optia system and a Prisma device with the TPE2000 set (Gambro) in both an abstract and a peer-reviewed publication.30,35

In terms of PRE, the Spectra Optia system clearly outperforms the Octo Nova device. This corroborates with literature indicating that mTPE devices exceed mTPE devices in terms of PRE.2 Higher flow rates used in mTPE devices do not always result in a difference of procedure time, as mentioned in the discussion above on the Spectra Optia system versus Amicus. Nevertheless, even with these settings, the Spectra Optia system outperforms both mTPE devices in procedure time. Platelet losses are significantly higher on the Octo Nova device, as well. Hafer, et al. describe a higher removal of fibrinogen and IgG with the

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**Table 3: Summary of published average values for procedures performed on the Spectra Optia system compared with the MCS+ system and the Amicus separator.** In the PRE/PE column, assume that PRE is used unless PE is indicated. When a specific parameter is not shown, the authors did not report it. Publication references in **bold** are peer-reviewed papers; the others are abstracts published at conferences and meetings. When statistical significance is mentioned in the publication, it is shown in the table (p value or NS for not significant).

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<tr>
<td></td>
<td>PRE/PE (%)</td>
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<tr>
<td>Spectra Optia System</td>
<td>Amicus</td>
</tr>
<tr>
<td>Cid, et al., 2013&lt;sup&gt;20&lt;/sup&gt; and</td>
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</tr>
<tr>
<td>2014&lt;sup&gt;21&lt;/sup&gt; (also versus</td>
<td></td>
</tr>
<tr>
<td>COBE Spectra system)</td>
<td></td>
</tr>
<tr>
<td>Cole, et al., 2014&lt;sup&gt;21&lt;/sup&gt;</td>
<td>116</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Spectra Optia System</td>
<td>MCS+</td>
</tr>
<tr>
<td>Lambert, et al., 2011&lt;sup&gt;22&lt;/sup&gt;</td>
<td>83.2 (PE)</td>
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<tr>
<td>(p&lt;0.05 for all parameters)</td>
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</tbody>
</table>

*Note: NS indicates not significant.*

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**Footnotes:**

1. **Bold** text indicates peer-reviewed papers; all others are abstracts published at conferences and meetings.
2. The statistical significance is indicated in the publication, so the p value is shown here.
3. The study by Cid and colleagues is one of a published review.
4. The study by Cole et al. was the first to use the Spectra Optia system.
5. The study by Tonev et al. was the first to compare the Spectra Optia system to the Amicus system.

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**References:**

1. Cid, et al., 2014
2. Cole, et al., 2014
3. Lambert, et al., 2011
4. Cid, et al., 2013
5. Cole, et al., 2013
6. Tonev, et al., 2014
7. Lambert, et al., 2011
8. Cid, et al., 2014
10. Lambert, et al., 2011
12. Lambert, et al., 2011
15. Cole, et al., 2014
16. Lambert, et al., 2011
17. Cole, et al., 2013
18. Lambert, et al., 2011
20. Lambert, et al., 2011
22. Lambert, et al., 2011
24. Lambert, et al., 2011
26. Lambert, et al., 2011
27. Cole, et al., 2014
28. Lambert, et al., 2011
29. Cole, et al., 2013
30. Lambert, et al., 2011
32. Lambert, et al., 2011
33. Cole, et al., 2013
34. Lambert, et al., 2011
35. Cole, et al., 2014
Spectra Optia system (64 percent versus 56 percent and 68 percent versus 63 percent in the Spectra Optia system and Octo Nova devices, respectively). The Octo Nova device also had to process more than three times as much blood as the Spectra Optia system (19,855 mL versus 6,456 mL) for a similar volume of plasma exchange/removal.

In nine procedures on the Prisma device, 13 filters were used due to clotting, while the Spectra Optia system required only one disposable set per procedure. In this publication, clotting on the Prisma device occurred in a total of 33 percent of procedures. In other published data, 7.3 percent and 15.5 percent of mTPE procedures either resulted in premature ending of the procedure or required the use of an additional disposable set. The percentage of clotting in the Puppe and Kingdom article is relatively high, which could be explained by possible differences in heparin usage. Nonetheless, clotting was never reported on the Spectra Optia system during a TPE procedure.

DISEASES TREATED

Several publications describe the disease types of the patients enrolled in the studies. Notably, it is specifically mentioned how many patients for each specific disease were treated on the Spectra Optia system (and other devices). 70 out of 124 disorders are neurological (56 percent). The other main disease types are hematological (n = 30; 24 percent), renal and rheumatological (n = 15; 12 percent) and oncological (n = 12; 10 percent). Table 5 summarizes these findings.

CONCLUSION

From this literature review, we can conclude that the Spectra Optia system has proven its effectiveness compared to other existing apheresis systems. The Spectra Optia system shows better results than the COBE Spectra system for TPE procedures in terms of several parameters: it achieves higher PRE, lower procedure time and lower platelet loss. In addition, less anticoagulant is infused to the patient by the Spectra Optia system. Compared to other cTPE devices, the Spectra Optia system has been shown to outperform on all these parameters, with the exception of procedure time. In the case of Amicus, it requires a comparison using the same conditions on both machines (for example, using similar inlet:AC ratios and blood inlet flow rates). The Spectra Optia system also surpassed the mTPE devices that were tested on PRE, procedure time and platelet loss. In the abstracts mentioning disease mediator removal efficiency, it more effectively removed the larger protein fibronectin than the Octo Nova device.

Several authors have come to the conclusion that the Spectra Optia system is a preferred choice for TPE, citing several aspects of its performance. Balint, et al. conclude that "Spectra Optia is a more acceptable device for upcoming clinical TPE protocols than COBE Spectra," while Hafer, et al. advise that "especially in centers performing many procedures per year cTPE in contrast to mTPE can reduce treatment time without compromising treatment efficacy." Lambert, et al. conclude that "the Spectra Optia has significantly higher extraction rate and exchange efficiency than the MCS+ allowing to remove the same amount of plasma in less time, by processing less blood," and Cole, et al. agree that "despite higher inlet flow rates, Amicus took an average of 14 minutes longer and processed 900 mL more blood to achieve similar exchange volume to Optia." The Spectra Optia system is an option for therapeutic plasma exchange.

Table 4: Summary of published average values for procedures performed on the Spectra Optia system compared with mTPE devices. When a parameter is not shown for a specific publication, the authors did not report it. Publication references in bold are peer-reviewed papers; the others are abstracts published at conferences and meetings. When statistical significance is mentioned in the publication, it is shown in the table (p value or NS for not significant).

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<td>Spectra Optia System</td>
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<tr>
<td>Golla, et al., 2011 \cite{26} and Hafer, et al., 2013 \cite{27}</td>
<td>84</td>
</tr>
<tr>
<td>Puppe and Kingdom, 2014 \cite{30} and Puppe, et al., 2013 \cite{35}</td>
<td>113</td>
</tr>
</tbody>
</table>

*The Spectra Optia system is an option for therapeutic plasma exchange. While this system does not have a specific indication for any disease as an immunomodulatory therapy, plasma exchange is an identified therapeutic option and has been demonstrated to remove inflammatory mediators. Use of this device must be evaluated and prescribed by the health care professional responsible for the patient’s care.
Table 5: Reported number of patients treated in the abstracts and peer-reviewed publications of procedures performed on the Spectra Optia system.

<table>
<thead>
<tr>
<th>Disease Type</th>
<th>Disease</th>
<th>Number of Patients</th>
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<tbody>
<tr>
<td><strong>Neurological</strong></td>
<td>Periphera nervous system disorders</td>
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<tr>
<td></td>
<td>Myasthenia gravis</td>
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<td></td>
<td>Guillain-Barré syndrome</td>
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<tr>
<td></td>
<td>Chronic inflammatory demyelinating polyradicuoneuropathy</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>Other/non-specified auto-immune neuropathies</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Central nervous system demyelinating disorders</td>
<td>23</td>
</tr>
<tr>
<td></td>
<td>Multiple sclerosis (1 Marburg's variant)</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Acute CNS inflammatory demyelinating disease</td>
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<td>Devic's syndrome/neuromyelitis optica</td>
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<td>Acute disseminated encephalomyelitis</td>
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<tr>
<td></td>
<td>Central nervous system disorders</td>
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<td></td>
<td>Limbic encephalitis</td>
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<td></td>
<td>Stiff person syndrome</td>
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<td><strong>Hematological</strong></td>
<td>Thrombotic thrombocytopenic purpura</td>
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<td>ABO-incompatible kidney transplantation</td>
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<td>Goodpasture's syndrome</td>
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<td>HELLP Syndrome</td>
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REFERENCES


