

The Role of Infusion Pump Technology in Optimizing Efficiency in Cancer Care Delivery

Results of a simulated chemotherapeutic regimen with the Plum 360[®] infusion system vs. a competitive system

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Overview

In this white paper, we examine the impact of technology in cancer care delivery. A hypothesis of improved chemotherapy delivery metrics with the Plum 360 infusion pump is presented, along with results of a bench study (n=5) supporting greater efficiency ($p<0.001$) and a reduced number of air-in-line alarms ($p<0.001$). A review of infusion safety that aligns the observations of the study to known patient and healthcare provider safety considerations is also presented.

Introduction

The cancer care delivery model has undergone significant change in the past twenty years. In particular, the shift to value-based healthcare is driving the development of cancer care that is both clinically effective and cost-efficient. Since the early 1990s, we have seen the delivery of chemotherapy move from the hospital setting to the outpatient environment.¹ In 2003, the Medicare Prescription Drug, Improvement, and Modernization Act substantially reduced payment rates for chemotherapy drugs given in an outpatient setting.

Despite the decrease in outpatient reimbursement and an increase in hospital employment of physicians, the overall impact on cancer care delivery setting is not yet clear. Additional considerations include the coming adoption of U.S. Pharmacopeial Convention <800> (USP <800>) and its impact on workflow requirements during the administration of hazardous drugs.

With the use of chemotherapy increasing and cost pressure continuing to decrease reimbursement, improvements in the efficiency of chemotherapy delivery is essential. The Plum 360 infusion pump may provide a unique opportunity for time and cost savings in cancer care through the concurrent delivery of two compatible infusion agents.

In addition, the Plum 360 infusion system utilizes unique technology that allows air to be removed through a secondary administration port and a pumping mechanism that may decrease air bubble formation. This creates opportunities to save time, reduce exposure to hazardous drugs, and minimize wasted medication.

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Objectives

We examined the capability of the Plum 360 infusion pump technology to concurrently deliver two compatible medications through a single line, combined with its ability to maintain a closed system by removing air via backpriming technology. We hypothesized that this translates into quantifiable benefits when used in cancer therapy.

Methods



Performance of the Plum 360 infusion system was compared to a competing large volume infusion pump, which is currently in service in the United States. Both pumps were evaluated using a simulated chemotherapy session based on a treatment protocol for ovarian cancer.² Time required for pump delivery of prehydration, premedication, and chemotherapy was the primary data gathered from the study. The number of air-in-line alarms recorded was a secondary data point.

The testing setup included clinically relevant configurations of both the Plum 360 and the competitor's system. The Plum 360 configuration included a Plum 360 pump SW15.02, a single primary PlumSet[®] IV tubing set, and two secondary tubing sets. The competitor's configuration included a single channel large volume infusion pump, a single primary tubing set, and two secondary tubing sets. The simulated infusion solutions included a compatible prehydration and premedication regimen and the chemotherapeutic agent. Concurrent administration of the prehydration and premedication was simulated but this protocol is not meant to replace or supersede clinical judgment.

In the study setting, participants prepared solutions and executed a simulated chemotherapy protocol. The protocol was completed five times per device. The times and events are presented in Table 1.

Results

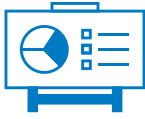
TABLE 1: RESULTS³

Primary Endpoint		Plum 360	Competitor
Average infusion time in minutes (average of 5 cycles, including air clearance tasks)	Prehydration 250 mL	37 minutes, 56 seconds (fluid and compatible premedication ran concurrently)	60 minutes, 9 seconds (fluid for 30 minutes, 7 seconds, followed by premedication for 30 minutes, 2 seconds)
	Premedication 50 mL		
	Chemotherapeutic placebo* 300 mL	179 minutes, 24 seconds	182 minutes, 26 seconds
Average total time to complete the infusion protocol		217 minutes, 21 seconds	242 minutes, 35 seconds
Time difference		-25 minutes, 15 seconds	N/A
% Time difference		-12%	N/A
Statistical analysis – difference in minutes, one-sided t-test		p < 0.001	

Primary Endpoint		Plum 360	Competitor
Air-in-line alarms	Total number	0	21
	Average number per cycle	0	4.2
Statistical analysis - difference in observed counts, chi-squared test		p < 0.001	

*The chemotherapeutic placebo may represent paclitaxel or other agents

Discussion



This pump evaluation, utilizing a simulated chemotherapy regimen, revealed significant differences between the two infusion systems, in both primary and secondary endpoints.

Primary endpoint analysis of the time required to complete the simulated chemotherapy infusion protocol demonstrated a time savings with the Plum 360 infusion system that averaged 25 minutes, 15 seconds ($p < 0.001$).

This difference in time can be attributed to the unique technology of the Plum 360 infusion system that enables concurrent delivery of two compatible medications through a single channel. In this case, the Plum 360 infusion system provided prehydration and premedication simultaneously over an average time of 37 minutes, 56 seconds.

In contrast, the competitor's pump was limited to delivering a single infusion through the single pump channel. (Note: Competing pumps can be configured to have multiple channels at incremental cost and footprint.)

The competitor single infusion requirement led to delivery of prehydration averaging 30 minutes, 7 seconds, followed by delivery of the premedication averaging 30 minutes, 2 seconds for an average combined time of 60 minutes, 9 seconds. The difference in infusion times between the pumps for prehydration and premedication was 22 minutes, 13 seconds ($p < 0.001$). The infusion time required for the delivery of the simulated chemotherapeutic agent was similar for both pumps as concurrent delivery with this agent is not indicated ($p = 0.10$).

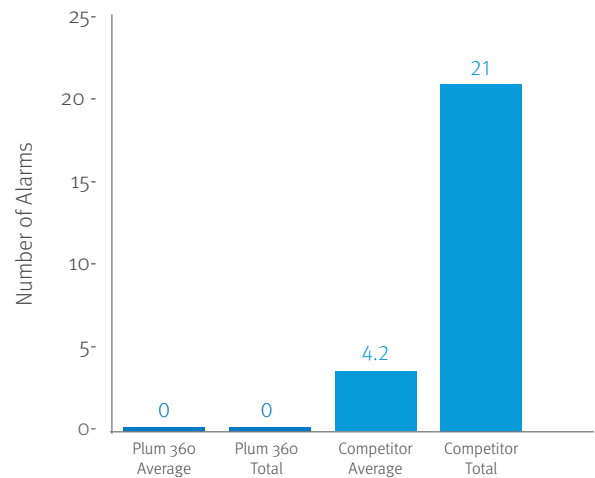
Thus, where opportunity for concurrent medication delivery is possible, the Plum 360 infusion system creates the potential for significant time savings. Over the total study period simulating infusion delivery for five patients, the Plum 360 pumped for 18 hours, 7 minutes, while the competitor pumped for 20 hours, 13 minutes, for an overall time difference of 2 hours, 6 minutes.

For an ovarian cancer patient receiving therapy matching this protocol, this represents over an hour and fifteen minutes less in the infusion chair over three cycles.

The impact of the time savings gains more significance with shorter duration infusion protocols.

For example, if the chemotherapeutic agent in this protocol was infused over one hour instead of three, the percentage of time savings would increase from 12% to 23%. A 23% reduction in infusion time would enable an infusion center to treat approximately five patients in the same amount of time it currently takes to treat four. Further significant opportunities for time savings with concurrent administration exist as patients frequently require additional infusions such as electrolytes, medications, and blood products.

FIGURE 1: AIR-IN-LINE ALARMS



Over the course of three administration cycles, the competitive pump registered a total of 21 air-in-line alarms while the Plum 360 registered zero alarms.

Concurrent medication delivery, along with a reduction in air-in-line alarms made possible with the Plum 360, can potentially save a patient an hour and fifteen minutes of chair time over three cycles.

The high incidence of alarms with the competitor's pump may lead to a scenario where multiple pumps are alarming simultaneously, stretching staff and delaying alarm resolution.

The secondary endpoint of the number of air-in-line alarms was chosen due to the implications of this alarm condition on workflows and the potential risk of harm to patients and caregivers.

We studied air-in-line alarms by simulating the infusion of paclitaxel since the drug presents challenges for infusion pumps, given its viscous nature and its observed tendency to “outgas,” leading to air bubbles or “froth” in the infusion tubing.^{4,5}

The presence of air-in-line may lead to a number of potential problems for patients and clinicians such as air-in-line alarms, infusion delays, disconnects of the IV set, risk of exposure to hazardous drugs, and the financial cost of wasted medication. Episodes of air-in-line require time to resolve, which may result in extended infusion times. During the infusion of the simulated protocol, the competitor's pump experienced a total of 21 air-in-line alarms, 18 of which occurred during the infusion of the paclitaxel placebo, for an average of 4.2 air-in-line alarms per protocol run. [The Plum 360 system experienced zero air-in-line alarms throughout the entire study period.](#) The difference in the rate of air-in-line alarms was statistically significant ($p < 0.001$).

The high incidence of alarms with the competitor's pump may lead to an infusion center scenario where multiple pumps are alarming simultaneously, stretching staff resources and delaying alarm resolution. Alarm management is a significant patient safety issue and has been highlighted by The Joint Commission through the 2014 National Patient Safety Goal on Alarm Management. The safety goal indicates that a high incidence of alarms has been associated with staff ignoring or disabling them, putting patient safety at risk.⁶

[The lower number of air-in-line alarms with the Plum 360 system may be attributed to the physics of the volumetric pumping mechanism and the capability to capture air in the PlumSet cassette's air trap chamber.](#) The competitor's system doesn't have an air trapping system and utilizes a peristaltic pumping mechanism.



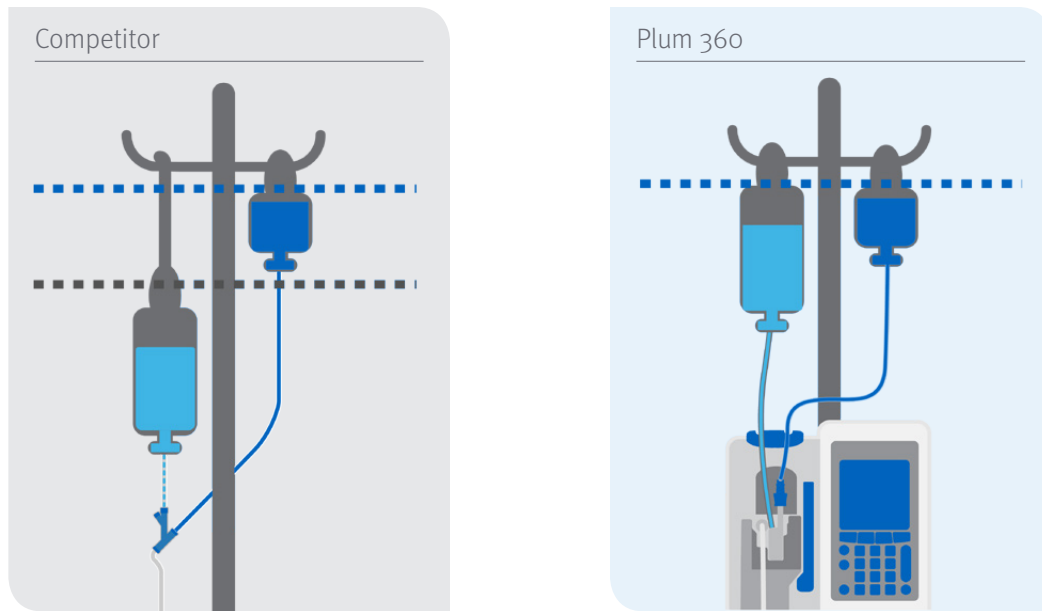
The PlumSet cassette allows for the clearing of air using a backpriming feature to maintain a totally closed system throughout chemotherapy administration.

The process of clearing air from the IV set differs between the pumps and has implications for efficiency and safety. The PlumSet used in the Plum 360 infusion system can capture 1 mL of air in its air trap before the alarm is activated. The system also has the capability to clear air through the secondary cassette port by utilizing the backprime feature of the pump, allowing the clinician to maintain a closed system.

Removing air from the competitor's pump line requires the clinician to choose from several manual options—“flicking” the air up the tubing into an infusion bag, aspirating the air from a Y-port, or disconnecting the tubing from the patient to prime the air through the tubing. The 21 air-in-line alarms from the competitor's pump all required manual clearing.

Disconnecting and priming air through the infusion line can have safety and financial implications. First, a disconnected line may expose the patient and clinician to a hazardous drug. Second, when clearing takes place by disconnecting and priming the line, medication intended for the patient is lost, potentially resulting in inaccurate dosing and cost to the facility. The unique capability of the Plum 360 to remove air from an infusion without disconnecting the line may minimize hazardous drug exposure and medication waste.

FIGURE 2: PLUMSET CASSETTE



With the Plum 360, there is no need to use different head heights for secondary drug administration, increasing patient safety by eliminating the opportunity for the secondary infusion to "back up" into the primary infusion.

An additional significant risk arising from disconnections of an IV set is contamination of the patient's infusion line. Despite best efforts to use aseptic technique, repeated access of peripheral IVs, PICC lines, or subcutaneous infusion ports increases the possibility of contamination and infection. In this study, the clinician was able to remedy the air in line by using the "flicking" method. Failure of this method could have required disconnecting and reconnecting the tubing every time air needed to be cleared from the line.

The requirement to adjust the head height of IV bags to ensure accurate infusion also has implications for the safety of secondary infusion administration. The Health Quality Ontario research team identifies administration of secondary infusions as a high-risk task due to requirements for programming and physical IV tubing setup, which may be nonintuitive and prone to error.⁷

Important secondary infusion considerations include the presence of a head height differential, use of a back check valve, and connection of the secondary infusion above the pump.⁷ In this study, the competitor's pump requires a specific head height adjustment when a secondary medication is attached to the primary line. If head height is not adjusted accurately, the pump may siphon or draw fluid from the incorrect source, leading to medication error and potential patient harm.⁸ Industry examples of head height differential requirements include a range from 8 to 20 inches for large volume infusion pumps.

The Plum 360 technology automates secondary delivery, eliminating the need

for head height adjustments (Figure 2). This, in turn, reduces the risk of IV solution and medication administration error. The Health Quality Ontario research team's summary of the benefits of the Plum infusion system includes the following: no requirement for bag height differential is required; there is secondary infusion line occlusion detection; and the secondary infusion cannot "back up" into the primary infusion.⁷

Alarm management is a significant patient safety issue and has been highlighted by The Joint Commission through the 2014 National Patient Safety Goal on Alarm Management.

Conclusion

The need to provide the highest quality of care in the most efficient and cost-effective manner has driven the continued shift from inpatient to outpatient cancer treatment. To this end, optimizing the workflow associated with cancer care delivery by leveraging technology in the administration of infusion therapy can deliver quantifiable savings in treatment times and improved patient experience.

The Plum 360 infusion system may have significant benefits in efficiency and air management when compared to a competing large volume infusion pump.

The use of the Plum 360 infusion system allows for the concurrent delivery of compatible medications at independent rates directly to the patient. In our bench study comparison with a standard large volume infusion pump, the Plum 360 demonstrated a statistically significant 25 minute, 15 second infusion time savings when delivering a simulated chemotherapeutic protocol.

In the outpatient oncology setting, time savings can translate into improved quality of life for patients (i.e., less time at the infusion center) and improved efficiencies for the facility. In addition, the Plum 360 infusion system showed a statistically significant difference (lower) in the number of air-in-line alarms that have multiple clinical consequences.

With the coming adoption of USP <800>, the task of clearing air from infusion lines will have additional significant implications.⁹ USP <800> requires the use of closed system transfer devices when administering hazardous drugs. The backprime feature of the Plum 360 system provides a closed system mechanism to remove air. Facilities using competitive devices may need to revisit procedures and protocols to determine safe air removal practices using closed system transfer devices.

Infusion pumps are an excellent example of a medical technology that can add value in the delivery of cancer care. This investigation provides an initial evaluation of the Plum 360 pump in oncology and highlights the need for a more robust evaluation of the technology in clinical practice. The results of this bench study suggest that the Plum 360 infusion system may have significant benefits in efficiency and air management when compared to a competing large volume infusion pump. Future studies in the oncology setting will provide valuable insights into the Plum 360 pump's ability to deliver quantifiable efficiencies within healthcare.

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