Original Article

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Efficacy evaluation of syringe pump developed for continuous drug infusion

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Background: In dental intravenous sedation, continuous intravenous infusion of a low-dose drug requires an infusion pump such as a syringe pump. To develop a new syringe pump for clinical use, the functions of the pump must meet certain international standards. Various safety and efficacy tests must be performed on the syringe pump, as stipulated by these standards, and an approval must be received from the approving agency based on such test results.

Methods: The authors of the present study developed a novel syringe pump and performed efficacy evaluation by testing its infusion speed at 1 and 25 ml/h, and infusion performance testing at 2 and 24 h. Moreover, performance evaluation was conducted by comparing the novel pump to an existing pump with the infusion speed varied from 1 to 5 ml/h.

Results: In the efficacy testing on the newly developed syringe pump, infusion with the infusion speed initially set to 1 ml/h resulted in infusion speeds of 1.00 and 0.99 ml/h in the 2- and 24-h assessment, respectively. Changing the infusion speed setting to 25 ml/h resulted in an infusion speed of 25.09 and 23.92 ml/h in the 2- and 24-h assessment, respectively. These results show no significant differences when compared with other commercially available pumps.

Conclusions: The efficacy testing of the newly developed syringe pump showed the accuracy to be within tolerance. Based on these findings, we believe that the newly developed syringe pump is suitable for clinical use.

Keywords: Data Accuracy; Flow rate; Infusion pumps.

* These authors contributed equally to this work.

INTRODUCTION

A syringe pump is a device that intravenously infuses fluids, drugs, or nutrients in the patient. The purpose of using a syringe pump in clinical settings is to administer an accurate amount of drug or fluid over a relatively long duration, and it can be especially favorable for continuous infusion of very small amounts such as 0.1 ml/h [1]. Moreover, recent advances in electronics have enabled controlled infusion by programming the infusion speed and time. The accumulation of pharmacodynamic and pharmacokinetic knowledge has allowed automatic infusion of a sedative or an opioid to its target dose [2].

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Such target-controlled infusion methods enable administration of anesthetics while promoting patient safety [3], and they have also played a major role in the advancement of dental intravenous sedation [4].

Owing to these advantages, the frequency of using such syringe pumps in clinical settings is increasing, while new syringe pumps are being introduced to the market. The authors developed a novel syringe pump, and for its clinical use, its safety and efficacy must be proven in accordance with set regulations; moreover, it must receive the approval of agencies such as the Korea Ministry of Food and Drug Safety (MFDS) [5]. A syringe pump must show electrical stability, mechanical strength, and durability, as well as stability to electromagnetic waves. Further, it is also required to have safety features against drug leakage, overdose, and clamping during drug infusion, as well as lockout time and backflow prevention functions. Above all, the efficacy evaluation on the safety and reliability technology of measuring the accuracy of total dose and flow rate takes precedence over anything [6]. The authors performed efficacy testing to obtain MFDS approval for a newly developed syringe pump and aimed to report the test methods used and the results obtained, with the intent of using the findings for developing other types of medical devices.

METHODS

The Infusion Device Analyzer 5 (IDA-5; Fluke Biomedical, Everett, WA, USA) was used to measure the accuracy of the newly developed Neo syringe pump (Bionet, Co. Ltd, Seoul, Korea) (Fig. 1). The sample used was 0.9% normal saline. To increase the measurement accuracy, 3 pumps were measured repeatedly under the same conditions, and the mean value of the 3 pumps was calculated.

For the measurement of short-term accuracy, pump performance was evaluated for 2 h by using IDA-5 with flow rates of 1 and 25 ml/h. For long-term accuracy, the test was performed for 24 h with flow rates of 1 and 25 ml/h.

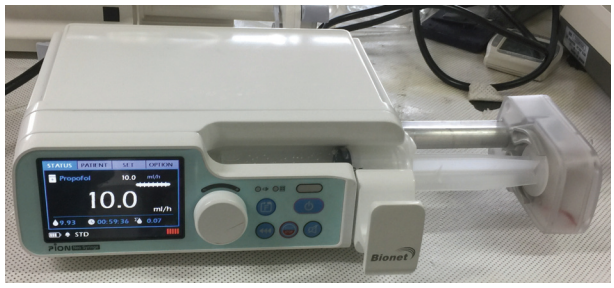

Fig. 1. The newly developed Neo syringe pump (Bionet, Co. Ltd, Seoul, Korea).

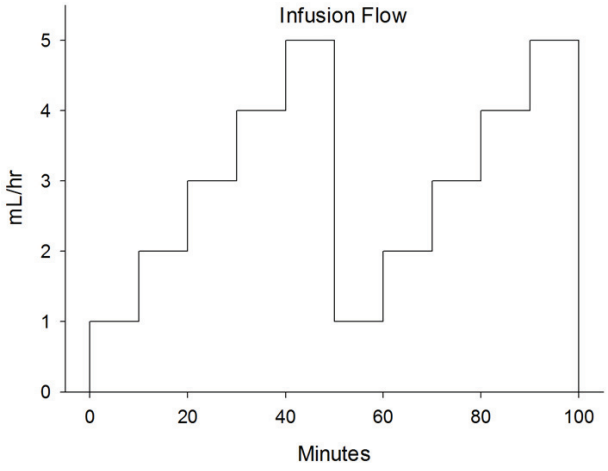

Fig. 2. Evaluation of accuracy based on infusion by increasing the flow rate from 1 to 5 ml/h in 10-min intervals.

After the tests, a trumpet curve was drawn by using the minimum and maximum values of accuracies for the mean perfusion and analysis periods. The trumpet curve was constructed by using an equation specified in IEC 60601-2-24, third edition [5].

A test was performed to compare the newly developed Neo syringe pump to others currently in use, including the PerfusorR space syringe pump system (B. Braun Medical Inc., Melsungen, Germany) and OrchestraR Modular DPS (Fresenius Kabi AG, Frankfurt, Germany). As shown in Fig. 2, the infusion speed was increased from 1 to 5 ml/h in 10-min intervals over 100 min by using a 50-ml syringe. In this experiment, the XPE 205 scale (Mettler-Toledo C., Barcelona) was used.

RESULTS

1. Short-term accuracy measurement

When the flow rate was measured with IDA-5 by setting the flow rate of the newly developed Neo syringe pump to 1 ml/h, the mean flow rate of the 3 samples was 1.00 ml/h, while the mean deviation value of the flow rate was 2.41%. Approximately 30 IDA-5 measurements were performed over 2 h, and the results are shown as mean values. Samples 2 and 3 showed increased flow rates of 1.54 and 1.44 ml/h, respectively, in the initial measures, but the flow rates subsequently decreased to their final average values of 0.99 and 1.03 ml/h, respectively (Fig. 3). Measurements using IDA-5 at a flow rate of 25 ml/h showed infusion at an average of 25.09 ml/h, while the mean deviation of flow rate was 1.97%. All 3 pump samples initially showed an increase in flow rate of 28.35 –41.88 ml/h, but the values decreased within a few minutes to the set value (Fig. 4).

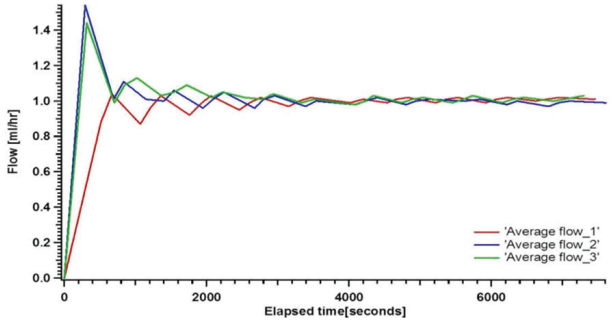

Fig. 3. Graph of the IDA-5 measurement of the flow rate of the Neo syringe pump for 2 h after setting the flow rate to 1 ml/h.

2. Long-term accuracy measurement

The flow rates of 1 and 25 ml/h were tested over 24 h in the newly developed Neo syringe pump. At the flow rate of 1 ml/h, the mean deviation of the flow rate of the pump was 1.28%, while the mean flow rate was 0.99 (Fig. 5). At the flow rate of 25 ml/h, the mean deviation was −4.32% and the mean flow rate was 23.92 ml/h (Fig 6a). Sample 2 showed results that deviated from the target value of ±5%, but the mean value for the 3 infusion pumps was within ±5% (Table 1). The equation specified in IEC 60601-2-24, third edition, was used to draw a trumpet curve, in which the maximum and minimum values were 15 and −15, respectively (Fig. 6b).

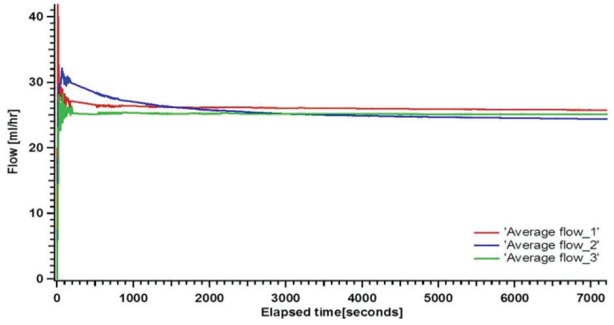

Fig. 4. Graph of the IDA-5 measurement of the flow rate of the Neo syringe pump for 2 h after setting the flow rate to 25 ml/h.

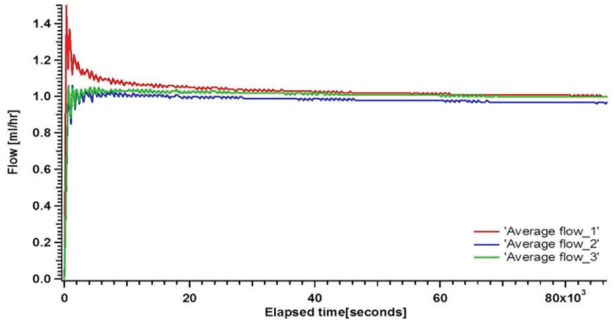

Fig. 5. Graph of the IDA-5 measurement of the flow rate of the Neo syringe pump for 2 h after setting the flow rate to 1 ml/h.

Table 1. Flow rate measurements and deviations of the 3 Neo syringe pumps

Set flow rate (ml/h)	Duration (h)	Pump No.						Mean	
		1		2		3			
		Flow rate	Deviation (%)	Flow rate	Deviation (%)	Flow rate	Deviation (%)	Flow rate	Deviation (%)
1	2	0.97	-3.00	0.99	-0.99	1.03	3.23	1.00	2.41
	24	1.00	0.27	0.97	-3.40	1.00	-0.17	0.99	1.28
25	2	25.77	3.07	24.39	-2.43	25.11	0.42	25.09	1.97
	24	24.11	-3.56	23.69	-5.24	23.96	-4.16	23.92	-4.32

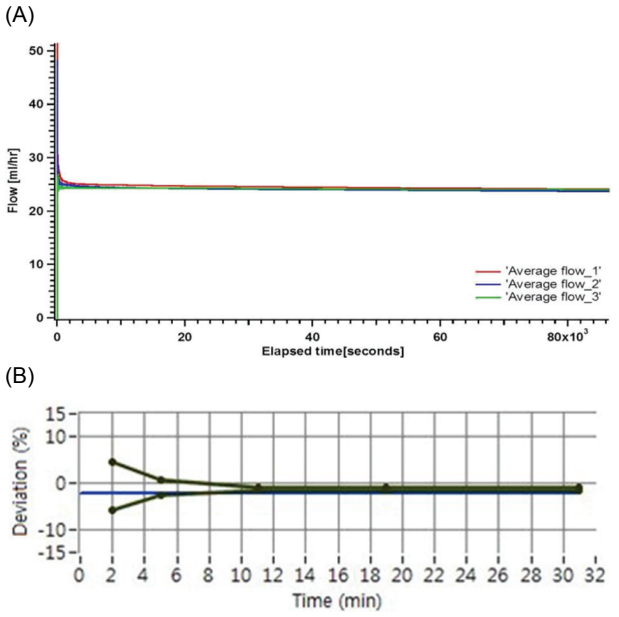

Fig. 6. (A) Graph of the IDA-5 measurement of the flow rate of the Neo syringe pump for 24 h after setting the flow rate to 25 ml/h, (B) The long-term accuracy trumpet curve of pump 1 with a flow rate of 25 ml/h.

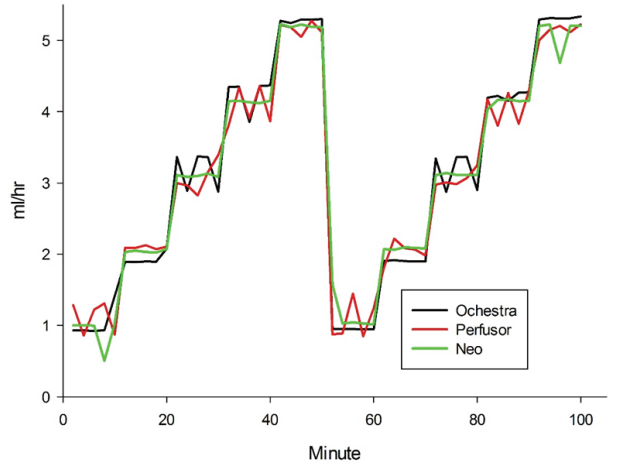

Fig. 7. Infusion speed comparisons among the 3 pumps with the infusion speed increased from 1 ml/h to 5 ml/h in 10-min intervals.

3. Comparison of the 3 pumps

Comparison of the Neo syringe pump, Perfusor^{R} space syringe pump, and Orchestra^{R} Modular DPS showed no statistically significant differences in flow rate changes and repeated measurements among the 3 devices (Fig. 7).

DISCUSSION

The Neo syringe pump (Bionet Co., Ltd, Seoul, Korea) used in the experiment is a completely mechanical product that was newly developed. Preliminary laboratory tests were performed in accordance with the specific requirements on the safety of medical infusion pumps and infusion controllers prior to their clinical use. In the infusion performance evaluation on the syringe pump at flow rates of 1 and 25 ml/h, both short- and long-term accuracies showed results that satisfied the criterion of ± 5%.

After the preliminary tests, other tests were also performed on continuous leakage current and patient leakage current measurements, the prevention of excessive perfusion under a free perfusion condition, and peak perfusion pressure (PPP). In addition to these, the service life of the drug infusion pump was tested, and reflux/siphon action, auto-clamp, and lockout time function tests were performed [7].

The risk factors associated with the clinical use of syringe pumps include overdose or underdose from not controlling the infusion speed, bleeding from backflow, and introduction of air. The most important factor among these is overdose, where not administering accurate amounts of drugs, including sedatives and analgesics, can lead to adverse events such as hypersedation, respiratory depression, and hypoxia [8,9]. In particular, administration of cardiovascular drugs can trigger adverse events involving a sudden increase or decrease in blood pressure [10].

The cause of such over- and under-infusion can be attributed mostly to mechanical malfunction, but other causes include siphon action, backflow, and free flow. The siphon phenomenon can allow the drug to flow from the pump into the patient without any mechanical actions, while backflow from the patient's vein to the pump may also occur. Moreover, if the plunger is not adequately fixed on the syringe, the drug may flow into the patient on its own, which can be dangerous. Therefore, safety tests on syringe pumps must include these items [5].

A syringe pump must have the capability to administer

very small doses such as 0.1 ml/h, which is impossible for a medical professional to administer by one drop at a time. In addition, recent requirements also include elimination of errors through a drug library by implementation of a smart pump function and administration of a preset hourly maximum dose through programming. Testing to maintain PPP within a safe range is also required, where PPP high enough to cause fluid leakage or rupture should not be generated. If a single large volume is injected in the patient as bolus or infusion is blocked, an alarm should sound immediately [11]. Continuous backflow under normal operating conditions or even with a simple defect can be dangerous, and the device must not allow this to happen under any circumstance. The device must also prevent introduction of air, which can cause air embolism in the patient. If the air bubble detection alarm is triggered, fluid infusion must stop immediately. As safety measures, the pumps also have alarm functions of door opening, insufficient battery capacity, and tube clogging.

IDA-5 is a device that was made to measure the flow rate of drug infusion pumps in accordance with the criteria given in IEC 60601-2-24, third edition (2012-10), which are used in most certified agencies and hospitals. A trumpet curve is a graph drawn from equating the maximum and minimum values of average perfusion accuracy and analysis period, which represents a more accurate flow rate as the perfusion error becomes smaller. In the present study, the Neo syringe pump was proven to be a mechanical drug infusion device that can be safe and effective for clinical use, which is expected to provide a more accurate and appropriate drug infusion in the growing field of dental sedation while the findings are also expected to be used as research data in future studies.

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