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Elastomeric Pump Infusion Failures Caused by Inadequate Luer Lock Connector Engagement to Needleless Connectors

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ABSTRACT

Needleless connectors are used widely across all types of vascular access devices and provide safe, needleless administration of intravenous fluids and medications. An analysis of patients from an outpatient parenteral antimicrobial therapy program is presented in which elastomeric pumps had failed to flow due to incomplete tightening of Luer lock needleless connections. An alert was issued to community nursing staff responsible for daily elastomeric pump changes to ensure that needleless connectors were properly checked for full tightening. The frequency of failure of flow events before and after the alert was reviewed. Force and torque profiles required to activate the internal mechanism of connectors were measured in the 4 most frequently used needleless connectors in the outpatient parenteral antimicrobial therapy program. The degree of torque and force required to activate the different needleless connectors varied and was identified as a factor contributing to inadequate connection with the elastomeric pump and consequent failure of flow. Repeated feedback to nursing staff over the study period about the force and torque required for needleless connector flow activation resulted in a highly significant decrease in the rate of failure of flow events per elastomeric pump from a rate of 0.0147 events per elastomeric pump per year in the last 3 months of 2018 to 0.0003 in the first 6 months of 2020 (difference = 0.0144 [CI, 0.0097–0.02]; $P < .0001$).

Key words: device safety, elastomeric pump, engineering, flow, Luer lock, needleless connector, OPAT, VAD, vascular access device

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The authors of this article have no conflicts of interest to disclose. Dr Lui acknowledges funding from the South Western Institute for Robotics and Automation in Health through the Ingham Institute in conjunction with Liverpool Hospital and the South-West Sydney Local Health District.

The Hospital in the Home (HITH) program at Liverpool Hospital Australia provides outpatient parenteral antimicrobial therapy (OPAT) as part of its services. On occasion in the OPAT program, failure of flow from an elastomeric pump (EP) is observed, but the vascular access device (VAD) is found to be patent on flushing with 0.9% sodium chloride. Apart from internal VAD occlusion, failure of flow from EPs can be attributed to mechanical obstruction from kinking of any flexible administration tubing of the VAD or failure of the reduction valve mechanism of the EP. A needleless connector (NC), which might incorporate either a simple or complex valve system, is routinely placed on the catheter hubs. This practice was introduced many years ago in New South Wales Public Hospitals to reduce the probability of needlestick injury when accessing intravenous devices. Failure to adequately engage the Luer lock system in these connectors has been reported to prevent connector activation and fluid flow.[1-4]

An NC is a device that allows for safe needleless connection to VADs while reducing the risks of extraluminal infection, air embolism with centrally inserted devices, and needlestick injuries among health care workers.[1,2,5,6] These devices come in numerous designs, which include positive, negative, and neutral fluid displacement abilities, using mechanical or pressure-sensitive valves.[7] Advances in NC design have reduced a number of undesirable design features, such as dead space, interstitial spaces, opaque housings, significant reflux volumes, priming volumes, and fluid displacement.[1,2,5,6] The potential for bacterial colonization of NCs and subsequent associated catheter-related infection has also been a major concern.[8] Clinical standards for the use of NCs in infusion therapy have recently been published.[9] There is no strong evidence that positive displacement NCs have an effect on central venous catheter-related infections, with low level evidence that thrombotic catheter occlusion is lower with use of a split-septum neutral displacement NC compared with a solid-surface neutral reflux NC.[10,11]

Most NCs are designed to couple with Luer connectors. The Luer lock mechanism is designed to provide a rapid, secure, and leak-free method of connection. The system relies on friction between the threads of the 2 components both to prevent the components from unscrewing and to provide a seal against leakage of fluid. A strong resistance to rotation is expected when connecting a Luer lock mechanism. The design was first standardized by the International Organization for Standardization (ISO) in 1986 in ISO 594, which has since been superseded by ISO 80369-7. ISO 80369-7:2016 states that "the thread may in certain extremes, collide with non-sealing features of the mating male Luer connector prior to a fluid tight seal being achieved," and that "this can be worsened by the allowable variations in thread profile, thread pitch and thread lead, of the features of the mating male Luer connector."[12] Despite this, the standardization committee did not change the level of interference from ISO594-2 because of the general lack of data indicating a problem in use.[12]

In December 2018, several patients receiving OPAT presented to the HITH clinic after a report of failure of flow from the EP. In these patients, the EP reservoir had remained fully inflated over the 24-hour infusion period. Inspection revealed that the male Luer lock connector on the tubing from the infuser had not been fully engaged with the NC. Tightening of the Luer lock system so that it became fully engaged with the NC restored the flow. This observation prompted the investigators to undertake an engineering study of the most frequently used NCs in the OPAT program to examine the degree of force and torque required to activate the internal mechanisms via the male Luer lock connector. The hypothesis was that the high torque encountered in connecting the NC to the Luer lock on the EP would lead to an inadvertent incomplete closure of the connection, with resultant failure of flow. The effect of feedback provided to community nurses responsible for managing EPs on the rate of unexplained failure of flow events with EPs was measured before and after alerting observations were made.

METHODS

The study setting was Liverpool Hospital, Sydney, Australia, a comprehensive tertiary referral hospital of 850 beds in the South West of Sydney with 50 000 emergency department admissions annually. Patients in the HITH program at Liverpool Hospital receiving a daily infusion of antimicrobial therapy via an EP who experience an episode of failure of flow are routinely asked to report to the HITH clinic for assessment of administration tubing, the EP, and VAD lumen patency for corrective action to enable OPAT to continue. Data about these events are routinely recorded. A cluster of events of failure of flow was observed in early December 2018. In each case, the Luer lock connection between the EP and the NC had not been fully engaged. In each case, no other cause, such as EP failure or VAD occlusion, could be identified. All EPs were of the same type and provided by the same manufacturer. In 5 consecutive cases of failure of flow where the connection to the NC had not been fully engaged, the EPs were returned to the manufacturer for investigation of the pump mechanism and flow properties. In all cases including these 5 consecutive cases, infusate flowed when the EP was disconnected from the NC. No alerts about product failure had been issued by any of the companies providing the NCs. Immediate testing

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DOI: 10.1097/NAN.0000000000000439

by connection to an EP of NCs replaced in the HITH clinic because of incomplete tightening showed that full tightening, which could be achieved in all cases, allowed flow of infusate. The companies supplying the NCs were not informed about the problem as it was operator dependent.

An email alert to the community nursing staff sent on December 21, 2018, outlined the problem and asked that staff ensure that the Luer lock connection to the NC was fully engaged when changing EPs. An analysis of failure of flow events was undertaken for the 3 months before the group email, from October 1, 2018, to December 21, 2018, and for the 18 months after the group email, from December 21, 2018, to June 30, 2020.

Feedback to the community nurses included a group email, telephone contact, and instruction to the involved nurse and their manager on each occasion of identification of an improperly attached NC, logging of events in an electronic incident management system, and repeated discussions with the community nursing service managers about the issue. The numbers of EPs provided to the HITH service during the study period were obtained from the Liverpool Hospital Pharmacy records.

Experiments were conducted using the 4 brands of NCs encountered in the HITH service at Liverpool Hospital and the single EP type involved in all of the events. NCs are chosen in everyday practice for use with a patient as convenient and not according to any particular property of the brand of NC. The NCs were labeled as A, B, C, and D. Type A is neutral displacement, type B is positive displacement, type C is negative displacement, and type D is neutral displacement. All of the NCs used in the bench test were brand new and indiscriminately selected from a batch, with the exception of 2 NCs that were recovered from incident cases. It is routine practice for community nurses to flush the VAD with normal saline using a 10-mL syringe before connecting a new EP, and no reports of failure to flow when using a syringe connected to an NC had been received. Brand new, indiscriminately selected 10-mL Terumo syringes and plastic connectors of the EPs were used as the mating male Luer lock connectors, with the syringes acting as controls.

Because the plastic of the syringes was softer than that of the EP connectors, the soft plastic syringe Luer lock connector is referred to as *SPLL* and the hard plastic EP Luer lock connector as *HEPLL*. The effect of residual isopropyl alcohol or isopropyl alcohol/chlorhexidine gluconate on the performance of the Luer lock was not tested. The standard procedure is to allow any sterilizing fluid to dry completely before connection of the Luer lock system.

Mounting Force and Torque Profiles of NCs

Measurements were made using a commercial system that translates compression force and rotary force (or torque) into electrical signals for analysis and measurement (ATI Automation F/T Controller System and Nano 17 force transducer). The force measuring apparatus or transducer was securely mounted to an acrylic base, which was fixed into a bench vice for stability. The other face of the transducer was fitted with a fiberglass adaptor for attachment of male Luer locks (Figure 1).

For control purposes, plastic syringes were used as the male Luer attachment by removing the plunger and fastening the syringe to the fiberglass adaptor. By using a specially designed clamp, unused male Luer locks recovered from returned EPs could also be securely attached to the fiberglass adaptor for force measurements.

Compression force and torque readings were digitally recorded. Each combination of Luer locks was fully locked using a single push-and-twist motion, with at least 10 successful repetitions. Calibration of the equipment was verified using a standard reference mass before conducting experiments. Force and torque data were digitally sampled by the unit, including calibration corrections, at a rate of approximately 580 Hz and recorded using an in-house program. The data are plotted in Figure 2A, with the horizontal axis divided into 100-sample units, which corresponds with time. Force and torque values were obtained over the first 10 successful trials and averaged to reduce the influence of test–retest variation since the locking is performed by hand and considerable variation between trials is expected.

Flow-Rates Under Gravity of NCs

With the establishment of the partial engagement of an NC with a male Luer lock, a flow rate experiment was conducted under gravity to determine the influence of partial

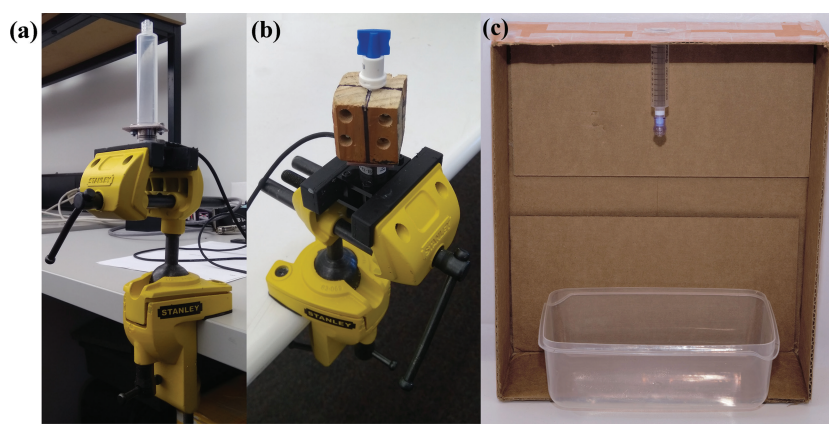

Figure 1 (A) Soft plastic Luer lock test set-up. (B) Hard plastic Luer lock test set-up. (C) Flow rate test set-up.

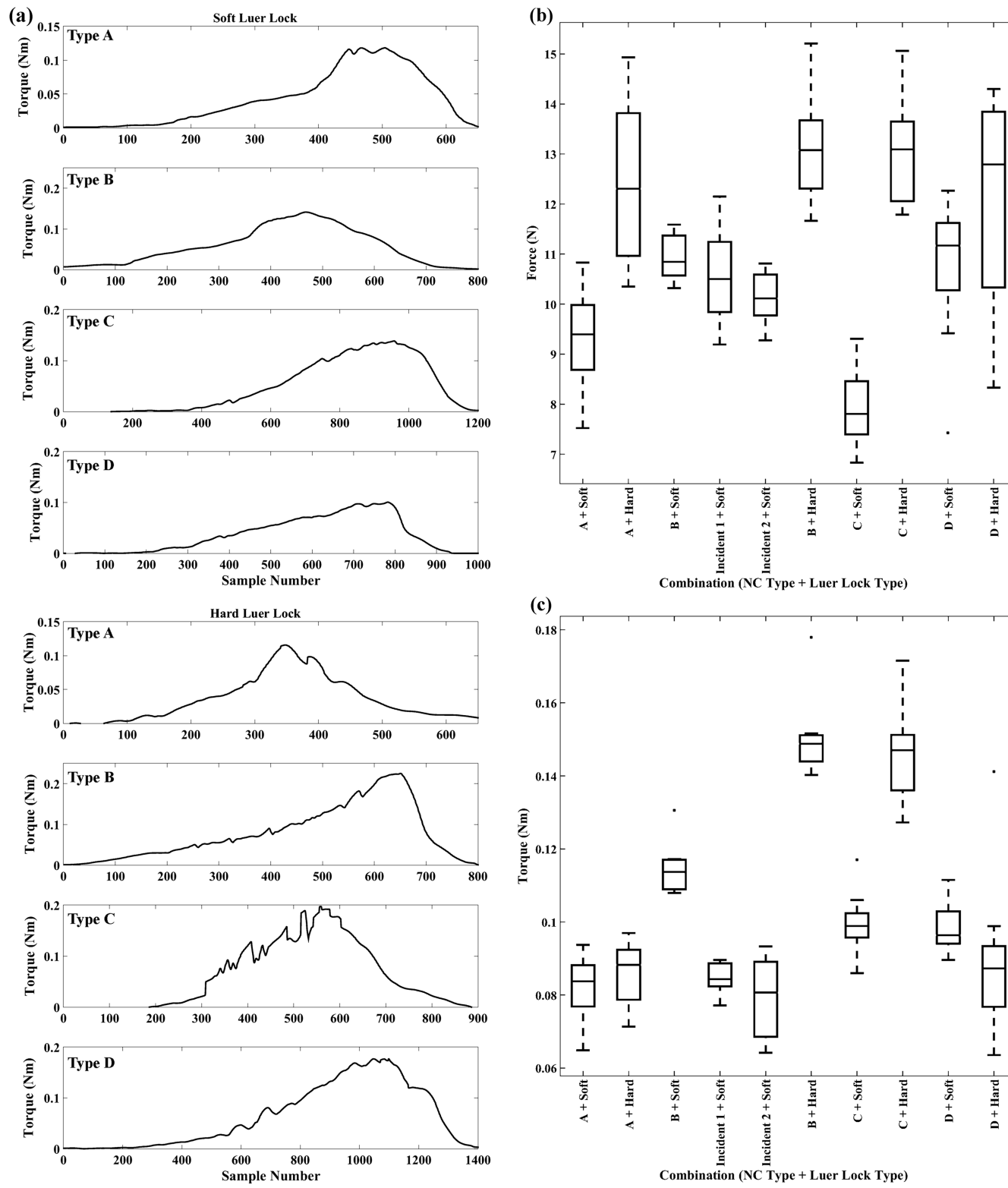

Figure 2 (A) Graphs of torque against time (measured as sample number) for the 4 types of needleless connectors with soft and hard plastic Luer locks. (B) Box and whisker graph of force profile for connection. (C) Box and whisker graph of torque profile for connection.

engagement on flow rates. Flow was assessed with a syringe fitted with a scale marked at 12° rotation intervals (30 intervals per revolution). NCs were sequentially fitted to the syringe and rotated to the fully engaged position. A corresponding mark was made on the body of the NC. The syringe and NC were suspended above a container with the NC outlet temporarily closed with a cap. The syringe was filled with 11 mL of water, the cap closing the NC outlet was then removed, and the time taken to empty to 1 mL under gravity was recorded using a Nikon D3300 digital

camera recording video at 50 frames per second. This was repeated with the NC being progressively unscrewed by one 12° interval at each repetition until the NC disengaged completely from the male Luer lock. This was repeated for all 4 types of NCs, with video analyzed frame-by-frame to derive the time elapsed for 10 mL to be delivered, and the average flow rate was subsequently determined.

Data Analysis

Observational patient data are presented using descriptive statistics. Differences in rates of failure of events per EP were calculated using MedCalc (MedCalc Software, Ostend, Belgium). Engineering data were analyzed using Microsoft Excel and MATLAB.

RESULTS

A total of 51 patients experienced at least 1 failure of flow event during the study period. A total of 11 255 EPs were used during the study period. Demographic details are provided in Table 1.

Failure of Flow Events

In the 3 months before the alerting observations, 47 failure of flow events were recorded, of which 29 were unexplained and were not related to occlusion of the VAD or external tubing. In the 12 months after the alerting email, 26 events of failure of flow were recorded, including 17 events where the Luer lock connection to the NC was not fully engaged, 5 events in which the VAD was occluded or external tubing to the hub was kinked, and 4 events that were unexplained because the EP had been replaced and flow re-established before examination by the HITH team. From January to July 2020, 1 episode of failure of flow was recorded, and this was secondary to an incompletely tightened NC. Details are provided in Table 2. The unexplained failure of flow events were converted to an event rate per total EP utilization per year. This rate declined significantly from 0.0147 in 2018 to 0.0035 in 2020 (difference = 0.0144 [CI, 0.0097–0.02]; $P < .0001$).

Elastomeric Pumps

There were no problems detected in the flow from any of the 5 EPs returned to the manufacturer for investigations of the pump mechanism and flow properties.

Force/Torque Testing of NCs

Measurements of mounting force and torque profiles were conducted, with the results of 10 mounting attempts shown in Figure 2. Mean mounting force ranged from approximately 8 to 13 Nm. In all cases, the mean mounting force was greater for HEPLL than SPLL. The mean mounting torque requirement ranged from approximately 0.10 Nm to 0.19 Nm, with 2 of the units registering significantly increased torque requirements during mounting to the HEPLL where thread binding occurred. The results are displayed as box and whisker graphs for force in Figure 2B and torque in Figure 2C.

The torques required for connecting HEPLLs are generally greater than those required for SPLLs. These differences are readily discernible from tactile feedback when tightening connections by hand. Mounting SPLLs generally results in smoother profiles compared with that of HEPLLs, which exhibit oscillations and discontinuities consistent with plastic thread binding during engagement.

Flow Rates Under Gravity

The flow rates vary between the types of NCs and also vary with the degree of rotation, with some requiring more rotation to commence flow than others. The recorded flow rates are graphed in Figure 3. Even when fully engaged, each type of NC has an intrinsic level of flow restriction because of their differing internal design. The different types of each NC required a different degree of rotation to fully engage with the male Luer lock, ranging between a 156° and 324° rotation (Figure 3).

DISCUSSION

Improper engagement of NCs with their male Luer lock counterpart can explain failure of flow events and would account for the majority of the previously unexplained incidents encountered by the HITH service. The mounting process of the HEPLL to the NC can, after an initial rotation, meet a strong resistance, which can be interpreted as full engagement, but there can be a need to continue to rotate the Luer lock connector beyond that point to reach full engagement. Consistent with this are the observations that some patients with episodes of failure of flow for which the connectors had not been adjusted since the initial connection in the community were noted to have the HEPLL only

TABLE 1

Descriptive Statistics of Patient Characteristics

Characteristics	Men	Women	Total
No.	38	13	51
Average age, y	60.0 ± 15.9	66.4 ± 17.0	61.7 ± 16.3
Age range, y	22.4 – 83.7	34.3 – 93.7	22.4 – 93.7

TABLE 2

Descriptive Detail of Events

Date range	Oct-Dec 2018	Jan-Dec 2019	Jan-July 2020
Failure of flow events	47	26	1
Unexplained events	29	4	0
VAD kink or occlusion	18	5	0
NC not tightened	NA	17	1
No. of EPs used	1979	5997	3279

Abbreviations: EP, elastomeric pump; NA, not applicable; NC, needleless connector; VAD, vascular access device.

engaged in the NC to the point of initial resistance. Turning the HEPLL to fully engage with the NC established flow of infusate.

Resistance to flow ranging from partial to complete occlusion as a characteristic of a particular brand of NC has been reported.[13] In that study, the restriction to flow was resolved if the valve was manipulated by tightening so that valve in the NC opened. Inadequate closure of NCs as a cause of repeated events of failure to flow from EPs has not been reported previously.

During the process of connection, some HEPLL emitted an audible noise as they approached full engagement. The HEPLL are made of a hard plastic, as are the bodies of the NCs. Friction between hard plastic threads contributes to differences in mounting torques. High friction between the threads explains the observation of audible "clicking" noises produced during the connection process and explains the increase in tactile resistance encountered.

Differences in Luer lock and NC thread profile may affect mounting forces. During testing, hard plastics were observed to wear during the connection–disconnection process with a white dusty residue visible on the threads of NC types A, B, and D after a number of connection–disconnection cycles. The presence of dusty residue was not visually observed with NC type C because the plastic was white in color and the mating thread surface is considerably smaller than for the other 3 types, but its presence could not be ruled out. The white dusty residue is abraded plastic from repeated connection cycles, because the fit between threads is very tight so as to achieve a lock action and a fluid seal. The type B NC appeared to have an oily residue in the silicone insert, which may spread after the connectors are engaged and disengaged and serve to lubricate the threads. The mounting force is also probably dependent on differences between Luer lock tip profiles and the manner of engagement of the Luer lock tip with the NC, with some of this variation being additionally attributable to unit-to-unit variations. Measurement of torque for 2 connectors collected from separate failure of flow incidents showed very similar torque requirements compared with an unused sample, indicating that the connectors were operating as designed (Figures 2B and 2C).

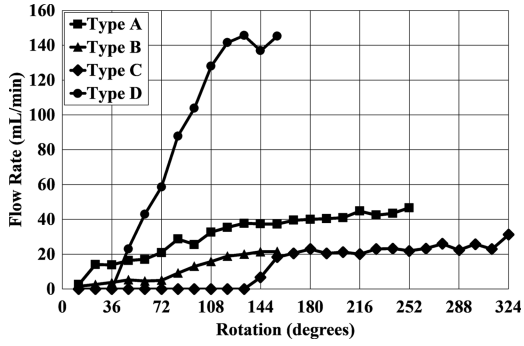

Figure 3 Graph of flow rate against rotation.

Flow rate tests revealed that there is a region ranging from the first 36° to 132° of rotation where NCs may remain attached to the EP but impede all flow. Partial engagement is also seen to cause flow restriction, which may contribute to underinfusion, which may not be easily recognized when using a slow-rate elastomeric infusor. The flow rates of open valves in all NCs tested vastly exceeded the maximum flow rate expected from the EP to which they were connected. The flow rate from the type of EP used in the HITH service is approximately 10 mL/h. The lowest flow rate in the sample of NCs with the valve fully open was between 30 and 40 mL/min. Flow rates from the study are indicative of the presence or absence of restriction of flow with respect to the degree of NC engagement with an EP. No difference in performance between NCs was observed clinically.

There is a potential for staff faced with an unfamiliar type of NC to not fully engage or to overtighten the device based on previous experience with the mounting force required for full engagement of other NCs. The common advice of manufacturers is to avoid overtightening of connectors, which is more likely to achieve partial rather than full engagement. The engineering studies provide an explanation for the failure to fully tighten the Luer lock connector between the EP and the NC. The torque curves all show a rapid increase in resistance, and inexperienced staff who do not wish to overtighten the connection stop turning the Luer lock connection too soon, leading to failure to open the valve. While theoretically overtightening can lead to

fracture of the plastics in the Luer lock, this has never been observed in the HITH service. The most common outcome from overtightening is an inability subsequently to undo the connection by finger pressure alone, and forceps that provide extra leverage are required to achieve disconnection.

Type C NC in this study required greater rotation to open the valve system of the NC but required less torque than the other NCs. Type C NC is a negative displacement type. The study did not investigate the claimed displacement properties of the NCs, which are positive, negative, and neutral, but these properties should not influence the Luer lock properties. The issue of failure to tighten fully was observed with all types of connectors, and failure of flow events occurred with all types of connectors.

The outcome of a highly significant reduction in events of failure of flow would most probably have been achieved without the engineering study. The engineering study enabled us to confirm that the pattern of resistance was a necessary feature of the Luer lock design, that failure to fully tighten would lead to no or reduced flow, and that the problem lay with the operator and not the manufacturer. The ability to provide a technical description of the NC probably enhanced the educational feedback provided to the nurses, but this aspect was not formally explored in this study.

The time course of the decline in the event rate after recognition of the problem reflects the reality of inducing change in clinical behavior.[14] The number of nurses working in the community in collaboration with the HITH service to provide OPAT is large and managed by a different administration to that of the HITH team. Shift patterns, leave, sickness, and personnel changes can all impede the task of educating nursing about a newly identified risk. The adage, "Repetition is the mother of skill," is relevant in this instance, because nurses need to learn the level of force and torque required to effectively close a connection between an EP and a NC by experience, and to appreciate that different forces and torques are required for various types of NCs. We tested the 4 most frequently used types of NCs available within the local health district. If the nurses only had to deal with 1 type of NC, then the time taken to learn the motor skills and appreciate the tactile feedback for an effective connection between the NC and an EP connector would obviously be less. The clinical standards recommend standardizing the type of NC within the organization to reduce the risk for confusion about the steps required for flushing, clamping, and disconnecting, and this study adds to the argument for standardization.[9]

LIMITATIONS

The HEPLL generally is used only once, rather than for the 10 cycles employed in this test. Repetition of tests allowed averaging of results, reducing the effect of variation in observations from test to test. Luer locks became easier to fully tighten over the period of testing, likely because of wear in the plastic threads of the devices. Forces and torques were measured with hand-mounting which, although consistent with the technique used in clinical practice, can result in substantial variations in observations between tests. Individual variations in Luer lock shape that occur during manufacture are another possible source of variation.

Flow rates are not representative of the actual flow rates achievable in clinical use and are not the same as those expected from connection to an EP. Flow in the study was gravitational, whereas in practice flow through an NC is usually the result of pump action.

In addition, the testing involved only a small sample of connectors, although it does corroborate the observed behavior in clinical settings. Because of the random variation in products, the forces, torques, and flow rates would vary between connectors, both within a specific type and between different types, but the conclusions from the observed trends would still be valid. A much larger sample would be necessary for definitive statements about the relative merits of the different types of NCs with regard to flow and ease of connection.

CONCLUSION

Tactile feedback of high resistance to applied torque may mislead staff into believing a Luer lock connection to an NC has been fully engaged when it is only partially engaged. Different types of NCs require different amounts of rotation for full valve activation. Full engagement is required to eliminate flow restriction. There should be no gap between the body of the NC and male Luer lock connection when connected. Instruction to nurses about the importance of full engagement of the EP to the NC resulted in an almost complete disappearance of failure to flow events in an OPAT program over a period of 18 months, in which the rate of failure to flow of EPs was reduced by 420%. Standardization of NCs to 1 or 2 models within a facility might ease training and help to prevent such errors. Repeated feedback to staff about the need to fully tighten connectors between EPs and NCs was required to eliminate the problem.

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