

The potential for catheter microbial contamination from a needleless connector

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Summary: Needleless connectors have been widely introduced into clinical practice to allow the connection of syringes and luers to peripheral and central vascular catheters. The potential for microbial contamination of catheters via these devices is currently unclear. A recently introduced connector, the 'Connecta Clave', was assessed by various in-vitro methods. The 'Connecta Clave' is specifically devised to separate external components from the fluid pathway. The compression seals of 50 devices were contaminated with 1×10^8 cfu *Staphylococcus epidermidis*, disinfected with isopropanol, and fluid passed through. Only one device allowed organisms to pass through, despite this challenge, representing a contamination rate of 2%. In comparison, when 50 connectors were challenged with 20 cfu of *S. epidermidis*, no organisms passed through the device during use. In the clinical situation, after manipulation, <16 cfu of skin organisms were found associated with the compression seal of the devices. It is, therefore, likely that the contamination rates in clinical practice will be extremely low. Three methods of disinfecting the compression seals and associated rims were also evaluated. A combination of alcohol chlorhexidine spray, followed by a 70% isopropanol swab, resulted in the most efficacious disinfection. The isopropanol swabs produced an adequate disinfection rate. The overall results suggest that by use of specially designed connectors, not only are needlestick injuries reduced, but the likelihood of microbial contamination of catheters via the internal route may also be diminished.

Keywords: Microbial contamination; needleless connectors; *S. epidermidis*.

Introduction

Needleless connectors have been introduced into clinical practice for use with intravascular catheters to prevent not only needlestick injury, but also, by leaving luers open, to facilitate aseptic technique, and reduce the time spent manipulating intravenous connections. It has been demonstrated that these connectors, when used correctly, result in a reduction in the number of needlestick injuries and the associated savings balance their acquisition costs.¹ However, it is currently unclear whether or not these devices may

act as a portal of entry for micro-organisms to central venous catheters, resulting in sepsis. It has previously been suggested that organisms primarily gain access to central venous catheters either via the external route from the skin insertion site, or internally from connectors, such as luer locks.^{2,3} In a recent survey it was found, for example, that up to 23% of entry ports were contaminated with micro-organisms during use.⁴ In comparison, there are only a limited number of reports on the potential for needleless connectors as a source of infection. Danzig *et al.*⁵ reported an increase in septicaemia associated with a needleless intravenous infusion system in patients receiving therapy at home. This increase in sepsis may have been related primarily to poor aseptic techniques. Conversely, Adams *et al.*,⁶ found that needleless connectors, when used in hospitals with appropriate aseptic technique, did not result in a greater incidence of catheter-related infection.

In order to further address the potential infection risk of needleless connectors, a newly-introduced device, the 'Connecta Clave' (ICU Medical Inc., San Clements, CA 92673, USA, distributed by Ohmeda, Hatfield, UK) was evaluated. The device was assessed by various in-vitro methods, simulating the clinical situation, and also included an evaluation of disinfection schedules.

Materials and methods

The needleless connector

The needleless connector [Figure 1(a)] consists of a silicone compression seal [Figure 1(b)] onto which a syringe or luer tip can be directly attached to allow the passage of fluid [Figures 2(a) and 2(b)]. The device's seal opens automatically on attachment of a syringe or luer by activation of an internal piercing element [Figure 2(b)]. This allows a direct fluid pathway through the connector. The device is specifically designed to ensure that when the pathway is opened, there is no contact between the external surfaces of the connector's compression seal and the fluid.

Disinfection of 'Connecta Clave'

Sixty needleless connectors were each subjected to 30 simulated clinical uses. This involved attaching a sterile 10 mL syringe to each connector, and injecting 1 mL of sterile normal saline through the device, as in clinical practice. After each injection, the devices were disinfected with a 70% isopropanol swab ('Steret'; Seton Healthcare, Oldham, UK), which is our hospital's current recommended policy in the clinical situation. One swab was used per needleless connector. The swab was firmly applied and rotated through 180°, five times over the silicone surface and associated rim of the device.

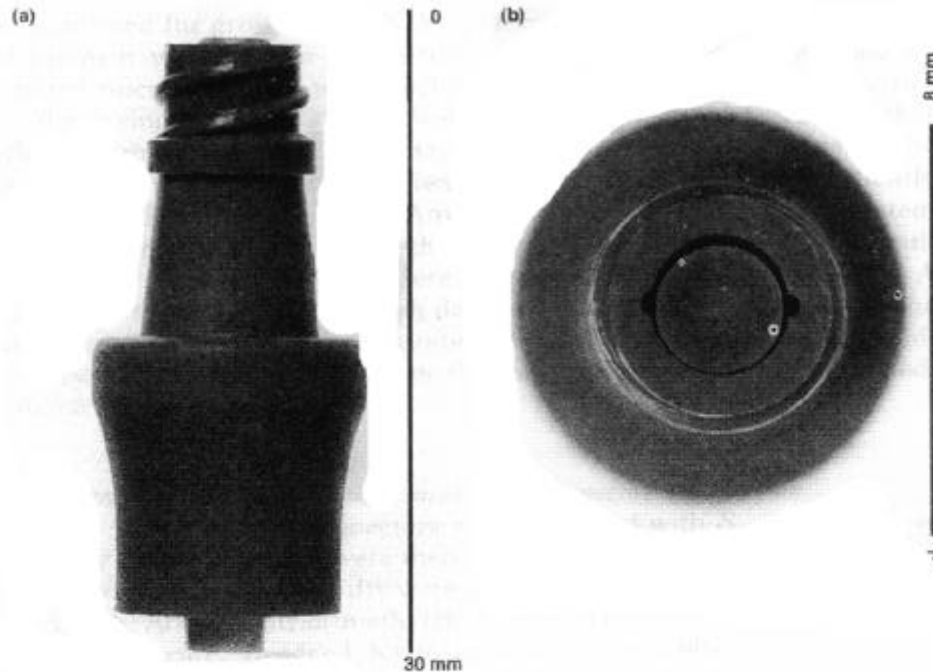


Figure 1(a). 'Connecta Clave' (1:4) showing the outside surface with locking threads (upper) which allow luer connection and distal end for attachment to catheters. (b) 'Connecta Clave' (1:5) showing the compression seal which is located in the upper end of the device with a surrounding rim.

Microbial contamination of the needleless connectors

After the simulated uses, the 60 needleless connectors were inoculated with *Staphylococcus epidermidis* (NCTC 9865). An overnight culture of the *S. epidermidis* in nutrient broth (Oxoid, Basingstoke, UK) was standardized to a concentration of 1×10^6 cfu/mL. This was achieved by measuring the optical density (OD) of the suspension at 570 nm and calculating the number of organisms with a standard curve of OD versus viable counts. The cultures were adjusted to the required concentration with fresh nutrient broth. Ten microlitres of bacterial suspension containing 1×10^4 cfu were then applied to the compression seal and surrounding rim of each connector. The devices were placed at 37°C in air for 30 min to allow the bacterial suspension to dry. Fifty of the connectors were then disinfected with isopropanol swabs, as above. Ten further connectors were left uncleaned to act as controls. A sterile 5 mL syringe was then attached to every device, and 5 mL sterile normal saline passed through each. The first 1 mL aliquot was collected, and 10 μ L inoculated onto the surface of a nutrient agar plate. Nine millilitres of nutrient broth was added to the remainder of the aliquot. The plates and tubes of broth were then incubated in air at 37°C

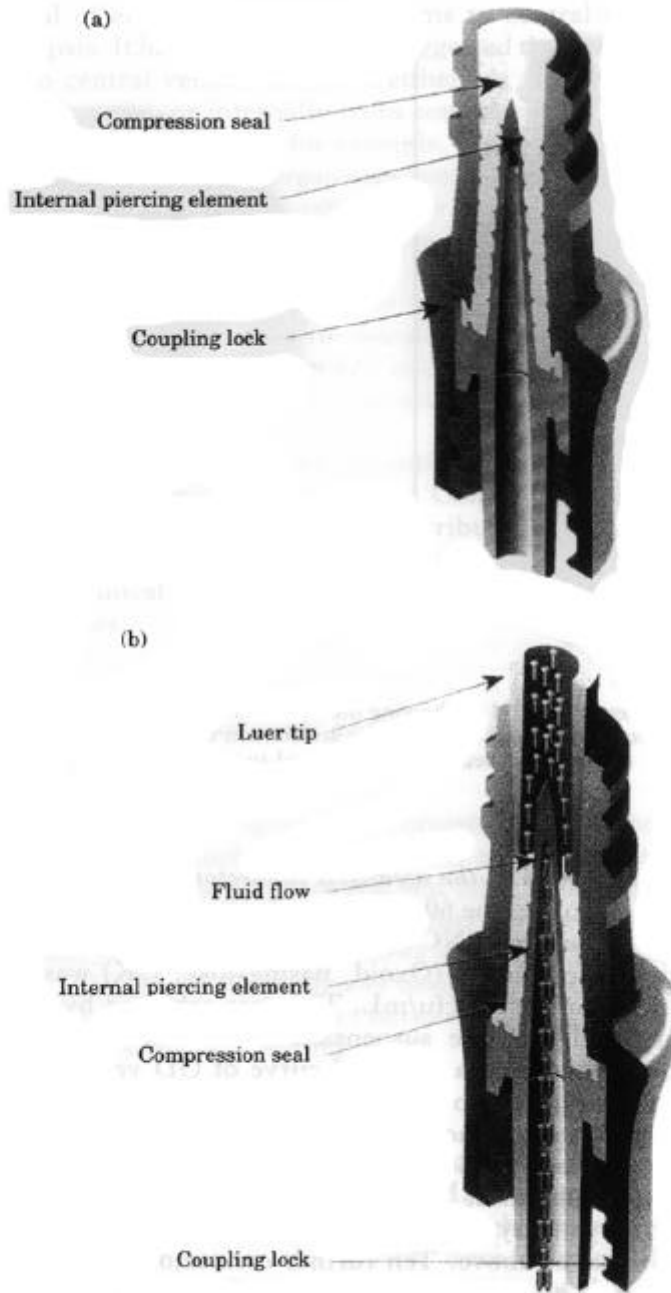


Figure 2. Diagrammatic representation (not to scale) showing the internal mechanism of the 'Connecta Clave'. The connector consists of a compression seal which is adherent to an internal piercing element. When a syringe or luer is attached to the compression seal [Figure 2(b)], the underlying internal piercing element penetrates the seal and allows the passage of fluid through the device, avoiding the external components.

and examined for growth at 48 h. *S. epidermidis* (NCTC 9865) produces a red pigment when grown on nutrient agar plates and was identified by standard microbiological tests, including this colonial appearance. After use, the syringe tips, which had been connected to the devices, together with the compression seals, were sampled for microbial contamination by imprinting onto the surface of nutrient agar plates, which were subsequently incubated at 37°C in air for 48 h. Any organisms present were enumerated.

The compression seals of a further 60 connectors were inoculated with 20 cfu of *S. epidermidis*. Fifty were cleaned with isopropanol swabs. A syringe was then connected to each device. Five millilitres of normal saline was injected through, and the number of organisms passing in the fluid, on the syringe tips, and remaining on the compression seals was determined, as above.

Evaluation of different methods of needleless connector disinfection

A total of 160 needleless connectors was inoculated with *S. epidermidis*, as previously described. Fifty were then disinfected with a swab impregnated with isopropanol, as above. Fifty were sprayed with chlorhexidine gluconate 2.5% v/v in 70% industrial methylated spirit (Hydrex DS Derma Spray, Depuy Healthcare, Leeds, UK) to produce a surface film of fluid, and subsequently allowed to dry in air at 20°C over 2 min. A further 50 devices were similarly disinfected with chlorhexidine, but this was followed by an isopropanol swab, as before. Ten devices were not disinfected and acted as controls.

Sampling of needleless connectors for microbial contamination

The compression seal and surrounding rim were sampled 2 min after disinfection. A sterile swab moistened in sterile normal saline was firmly applied three times over the entire surface of each seal and rim. The swab was then inoculated onto a nutrient agar plate, which was incubated at 37°C in air and examined for growth at 48 h.

Determination of compression seal microbial contamination in clinical use

The number of organisms that may contaminate a needleless connector during routine clinical manipulation was determined. Ten healthcare workers manipulated one device each, as in the clinical situation. The device was then assessed for any microbial contamination by swabbing, as above.

Statistical analysis

Comparison of the different methods used to clean the 'Connecta Clave' were performed by the Wilcoxon-Mann Whitney test. $P < 0.05$ was considered significant.

Table I. The number of 'Connecta Claves', after contamination of compression seal with 1×10^4 *Staphylococcus epidermidis* (NCTC 9865), followed by either disinfection with 70% isopropanol swabs or no disinfection, which subsequently allowed the passage of organisms during use

Disinfected	Number of 'Connecta Claves'			Total studied
	Number of 'Connecta Claves' which did not allow any organisms to pass through	Number of 'Connecta Claves' which allowed passage of 1-100 organisms/mL	Number of 'Connecta Claves' which allowed passage of >100 organisms/mL	
Yes	49	0	1	50
No (controls)	0	5	5	10

Table II. The number of organisms remaining on the syringe tips and compression seals following inoculation of 60 devices with 1×10^4 *Staphylococcus epidermidis* (NCTC 9865), followed by disinfection with 70% isopropanol swabs (50 connectors) or no disinfection (10 connectors)

Disinfected	Number of syringe tips with:				Number of compression seals with:			
	No organisms detected	1-10 cfu	11-20 cfu	>20 cfu	No organisms detected	1-10 colonies detected	11-20 colonies detected	>20 colonies detected
Yes	19	20	11	0	14	18	10	8
No	0	0	0	10	0	0	0	10

Results

The number of needleless connectors that allowed the passage of organisms following simulated clinical use and contamination of the compression seals with 1×10^4 organisms is shown in Table I. Following disinfection with a 70% isopropanol swab, out of the 50 needleless connectors studied, only one allowed organisms to pass through during injection of normal sterile saline via an attached syringe. The numbers of organisms present on the syringe tips and the compression seals were also evaluated after use (Table II). When the syringes were attached to disinfected devices, 19 tips had no organisms impacted onto their surface. Between one to 20 organisms were detected on the remaining syringe tips. In comparison, 14 of the compression seals were sterile after disinfection. Of the remainder, 28 had <20 cfu and eight had >20 cfu on their surface. When the 10 contaminated devices were not disinfected, all had >20 cfu attached to their septal and syringe tip surfaces, and all allowed >100 cfu to pass through with the saline injection.

In the experiment, when 20 cfu were inoculated onto the compression seals of 50 devices, after disinfection with isopropanol, none passed through with injection of normal sterile saline. Of the syringe tips, two had 2 cfu

Table III. The number of 'Connecta Claves' from which organisms were recovered following inoculation with 1×10^7 *Staphylococcus epidermidis* (NCTC 9865) and disinfection with alcohol chlorhexidine spray, 70% isopropanol swab, or a combination of both

Method of disinfection	Number of compression seals and rims with organisms			
	No growth	≤ 50 cfu	50-100 cfu	>100 cfu
Alcohol chlorhexidine spray	16	28	5	1
Isopropanol swab	32	16	1	1
Isopropanol swab followed by alcohol chlorhexidine spray	40	10	0	0
No cleaning (control)	0	0	0	10

All disinfectants were allowed to dry over 2 min before sampling.

The number of organisms isolated from the seal and rim after treatment with alcohol chlorhexidine were significantly greater when compared with the other two methods used for disinfection ($P < 0.05$).

present and one seal had 3 cfu. In comparison, when the 10 control devices were not disinfected, two allowed organisms to pass.

Of the 10 devices manipulated, as in the clinical situation, seven were found to be contaminated with up to 16 cfu of skin microflora, predominantly coagulase-negative staphylococci. The other three devices had no detectable organisms on their compression seal and associated rim.

The efficacy of three different disinfection schedules applied to the needleless connectors were also evaluated. Of the three methods used, the combination of the chlorhexidine gluconate 2.5 (v/v) in 70% industrial methylated spirit, followed by a 70% isopropanol swab, resulted in the greatest number of sterile devices (40 out of 50), although this was not significantly different from disinfection with the isopropanol swab alone, which resulted in 32 out of 50 sterile devices. The alcohol chlorhexidine spray proved least effective at disinfection, with only 16 out of 60 sterile devices (Table III).

Discussion

Needleless connectors have been widely introduced into clinical practice in order to reduce needlesick injuries, to prevent luers being accidentally left open, to facilitate aseptic technique, and to reduce time spent manipulating intravenous connections. Their potential for contamination of peripheral cannulae and central venous catheters, however, has not been fully evaluated. Conflicting reports to date suggest that the valves may either be a potential source for contamination,⁵ particularly when aseptic techniques are questionable, whereas other findings have suggested that they are relatively safe to use.⁶ In the current study, we have evaluated, *in vitro*, the potential of a new type of connector for microbial contamination. The results of our study demonstrated that when devices are challenged with a relatively high inoculum (1×10^7 cfu) to that found in the clinical situation (<16 cfu), and

subsequently disinfected with isopropanol swabs, the potential for micro-organisms to pass via the device when injecting a fluid, is less than 2%. In comparison, when the compression seals were contaminated with 20 cfu, similar to that found in the clinical situation, no organisms were able to pass. This suggests that in clinical use, with appropriate disinfection, the 'Connecta Clave' is unlikely to allow micro-organisms to pass during use. It is, therefore, likely that the potential for contamination during use of these devices with either peripheral or central vascular catheters will be extremely low, and this offers an advantage over other methods of making intravenous connections, such as luer ports, which have a proven contamination rate of 23%.⁴

When using the needleless connector following contamination and disinfection, some of the syringe tips had micro-organisms impacted onto their surface during connection. The 'Connecta Clave' is specifically designed to keep the external surface, including the compression seal, apart from the channel opened up for injection, thereby avoiding contamination. This was confirmed by the finding that only one connector allowed organisms to pass when challenged with 1×10^4 cfu, despite 36 out of 50 compression seals still having organisms on their surface post use, and no connectors allowed passage when 20 cfu were used.

The method of disinfection of needleless connectors needs to be given careful consideration in clinical practice. Whereas we have clearly demonstrated that disinfecting the connectors with isopropanol swabs will reduce the contamination considerably, by a factor of at least 100-fold, in critical areas where attention to asepsis needs to be given a greater priority, then the use of alcohol chlorhexidine, followed by 70% isopropanol swab should be considered. Our results suggest that by using this disinfectant combination, the potential for contamination is likely to be minimal. We would therefore recommend that defined protocols need to be developed for the application of these connectors and if used appropriately they should offer a decrease in the risk of microbial contamination of peripheral and central vascular catheters via the internal route.

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