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Experimental study on the chemico-physical interaction between a two-component cyanoacrylate glue and the material of PICCs

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ABSTRACT

Introduction: The use of cyanoacrylate glue as sealant on the exit site of peripherally inserted central catheters (PICCs) may offer some important clinical advantages. However, concerns exist about the potential interaction between cyanoacrylate and the material of the catheter itself. The aim of this study was to investigate the possibility of damage to the catheter secondary to a long-term contact with a two-component skin glue (N-butyl + octyl cyanoacrylate).

Methods: Twelve PICCs of different brands and types were selected (11 made of polyurethane and one made of silicon). PICCs were glued onto artificial skin pads, slightly wetted with Earle solution. The pads were kept in an egg incubator at 34°C and 60% humidity, for up to twelve weeks. Possible signs of degradation were monitored by surface analyses and mechanical tests. Scanning electron microscopy observations, surface roughness measurements, pressure strength and uniaxial tests were performed.

Results: Samples were analyzed after 4, 8 and 12 weeks of contact with the glue. No chemical reaction between the glue and the material of the catheters was evident. The mechanical strength of PICCs was consistently within the ranges of ISO standards. An expected increase in the stiffness of the samples covered with glue was observed in uniaxial tests. The silicon catheter was weaker than the polyurethane catheters and was damaged while trying to remove it from the pad for tests.

Conclusions: The long-term use of N-butyl + octyl cyanoacrylate glue on polyurethane PICCs is not expected to be associated to any damage to the catheter.

Keywords: Cyanoacrylate glue, Material degradation, Mechanical properties, Peripherally inserted central catheters, Polyurethane, Silicon

Introduction

In the last decade, the use of peripherally inserted central venous catheters (PICCs) has increased rapidly for many different clinical indications both for the hospitalized and for the non-hospitalized patients requiring a short- or medium-term central venous access (1, 2). Some of the advantages of the use of PICCs are related to the optimal exit site, which is typically located in the mid-third of the upper arm: this position is particularly favourable, being associated with reduced risk of bacterial contamination, easy maintenance of the dressing and very good patient compliance. Still, the currently used technique of PICC placement – i.e., the modified Seldinger technique – carries the inevitable risk of some minor bleeding at the exit site in the first minutes and hours after insertion. Such bleeding, which can be relevant in some populations (such as patients with haematological diseases, chronic renal failure, hepatic insufficiency or in treatment with anticoagulant drugs) may require the early change of the dressing; also, it is associated with increased patient anxiety and it may theoretically increase the risk of local infection. Local apposition of glue at the exit site soon after insertion has been used recently to prevent bleeding (3, 4). In this regard, glue is not only safe and effective, but also cost effective: in fact, when sealing with glue, it is possible to cover the exit site with a definitive transparent dressing, thus avoiding the costs and the inconveniences related to the placement of a temporary gauze dressing to be changed after 24 hours. Sealing the exit site with glue may also have some collateral advantages as an aid in increasing the stabilization of the catheter (5-7) and in reducing the possibility of extra-luminal contamination from skin bacteria (8-10).

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Although several recent studies have addressed this promising indication of glue as a sealant of the exit site, some concerns still exist about the risk of possible physical and chemical interactions between cyanoacrylate and the material of the catheters.

The aim of our study was to investigate the possibility of damage due to chemico-physical changes of different types of PICCs after long-term exposure to cyanoacrylate glue.

Materials and methods

To investigate in vitro the interaction between the PICCs and the glue, a critical point was to reproduce the in vivo conditions at the insertion site. The other main point was to define a procedure capable of identifying a possible degradation of the catheter, which was based on both visual and mechanical approaches, similar to what had been done in a previous study on PICCs (11, 12).

The samples

Twelve types of PICCs were considered (Tab. I), from different brands and different types, among which eleven made of polyurethane and only one of silicon (Groshong, Bard). Samples were either 4 or 5 Fr, single or double lumen, power (PI) or non-power injectable (NPI), as detailed in Table I. For some models, both 4 Fr (1 lumen) and 5 Fr (2 lumen) catheters were provided, while for others only one type was available. Note that only one (BluCath, Alfamed) was 4 Fr and double lumen.

TABLE I - List of the peripherally inserted central catheters (PICCs) tested in the present study

ID	Company	Model	Type	4 Fr # Lumen	5 Fr # Lumen
AV	Vygon	Maxflo Expert	PI	1	2
AK	Kimal	PICC-line	PI	1	2
AC	Cook	Turbo-Ject	PI	1	2
AM	Medcomp	Pro-PICC	PI	1	2
BA	Alfamed	PICC-BluCath	PI	2	2
CB	Bard	Power-PICC	PI	1	-
CV	Vygon	Lifecath	NPI	1	-
DH	Healthline	Synergy-PICC	PI	-	2
DP	Plan 1 Health	HealthPICC	PI	-	2
DA	Teleflex	Arrow PICC	PI	-	2
DB	BBraun	Celsite PICC-Cel	PI	-	2
EB	Bard	Groshong PICC	NPI	1	-

The glue

In our tests, we used a cyanoacrylate glue currently available on the market (Glubran Tiss2®, GEM srl, Italy). Glubran Tiss2® is a two-component skin adhesive, based on NBCA (n-butyl 2 cyanoacrylate) and OCA (2-octyl cyanoacrylate). It is used in many clinical centres in Italy as a sealant of the PICC exit site, mainly because of its haemostatic effect (13), but also because it creates an efficient antiseptic barrier against the most diffused infective or pathogenic agents coming from the surrounding skin (14). The blend of the two monomers (NBCA+OCA) provides a high tensile strength and improves the elasticity (13) of the glue.

Sample preparation and conservation

One of the most critical points of the study was to reproduce in vitro the polymerization of the glue, which in vivo is very rapid and strong. The direct apposition of the glue over the PICC line did not produce any polymerization, an effective support was thus necessary. The final and most satisfactory solution was to put the samples on a pad of artificial skin (Wound Closure Pad by *Limbs & Things*), preliminarily wetted with a few drops of Earle saline solution (Biological Industries Israel Beit Haemek LTD) (Fig. 1 A-B-C).

In order to check the results of this procedure, optical microscope (OM) and scanning electron microscope (SEM) analyses were carried out, which confirmed a smooth and rather uniform deposition of glue over all samples.

To investigate possible degradation of the PICC secondary to several weeks of contact with the glue, distinct pads were prepared and conserved in an egg incubator at 34°C and relative humidity of 60%. Such values were chosen to simulate in vivo-like conditions (Fig. 1D). Once the desired duration was reached, the due pad was taken out from the incubator and each sample carefully removed from the skin support (Fig. 1E). This step was critical but necessary to observe the PICC surface underneath the glue. In all polyurethane catheters, when detaching the sample from the pad, the glue remained upon the artificial skin, thus exposing the catheter surface to be analyzed (Fig. 1E). On the other side, the silicon catheter (Groshong, Bard) could not be tested: it was weaker than the glue so it broke in the attempt to remove it from the skin pad.

Experimental design

The possible degradation of the catheter was investigated by means of surface analyses and mechanical tests, as schematically shown in Figure 2.

Surface analyses

The analyses of the PICC surface included OM and SEM observations. Additionally, 3D surface reconstructions were performed, starting from roughness measurements (Hommelwerke LV 150). In particular, for each sample, a rectangular region of dimensions 0.5 mm $\times$ 1.5 mm was scanned. Surface line profiles were acquired in the direction of the catheter axis, equally spaced every 10 µm (i.e., 50 per sample). They were then processed through a specific software (HommelMap Basic-Surface analysis software V6.1) in order to obtain 3D surface plots.

Mechanical tests

Uniaxial tensile tests were carried out at two different strain rates: a low rate (0.1 min^{-1}) was used to obtain load-strain curves [as in (11)] to estimate the catheter stiffness,

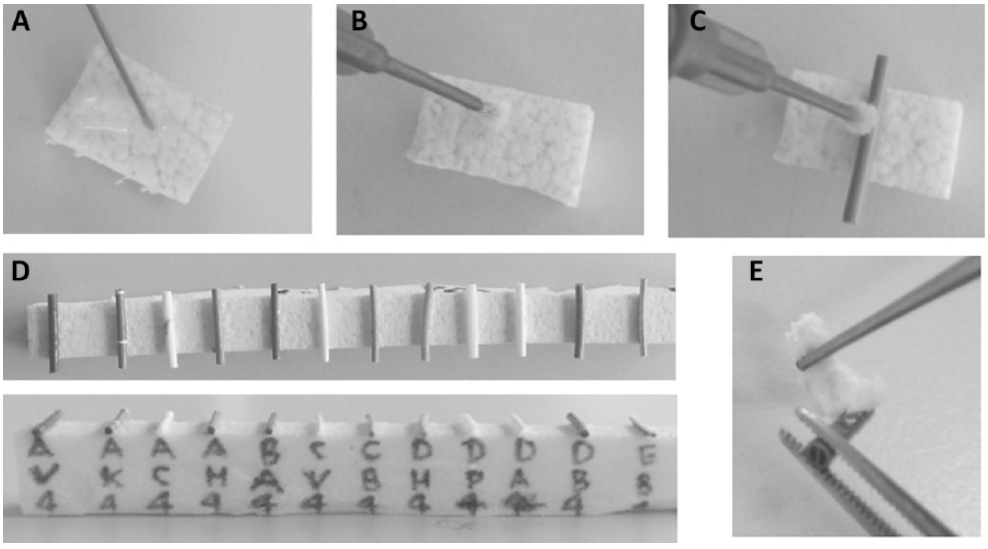

Fig. 1 - Sample preparation procedure: **(A)** a syringe puts a few drops of Earle solution over the artificial skin pad; **(B)** a layer of glue is dropped over the skin; **(C)** the sample is positioned on the skin pad and covered with the glue; **(D)** Pad of samples to be tested at week 4, ready to be put in the incubator; **(E)** Sample removal from the skin pad.

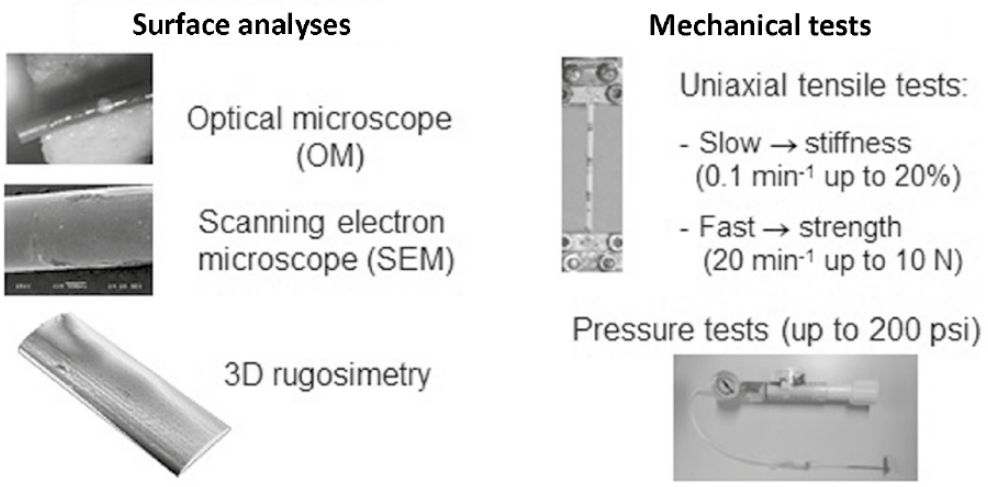

Fig. 2 - Experimental activities: both surface analyses and mechanical tests were performed to detect possible catheter degradation.

while a high rate (20 min^{-1}) was used to check its strength. In the first case, the test was stopped at 20% strain, while in the second case when the load reached 10 N according to ISO 10555-1 (15). The nominal strain of the sample was estimated as the ratio between the displacement u, measured by the transducer of the test machine, and its initial length l_0, which was about 45 mm. Conversely, the required strain rate was set by specifying the proper velocity to the clamps.

The central part of the sample was covered with glue as described above. When detached from the skin, a portion of the glue layer was removed, resulting in an unavoidable asymmetry. Nonetheless, it was evident, simply by touching the sample, that the central part of the PICC was much stiffer than the distal ends, due to the glue. A video extensometer was used to estimate the different stiffness of segments with/without glue of each sample. Such extensometer was developed in our laboratory and is based on image processing (16). It employs micro markers positioned along the PICC and follows their displacements in successive pictures or video frames. In this application, pictures were taken at given instants, corresponding to a nominal strain of the specimen equal to 0%, 5%, 10%, 15%, 20%.

Additionally, pressure tests were performed to verify the burst strength of power injectable catheters. An angioplasty syringe (provided by BBraun) was used, which enabled a manual pressurization of the PICC line. The level of pressure inside it was checked by means of an analogue manometer. The test was considered 'passed' if a 200 psi (1.38 MPa) level was reached without any line damage, according to ISO 10555-1 (15). The pressure rate was estimated as the ratio of pressure increment and pressurization time and resulted in about 100 psi/s (0.7 MPa/s). Mechanical tests were performed at room temperature.

While surface analyses were performed for seven durations (from week 0 to 12 every 2 weeks), mechanical tests were limited to four durations (from week 0 to 12 every 4 weeks).

Results

Surface analyses

OM observations were useful to check the preparation procedure of the samples, both for the correct deposition

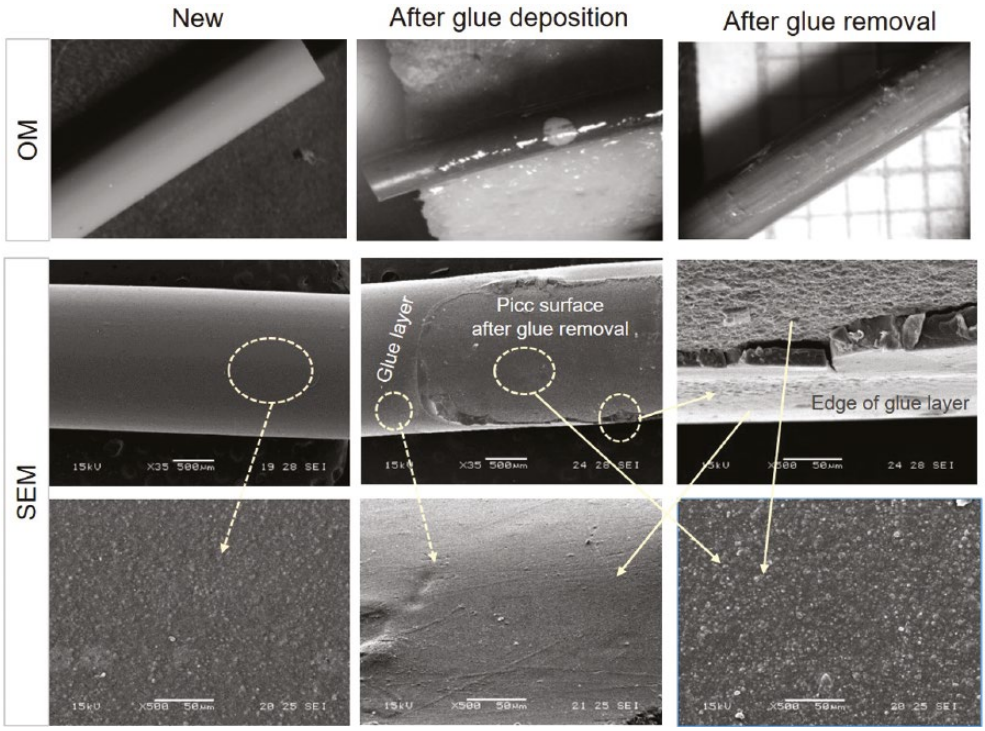

Fig. 3 - Examples of pictures from optical microscope (OM) and scanning electron microscope (SEM) analyses, comparing the initial surface of the PICC to the one covered with glue and to the final one, exposed after glue removal at 8 weeks.

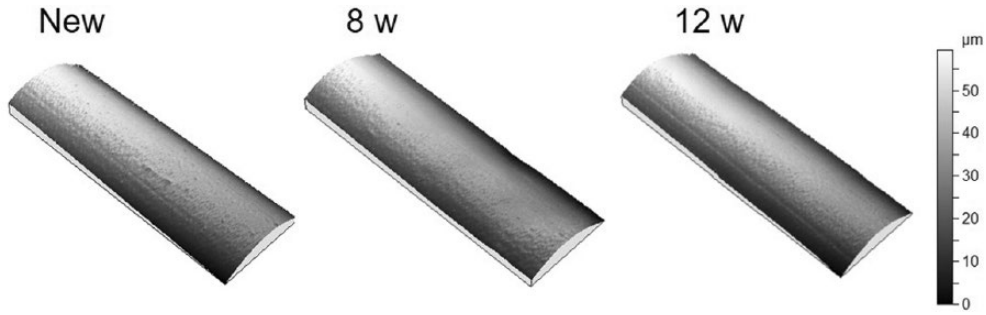

Fig. 4 - Examples of 3D plots of PICC surface, reconstructed by roughness tests: comparison of the initial original (new) PICC surface and the final surfaces at weeks 8 and 12, after glue removal.

of the glue and for its removal. More detailed information was obtained from SEM analyses, as shown in Figure 3. It can be observed that the pictures of the original PICC surface, compared with those of the surface underneath the glue, exposed after glue removal, show no visible sign of deterioration. The same conclusion was reached for all the samples, i.e., for all tested samples for any duration. The silicon catheter could not be tested after glue removal, as explained above.

In order to get quantitative information on the PICC surface, 3D reconstructions were used. An example of the obtained plots is reported in Figure 4, where the PICC surface is shown in brand new conditions and after glue removal at 4, 8 and 12 weeks from deposition. It can be observed that the manufacturing lines are parallel to the cylinder axis and are still visible also after glue removal, proving that the surface has maintained its micrometric features without detectable signs of damage. As already mentioned, the silicon PICC was not observed as it broke during the preparation phase.

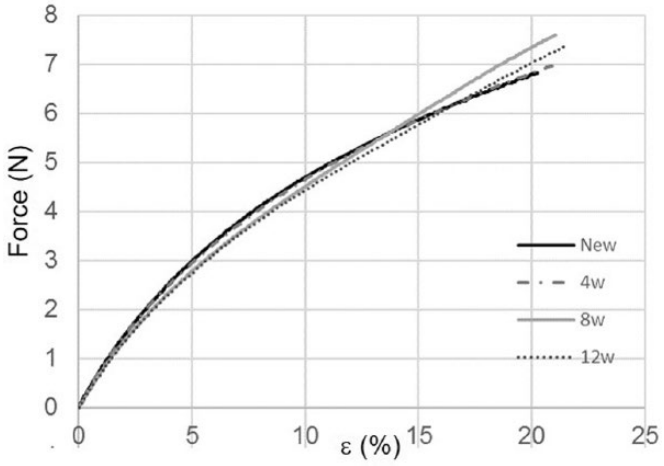

Fig. 5 - Example of load-strain curves obtained from uniaxial tensile tests at slow speed of samples tested after different weeks from glue deposition.

Uniaxial tensile tests

Figure 5 shows an example of the trends of force-strain plots from slow speed tests, obtained for the same model of PICC, but from samples tested after 0, 4, 8, and 12 weeks from glue deposition. In the plots, the nominal strain of the entire PICC is considered. It can be observed that curves are highly overlapped, particularly up to 15%; at higher strains, local effects near the clamps can cause some differences.

Thanks to the video extensometer, it was possible to estimate that segments without glue were more compliant than those covered with glue, as expected, with differences in order of 20%-30%.

All the samples tested at high rate reached the threshold load 10 N, which is the requirement in ISO 10555.1. None of them reached the rupture condition, despite being stretched in some case up to 100%.

It is worth noting that tensile tests did no show differences between the mechanical response of the Non-Power Injectable and the Power Injectable PICCs, i.e., CV versus CB.

Pressure tests

Pressure tests were aimed at verifying the strength of the PI PICC lines. All tested samples reached 200 psi without having signs of damage.

Conclusions

The aim of the present study was to investigate the possibility of damage to the PICC material due to chemico-physical changes secondary to long-term exposure to a two-component skin glue (N-butyl + octyl cyanoacrylate). Such possible damages were supposed to modify the surface properties at the interface and to reduce the strength of the PICC. Therefore, a test campaign was defined to assess the surface conditions and the mechanical properties of catheter after the interaction with the glue. Visual observations of the surface were carried out using OM and SEM. Quantitative measurements were performed by means of a roughness tester and 3D surface reconstructions were obtained from them. No damage was observed in the samples made of polyurethane, not even 12 weeks after glue apposition. Only the silicon catheter was weaker than the glue and it broke during glue removal. Thus, the use of glue with this type of catheter should be discouraged. Both uniaxial and pressure tests confirmed that all polyurethane samples had conserved their strength. We conclude that the glue we tested (Glubran Tiss2®) could be a good candidate as a sealant at the catheter exit site.

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Disclosures

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Conflict of interest: None of the authors has financial interest related to this study to disclose.

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