Plastic migration from implanted central venous access devices

P A Dewan, S K Condron, P N Morreau, R W Byard, J Terlet

Abstract

***Background*—This is the first reported study of histologically confirmed migration from intravenous access devices in children.**

***Methods*—The capsules from around intravenous access devices were examined by light microscopy to determine the extent of the foreign body response; energy dispersive *x* ray analysis was performed to document the elemental content of the foreign material.**

***Results*—A fibroconnective tissue capsule was found around all the samples. Elemental silicon was found in six of 13 tissue samples, and a foreign body giant cell reaction was seen in three of these.**

***Conclusions*—The pseudocapsule that surrounds an implanted vascular access device often has residual foreign material, including silicone.**

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Keywords: silicon; intravenous access device; plastic; migration

Silicone is used as an injectable particulate form for tissue augmentation, as a solid implant (breast implants, artificial joints, urinary prostheses), and as part of intravenous and haemodialysis lines. However, the migration of plastic particles, which was first described in 1967, has now been reported from a wide range of medical devices including plastic particle injections,[1] solid orthopaedic and urological implants, and intravenous fluid lines[2]; both vascular and lymphatic spread of silicone have been documented.[3]

Migration of silicone has been reported to many organs, including the lungs, brain, liver, spleen, and kidneys, and the clinical picture varies accordingly.[4] The usual histological response to silicone is a foreign body giant cell reaction, with variable degrees of fibroconnective tissue and sometimes an acute inflammatory infiltrate. Both the migration risk and histological responses were explored in this study of 11 children who had had an indwelling intravenous access device in place.

Materials and methods

Eleven patients (three boys and eight girls) who had a vascular access device removed were studied. The devices had been in situ for between 27 and 1854 days (median, 346 days) for treatment of malignancy in eight cases and gastrointestinal disorders in three (table 1). The devices used were Infusaports (n = 5), Therex low profile port (n = 4), Portacath (n = 1), and Microport (n = 1).

Table 1 Sex and diagnosis of patients, duration of intravenous access implantation, and capsule tissue sample number

Sex	*Diagnosis*	*Duration (days)*	*Tissue sample*
F	Short gut	1854	1
M	Gastrointestinal bleeding	997	2
F	Hodgkin's disease	202	3
F	Ewing's sarcoma	334	4
M	Hepatoblastoma	346	5
F	Germinoma	310	6
F	Osteosarcoma	624	7
F	Sacrococcygeal teratoma	338	8
M	Short gut	27	9, 10
F	Rhabdomyosarcoma	613	11, 12
F	Wilms's tumour	470	13

The venous access device and the surrounding soft tissue capsule were removed during surgery. The capsule surrounding the device was submitted for histological examination. Samples of the capsule were also examined by a scanning electron microscope for elemental identification of any particulate matter. Sections of the wax mounted tissues were taken from the samples and repeatedly washed in xylene, rinsed in alcohol and then in acetone, before being dried in a critical point drying apparatus. The samples were then mounted on aluminium stubs and coated with a thin (20 nm) carbon layer in a vacuum evaporator to reduce the effects of electron build up in the microscope. Sections of five catheter samples and one of the devices were also mounted in a similar way to the tissue and coated with a carbon layer as above. They were then analysed in a Philips XL20 scanning electron microscope with an integrated EDXA (DX4i energy dispersive *x* ray analyser). The detector collects *x* rays over the elemental range boron (Z = 5) to uranium (Z = 92) and was of the ultrathin window type. A 20 kV accelerating potential was used.

Results

Foreign body inclusions were found in the excised capsule of six of the 11 patients (table 2). The six capsules containing elemental silicon (Si) surrounded devices that had been implanted for 202 to 1854 days (median, 470 days). The samples that did not yield a positive result on the EDXA were from capsules surrounding devices that had been implanted for between 27 and 997 days (median, 346 days). Foreign body inclusions positive for silicon also included calcium, aluminium, sodium, and chloride. In addition, one of the samples was positive for copper and zinc, probably released from brass. A foreign body giant cell reaction was seen in five of the

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Table 2 Capsule histology, energy dispersive x ray analysis findings, and device type

Tissue sample	*Si*	*Ca*	*Al*	*Foreign material/ giant cell reaction*	*Focal chronic inflammation*	*Device*
1	Yes	Yes	Yes	–	Yes	Infusaport
2	–	–	–	–	–	Portacath
3	Yes	Yes	Yes	Yes	–	Therex low profile port
4	–	Yes	–	–	–	Infusaport
5	–	–	–	–	–	Therex low profile port
6	Yes	Yes	Yes	–	Yes	Therex low profile port
7	–	–	–	Yes	–	Infusaport
8	Yes	–	–	Yes	Yes	Therex low profile port
9	–	–	–	Yes	Yes	Infusaport
10	–	–	–	–	Yes	Infusaport
11	Yes	Yes	Yes	–	–	Microport
12	–	–	–	–	–	Microport
13	Yes	Yes	Yes	Yes	–	Infusaport

Si, silicon; Ca, calcium; Al, aluminium.

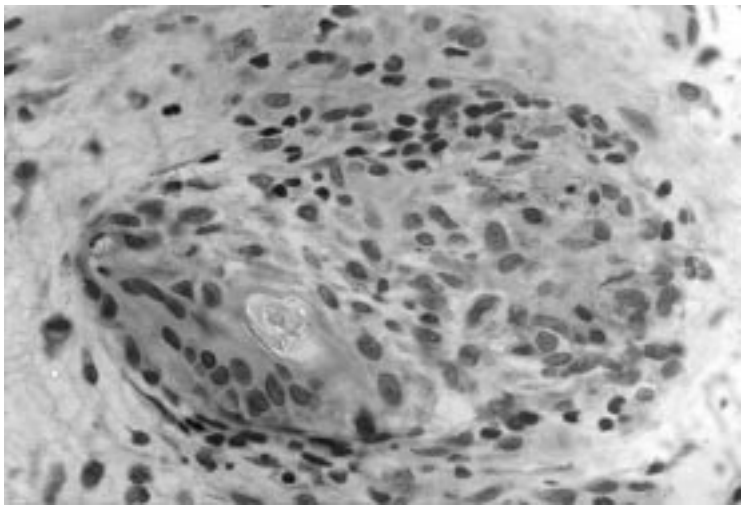

Figure 1 A foreign body giant cell containing material that was shown to be silicone on energy dispersive x ray analysis.

samples (five patients) (fig 1). Elemental Si had been identified in three of these capsules; foreign material resembling suture thread was seen on the slides in the remaining two; no Si was identified on EDXA. However, the tissue samples examined were small and may not be totally representative of the bulk sample.

A fibroconnective tissue capsule was seen in tissue samples from all of the patients. This was associated with an acute inflammatory infiltrate in two of the cases, and with a hyalinised connective tissue appearance in 10 of the samples (nine patients). Six of the samples (five patients) in which fibroconnective tissue was seen had negative EDXA findings. Of the 10 samples with hyalinised connective tissue, there were four with negative EDXA findings.

Focal chronic inflammation was seen in five of the tissue samples (four patients). Silicon, calcium, aluminium, sodium, and chlorine were identified by EDXA in two of these samples; no inclusions were identified in the remaining three.

Energy dispersive *x* ray analysis was performed on five of the catheters that had been used (Therex low profile 2, Infusaport 2, and Microport 1). They were all found to be an Si based material embedded with titanium oxide, similar to the elemental make up obtained from the tissue samples. The elemental composition of the Infusaport device examined was true to the label. The silicone rubber and the sulfinated epoxy (PolySulfone) were just that.

Discussion

Silicone was originally chosen for medical use because of its chemical inertness and the assumption that it would also be biologically inert. However, reports on the histological response to silicone have been variable. Foreign body giant cell granulomas have been described, with silicone inclusions and a surrounding inflammatory infiltrate often seen as a fibrous tissue capsule around the device.[5] There have been suggestions that the silicone may have a carcinogenic effect, after the discovery of malignancy in patients who had had intra-articular joint prostheses for rheumatoid arthritis. However, given the large number of joint prostheses that have been inserted since their development in the 1960s, the very low number of reported cases suggests that the risk is minimal.

In our study, intravenous access devices from a group of 11 children were removed complete with surrounding capsule. The devices had been implanted for between 27 and 1854 days. On removal, the capsule was examined by EDXA and Si was identified in five of the capsules. These five capsules were made of fibroconnective and hyaline connective tissue; and two of these showed a foreign body giant cell reaction. Two of the other capsules showed a focal chronic inflammatory reaction. All the capsules with silicon had been implanted for longer than 202 days, with a median of 470 days.

In a similar study, elemental silicon was found in six of 15 capsules surrounding Port-a-Catheter devices.[6] However, Evans and Baldwin did not report the association, although concentrations of Si were greater than measured previously in cadaver tissue from patients with no medically induced Si contact.[7]

Our results show that silicone does migrate from long term indwelling devices, and does cause a local inflammatory response. To determine the importance of our findings, longitudinal studies are necessary, both to substantiate our findings and to monitor carcinogenicity. The use of these devices in children for the past several years without any reports of long term adverse effects suggests that complications are rare. However, more research is needed to enhance our understanding of the long term sequelae of these devices in children.

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