A Comparative Assessment of Three Common Catheter Materials

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Catheters are medical devices, typically in the form of a tube, that are inserted into the body to remove fluid, create an opening, or deliver a drug. The biocompatibility of catheters, as with other medical devices, can be defined as the ability of the device to perform its intended function without eliciting undesirable side effects. Biocompatibility will be dependent on physical properties of the device (e.g., rigidity, surface smoothness) and its chemical nature; is it allergenic, are there toxic leachables? Catheter biocompatibility is also dependent on whether the body's reaction to the device will affect its function. A relevant example is mineral salt encrustation of urological catheters.

While there is no ideal catheter material, some are much more biocompatible than others. Their biocompatibility is related not only to the basic polymers, but also to the various additives used. What follows is an overview of the biocompatibility of three common catheter materials: silicones, polyvinyl chloride (PVC), and latex rubber. The focus is on some of the principal problems that have been encountered: allergies, phlebitis, encrustation, infection, and deflation.

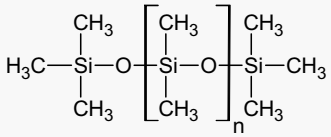
Silicones

Silicones, one of the most thoroughly tested and widely-used groups of biomaterials, are well known for their intrinsic biocompatibility and biodurability. These key characteristics have been attributed to the material's inherent chemical and thermal stability, low surface tension and hydrophobicity. As a result of these properties, silicones have the benefit of extensive application in catheters and other medical products. Silicones have been successfully applied in short- and long-dwelling catheters, drains, and shunts for over sixty years. They remain materials of choice in many demanding applications.[1]

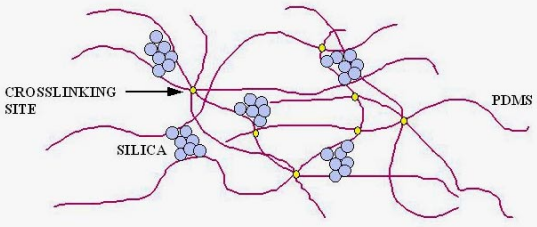
Silicone elastomer is a thermosetting material, capable of being processed by various molding, dipping, and extrusion methods. Once cross-linked into the desired configuration, silicone catheters are thermally stable (reported operating range from -80 °C to +230 °C),[3] remaining essentially unaffected by repeated autoclaving. They can usually be dry-heat sterilized as well.

Composition of Silicones

Silicones are a group of synthetic polymers whose backbone is comprised of repeating silicon to oxygen bonds. In addition to their bonds with oxygen to form polymeric chains, the silicon atoms are also bonded to organic groups, typically methyl groups. This most common form of silicone is known by the International Union of Pure and Applied Chemistry (IUPAC) name polydimethylsiloxane, abbreviated as PDMS.

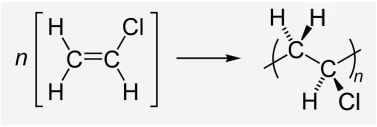


PDMS is a liquid of varying viscosities depending upon chain length. PDMS polymers can be transformed into three-dimensional elastomeric networks by way of catalyzed cross-linking reactions, which create chemical bonds between adjacent chains. Silicone elastomers used in medical device applications normally include reinforcing filler, typically fumed amorphous silica, which becomes inextricably bound within the overall elastomeric network. Incorporation of reinforcing filler into the cross-linked matrix reduces material stickiness, increases hardness, and enhances mechanical strength.[2]



Polyvinyl Chloride

Polyvinyl chloride is generally referred to by the abbreviation PVC and has the IUPAC name polychloroethene. It is prepared by the addition polymerization of vinyl chloride monomer. A chemical initiator is used to facilitate the reaction by opening the double bond, thereby presenting another initiation site on the opposite side of the monomer bond for continuing molecular growth.[4]



PVC is thermoplastic, although the pure polymer is hard and stiff.[5] The addition of chemicals known as plasticizers is necessary to make PVC soft and flexible. These plasticizers, which can comprise a third by mass of the compounded plastic,[6] are not chemically bound in the polymer molecules. As such, these additives can be extracted in vivo causing several problems: induction of an acute inflammatory reaction to the leached plasticizer,[7] increased polymer stiffness/brittleness, and an increased failure rate due to breakage when compared to other biomaterials.[8]

In 2002, the US FDA issued a Public Health Notification concerning PVC.[9] The agency expressed concerns regarding exposure to the PVC plasticizer DEHP (di(2-ethylhexyl)phthalate) that is used in numerous medical devices including catheters, blood bags, and extracorporeal tubing. Exposure to DEHP had produced a range of adverse effects in laboratory animals, most notably liver toxicity and testicular atrophy.[10] In view of the available animal data, the agency advised, "precautions should be taken to limit the exposure of the developing male to DEHP."[9]

In the wake of public health concerns regarding phthalate plasticizers, PVC is becoming an outdated legacy material overtaken by others "better suited to the demands of healthcare applications."[11]

Latex Rubber

Latex rubber is the term often applied to the natural milky-white thick colloidal suspension containing hydrocarbon polymer and the articles made from it. Latex rubber is most often obtained commercially from the sap of the Pará rubber tree (*Hevea brasiliensis*), named for the Brazilian state in which the plant was discovered.

The chemical composition of latex materials varies but is generally as shown in Table 1.

Table 1:
Chemical Composition of Latex[16]

Percent	Component
55-65	Water
30-40	Cis-1,4-polyisoprene particles
2-3	Plant proteins
1.5-3.5	Resin
1.0-2.0	Sugars
0.5-1.0	Ash
0.1-0.5	Sterol glycosides

Primarily due to the human immunodeficiency virus (HIV) pandemic, the use of latex gloves and condoms sharply increased in the 1980s. This increased usage coincided with increased reports of latex allergies, especially among healthcare workers. The prevalence of latex allergies among medical professionals has since been estimated to be between 8 and 17%.[13,14]

Other populations are also at risk, such as spina bifida and spinal cord patients who have had repeated or chronic exposure to latex catheters. Studies have reported the prevalence of latex sensitivity in children with spina bifida ranging from 30 to 41%.[15-17] In a study of incontinent adult spinal cord injury patients, 47% had an allergic response to latex.[18] The prevalence in the general population is believed to be lower, ranging from 1 to 6%.[13]

For some people, contact with latex products such as catheters can be life-threatening.[19,20] For example, deaths have been attributed to anaphylaxis from latex retention balloons used in barium enema exams.[21] Latex allergies usually present as a Type I (IgE-mediated) immediate allergic reaction to proteins contained in the natural rubber. Powder lubricants such as corn starch can bind with natural latex proteins and thereby exacerbate exposure.[22] Aside from proteins, several of the additives used during manufacture have also been implicated as causal agents. For example, remnant amounts of some of the accelerators (e.g., carbamates, thiurams, mercaptobenzo-thiazole) might cause a Type IV (T-cell mediated) delayed hypersensitivity reaction.[14,23]

Latex allergies are now regarded as a major healthcare issue and many hospitals have adopted risk management policies restricting use of latex-containing products in order to protect patients and healthcare workers alike.[19,20] The conversion of medical facilities to "latex-safe" can reduce employee sensitization, impairment, and disability. Healthcare facilities, regardless of size, are thereby likely to benefit financially from becoming latex-safe.[24]

Manufacture of Dipped Latex Rubber Medical Devices

After the milky fluid has been gathered from the tapped trees, stabilizing ammonia-based preservatives are added to discourage microbial spoilage. The latex is then concentrated through centrifugation, evaporation, or a process called *creaming* in which a chemical is added causing the polymer particles to swell and rise to the surface. Next, the material is compounded with additional chemical additives such as accelerators (to help vulcanization occur), surfactants (to prevent phase separation) and antioxidants (to prevent degradation).

Medical devices, such as balloon catheters, condoms and surgical gloves, are typically generated from latex using a dip-molding process. Dipped goods account for more than half of the latex used in the United States.[25] A rigid tool known as a mandrel is prepared of the proper shape and size. The tool is pre-dipped into a solution of coagulant, such as calcium nitrate. The mandrel is then immersed into the vat containing the stabilized, concentrated, compounded liquid latex material. The coagulant causes the milky latex to gel and thereby coat the mandrel. The mandrel is then slowly withdrawn from the liquid. Passage through an oven (or heat zone) completes the coagulation process. Additional dips into the vat can be used, if necessary, to increase the coating thickness. Next the coated mandrels are dipped into or sprayed with water to wash out some of the coagulant and other additives.

The vulcanization step occurs next. As the coated mandrel is heated, the vulcanizing agent (a sulfur-containing compound) reacts with the isoprene polymers resulting in a cross-linked rubber. After cooling, the cured rubber can be removed from the mandrel. Typically the rubber articles are again leeched in water in an attempt to remove remnant sulfur and other additives.

A powder lubricant such as corn starch may be used to prevent the latex products from adhering. In some cases, surface treatments such as chlorination may be used as an alternative to lubrication.[12,25]

Material Comparisons

Unlike latex, Dow Corning healthcare silicones contain no proteins and are non-allergenic.[26-28] Unlike PVC, they contain no phthalates or other organic plasticizers which might leach out.

Silicone catheters[29] and tubing[30] appear to be less thrombogenic than standard PVC tubing and catheters. In one study, an ex vivo shunt in a canine model was used to compare thrombogenic response to two different standard reference materials: National Heart Lung and Blood Institute primary reference material polydimethylsiloxane and IUPAC reference material polyvinyl chloride. While leukocyte affinity and the fibrinogen adsorption rate were not significantly different for the two reference materials, platelet affinity was significantly higher for the PVC.[31]

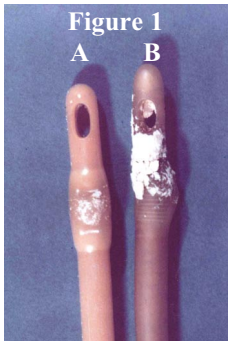
Phlebitis, an inflammation of the veins sometimes associated with thrombosis, can be caused by mechanical trauma from insertion and movement of venous catheters. When silicone was compared to PVC intravenous (IV) catheters for parenteral nutrition, a lower complication rate, higher rates of IV therapy completion, and longer service life were demonstrated (Table 2).[32] Consistent with these results, most modern central venous catheters intended for chronic use are made of silicone elastomer.[5]

In another study that compared silicone and PVC catheters for parenteral nutrition, the silicone catheters had significantly less sepsis, prolonged service life (by 50%) and fewer catheter insertions per patient.[8]

Table 2:
Catheters for Parenteral Nutrition[32]

Count \ Catheter	Silicone	PVC
Catheters	43	40
Patients	40	40
Average number of days in use	23½	10¾
Reasons for IV Catheter Removal		
Therapy Completion	25	5
Phlebitis	1	8
Thrombosis	0	4
Sepsis	0	6
Plugged	3	8
Death	10	9
Other	4	0

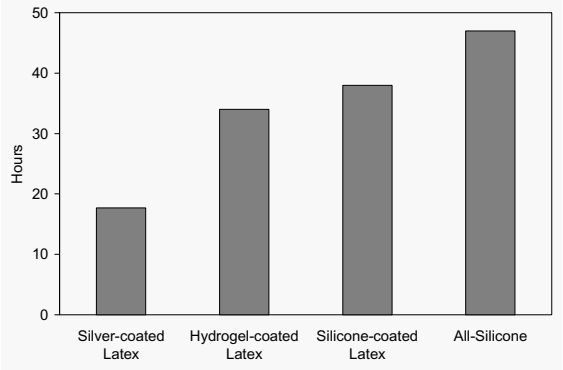
Premature infants are particularly predisposed to phlebitis. One study compared the complications observed for silicone catheters in premature babies with those associated with PVC catheters. The researchers found that the silicone catheters were better at maintaining their physical properties and flexibility over time when compared to the PVC catheters.[33]



A common problem with urinary catheters is mineral encrustation, which occurs when urease-producing bacteria hydrolyze urea to ammonia making the urine more alkaline. The increased pH results in formation and precipitation of calcium- and magnesium-containing crystals. This mineral deposition can block the catheter eyelet and cause pain during extraction.[34] Figure 1 shows a silicone-coated (A) and uncoated latex catheter (B). The silicone coating may help reduce mineral encrustation on the tip or within the lumen of the catheter.[35]

An in vitro study compared four types of catheters using human urine inoculated with the gram-negative anaerobic bacterium *Proteus mirabilis* which has been associated with the formation of uroliths (bladder stones). The mean time before each catheter type became blocked was monitored. Of the four test materials, the all-silicone and silicone-coated catheters remained patent the longest as shown in Figure 2.[36]

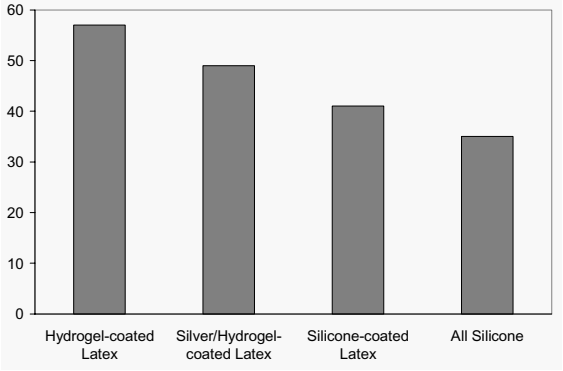
Figure 2: Patency Duration of Urinary Catheters



In another study comparing 14-day indwelling urinary catheters in elderly patients, formation of encrustations and blockage was significantly less in patients with silicone catheters as compared to Teflon®-coated latex or all-latex catheters.[37] As noted by others, "Constructing catheters of the best biomaterial to discourage biofilm formation, i.e., silicone elastomer, has been a great advance."[5]

In addition to sub-clinical biofilm colonization, clinically-evident infection is another possible complication associated with catheter use. One study found that Foley catheters made entirely of silicone had less potential for bacterial migration compared to latex catheters with various coatings, including a silver-containing hydrogel, as shown in Figure 3.[38]

Figure 3: Bacterial Migration Index



Another study used radio-labeled gram-negative bacilli to examine bacterial adherence to various catheter materials. Adherence was found to be significantly less to siliconized rubber than to pure latex.[39]

Besides encrustation and infection, another complication with balloon catheters is deflation. Premature deflation can be a problem, regardless of where in the body the balloon is used. Researchers compared latex and silicone embolization balloons in the treatment of varicocele, a widening of the veins along the spermatic cord. The time until deflation was found to be significantly longer for the silicone balloons, 9.9 months compared to 5.1 months for the latex.[40] In addition to the main intended use for bladder drainage, the readily-available Foley catheter finds application in unusual spots, for example, post-nasal packing. A comparison of silicone and latex Foley catheters found 30% of the latex catheters failed, whereas the silicone type was "100% reliable."[41]

Economy of Using Silicone

Silicone catheter raw materials are more expensive than legacy materials such as latex and PVC, but when examining healthcare choices other factors should be taken into account. For example, consider infection. Urinary tract infections account for over 40% of all nosocomial infections, and almost all these infections are associated with indwelling catheters. The acquisition of urinary tract infections following urinary bladder catheterizations is associated with nearly a threefold increase in mortality among hospitalized patients. An estimate of the economic impact indicates that patients with hospital-acquired urinary tract infections secondary to indwelling catheters, spend an average of 2.4 additional days in the hospital. Bearing this in mind, even a marginal decrease in urinary tract infections may be cost-effective.[42]

PVC Disposal

Disposal of medical products made from PVC can be problematic. The preferred biohazard waste disposal method for hospitals is often incineration. Incineration of used PVC medical devices such as catheters and tubing generates hazardous gases including hydrochloric acid (HCl), dioxins, and polychlorinated biphenyls (PCBs). In addition to the environmental impact of such air population, the HCl shortens the life of the incinerator.[43-46]

In summary, catheters produced from silicone have been reported to improve patient comfort and reduce total patient cost by reducing the:

1. Occurrence of allergic responses
2. Incidence of phlebitis
3. Frequency of sepsis
4. Number of catheter insertions
5. Likelihood of mineral encrustations
6. Potential for bacterial migration
7. Occurrence of premature balloon deflation
8. Potential for nosocomial infections

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