CHAPTER II.5.18 MEDICAL APPLICATIONS OF SILICONES

Jim Curtis¹ and André Colas²
¹Dow Corning Corporation, Midland, MI, USA
²Dow Corning Europe S.A., Parc Industriel, Seneffe, Belgium

MEDICAL APPLICATIONS

Silicones, with their unique material properties, have found widespread application in healthcare. Properties attributed to silicone include biocompatibility and biodurability, which can be expressed in terms of other material properties such as hydrophobicity, low surface tension, and chemical and thermal stability. These properties were the basis for the initial use of silicone in the medical field. For example, their hydrophobic (water-repellent) character caused silicones to be considered for blood coagulation prevention in the mid-1940s. Researchers from the Universities of Toronto and Manitoba obtained a methylchlorosilane from the Canadian General Electric Company and coated syringes, needles, and vials with the material. When rinsed with distilled water, the silane hydrolyzed, forming a silicone coating on the substrate. The researchers published results from their clotting time study in 1946, finding that the silicone treatment “on glassware and needles gives a surface which preserves blood from clotting for many hours” (Jaques et al., 1946) (see Chapter II.3.5). Researchers at the Mayo Clinic took notice of the work by their Canadian colleagues, indicating that silicone: “was the most practical of any known [substance] for coating needle, syringe and tube” (Margulies and Barker, 1949). They also demonstrated that leaving blood in silicone-coated syringes had no significant effect on the blood as measured by coagulation time after being dispensed from the syringe. Soon the use of silicone precoating of needles, syringes, and blood collection vials became commonplace. In addition to the blood-preserving quality of silicone, it was soon discovered that silicone-coated needles were less painful (Figure II.5.18.1). Today most hypodermic needles, syringes, and other blood-collecting apparatus are coated or lubricated with silicone.

In addition, silicone materials have found other uses in the medical laboratory. Silicone tubing is used for fluid transport between vessels. Another application is in dentistry, where silicone impression materials have been used since the 1950s (Starke, 1975). Modern silicone impression materials can be obtained using addition or condensation polymerization methods to cure the implants (Ciapetti et al., 1998).

Extracorporeal Equipment

Silicone tubing and membranes found application in numerous extracorporeal machines, due in large part to their hemocompatibility and gas permeability properties. Silicone has been used in kidney dialysis, blood oxygenators, and heart bypass machines. Blood compatibility was also a factor in the application of silicone in several mechanical heart valves (Figure II.5.18.2). The use of silicone in extracorporeal applications continues today. Hemocompatibility testing has suggested that platinum-cured silicone tubing may be superior to poly(vinyl chloride) (PVC) in several respects (Harmand and Briquet, 1999).

Catheters, Drains, and Shunts

The properties of silicone elastomers have also found application in numerous catheters, shunts, drains, and the like (Figure II.5.18.3). These include devices fabricated with silicone extrusions, as well as devices with non-silicone substrates that are silicone-coated to provide less host reaction. For example, although several all-silicone urology catheters are on the market, the Silastic® Foley is a latex catheter whose exterior and interior are coated with silicone elastomer (Figure II.5.18.4).

Figure II.5.18.5 shows the various components of the Cystocath® suprapubic drainage system (Baeham, 1973), which was used for bladder drainage after gynecological surgery that complicated or prevented normal urethral urination. The system included: (A) the catheter, a silicone tube whose non-wetting surface minimized encrustation; (B) the body seal made of flexible silicone elastomer that conformed easily to the body contour and allowed the patient freedom of movement; (C) pressure-sensitive silicone adhesive that adhered well to skin; and (D) the trocar needle used to pierce the bladder and overlying tissue. After
SECTION II.5 Applications of Biomaterials

(A) Penetration force of silicone coated and non-coated hypodermic needles as measured by (B) Melab equipment using DIN 13097. (Photo courtesy of Melab GmbH © Dow Corning AV12291).

Examples of early heart valves containing silicone elastomer. (© Dow Corning, top: AV06433, bottom: AV06434)

Examples of silicone in catheters, drains, tubes, and cannulae. (© Dow Corning AV06432)

Silastic® Foley catheter. (Courtesy of C. R. Bard, Inc.)
vaginal surgery the bladder was inflated and located. Silastic® Medical Adhesive B was applied by brush to the clean abdomen over the bladder and the bottom of the body seal component. The pressure-sensitive adhesive (described in Chapter I.2.2.B) had excellent properties conducive to the application. It provided good adherence to dry or wet skin, without causing irritation or sensitization, and good permeability to oxygen, carbon dioxide, and moisture vapor; it also formed a waterproof and urine-proof seal. After a short wait for the solvent to evaporate, allowing the adhesive to become tacky, the body seal was adhered to the abdomen. The trocar was advanced through the center of the body seal and pierced through the skin and bladder. The stylet was removed and the silicone catheter threaded through the needle and well into the bladder. The needle was withdrawn, leaving the catheter in place. The silicone tube was secured in the retention groove and the distal end was withdrawn, leaving the catheter in place. The silicone catheter was threaded through the needle and well into the bladder. The needle was withdrawn, leaving the catheter in place. The silicone tube was secured in the retention groove and the distal end was withdrawn, leaving the catheter in place.

**Long-Term Implants**

The chemical stability and elastic nature of silicone are beneficial for many applications involving long-term implantation. The first published report of silicone elastomers being implanted in humans was in April 1946, when Dr. Frank H. Lahey told of his use of these materials for bile duct repair. He obtained the material, called “bouncing clay” at the time, from the experimental laboratory of the General Electric Company (GE). Citing its elastic properties, he reported: “It is flexible, it will stretch, it will bounce like rubber, and it can be cast in any shape” (Lahey, 1946).

In 1948, Dr. DeNicola implanted an artificial urethra fashioned from the same type of GE silicone tubing used previously by Lahey. The first apparently successful replacement of the human male urethra by artificial means was conducted under general anesthesia. The 3¼ inch (9.5 cm) long silicone tube was threaded over a narrow catheter whose distal end was in the bladder. Fourteen months after implantation, the artificial urethra “had been retained with normal genitourinary function. ... There is no evidence at this time that the tube is acting as a foreign body irritant…” (DeNicola, 1950).

A particularly notable early silicone implant was the hydrocephalus shunt, which benefitted from the thermal stability of silicone. This application became quite celebrated when tenderly described in *Reader’s Digest* (LaFay, 1957). Charles Case “Casey” Holter was born on the seventh of November 1955 with a neural tube defect called lumbosacral myelomeningocele. By December, the baby had contracted meningitis, and surgeons at the Children’s Hospital of Philadelphia closed the defect. A few weeks later, hydrocephalus caused young Casey’s head to swell as cerebrospinal fluid (CSF) collected in his brain. At the time, there were few treatment options, and this affliction was fatal for most children who contracted it. After infection concerns with the daily venting of CSF through the fontanelles (spaces between cranial bones that have not completely fused), Dr. Eugene Spitz implanted a polyethylene shunt catheter in Casey to drain excess CSF from the brain into the atrium of the heart. A valve was needed that would allow the CSF to drain when pressure began to build in the brain, but would close to prevent backflow when the pressure equalized. Spitz did his neurosurgery residency at the University of Pennsylvania in 1952, gaining clinical experience with a ball and spring valve developed by the Johnson Foundation, an arm of Johnson & Johnson. So it was this valve that was first implanted in young Casey. Basically a scaled-down version of an automotive pressure relief valve, it frequently clogged with tissue. Casey’s father John, a machinist by profession, asked Spitz about the valve, the CSF, and the pressures involved. Spitz confided in Holter that “a competent one-way valve” that would be stable in the human body was needed (Baru et al., 2001).

It is said that necessity is the mother of invention, and this is a poignant example. A desperately concerned father went home to his garage workshop that evening and constructed a prototype valve from two rubber condoms and flexible tubing. However, autoclaving caused the material to shrink a bit and the valve to leak. Holter discussed the shrinkage problem with a local rubber company, where the head of research suggested he replace the natural rubber with a thermally stable material known as silicone. Holter obtained Silastic® brand silicone elastomer and tubing free of charge from Dow Corning. In March of 1956, Holter believed the valve that would come to bear his name was ready. At the time, Holter’s son was too ill to undergo the surgery; however, Spitz saw promise in the valve design and successfully implanted the ventriculooatrial shunt in another hydrocephalic child. Casey was sufficiently stable for surgery by April, when Spitz...
SECTION II.5  Applications of Biomaterials

implanted him with a Holter valve (Baru et al., 2001). The Holter valve was so successful that its production began that summer, and the valve is still being made in almost unchanged form today (Aschoff et al., 1999) (Figure II.5.18.6).

![Figure II.5.18.6](image)

**FIGURE II.5.18.6** (A) Original Silastic hydrocephalus shunt. (B, C) Modern Codman Hakim programmable valve shunt. (Courtesy of Codman, a Johnson & Johnson company).

Early healthcare applications resulted in substantial interest in the emerging silicone materials and their promising properties. The two leading silicone suppliers, General Electric and Dow Corning, began receiving inquiries from the medical field at unprecedented rates. By 1959, Dow Corning was so inundated with requests for materials and information that the Dow Corning Center for Aid to Medical Research was established to act as a clearing house for all information on medical uses of silicone, and to supply medical scientists with research quantities of various silicone materials, all without cost to the researcher. The Center corresponded with more than 35,000 physicians and researchers from all over the world and in numerous areas of healthcare (Braley, 1973).

The upsurge of interest in silicones for healthcare applications continued in the early 1960s. Before the end of the decade, silicone materials were being employed or evaluated in numerous healthcare applications – in orthopedics, catheters, drains and shunts of numerous descriptions, as components in kidney dialysis, blood oxygenators, and heart bypass machines, heart valves, and aesthetic implants, to name just a few.

Silicone Orthopedic Implants

The most significant orthopedic applications of silicone are hand and foot joint implants. Dr. Alfred Swanson, with assistance from Dow Corning, developed silicone finger joint implants such as those shown in Figure II.5.18.7 (Swanson, 1968). Similar implants were

First launched in 1999, this innovative lens material greatly increases the amount of oxygen that reaches the cornea, allowing the lenses to be worn for as long as one month of continuous wear. The use of these lenses has resulted in fewer complications, and much improvement in patient symptoms of dryness and discomfort compared with the previous soft lenses (Dillehay, 2007).

In the ear, examples include silicone elastomer tubes for otological ventilation, as well as electronic cochlear implants that are encapsulated and insulated with silicone. Silicone elastomers are used in voice prostheses placed in the throat between the trachea and esophagus after laryngectomy. This is a particularly challenging location for any elastomeric material, as yeast and bacterial biofilm colonization often develop with long-term use (Delank and Scheuermann, 2008).

Silicone elastomers find application in many devices implanted in the thoracic cavity. A key example is the cardiac pacemaker, where silicone is used to encapsulate and insulate. Two interesting examples involving the stomach are the popular gastric band implant (Lap-Band®) for weight loss, and the Angelchik anti-reflux device for management of gastro-esophageal reflux or hiatal hernia which have not been resolved by more conservative treatments (Timoney, et al. 1990). The latter has the distinction of being the first medical device containing silicone gel to be approved by the US Food and Drug Administration (FDA) (FDA approval P790006, 1979).

Silicone materials continue to find application in various parts of the body today. Including orthopedic applications, silicone implants are literally found from head to toe. In the eye, silicone foam and elastomer scleral bands and bucklers, silicone vitreous fluid replacement, and elastomer intraocular lenses help restore vision after retinal reattachment or cataract surgery. In addition, the incorporation of siloxane into soft contact lens material resulted in the development of the silicone hydrogel contact lens.
CHAPTER II.5.18  Medical Applications of Silicones

FIGURE II.5.18.7  Silicone elastomer finger joint implants: (A, C) Photograph and X-ray of arthritic right hand prior to restorative implantation surgery. (B, D) Postoperative photograph and X-ray view of the same hand. (© Dow Corning, top: AV06438, A: AV06439, B: AV06441, C: AV06440, D: AV06442.)
developed for the other small joints of the foot and hand. In addition to double-stemmed finger joint implants in each of the metacarpophalangeal joints (large arrow), Figure II.5.18.7D also shows a single-stemmed Silastic ulnar head implant at the distal terminus of the ulna (small arrow). Nearly four decades later, silicone remains the most prevalent type of small joint implant.

Cement restrictors made of silicone elastomer with added barium sulfate for radiopacity (Figure II.5.18.8A) are used in joint replacement surgery involving cement. For example, one of these implants, also known as a bone plug, is inserted deeply into the prepared intramedullary canal of the femur during hip replacement surgery (Figure II.5.18.8B). It fits securely to restrict distal migration of poly(methyl)methacrylate bone cement intra- and postoperatively.

Another early orthopedic application of silicone was in 1969, when the French GUEPAR (Groupe d’Utilisation et d’Étude des Prothèses Articulaires) posterior-offset hinged total knee implant was introduced. This design was constructed of the metal Vitallium, with a shock-absorbing silicone bumper that prevented impact of the anterior portions of the tibial and femoral components during knee extension (Mazas and GUEPAR, 1973).

**Aesthetic Implants**

Silicones have been used extensively in aesthetic and reconstructive plastic surgery for over 40 years. Silicone elastomer is used in implanted prosthetics of numerous descriptions. Silicone implants are widely used in the breast, scrotum, chin, nose, cheek, calf, and buttocks. Some of these devices may also employ a softer-feeling substance known as silicone gel. The gel is a lightly cross-linked silicone elastomer, without silica or other reinforcing filler, that is swollen with polydimethylsiloxane fluid. The gel is contained within a silicone elastomer shell in breast, testicular, and chin implants. Surgeons implant these medical devices for aesthetic reasons, to correct congenital deformity or during reconstructive surgery after trauma or cancer treatment.

The most prominent of these aesthetic implants is the silicone breast implant. Breast enlargement by surgical means has been practiced for over a century. In 1895, Czerny reported transplanting a lipoma to a breast in order to correct a defect resulting from the removal of a fibroadenoma (Czerny, 1895). The insertion of glass balls into the breasts was described by Schwartzmann in 1930, and again by Thorek in 1942. The Ivalon sponge, introduced by Pangman in 1951, was the first augmentation prosthesis to be retained fairly consistently. This surgical sponge, formulated of poly(vinyl alcohol) cross-linked with formaldehyde, was at first hand-trimmed to the desired shape by the implanting surgeon, and later preformed by Clay Adams, Inc. There was some early recognition of the tendency for tissue growth into the open-cell foam, and in 1958 Pangman patented the concept of encapsulating the foam with an alloplastic (manmade) envelope. His patent also contemplated the use of other fill materials, such as silicone, in place of foam. The Polystan and Etheron polyurethane sponge implants began to be used as breast implants in 1959 and 1960, respectively. These sponge implants became popular in the early 1960s, later being supplanted by the Cronin-type silicone gel-filled breast implants.

With silicone materials and prototypes supplied free of charge from Dow Corning, Doctors Cronin and Gerow developed and tested their silicone gel-filled breast implant in 1961. They implanted the first pair in a woman in 1962 (Cronin and Gerow, 1963). Word of their success and the superiority of these silicone implants to the existing foam type led to the popularity of the silicone gel breast implant (Gerow, 1976).

Figure II.5.18.9 shows the appearance of these implants in 1964. The shells of Cronin-type implants were vacuum-molded with anterior and posterior elastomer pieces sealed together creating a seam around the perimeter of the base. The posterior shell had exposed loops of Dacron® mesh attached. The surgeons believed that prosthesis fixation to the chest wall was necessary to prevent implant migration.
Since this early 1964 design, Dow Corning and the numerous other companies that manufactured silicone breast implants made prosthesis design improvements, including elimination of the seam and realization that fixation is frequently unnecessary.

In the early 1990s, these popular devices became the subject of a torrent of contentious allegations regarding their safety. The controversy in the 1990s initially involved breast cancer, then evolved to autoimmune connective tissue disease, and continued to evolve to the frequency of local or surgical complications such as rupture, infection or capsular contracture. Epidemiology studies have consistently found no association between breast implants and breast cancer (McLaughlin et al., 1998, 2007; Park et al., 1998; Brinton et al., 2000; Mellemkjær et al., 2000). In fact, some studies suggest that women with implants may have decreased risk of breast cancer (Brinton et al., 1996; Deapen et al., 1997). Reports of cancer at sites other than the breast are inconsistent or attributed to lifestyle factors (Herdman and Fahey, 2001).

The epidemiologic research on autoimmune or connective-tissue disease has also been remarkably uniform, and concludes there is no causal association between breast implants and connective-tissue disease (Gabriel et al., 1994; Sánchez-Guerrero et al., 1995; Hennekens et al., 1996; Edworthy et al., 1998; Nygren et al., 1998; Kjøller et al., 2001; McLaughlin et al., 2007).

Numerous systematic reviews (UK IEAG, 1993; France ANDEM, 1996; US IOM, 1996; Australia TDEC, 1997; Germany BgVV, 1998; UK IRG, 1998; EU EQUAM, 2000; US NSP/MDL926, 2001; Spain/EU STOA, 2003) commissioned by various governments have repeatedly and consistently borne out that the evidence fails to support a cause-and-effect relationship between silicone breast implants and systemic diseases. Following FDA approval action on 17 November 2006 making silicone gel breast implants widely available in the United States again, the controversy has diminished.

Largely without any specific safety concern or allegation critical of it, another silicone gel-filled implant was swept up in the breast implant controversy. At the time, most testicular implants were constructed of the same materials as silicone gel breast implants. Silicone artificial testicles had been used nearly as long as the breast implants. Dow Corning, one of several companies that manufactured these implants, was producing them as early as 1964. These devices served to ameliorate psychological stress associated with testicle loss due to cancer, traumatic injury or those absent at birth. The Teflon® strips seen in Figure II.5.18.10 shield each implant shell during suturing through an elastomer loop at the superior pole to achieve fixation for proper anatomical orientation in the scrotum.

BIOCOMPATIBILITY

There has been much discussion regarding the various definitions of the term biocompatibility. We now take it to mean “the ability of a material to perform with an appropriate host response in a specific situation” (Black, 1992; Remes and Williams, 1992). Historically it has been tacitly understood that silicone materials are intrinsically biocompatible, since they have been used successfully in so many healthcare applications. However, given the modern definition of the term, no material can be assumed to be universally biocompatible, since this implies that it is suitable for every conceivable healthcare application involving contact with the host patient.

Numerous silicone materials have undergone biocompatibility testing. Many have passed every bioqualification test; however, others have not. Several factors can affect the results of such testing, including the composition of the material. As described in Chapter I.2.2.B, the basic polydimethylsiloxane (PDMS) polymer can be modified to replace methyl with other functional groups. In some cases, those groups may be responsible for untoward host response. There may be by-products from

FIGURE II.5.18.9 Silastic mammary prosthesis, 1964. (© Dow Corning, AV06444.)

FIGURE II.5.18.10 Silicone testicular implants. (© Dow Corning, AV06437.)
the preparation of silicone materials that might trigger tissue reaction. For example, these could come from the use of a peroxide initiator under inappropriate temperature and processing conditions.

Purity is another factor that can affect biotest results. Medical silicone materials, including fluids, gels, elastomers, and adhesives, are manufactured by several companies today. Some of these firms manufacture these medical materials following good manufacturing practice (GMP) principles in dedicated, registered, and inspected facilities. Others sell materials generated on their industrial production line into the healthcare market.

Selection of appropriate preclinical material bioqualification tests for their application is the responsibility of the medical device or pharmaceutical manufacturer. Several national, international, and governmental agencies have provided guidance or regulation. Several silicone manufacturers offer special grades of materials that have met these specific requirements. The buyer should carefully investigate the supplier’s definition, since there are no universal special grade definitions. At Dow Corning, Silastic BioMedical Grade materials have been qualified to meet or exceed the requirements of ISO 10993-1, USP (United States Pharmacopeia) Class V Plastics tests (acute systemic toxicity and intracutaneous reactivity), hemolysis, cell culture, skin sensitization, mutagenicity, pyrogenicity, and 90 day implant testing. Other physio-chemical qualification tests have been conducted, such as certain tests from the European Pharmacopoeia. Specific information regarding material biotesting can be found in other chapters of this text. Testing of the device in finished form should follow material bioqualification tests such as those described above.

**Biodurability**

Traditionally we have thought of biocompatibility as the situation in which the biomaterial has minimal adverse impact on the host. Conversely, biodurability is where the host has a minimal adverse effect on the biomaterial (see Chapter II.4.2). The material properties of silicone, such as hydrophobicity, have been related to biocompatibility properties such as hemolytic potential, and the relative purity, and high molecular weight polymeric nature and chemical structure of the material, provide a theoretical basis for its lack of toxicity. The biodurability of silicone in medical applications is probably related to its exceptional thermal and chemical stability properties.

Silicones are used in numerous applications requiring high temperature resistance (Noll, 1968; Stark et al., 1982). During thermogravimetric analysis and in the absence of impurities, poly-dimethylsiloxane degradation starts only at around 400°C. Thus, silicones remain essentially unaffected by repeated sterilization by autoclaving, and they can usually also be dry-heat sterilized. Other sterilization methods can be used, such as ethylene oxide exposure and gamma and e-beam irradiation – although care must be taken to ensure complete sterilant outgassing in the former, and that dosage does not affect performance properties in the latter.

Although silicones can be chemically degraded, particularly at elevated temperatures, by substances capable of acting as depolymerization catalysts (Stark et al., 1982), their hydrophobic nature limits the extent of their contact with many aqueous solutions. Typically, the biologic milieu does not present a particularly hostile chemical environment for silicone. A notable exception, however, is the stomach, which excretes large amounts of hydrochloric acid, capable of attacking PDMS if it remains there too long. Based on silicone elastomer performance in long-term implantation applications, its biodurability is generally considered excellent (Table II.5.18.1).

The chemical stability associated with silicones became so well-established that it has been formulated into other biomaterials, such as polyurethane, to enhance their biodurability (Pinchuk et al., 1988; Ward, 2000; Christenson et al., 2002; Ward et al., 2006a,b).

Notwithstanding the chemical stability of silicone, certain factors have been shown to affect its durability in terms of long-term in vivo performance. The hydrophobic elastomer is somewhat lipophilic, and can be swollen by lipids or other nonpolar agents. Early experience with in vivo failure of silicone-containing heart valves was traced to elastomer absorption of lipids from the blood that resulted in significant dimensional swelling (McHenry et al., 1970). In most cases the absorption was low and failures did not occur, but in a small percentage of cases, the silicone was absorbing quantities sufficient to render the valves variant. Researchers speculated that variations in silicone poppet manufacture, such as cure, might have been a factor (Carmen and Mutha, 1972). Absorption of lipids was a variable reported by Swanson and LeBeau (1974) and Langley and Swanson (1976). The work of Brandon et al. (2002, 2003) has shown that the shells of silicone gel-filled breast implants also absorb silicone fluid (from the gel), causing a minor diminution in mechanical properties, one that is reversed after extraction of the elastomer.

**Conclusion**

A variety of silicone materials have been prepared, many possessing excellent properties including chemical and thermal stability, low surface tension, hydrophobicity, and gas permeability. These characteristics helped originate the use of silicones in the medical field and are key to the materials’ reported biocompatibility and biodurability. Since the 1960s, silicones have enjoyed expanded medical application and today are one of the most thoroughly tested and important biomaterials.
### Biodurability Studies of Silicone Elastomer and Medical Implants

<table>
<thead>
<tr>
<th>Year</th>
<th>Researcher</th>
<th>Synopsis</th>
</tr>
</thead>
<tbody>
<tr>
<td>1960</td>
<td>Ames</td>
<td>Explant examination of a clinical silicone ventricularcisternostomy shunt used in the treatment of hydrocephalus showed the silicone rubber tubing was unchanged by three years implantation in the tissues of the brain and in the cervical subarachnoid space. Similarly, after over three years’ implantation of silicone tubing in the peritoneal cavity of dogs, Ames wrote: “The physical properties of the tubing itself are apparently unchanged by prolonged contact with tissues.”</td>
</tr>
<tr>
<td>1963</td>
<td>Sanislow and Zuidema</td>
<td>Silastic® T-tubes were placed in the common ducts of dogs and explanted nine months later. They were found to be free of bile-salt precipitation and completely patent. Four were tested for tensile strength and compared with a control sample from the same lot of elastomer. “These tests suggested that little physical change occurred in the Silastic as a result of prolonged contact with animal bile.” The tensile strength after nine months was reported as 1130 psi (7.8 MPa), the same value as reported for the non-implanted control.</td>
</tr>
<tr>
<td>1964</td>
<td>Leininger et al.</td>
<td>The Battelle Memorial Institute examined the biodurability of five plastics by implanting films in dogs for 17 months’ duration. The materials tensile strength and elongation were measured and compared with non-implanted controls. Although sizeable changes were seen in the tensile properties of polyethylene, Teflon®, and nylon, the results for Mylar and Silastic® remained essentially the same.</td>
</tr>
<tr>
<td>1974</td>
<td>Swanson and LeBeau</td>
<td>“Dog-bone”-shaped specimens of medical grade silicone rubber were implanted subcutaneously in dogs. Tensile properties and lipid content were measured at six months and two years postimplantation. A slight, but statistically significant, decrease in measured ultimate tensile strength and elongation were observed, as well as a small weight increase attributed to lipid absorption.</td>
</tr>
<tr>
<td>1976</td>
<td>Langley and Swanson</td>
<td>Mechanical test specimens were implanted in dogs for two years. Tensile strength, elongation, and tear resistance showed no statistically significant changes. Lipid absorption into the elastomer ranged from 1.4 to 2.6%.</td>
</tr>
<tr>
<td>2000</td>
<td>Curtis et al.</td>
<td>Six silicon breast implants surgically excised after 13.8 to 19.3 years, and 10 similar non-implanted units were tested to determine shell tensile properties and molecular weight of silicone gel extracts. The study observed only minor changes (less than the explant or implant lot-to-lot variation range) in the tensile strength of Dow Corning silicone breast implants after nearly 20 years of human implantation.” The gel extract molecular weight was either unchanged by implantation or increased slightly.</td>
</tr>
<tr>
<td>2003</td>
<td>Brandon et al.</td>
<td>In the most comprehensive study of breast implant biodurability heretofore published, the authors reported their results of tensile, cross-link density, and percent extractable measurements made on 42 explants and 51 controls. The study included some of the oldest explants, with human implantation durations up to 32 years. The researchers also performed a literature search, and plotted all published explant tensile modulus data against implantation duration, finding no temporal relationship. Neither was a relationship with implant time seen for the cross-link density results, supporting the biodurability of the silicone elastomer utilized in the implant shells. The researchers concluded, “There was little or no degradation of the base polydimethylsiloxane during in vivo aging in any of the implants we examined.”</td>
</tr>
<tr>
<td>2008</td>
<td>Taylor et al.</td>
<td>Silicone biodurability after long-term implantation was examined by a highly sensitive NMR spectroscopy technique, as well as NMR relaxometry measurements of explanted gel breast implants and matched non-implanted controls. No evidence of chemical degradation of the cross-linked silicone matrix was observed in specimens explanted after as many as 32 years in vivo, underscoring the biostability of the cross-linked silicone shell and gel.</td>
</tr>
</tbody>
</table>

### ACKNOWLEDGMENTS

The authors thank Doctors S. Hoshaw and P. Klein, both from Dow Corning, for their contribution regarding breast implant epidemiology.

### BIBLIOGRAPHY


Germany, Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin (BgVV). (1998).


