Investigation of and Use of Dimethyl Siloxanes, Halogenated Carbons and Polyvinyl Alcohol as Subcutaneous Prostheses *

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DEFORMITIES of the face and elsewhere in the body, due to dysgenesis, cancer, trauma and infection, may result in problems of physiological, educational, economical, social and psychological natures. Reconstructive surgery of the defects is difficult and may require using subcutaneous permanent prostheses to restore function, and acceptable contour anatomy. An important function of the face is for it to appear normal and this should be considered in all surgery about the face.

Fresh autogenous transplants should be ideal prosthetic materials but these are not always available or advisable; their procurement requires an added operation with added scarring and discomfort for the patient. Where its consistency will suffice, cartilage, fresh-homo, (or auto), or preserved-homo, has been used most often, as is considered later.

Search for acceptable substitutes for autogenous live transplants has gone on for many years by many workers. It has included study of celluloid (the first synthetic to be used), various metals, "breast bone of a duck" and other "zoografts," leather, pith wood, latex, vulcanized rubber, but with no long series of satisfactory results. Beef cartilage, in our investigation was usually violently extruded and was not used clinically. Dr. Halsted used gutta percha.[10] A silver jaw put in by J. B. Murphy, in 1908, was reported 51 years later as still being retained and serviceable, but broken.[23]

The problem of prostheses is different for different locations and depths in the body, and for rigidity of fixation. Many metal and synthetic fixations and replacements of bone are successful, in deeply placed positions, held rigid by fixation.

But in reconstructive surgery, close to the surface, with little normal covering, and especially if movement of the implant or of tissues around it occurs, there is difficulty in getting a foreign body to be retained.

Synthetic polymers or poly chemicals have been investigated and used on this service for 12 years and some have shown good clinical application.[7-9, 20] The ones now being studied and used here include dimethyl siloxanes (silicones), halogenated carbons (Teflon), and polyvinyl alcohol (Fig. 3). (Other workers have reported on various synthetics and their findings are recognized as valuable contributions. Specific reference to the various reports are omitted here as they are well known, and we have no basis of judgment of them.)

Inertness is the key attribute of the synthetics that makes them worthy of consideration for implantation, with the hope that they may be as inert in the body as they are physically and chemically, as to cold, heat, chemicals, breakage, and persistence of form and consistency. Some are so inert (such as silicones and halogenated

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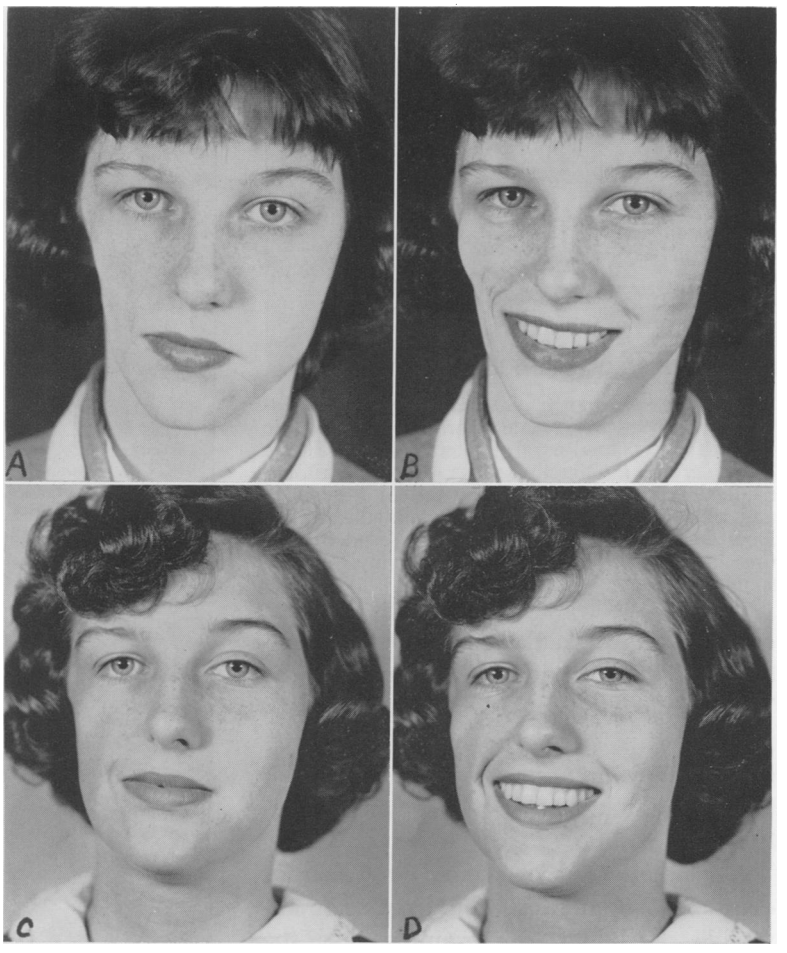


FIG. 1. A, B Severe facial hemiatrophy. C, D Correction with polyvinyl alcohol sponge as subcutaneous prosthesis, in place 3½ years.

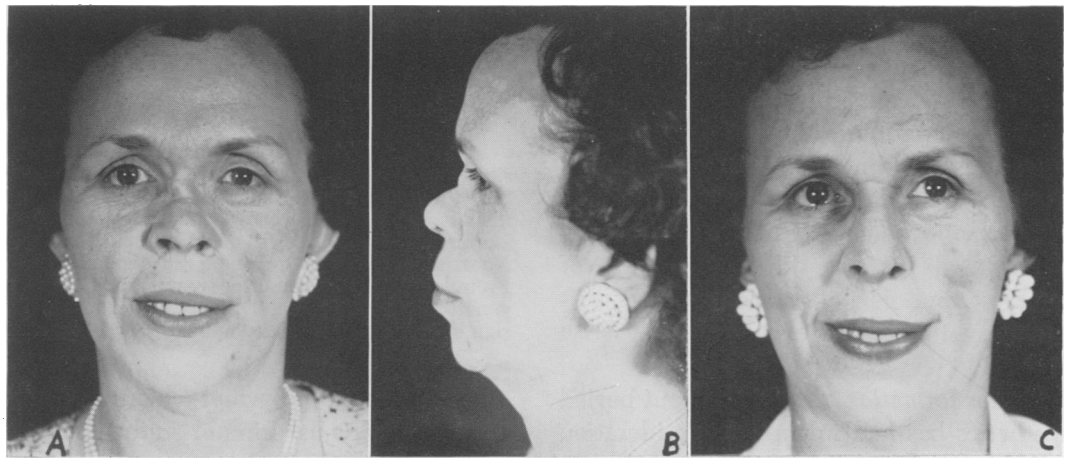


FIG. 2. A, B Severe facial crush, entire middle third moved backward and crumpled *upward*. C. Nasal correction with silicone medical grade Dow Corning as one piece L-shaped implant along dorsum and in columella. In place 17 months.

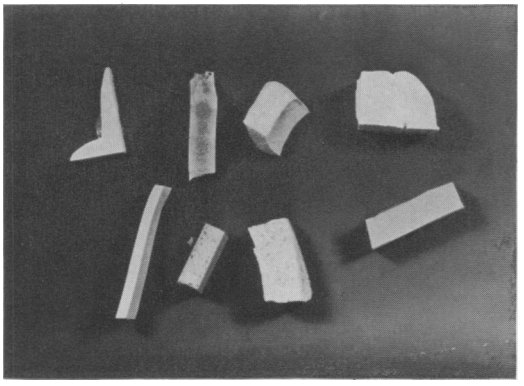


FIG. 3. Appearance of various synthetics. *Upper left:* White halogenated carbon, Teflon, basic design for L-shaped nasal implant. Used in Figure 8. *Lower right:* Dimethyl-siloxane silicone rubber medical grade Dow Corning. Used in Figures 2, and 12. *Middle five:* Silicone sponge medical grade Dow Corning in various sized cells. Used in Figures 5 and 9. *Upper right:* Polyvinyl alcohol sponge.

carbons) as to "float" free without the fixation usually surrounding a foreign body. This has led some workers to applying a shell or strips of a more reactive synthetic such as polyvinyl alcohol to the surface of the main implant to allow for scar infiltration and fixation (Fig. 3, 4).

A synthetic out of which plasticiser or elastomer is being lost would not seem advisable. Celluloid, for example, has the odor of camphor which must mean that it is losing some element which might not be acceptable to the body. On the other hand, some synthetics not being thought to be losing any element have been extruded.

A subcutaneous prosthesis should be inert, but compatible with physiological processes and should not cause inflammation or neoplasm. Its density and physical properties should be similar to the tissue it replaces, and because different degrees of hardness and flexibility are required, different synthetics will be needed.[1, 10-12, 14, 17, 22]

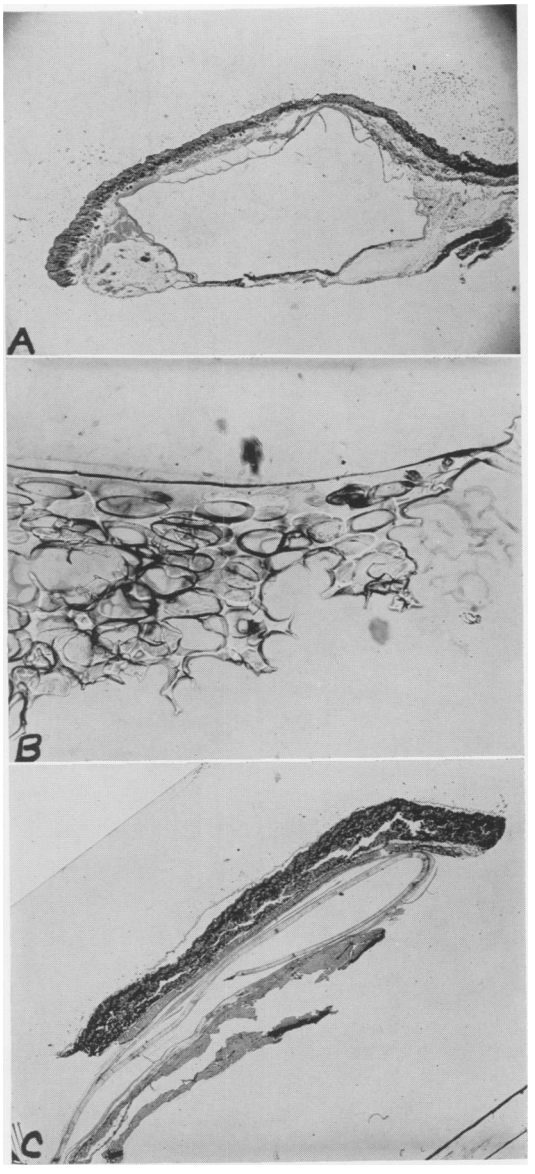


FIG. 4. A. Silicone subcutaneous implant. Practically no reaction around it. No sign of inflammation or tumor. From laboratory animal after six months. B. Silicone sponge medical grade Dow Corning. Has unit cells, not continuous sponge. No reaction; no inflammation; no sign of tumor. From laboratory animal after six months. C. Halongenated carbon, Teflon, DuPont. No reaction. No sign of tumor in laboratory animal after 14 months.

Tumor formation possibility about buried synthetics has had important consideration called to it by the Oppenheimers, Small, Stout, Russel *et al.*,[21, 24] and others. The Oppenheimers [13] found occasional tumors, especially with polyvinyl chloride (polyvinyl alcohol is used in our study).

We found a single fibroma near one polyvinyl alcohol implant in a series of 50 mice observed throughout the life cycle.[8, 20] In a

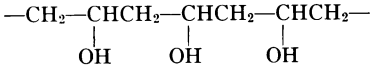
total group of 245 small animals with 284 implants of silicone, halogenated carbons and polyvinyl alcohol, no further tumors were found (although complete serial sections were not made). Several reports of polyvinyl alcohol sponge have been made without evidence of tumors.

The tumor question has several facets such as differences between laboratory animals and humans, the size of the implant and whether it is perforated to interrupt a wide plane surface. This problem has been summarized by Russel *et al.*[24] They found five malignant tumors at the site of the implant in 299 *rats,* and suggest further animal experimentation.

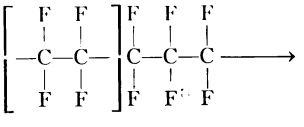
So far as we know, no one has found malignant changes complicating the use of synthetic blood vessels and these number into the thousands. We have not seen tumors in 100 clinical uses of synthetic materials, and the silicones and fluorocarbons have shown less tissue reaction than polyvinyl alcohol. The possibility of tumor formation around synthetic implants in animal experiments should be explained to patients in whom synthetic material is to be considered. The explanation should include the situation that these synthetics are so new that there has not been time to follow any such implants through a full human lifecycle. The advantage of synthetics possibly outweigh the inference that tumor formation in laboratory animals implies a significant risk of clinical use, of medical grade synthetics.

The chemical structures of the synthetic materials used on our service are as follows:

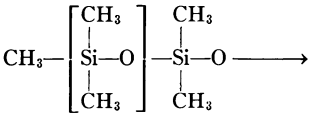
POLYVINYL ALCOHOL



HALOGENATED-CARBON, FLUOROCARBON, TEFLON



DIMETHYL-SILOXANE SILICONE



Silicones

Silicones are a group of materials which may be liquid, resin or solid; they are *polymers* of *dimethyl-siloxane.* The viscosity increases as the chain is lengthened, from a thin liquid to putty-like resins.[19]

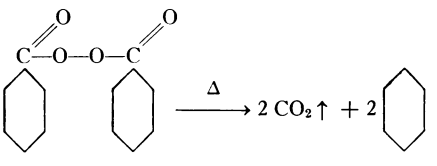
The dimethyl-siloxane radical is the basic unit and may be polymerized several thousand times. The end groups may be methyl or hydroxy radicals.

The viscous liquid types were used in our early experiments [7, 8] and although these were inert to body tissues and fluids, they tended to gravitate to dependent areas; they had no intrinsic permanent form and assumed the shape of their confines; in other words, they remained liquids.

The term *Silicone* was coined by F. S. Kipping in Nottingham, England, but he apparently thought that the synthetic had only academic interest.[25]

Silicone Rubber

A silicone rubber has been produced for medical uses by Dow-Corning, and invaluable help has been given by Silas Braley [25] and R. R. McGregor [26] for this report. This material is made from a viscous highly polymerized dimethyl-siloxane to which is added fine, pure silica and a vulcanizing agent, benzoyl peroxide. When the mixture is heated, a reaction takes place which forms cross linkages between some chains of silicone molecules:



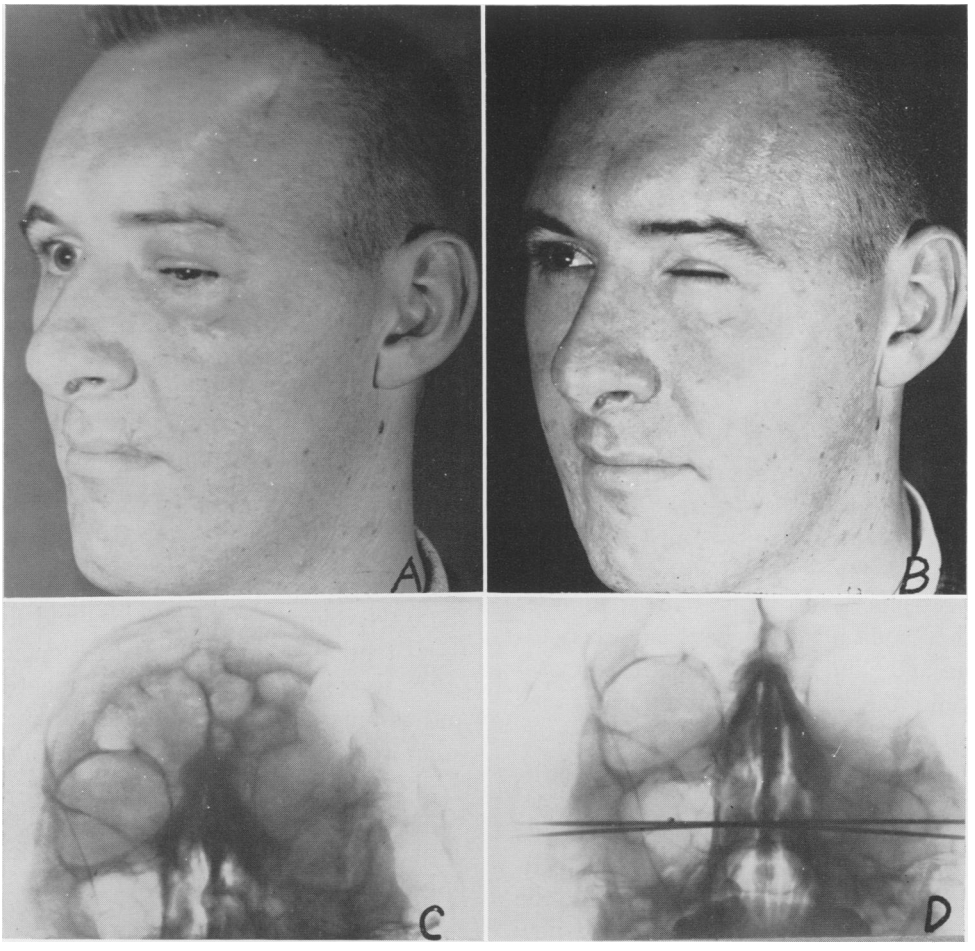
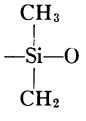
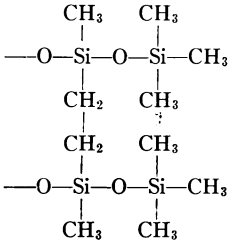


FIG. 5. Severe cranial and facial injuries in atomic research worker. Internal wires for support of middle third. Skull had large loss and has been filled out with silicone medical grade sponge.

The CO_2 is driven off by heat and the phenyl free radical attacks a methyl group on the silicone, pulling off a hydrogen to form benzene. This leaves:



as a radical. When two such radicals in different chains meet, they join, satisfying the valance structure and form a cross link between the two polymerized chains; it is interesting that very few chains are cross linked—estimated at 15 out of 10,000.



The resulting material is a soft, resilient clear-amber material which is difficult to distinguish on casual inspection from organic rubber. The physical properties are stable from − 56° to + 540° C. The material has a specific gravity of 1.13 and is easily sculptured or cut with a sharp blade.

The product developed for medical use is free of any leachable material or particles (Fig. 2, 3, 4, 5, 7, 12).

A silicone sponge of medical grade has been made by Dow Corning by converting dimethyl siloxane to a "sponge rubber" with a permanent form.[25] The resulting material is non-reactive and is not invaded by scar tissue in our experiments (Fig. 3, 4, 5, 9). This form may have a wide adaptability and possibly avoid the excessive scar tissue hardness of other synthetic sponges.

The chemistry of these synthetics as developed in this instance of silicones by McGregor and Braley at Dow Corning is of intense interest and when one considers that the polymers may extend to many thousands the possibilities seem endless.[19, 25, 26]

Any unusual combination of properties in a basically new material enables one to do many things that were previously impossible.

Silicones are built on a molecular structure of (Si-O)atoms just as hydrocarbons are built on a skeleton of (C-C) atoms.

Carbon-based groups, never combined in nature with silicon, are bonded to this silicon-oxygen skeleton to impart some of the more desirable properties of organic materials, i.e. flexibility, elasticity, lubricity and water-repellency, and also to have the qualities of stability and heat and cold resistance, from the (inorganic) silicon.

Halogenated Carbons

The *halogenated carbon* polymers are simple long chains of saturated fluorocarbons, the most chemically inert materials that have been produced. Reaction of animal tissue around them is less than with any other synthetic material (perhaps too little for stabilization unless fastened to bone or having a more reactive substance fastened to the surface). They have no known solvent, being resistant to strong acids and alkalis and they are stable from − 195.5° C. to + 326.7° C. Halogenated carbons may be either white or transparent. Our experience has been with a polytetrafluoroethylene or "Teflon," Du Pont. It is made by polymerization of tetrafluoroethylene gas at high temperatures and pres-

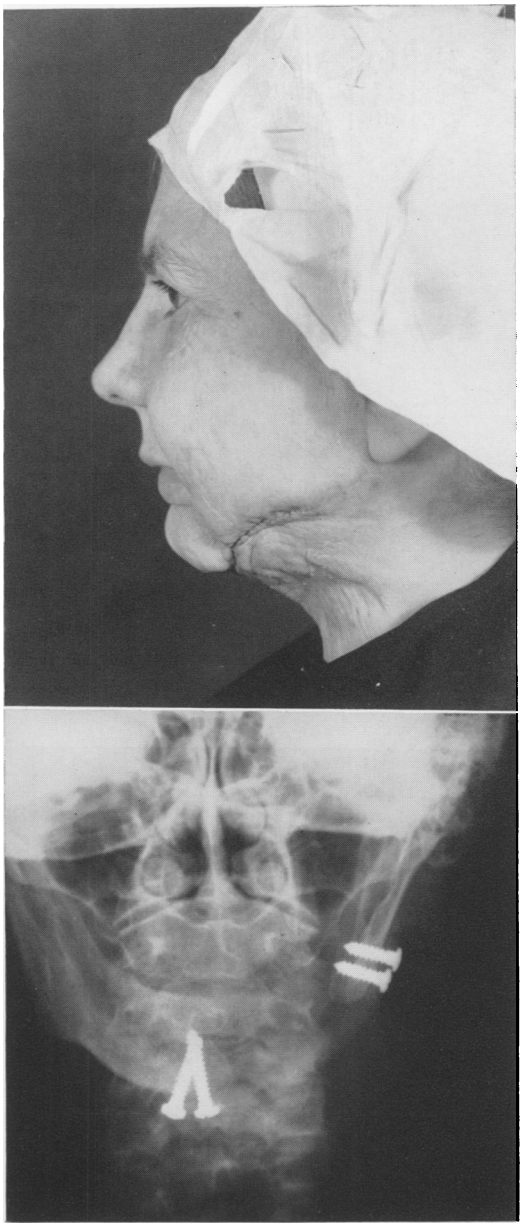


FIG. 6. Carcinoma buccal mucosa. Radiation treatment followed by radical jaw-neck. Secondary permanent-pedicle blood-carrying flap closure. Jaw stabilized with bar of Teflon, for good function. The Sister returned to teaching. Teflon shown by four screws only as it is transparent to x-ray.

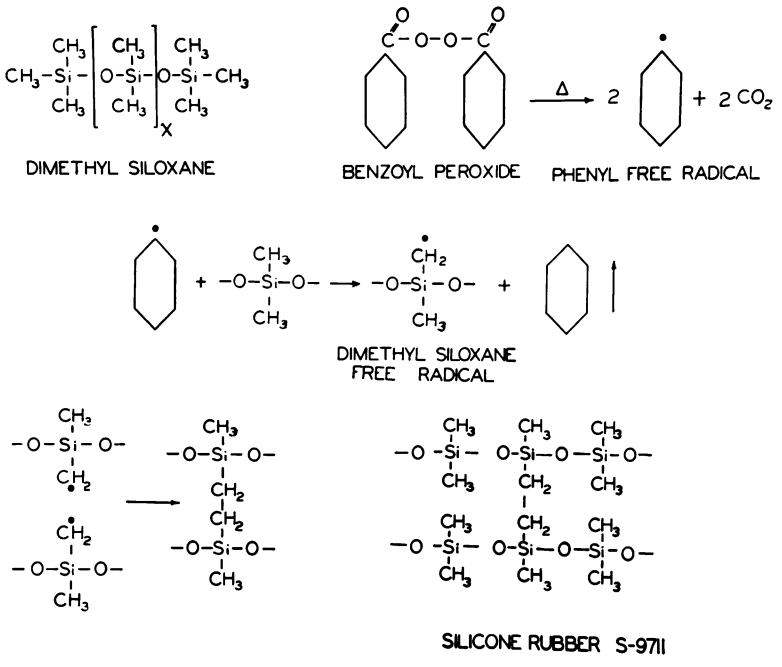


FIG. 7. High polymer dimethyl-siloxane silicone rubber medical grade Dow Corning. The link between the CH_2 groups is the basis of change of silicone resin to silicone rubber. Estimated that only 15 dimethyl chains in 10,000 are so cross-linked by the benzoyl peroxide reaction, and that this small cross-linkage is important to get the rubber characteristic. If more cross-links, the rubber is hard and less resilient.

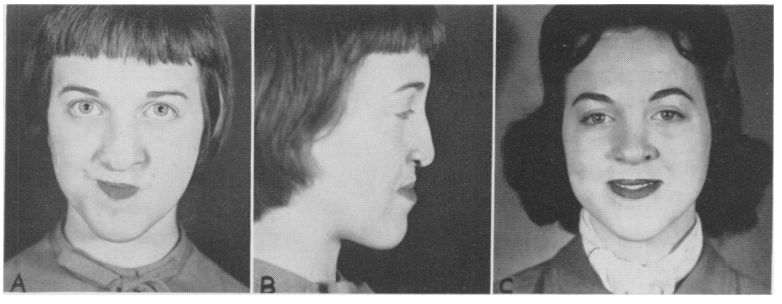


FIG. 8. Secondary cleft lip nasal deformity corrected with L-shaped dorsal implant of Teflon through columellar incision. In place 16 months.

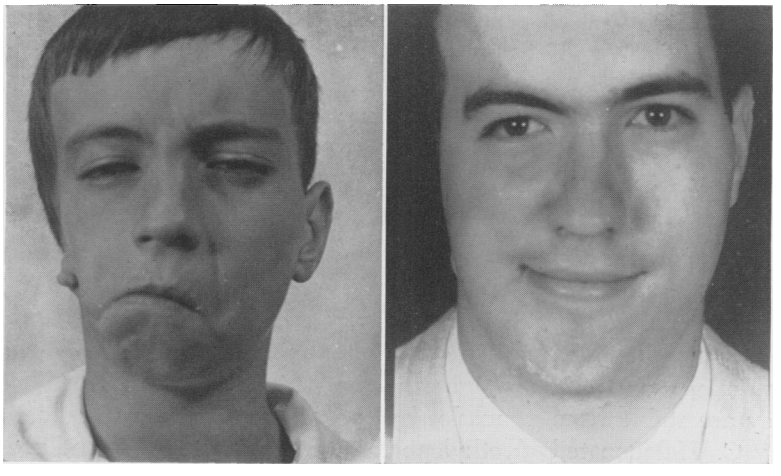


FIG. 9. Severe agenesis of face, jaw and ear. Has large preserved cartilage implant from glenoid to chin. This is covered and the face built out with fine cell silicone sponge medical grade. In place 16 months. Patient has made fine recovery and with superior understanding, patience and help by mother and father. Studying in college. Ear in scalp flap to be brought out on patient's decision. Preservation of 7th nerve even though entire side of face has been undermined.

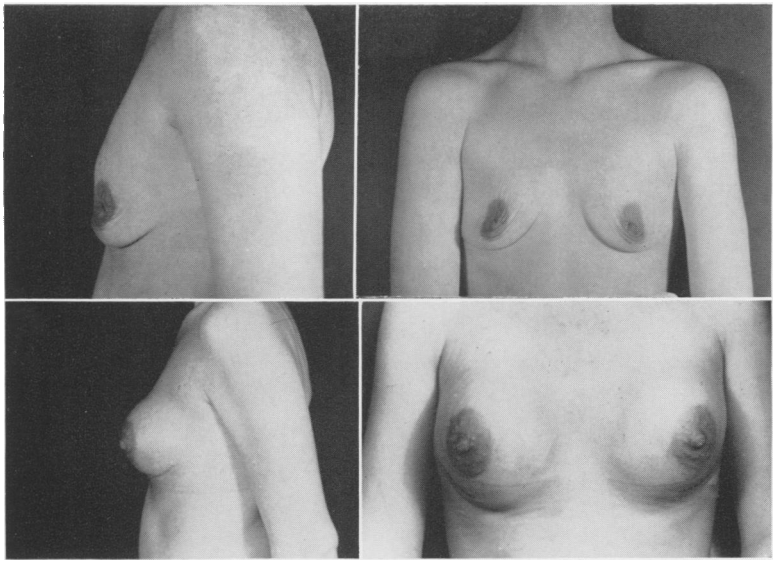


FIG. 10. Breast enlargement with polyvinyl alcohol sponge, put in under breast tissue on muscle, through small incision left outer quadrant. Normal size, shape and position results. Usual hardness from scar infiltration.

sures. The resulting powder may be molded into the desired shape by means of high pressures and temperatures. Teflon is heavier, harder and more difficult to cut than silicone. It is available in blocks, sheets, rods and tubes and has been fabricated into a true sponge and a linter consisting of fine fibres from three-quarters to two and one-half inches in length. The latter material handles like fine cotton linter but has the chemical and tissue stability of Teflon (Fig. 3, 4, 6, 8).

A similar material to Teflon which is available in both transparent and opaque white fabrications is polytrifluoromonochloroethylene (Kel F.) from Minnesota Mining & Manufacturing Company. This material has characteristics similar to Teflon. Both materials are amenable to heat treatment and can be annealed at 270° C. When blocks or strips of these halogenated carbons are twisted or formed into a desired shape the internal molecular stresses are relieved at temperatures be-

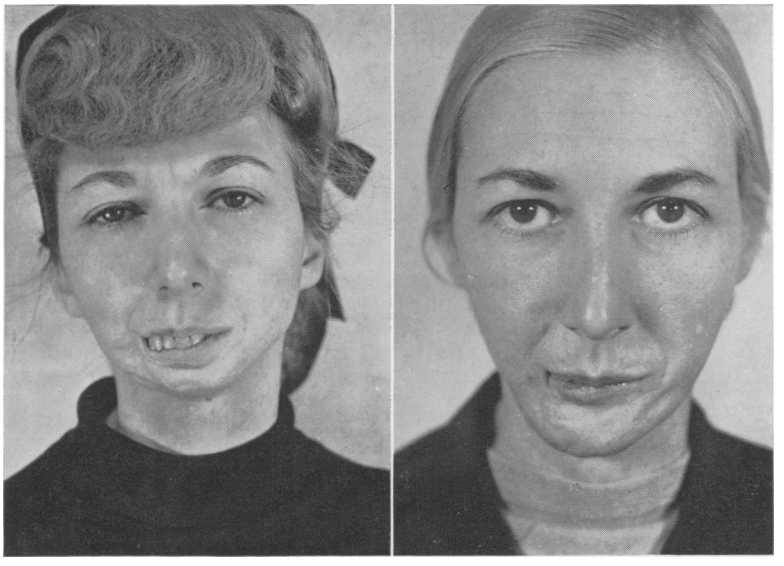


FIG. 11. Restoration of facial contour using combination of preserved cartilage, from ramus clear around chin, and final correction with overlying polyvinyl alcohol. Patient had sarcoma cured 20 years previously by Dr. Dallas Phemister.

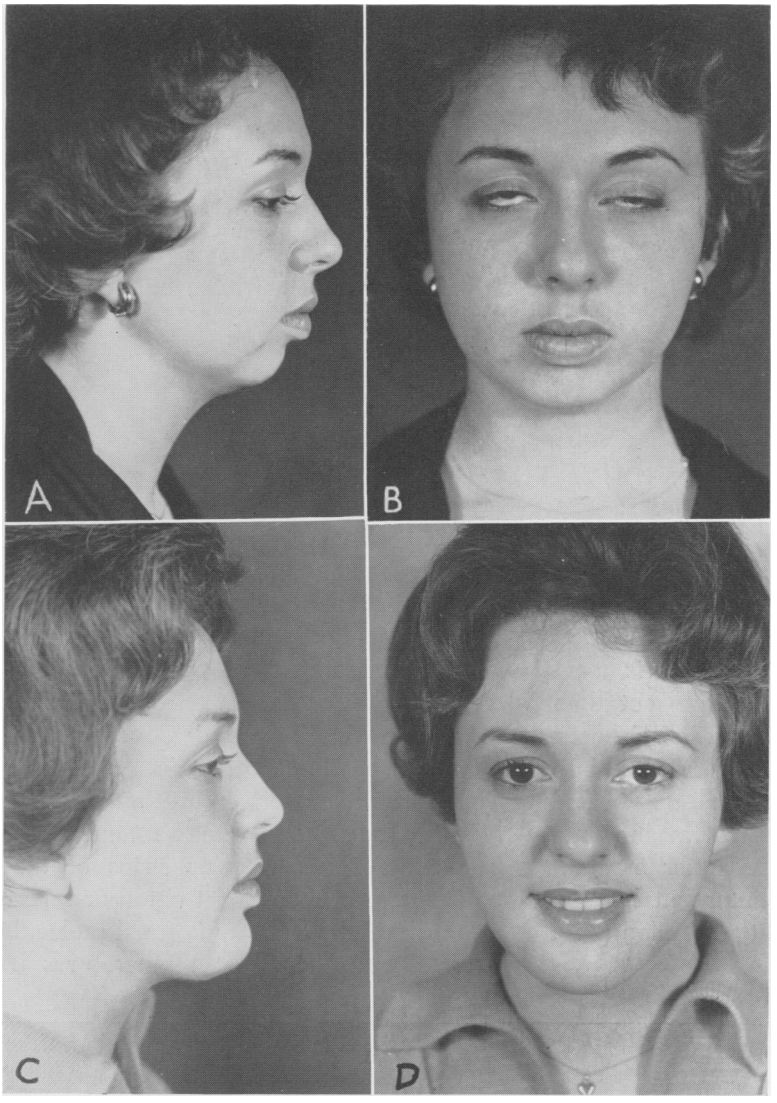


FIG. 12. A, B Lack of normal forward progression of jaw and chin. Patient's reaction well shown in unposed photos. C, D Correction in single operation with silicone rubber high polymer dimethyl-siloxane Dow Corning. Patient's reaction again well shown in unposed and unretouched photos. Implant should be permanent. Patient hasn't had to have second operation on chest and has implant of good resiliency.

tween 270° and 300° C. After cooling they have a "plastic memory" and tend to maintain the shape they were given during heat treatment.

Polyvinyl alcohol sponge consists of large chains of the basic molecule, as shown in the chemical structure paragraph. It is light in weight and easily sculptured into required shape. The foamed polyvinyl alcohol sponge is tolerated subcutaneously and its communicating interstices soon become invaded by dense fibrous tissue. Thus its softness and lightness are converted into dense scar tissue. This would seem to be an ideal foreign implant in that it is literally turned into living host tissue.[8, 12, 14, 20] Objections are tendency to infection and loss, marked hardness of the dense infiltrating scar with abnormal hardness if supplementing soft resilient tissue such as the breast, and the question of its not withstanding trauma. In spite of these objections, improvement of depressed contours may be of worth while relief to patients (Fig. 1, 3, 10, 11).

The *gross appearance* of these synthetic materials is shown in Figure 3. The white

sponge is polyvinyl alcohol, it is stiff when dry and sponge-like when wet. The white solid is Teflon. The other pieces are silicone rubber and silicone sponge. The L-shape pieces are cut for nasal implants, of both Teflon and silicone rubber. They have proved satisfactory in correction of traumatic and congenital nasal deformities, and can be cut sufficiently thin in an L-shape to give support to the columella.

Laboratory investigations by implantations in animals have been made for local reactions, long term retention, for microscopic studies, possible tumor formation, infection, adaptability of form and usefulness, reactions of the implants, and other data.

Animals do not afford complete answers of human problems. Infection in animals is not as noteworthy as in humans. The platysma-like animal skin is more adaptable to covering implants than human integument and healing has occurred over exposed implants whereas this would seldom occur in humans, satisfactorily.

Tumor formation in animals seems more likely than in humans, as so far tumors around human implants have not been recorded. In this instance the animal findings may suggest trouble that may not occur in humans—though no implants have been observed throughout a human life cycle.

Relative tissue reactions of Acrilic and Silicone and Teflon can be seen on inspection of laboratory implants. Acrilic rods left in a guinea pig for 3 months were found surrounded and eroded by a dense cicatrix. By contrast, pieces of Teflon buried subcutaneously for over a year were found to have minimal surrounding reaction and no change in the implants. The same is true of silicone.

Clinical investigations are considered with the laboratory findings, along with actual applications, and are evaluated and summarized in the following paragraphs.

Advantages: The general indication for use of synthetics is where contour restoration is needed and live autogenous replacements are not available or are not advisable.

Uses: This group of synthetics has been used in congenital, traumatic, developmental, neoplastic, surgical, and infection deformities of the chin, nose, cheeks, forehead, orbit, skull, jaws, ears, breast, tendons and other specific indications, such as hemiatrophy of the face. They are considered for wider applications, in joint, tendon, bone, genito-urinary work and for temporary support in reconstructive surgery (Fig. 1, 2, 5, 6, 8, 9–12).

Faults: Extrusion, infection and losses have been encountered in early work and will continue, but may be lessened with careful selection and technical application. Technical difficulties and poor risk selections shouldn't be charged to the implants themselves, but to method of use.

Loss: Loss due to erosion may occur from sharp edges and motion from within, and from trauma from without over a thinly covered implant. To avoid such loss, implants can be given rounded edges, the thickest coverage of live tissue, and fixation for as little movement as possible around the implant, or of itself.

Slipping from position can occur; it may be corrected with trimming and reclosure or may require replacement. Replacement is relatively simple for silicone rubber and Teflon, but not for polyvinyl or other sponge or linter.

Infection is perhaps the worst complication as in any implantation of live, preserved or synthetic material. Animals may possibly overcome contamination and retain the implant. In human use, silicones and Teflon and other solids might withstand moderate infection, but this would seldom be true in using sponged material regardless of antibiotics. The continuous sponges with connecting interstices afford a perfect culture medium, with serum and blood throughout all the channels, and body warmth for incubation along with no available protective

"live" blood circulating through the sponge. Such infections usually cause very little cellulitis after drainage tracts are established. In fact, the absence of cellulitis and the rapid clearing with removal of the implant might even suggest the *use* of sponge in cryptic infections and chronic sinuses as a collecting agent and find out if a properly timed removal of the implant might help *clear* the infection.

Polyvinyl and other sponges once infected and draining may have to be removed and a fresh start made later. Very few, will clear up and delay and debility might be saved by prompt decision. Breast implants may have sufficient tissue coverage to withstand some infection, but implants closer to the surface are less apt to be retained if once infected. Removal of such sponge material may be difficult, whereas solid implant of silicone rubber and Teflon may be easily removed.

Losses or extrusions can be reduced as technical perfection and proper selection of use is improved. Some losses may be occasioned by extreme conditions of tissue adequacy, and the qualified selection of an implant *knowing* of possible failure. In these situations live autogenous transplants also might be lost and the temporary or staged use of a synthetic may be preferable, but not counting such possible losses against the implant itself.

Hemorrhage or retained blood around implants may be troublesome with infection a possibility. This is a risk of all implants and especially in reconstructive surgery where wide undermining may be required to make the restoration, and where there cannot be drainage of the wound or subcutaneous pocket. Careful dissection and hemostasis and pressure-fixation dressings will do most to avoid collection of blood.

Abnormal relative consistency of implants may be a disadvantage, as shown mainly in polyvinyl sponge breast implants. Whereas the contour may be satisfying to the patient, the scar mass from the fibrous infiltration of the sponge becomes dense, hard, and unlike the usual resiliency of breast tissue. Patients may not be able to sleep on the stomach and breasts and the restoration is not very close to normal in these respects. The use of soft resilient sponge material that does not harden because of scar infiltration will relieve this objection of hardness (Fig. 10).

Full explanation to the patient and family should cover these vagaries, and operation should be delayed until they are understood.

Motor and sensor nerve supply overlying and near implants should be preserved as well as possible. In the face after wide undermining, it is surprising how much sensation and movement is retatined—and this should be guarded throughout the operation (Fig. 1, 2, 5, 9–11).

Microscopic studies of the various implants are recorded in Figure 4 and in previous publications.[7, 8, 14, 20]

Applications of these Synthetics: Facial hemiatrophy heretofore has been extremely difficult of improvement, but worth while results have been obtained with synthetic sponge implantation following wide undermining, in stages if necessary. Continuous cell polyvinyl sponge has been used in Figures 1, 10, and 11, but closed-cell sponge might prove better in this as in other areas where sponged material is to be used, such as the breast, and elsewhere about the body.

Silicone rubber (medical grade—Dow Corning) has been used for traumatic, congenital and developmental nasal deformities, in L-shaped supports as in Figure 2 for traumatic loss; for congenital deformity and in many other defects, e.g. ears, forehead, jaw, chin (Fig. 12).

Silicone sponge (medical grade—Dow Corning) is applicable where a softer and less rigid contour is needed. This soft material makes the most acceptable surface contour and resiliency as shown in Figure 5 for face and skull traumatic loss, and in

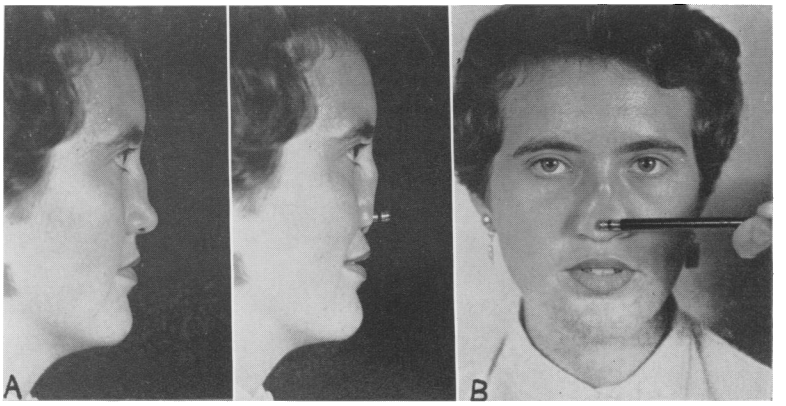


FIG. 13. A, B Loss of septum from trauma and operative removal with no support at tip. Restoration required for breathing and for economic reason of work as professional singer.

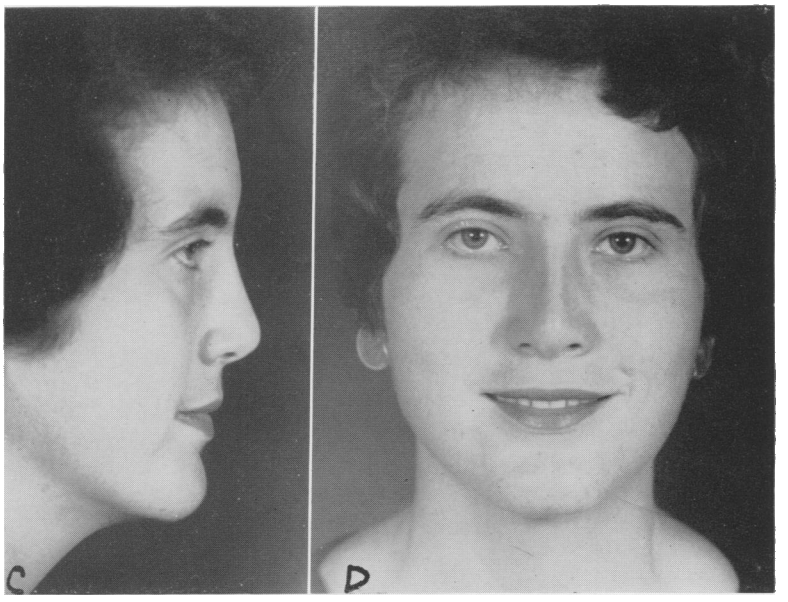


FIG. 13. C, D L-shape preserved cartilage put in through columella. In place six years, patient happy and professional career again possible. Function of airways restored because of elevation of tip. Illustrates instance of continuing value of cartilage when indicated.

Figure 9 for dysgenesis of jaw, face and ear.

Halogenated carbons, because of their hardness and rigidity, can be used for bone replacement in traumatic, neoplastic and congenital defects (Fig. 6). In L-shaped or stem root shaped implants, it can be used to support badly damaged noses if there is enough soft tissue to surround a narrow, slim transplant, that could not be fashioned out of cartilage, or bone because of bulk (Fig. 8).

Combination of implants of fresh-auto, or homo or preserved post-mortem cartilage and synthetics may be used. Basic enlargement in congenital or development or neoplastic losses may be carried out with a cartilage armature or framework and then covered or finished with silicone rubber or sponge or other sponge (Fig. 9, 11).

Operative details require careful study, diagnosis, which is mainly decision as to what is missing and needed, preliminary measurements, and casts of the defect and surrounding areas are of marked help. Strictest sepsis is essential. Incisions should be away from the implants, if possible, so the closure line does not overlap the synthetic. Minimal blood collections and accurate closure with careful pressure-fixation dressings are necessary. Support of the wound and area with strapping for three weeks, and vigilent care that any overlying

area of anesthesia is not damaged by the patient during the regeneration period are essential. Careful follow-ups are needed and of importance is understanding and cooperation of the patient and family in regard to the difficulties, chances and possibilities involved.

These procedures are new, they possibly may not stand the test of time, but can be arranged so the implants can be changed, or replaced, and have the possibility at least of being equal to, or of advantage over, auto, homo, fresh, or preserved-implants.

Cartilage

Cartilage may be used successfully, and it probably will not be replaced entirely by synthetics.

Preserved human cartilage from post mortem sources is of value and many patients maintain such implants for years, but they are often absorbed. Preserved homo-cartilage was used on this service first in 1928 based somewhat on reports of bone flaps of the skull being boiled and then put back in place. This early preserved cartilage work was reported generally, but our first publication was delayed until 1940.[3] Use was continued throughout World War II and reported again in 1947.[4] The establishing of a cartilage bank was described in 1948.[5] Further chapters have dealt with preserved cartilage in 1952.[6]

If absorption occurs, the cartilage implant can be replaced or changed to silicone.

A restoration with preserved cartilage is shown in Figure 13, in good condition after five years.

Many others have contributed to the use of cartilage—Bert [2] in 1865 and Koenig [18] in 1898 were early workers. Recent reports are by Gibson [13] on the selection of grafts of fresh auto cartilage to avoid curling, and by Hagerty *et al.*[15] on the characteristics of fresh cartilage.

Cartilage in several forms is valuable but the search for acceptable substitutes still should go on.

Summary

Synthetic materials have been produced with the important quality of inertness that makes them worthy of consideration for subcutaneous implantation.

Silicones and *Halogenated Carbons,* as investigated here, have the following advantages:

1. They are easily obtained and require no other operations or cartilage banks.
2. They may be shaped into a variety of forms.
3. There is no antigenic activity and they cause minimal tissue reaction.
4. The materials are homogeneous without intrinsic weakness and for this reason they do not warp or break, even in thin layers.
5. They do not calcify or degenerate as cartilage occasionally does.
6. They are inexpensive.
7. They can be repeatedly sterilized in an autoclave or antiseptic solutions. Silicone and other unit cell sponges need to have slow cooling in the sterilizer requiring about five minutes longer than usual.

Polyvinyl alcohol sponge has some of the same advantages and has been useful. It takes on a sort of living quality with infiltration of fibrous tissue throughout its interstices, but thus becomes a dense mass without much resiliency.

Difficulties in use and retention may occur from infection, shift and trauma. The application may be complicated technically and full consideration with the patient should be made. The materials should not be used without full appraisal of the difficulties, including word of tumor formation is some laboratory animals.

Cartilage—fresh-homo, fresh-auto and preserved-homo will continue to prove useful when indicated.

Laboratory and clinical investigations of synthetic polymers have been done and it seems evident that these compounds have

been established as adjuncts in reconstructive surgery, with the reservation that observations through full human life cycles cannot be completed for several more years.

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