Silicone and Teflon Prostheses, Including Full Jaw Substitution: *
Laboratory and Clinical Studies of Etheron

JAMES BARRETT BROWN, M.D., MINOT P. FRYER, M.D., PETER KOLLIAS, M.D., (Athens, Greece), DAVID A. OHLWILER, M.D. (Orlando, Florida), JAMES B. TEMPLETON, D.D.S.

Plastic and Reconstructive Surgery, Tumors of Head and Neck Service, Department of Surgery, Washington University School of Medicine, St. Louis, Missouri

THIS IS A REPORT of further studies and uses of *Silicone* (dimethylsiloxane) and *Teflon* (halogenated carbon) as subcutaneous prostheses, basic work of which is recorded in References 1 to 4.

This is also a laboratory and clinical study of *Etheron* (di-isocyanate) as a soft subcutaneous prosthesis. This includes investigations of Etheron in mice, guinea pigs, rabbits and dogs, which we believe is substantiation of clinical use, from a laboratory viewpoint. Other reports have been mainly of clinical use of, or association with, tumor transplantation.

Teflon Substitute for Total Loss of Lower Jaw. The patient shown in Figure 1 had complete loss of the lower jaw, throughout its full extent with no bony elements left and with no regeneration. Substitution for the totally absent jaw has been made with a bar of Teflon annealed into the proper curve and implanted through the front of the neck. This implant has been in place four years, the patient has a functioning dental prosthesis made and uses it quite well.

The diagnosis of this lesion was thought to be Hand-Schuller-Christian, or a related disease, with complete loss of all osseous elements in the lower jaw, and with some destruction in the skull. She has outgrown this tendency, or retrogression has occurred with x-ray treatment. During the time of activity some pieces of bone were lost from infection. She has remained well under close observation, has been married and has one child.

The problem of reconstructive surgery was to get an armature throughout the area and to try to engage the muscles of the jaw without a completely open dissection. There were no bone elements left to give attachment with any bone implant or with any processed animal bone material.

The Teflon replacement is shown in Figure 1F, G, H, is considered fortunate and might not be duplicated routinely. The total absence of jaw bone can be noted in Figure 1F in the x-ray of the Teflon implant. The loss of the teeth was gradual, as shown near its final stage in Figure 1C. The edentulous outcome is seen in Figure 1D, and the replacement with the denture, as made by Dr. Templeton, being retained over the Teflon implant in Figure 1E.

This probably is the first such synthetic substitution that has been made for total loss of the jaw. It is, necessarily, a floating implant with no connection with the skull, but with a fortunate implantation having been done within the muscle action, somewhat blindly, but very carefully. It is of importance that the sensory nerves in the area have been maintained, presumably due to the slow degeneration and absorp-

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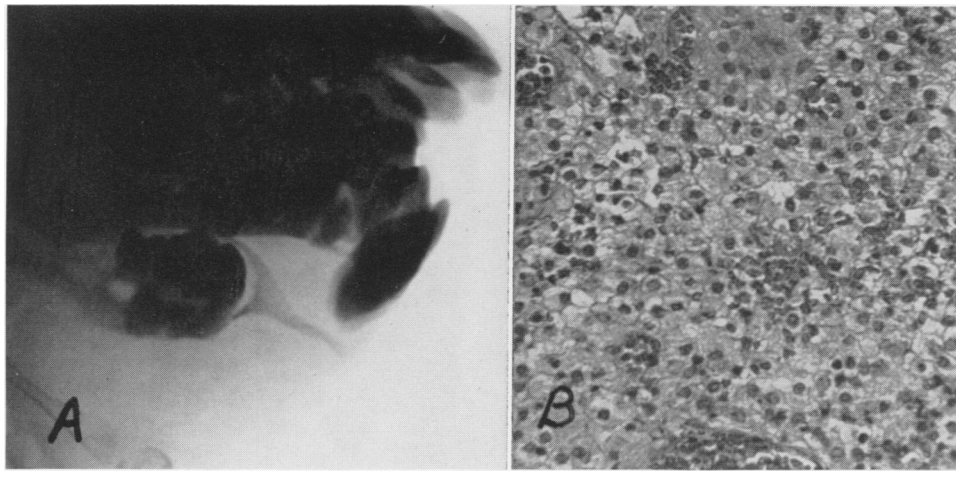

FIG. 1A. Total loss of lower jaw toward final stage, thought to be from Hand-Schuller-Christian or related disease and infection in area. No regeneration at all. One molar retained in soft tissues. B. Giant cells, histiocytes with lipids and eosinophils during absorption.

tion and rejection of her own natural jaw bone.

We believe this to be an extremely worthwhile restoration of, or substitution for, feature, function and bone, shown after three years in Figure 1G, H. The fact that it is so well tolerated and retained, is one of the best expressions of our hope, from the start, that such inert synthetic materials might be retained as subcutaneous prostheses. A needed element for success was that the patient was cooperative and appreciative of all efforts made for her.

Silicones have been extended in use; an important one is shown in Figure 2. This patient had solid bony ankylosis of both temporomandibular joints from infancy, with no movement at all and no forward progression of the chin. Here again important elements of success have been the patient's desire to be relieved, along with full cooperation of the parents.

These solid joint areas were resected, from the rami to deep under the skull because of the excessive hypertrophy. This is an extensive and difficult procedure, with large blood loss; most careful attention of the anesthetist, and of all concerned with the patient's care is required. One of the main concerns is protection of the seventh nerve which has been done successfully on both sides.

Resection was carried out to get empty spaces of about a cubic inch on each side.

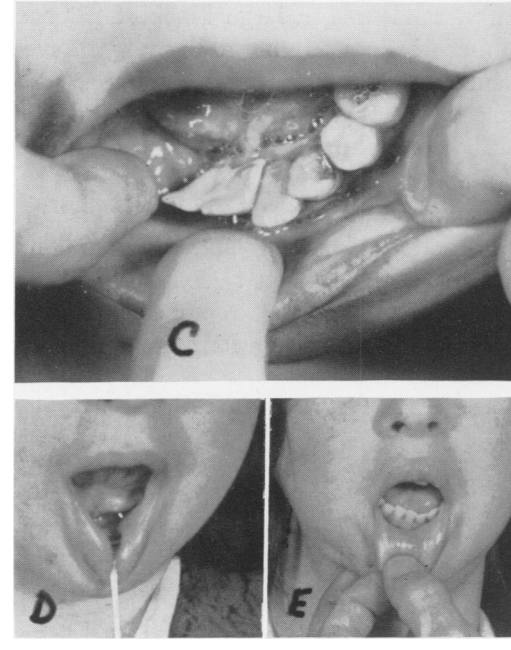

FIG. 1C. Toward final stage of bone and dental loss. D. Total loss of bone and teeth. E. Useful dental prosthesis fitted over subcutaneous prosthesis of Teflon.

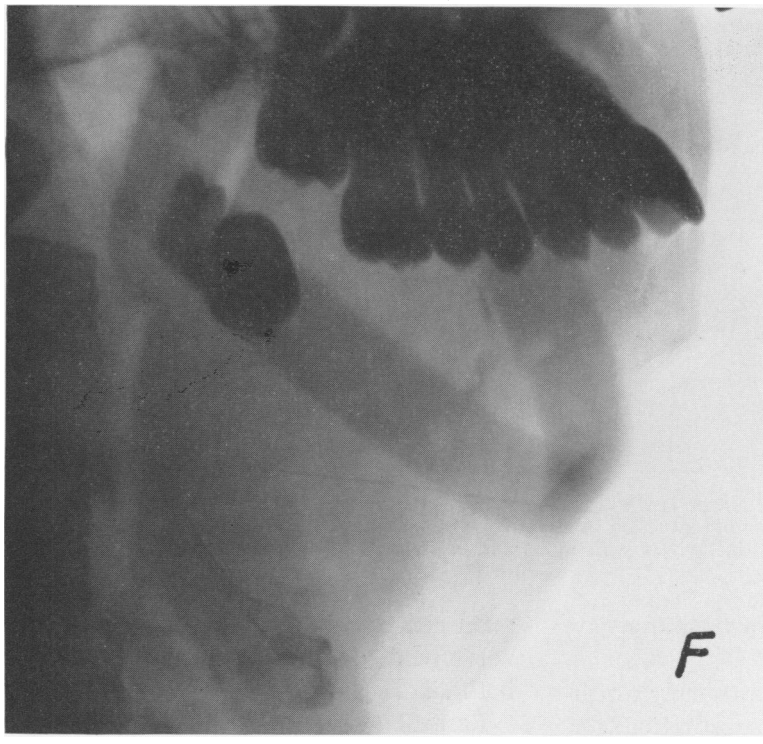

FIG. 1F. Teflon substitution for total loss of jaw, fortunately placed for functional muscle action (able to eat even potato chips). Tooth retained in soft tissues. Total loss of jaw without any osseous regeneration.

To maintain this resected ramus away from the glenoid area, a large block of silicone rubber was inserted into each cavity. Movement was encouraged after two weeks; excellent function has developed and the patient can chew for the first time in his life.

An important point of consideration [2-5] is that motion of an implant, or around an implant, is apt to cause rejection of it. Both of these implants were removed after several months, but their long stay in place successfully held the joint space open, so that function of the jaw has remained excellent over a 2½-year period and continues.

Persistence of function and contour has occurred in a few other instances of build up of soft tissues with implants in which the stretch and the realignment of the soft tissues is such that even though the implant might be rejected or removed the defect has remained in satisfactory contour and surface anatomy.

Silicone sponge has been used further in this patient to build the chin forward after a pocket had been prepared in front of the retruded bone, and, again, with preservation of both motor and sensory nerves. This restoration is of 2½ years' duration, with every sign of continuing.

This patient, who was greatly handicapped from lack of function and lack of the fourth function of the face, that of looking normal, is now able to go ahead with musical studies and with great promise (Fig. 2).

FIG. 1G, H. Form and function restoration with Teflon substitution for total loss of jaw (3 years). Now married; one child.

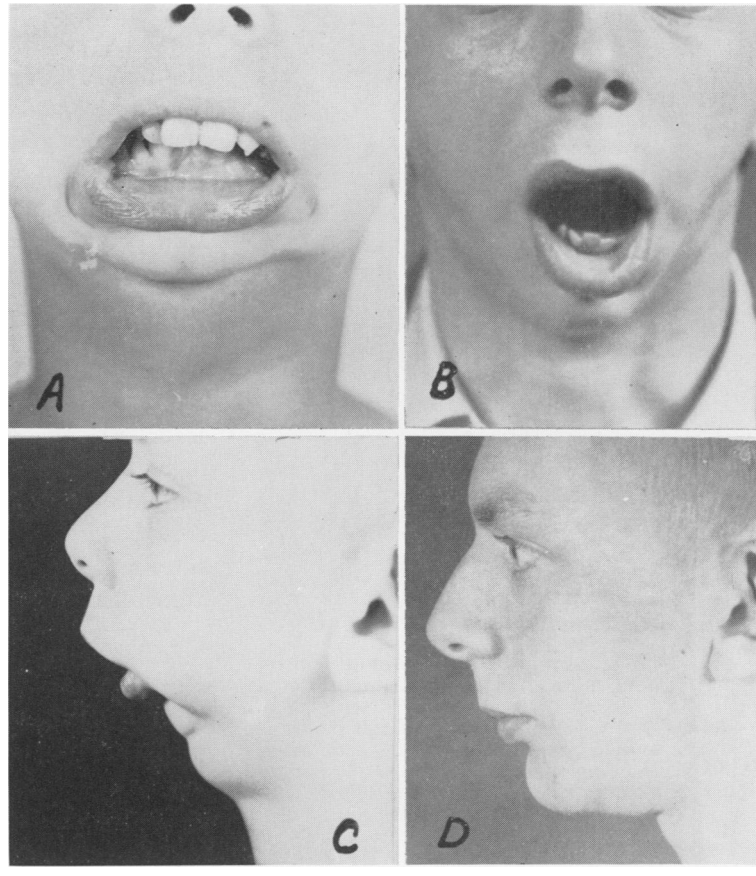

FIG. 2A, C. Solid ankylosis from early infancy. No motion. No development of chin area. B, D. Ankylosis relieved by wide bone resection and silicone rubber implant to maintain separation of jaw and skull. Chin area built out with silicone sponge. Patient rehabilitated to normal life; educational, social, physical and spiritual. Able to chew for first time in life (2 years). Now has a public career in music.

Trauma about the face in compound facial injuries and losses, has had *silicone* used in more instances to maintain contour at the primary repair. Because of irregularity of healing in extensive crushes such primary implants may be rejected, but they are most often retained.

Secondary corrections of traumatic facial deformities with synthetic implants are shown in Figures 3 and 5. A large loss of bone of the maxilla and the nose and the middle third of the face is seen in Figure 3A, B. This defect has been filled in secondarily with a triangular block of silicone rubber with its base upward as the greatest loss was above, which has been maintained 2½ years with no trouble (Fig. 3C, D).

The patient shown in Figure 4 has been done in consultation with the neurosurgical department, following a vicious injury to the orbit, with the frontal lobe streaming out of the empty eye socket. This was dammed back with the remnants of the sclera at the first operation. The nose was flat with no bony support in its upper two-thirds and this depression was filled in with bank cartilage with the bulk of it at the top. Silicone can be substituted if the need arises (5 years).

One of the most difficult types of injury for correction may have comparatively slight deviation, but be difficult to hold in correct alignment as far as an implant is concerned. The patient in Figure 5 had correction in two operations depending on an L-shaped silicone rubber implant along the dorsum and into the columella, and local flap corrections of the distorting scars. The implant has been in place 2½ years.

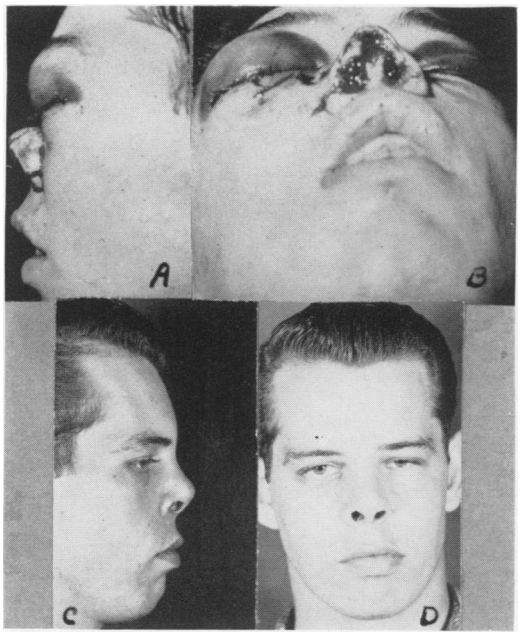

FIG. 3A, B. Loss and destruction most of bony support of nose, maxilla, lacrimal, nasal and frontal bones. Nose driven up between eyes with many small fractures. C, D. Restoration of function, airways and contour with careful sorting and saving of all possible bone and soft tissues. Secondary support with large triangle of silicone rubber with base up in area of greatest loss (2 years).

As is evident, these implants have to be cut to pattern and finally shaped at the time of operation with as little handling as possible, but requiring considerable time and possibly several trials.

Cartilage, fresh, auto or homo, and preserved, is mentioned in this report, because it is used as indicated.[2-5, 9, 13] Figure 6 shows a patient requiring a combination of three implants to hold the face, nose and lip forward and in position, and to restore alignment and function of the eye by relieving diplopia.

In this patient (Fig. 6A, C, E), the right eye is down out of position because of the fractured and depressed orbital floor. This globe has been elevated with an implantation of bank cartilage along the orbital floor to level the eye as well as possible to relieve diplopia (Fig. 6B, D, F). This is not a fully predictable procedure as far as measurements are concerned, but in many instances patients can adjust to the new position of the globe and have freedom from diplopia. This has been attained even in airplane pilots, with return to flying status.

This patient (Fig. 6C, D) also has an L-shaped implant of preserved cartilage along the dorsum of the nose and down into the columella to hold the dorsum and the tip forward, as in the photographs taken from below (Fig. 6B, D, F). She has a cross-bar of cartilage put under the lip across the alveolus, under the nasal floors to build forward this part of the retruded middle third (Fig. 6E, F). The dorsal and cross-bar cartilages can be replaced with silicone if the need arises. She has reported after four years that she is in excellent con-

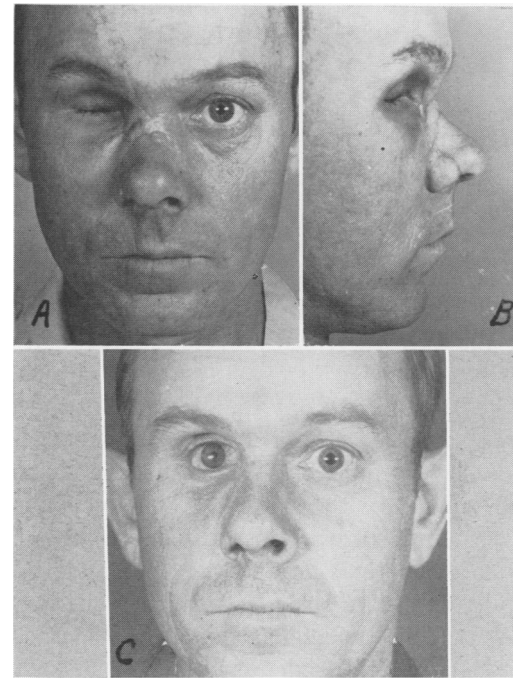

FIG. 4A, B. After primary repair orbit, nose, maxilla, ethmoid, frontal injury with frontal lobe loss through orbit. Dural opening dammed with remains of sclera, and careful saving of all viable bone and skin. C. Large triangle of bank cartilage with base up to fill area of greatest loss. If absorption occurs defect can be filled with silicone. Prosthetic eye (5 years).

dition and is glad to have her photos recorded.

Congenital deficiency application of synthetics has been extended, as in the patient shown in Figure 7. Agenesis of the chin region can arrive at a disturbing deformity, and upset a child's progress in many ways. This patient has had her chin area built out with bank cartilage to a successful degree, as noted from her pleasant features, in function and in smiling (Fig. 7C, D), in early childhood.

There may be absorption of homocartilage, both fresh and preserved, as in this patient after several years, as noted by the reappearance of the deficiency when she is older (Fig. 7E, F). At this time the patient is large enough to use her own bone or cartilage, but satisfactory support can be obtained with synthetics and thus save the patient from a rib or an ischial operation. This correction has been done with Silicone and she is shown with persistent contour after 3½ years and normal in development (Fig. 7G, H). Both sensor and motor nerve functions are preserved, and it is important to stress the fine cooperation of patient and parents.

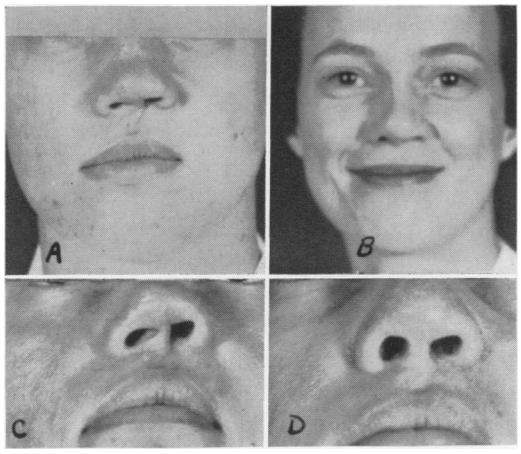

FIG. 5A, C. Disruption of nasal bones, and cartilage and soft tissue distortion from traffic accident. B, D. Restoration in two operations of flap mobilization and realignment and L-shape silicone implant through dorsum and columella. Small changes may be the most difficult (2½ years).

Facial hemiatrophy, a developmental deficiency, also has been further corrected by implantation of *soft synthetics.* The patient shown in Figure 8 has been built up in two procedures so that she becomes a different individual in her own normal appearance; looking normal, to repeat, is considered the fourth function of the face.

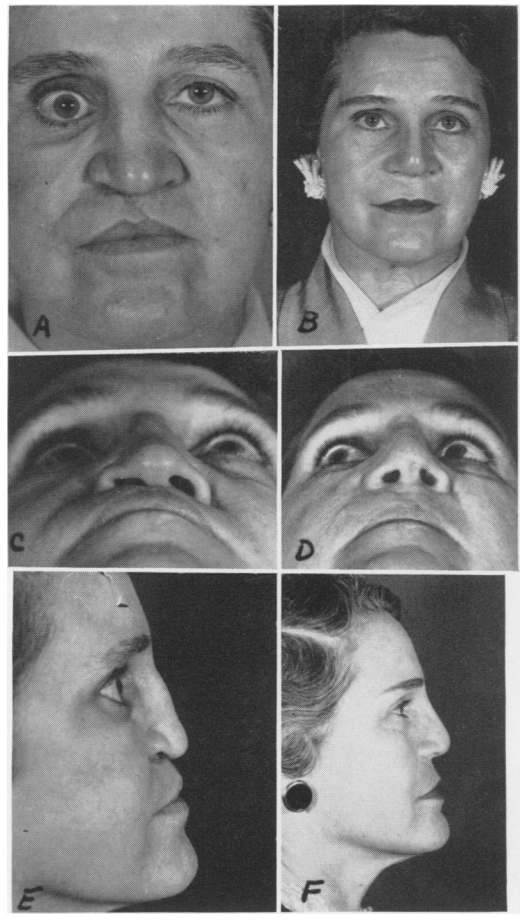

FIG. 6A, C, E. Crushing loss and deformity of orbit, nose, maxilla, lacrimal and ethmoid bones. Soft tissue disruption, diplopia and blocked airways following traffic accident. B, D, F. Restoration of function and contour, normal vision, open airways, and 4th function of face—that of looking normal. *Bank cartilage implant* to reposition dropped eye and allow normal extra ocular muscle function to relieve diplopia. L-shaped cartilage implant to dorsum of nose and columella with restoration of airways. Cross bar cartilage to build out middle third. Patient has offered presentation of photos (5 years). If absorption occurs further cartilage could be used or substitution made with synthetic silicone.

The material for such use could be any of the soft synthetics, in this instance it being polyvinyl alcohol sponge, which is soft when wet and when implanted.

Etheron (*di-isocyanate*) is a soft white spongy material that has been used for augmentation of soft tissues, such as the face and breast (Fig. 9, 11). At this time Etheron is thought to be superior to polyvinyl alcohol, but it is possible that a soft silicone may be relied on, as has been suggested.[2-4]

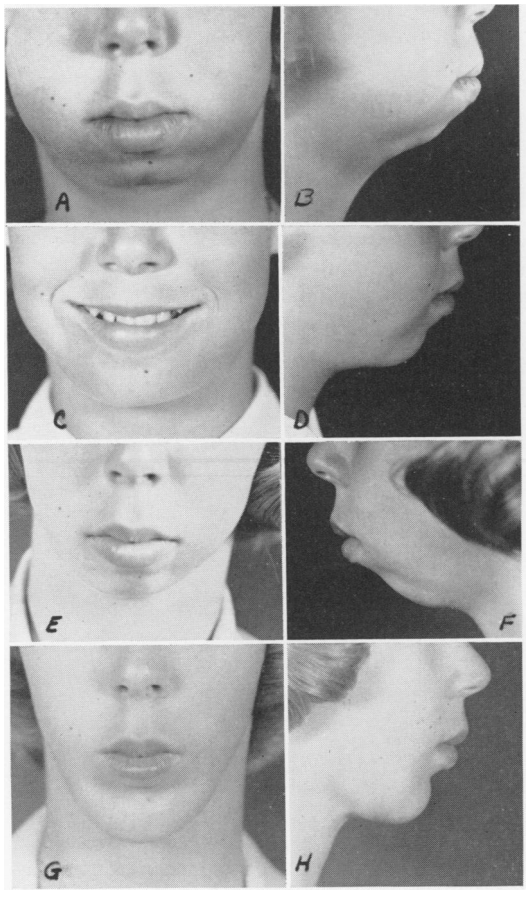

FIG. 7A, B. Lack of forward progression of jaw and chin. C, D. Building out of jaw and chin in early childhood to normal contour in early childhood with bank cartilage. E, F. Absorption of cartilage implant several years later as is always considered, though many remain permanently. G, H. Final restoration of function and contour, with Silicone implant put from skin surface in one operation. Along with other perfect features patient gains beautiful contour and normal function (3 years).

Robbins[13] indicates that a copy of a reprint by Arons[1] is sent with each order of Etheron, that describes work with mice in relation to tumor transplantation. No tumor formation was reported, but some foreign body response and fragmentation (in mice).

We have limited clinical use pending our own laboratory investigation and believe the following to be the first recorded factors from the experimental laboratory for this synthetic for human use. We have done 200 implants in 85 animals (mice, guinea pigs, rabbits, dogs) with the following findings: tumors—none have been noted; toxicity—none has been noted; rejection if implants—none noted; retention of synthetic through full life cycle—these animals are gradually completing their life cycles and through such cycles all will be observed. The gross material and the microscopic study are shown in Figure 10 (Etheron).

From *a tumor standpoint,* including four synthetics, and six hundred animals we have noted no definite tumors other than one fibroma reported in December, 1952 adjacent to a polyvinyl alcohol implant. This does not mean that there may not have been some microscopic tumors not recovered, as serial sections of all of these various 600 subcutaneous envelopes have not been made, although a great number have been, and all of them have been studied grossly.

For *soft tissue filling* there is as much difficulty as with the solid Teflon and silicone rubber. Reasons for this are the shrinkage element of the sponge meshes, and the ability of the pocket into which the implant is placed to contract and either diminish or possibly hump up a soft implant. However, silicone, Etheron and polyvinyl alcohol have given worthwhile results.

A noteworthy soft tissue filling (or augmentation if one prefers) is in the young nurse in Figure 11 who has suffered a se-

FIG. 8A, B. Hemiatrophy of face. C. Face filled out before surface foreshortening was too marked to be relieved. Building out of soft tissues with soft synthetic polyvinyl alcohol. Realignment of defect with other beautiful features, restoration of contour and function, preservation of motor and sensor nerves in spite of necessary wide undermining.

vere traffic destruction of her face, which has been resurfaced with lateral flap mobilization and free skin grafts across the lip and the cheek and then the bulk filled out with soft Etheron sponge under the central depressed area of three inches. Here again it is noted as important the patient's and parents' fine attitude and acceptance in this pioneer work.

The patients themselves, or the parents should be apprized of the use of these synthetic materials, explaining the care and selection, and the fact that none of the synthetics have had time to go through a full human life cycle.[2-5] The several hun-

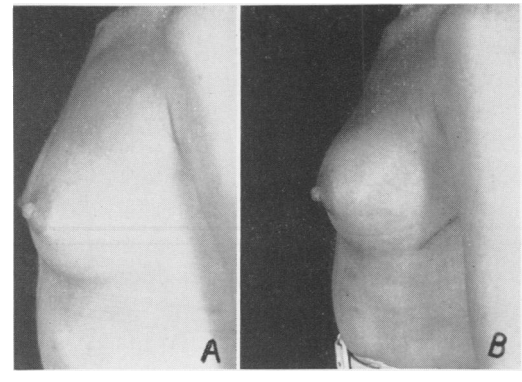

FIG. 9A, B. Enlargement to normal size and appearance of atrophic breasts, with soft synthetic Etheron implants. One operation (2½ years).

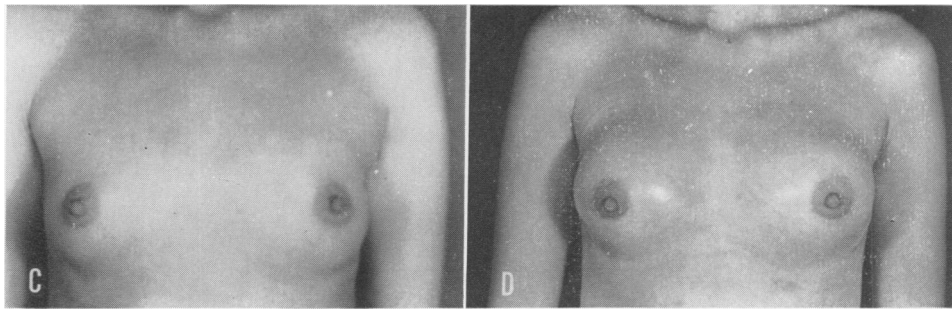

FIGURE 9C, D.

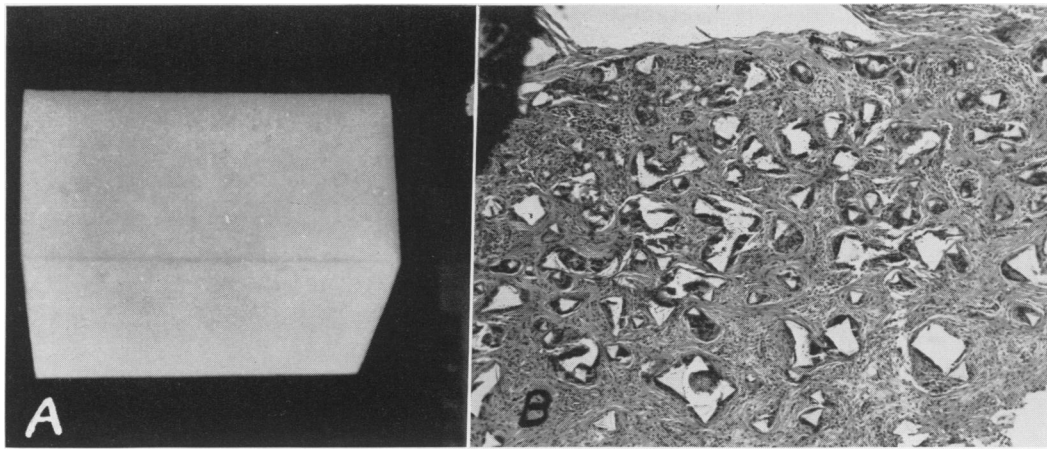

FIG. 10A. Gross appearance soft synthetic sponge Etheron, white to yellow on exposure. B. Etheron implant biopsy after several months.

dred animals without tumor formation on this service are good assurance, however, as are also the thousands of vessel implantations that have been made on other services with no tumors being reported from any clinic. But with the present urge for caution in the use of drugs, it is important to have the patient, or the parents recognize these simple but important statements about the use of these materials. So far we have had no adverse reaction even though there have been rejections of the implants.

Rejections of implants have taken place from slippage, lack of covering, scar around the implant, trauma, and from movement such as the jaw that was freed in Figure 2, and the chewing that the patient did for the first time in his life. This motion of the jaw, in his new found freedom, probably has lead to the rejection. The patient and his parents accepted this situation, because function has been made possible, and is being maintained by the joint space that was developed by the silicone.

Late results of the patients published so far: one implant was lost from an ear because of trauma. One polyvinyl alcohol sponge implant over a jaw was rejected after ten years because of calcification in the interstices, along the edge which became sharp. The patient did not realize this and did not report for observation. The sponge materials may be more apt to calcify than solid material.

In the fine-mesh silicone sponges there is not as much ingrowth of tissue and these will not be expected to be calcified although more years observation will be necessary. The calcification might not be harmful if it did not produce sharp edges and have the combination of overlying injury, except that it would give still further hardness where softness is wanted.

One silicone sponge implant in a skull defect was rejected, possibly because of the tendency of the patient to allergies and chemical irritations, beyond the degree found in most patients. This defect will be replaced with a different synthetic, or with autogenous bone, or possibly with processed heterogenous bone from the calf (Squibb).

A fourth implant has been rejected from the jaw of a patient apparently cured of cancer, but with so much scar around the area that the blood supply was insufficient to retain coverage over the implant. This can be replaced with a synthetic or possibly with processed calves bone, but whatever is used will require the staged introduction of a blood-carrying flap to replace the scar

which could not be maintained over the original Teflon implant.

A few other implants have been rejected, from abscess formation over them involving the tissues around the implant secondarily, and from injuries and falls that have dislodged the implants or opened the skin over them. In some instances, inflammation may be controlled and tissues may be closed over exposed implants, but in implants close to the surface there is no extra tissue in the area to work with, and so a few implants have been removed to allow an inflammatory process to settle down and then consider re-applying it. In some of these instances the tissues have been so stretched by the implant that secondary repair was not necessary even after rejection. This is well illustrated in the boy with the long standing ankylosis, but with relief of it and excellent function resulting even though the implants were rejected (Fig. 2).

From our own laboratory work and clinical use and clinical reports of others these materials can be used, but final decisions as to permanency and the permanency of the fibrous tissues replacement is open to a long-term observation in regards to maintenance, reaction to trauma and infection, and to continuance of the desired consistency of the material, or of its scar replacement.

The chemical nature and structure of silicone, Teflon and polyvinyl alcohol are shown in earlier work.[2-5] Robins[13] omits a definite final formula for Etheron, but lists the physical characteristics: "1) Lighter than any other implant material; 2) Takes all the standard methods of sterilization, boiling, gas, and autoclaving; 3) It is noncarcinogenic; 4) It can be easily shaped and sheared with a knife and scissors; 5) It is completely inert; 6) It does not harden or change its resilience; 7) It holds stitches and can be sutured, anchored or stretched in any direction; 8) It is elastic all around without being spry or bouncy; 9) It is well tolerated by human and animal tissues; 10) It is nonirritating and nontoxic and nonallergic; 11) It does not have a slippery surface; 12) It is odorless and pure; 13) It is translucent on x-ray film; and 14) It is hydrophobic and does not harden on drying."

Desirable Developments in the consistency of implants of silicones would be that a soft silicone rubber be prepared that would have the consistency of soft tissues. This would be a state between liquid dimethylsiloxane and silicone rubber. This has been requested from Dow Center for Medical Research over a period of three years and as of personal communication from Mr. Silas Braley of November 12, 1962 this is finally being accomplished with a slight amount of cross linkage of CH-2 groups in the dimethylsiloxane.

FIG. 11A. Distortion and loss of tissue and contour from traffic accident. B. Resurfacing with free skin grafts across lip and cheek. Filling of cheek depression with soft synthetic Etheron. Normal function and contour (2 years).

For changes in Teflon the same availability would be of help, but so far, as we know, it is not forthcoming at present.

It can be noted that a synthetic actually can be *too good* in lack of reaction and fixation in the tissues. These elements, however, would not avoid displacement and loss from trauma or infection.

It may be repeated [2-5] that, in the field of reconstructive surgery, live autogenous tissue should be most satisfactory when available—some live homogenous tissues such as cartilage are also useful and some preserved homo-tissues may be available and advantageous. Successful transfers of skin and other organs in identical twins have been established [7, 8, 12] and also the use of postmortem skin grafts. But these inert synthetic materials may be considered as useful adjuncts in striving for relief of deformity in reconstructive surgery, to be accepted or rejected as the individual patient and surgeon choose.

This study of inert synthetics might be thought to be the reverse of the effort and research in trying to level everyone to a common stock, in the hope of accomplishing permanent, lasting, live homotransplants. For this we suggest the term *artificial twins*. So far there is no finally established breakthrough, although several approaches show promise and one Nobel prize has been attained. Murray *et al.*[12] have the most favorable reports in work with kidneys which seem the most adaptable because of the chance of flooding the tissues. One may hope for such possibilities, as in inbred mice and possibly some natural species, but if the condition of *artificial twins* is attained in humans there would be the need of great forward strides in human ethics and morals. If these strides could not be gained, untoward effects might follow the closing out of individuality with serious questions as to who would be the donors.

For the present, patients need help in reconstructive surgery and the possibility of their retaining inert material seems worth investigation. The outlook is favorable, but investigation and the important follow up of patients are still to be done. There are many difficulties and challenges and it is necessary to remember that the body does not prefer to retain foreign bodies. Every care needs to be taken to circumvent or avoid the natural preference of the body. These compounds might be found preferable to fresh tissue implants in some instances. At the present time, patients or their families should have these explanations made to them.

Laboratory and clinical investigations have been carried out on this service over 13 years and these synthetics have been established as adjuncts in reconstructive surgery.

Summary

This paper is not intended to be a series of case reports, but the pictured record is so important that these are incorporated as part of the text. The paper is summarized in the introduction.

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Discussion

Dr. David Ohlwiler (closing): After Dr. Brown's fine presentation, to add anything more would be somewhat like a person commissioned to paint a lily. The photographs speak emphatically for themselves of the possibilities in this field. It is worthy of mention that when we first started this work there was considerable opposition to it but Dr. Brown's foresight made it possible to start the work. Extensive laboratory work has been done as he mentioned—with about 600 animal implants—to try to establish safety measures for work with humans. We believed that any tissue to be implanted in the human body should have a very low solubility constant. These materials discussed here, I think, can modify our views of the old adage, that nature abhors and will extrude a foreign body. Formerly we did not have these materials but now with tetrafluoride and silicones, we have materials for implantation which have no known solvent and open a new horizon to us in foreign body implantation.

The fact that no secondary operations are needed is another tremendous asset. We can produce these materials and relieve all their internal stresses by heating in the normal autoclaving range, so that they are implanted with no stress whatever. Therefore, there is no warpage. They are easily carved in the operating room, and they are readily sterilized. They are not invaded by body tissues and do not calcify.

I think they offer considerable promise for the future. The patient is more comfortable since one operation often accomplishes a result which would require several stages if his own tissues were used. They are inexpensive. I think the pictures themselves are the best proof that when these deformities are properly corrected with synthetic materials, the results can be very gratifying.