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المحاضرة التاسعة

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SOFT TISSUE REPLACEMENT I: SUTURES, SKIN, AND MAXILLOFACIAL IMPLANTS

In soft tissue implants as in other applications that involve engineering, the performance of an implanted device depends on both the materials used and the design of the device or implant. The initial selection of material should be based on sound materials engineering practice. The final judgment on the suitability of the material depends on observation of the in vivo clinical performance of the implant. Such observations may require many years. This requirement of in vivo observation represents one of the major problems in the selection of appropriate materials for use in the human body. Another problem is that the performance of an implant may also depend on the design rather than the materials per se.

The success of soft tissue implants has primarily been due to the development of synthetic polymers. This is mainly because the polymers can be tailor-made to match the properties of soft tissues. In addition, polymers can be made into various physical forms, such as liquid for filling spaces, fibers for suture materials, films for catheter balloons, knitted fabrics for blood vessel prostheses, and solid forms for cosmetic and weight-bearing applications.

It should be recognized that different applications require different materials with specific properties. The following are minimal requirements for all soft tissue implant materials:

1. They should achieve a reasonably close approximation of physical properties, especially flexibility and texture.

2. They should not deteriorate or change properties after implantation with time.

3. They should not cause adverse tissue reaction.

4. They should be noncarcinogenic, nontoxic, nonallergenic, and nonimmunogenic.

5. They should be sterilizable.

6. They should be low cost.

9.1. SUTURES, SURGICAL TAPES, AND ADHESIVES

The most common soft tissue implants are sutures. In recent years, surgical tapes and tissue adhesives have been added to the surgeon's armamentarium. Although their use in actual surgery is limited to some surgical procedures, they are indispensable.

9.1.1. Sutures

There are two types of sutures, classified as to their long-term physical in vivo integrity: absorbable and nonabsorbable. They may also be distinguished by their raw material source: natural sutures (catgut, silk, and cotton) and synthetic sutures (nylon, polyethylene, polypropylene, stainless steel, and tan- talum). Sutures may also be classified according to their physical form: monofilament and multifilament. The absorbable suture, catgut, is made of collagen derived from sheep intestinal submucosa. It is usually treated with a chromic salt to increase its strength and is cross-linked to retard resorption. Such treatment extends the life of catgut suture from 3-7 days up to 20-40 days. Table 9-1 gives initial strength data for catgut sutures according to their sizes. The catgut sutures are preserved with needles in a physiological solution in order to prevent drying, which would make the sutures very brittle and thus not easily usable.

It is interesting to note that the stress concentration at a surgical knot decreases the suture strength of catgut by half, no matter what kind of knotting technique is used. It is suggested that the most effective knotting technique is the square knot with three ties to prevent loosening. According to one study there is no measurable difference in the rate of wound healing whether the suture is tied loosely or tightly. Therefore,

loose suturing is recommended because it lessens pain and reduces cutting soft tissues.

Table 9-1. Minimum Breaking Loads for British-Made Catgut.

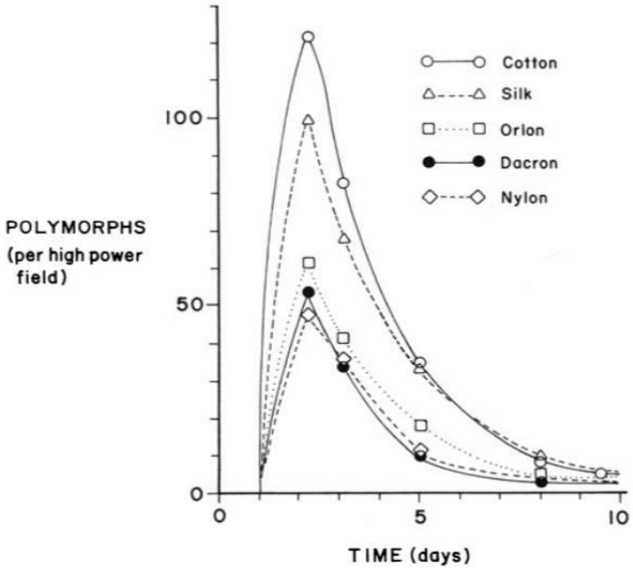
	Diameter (mm)		Minimum breaking load (lbf)	
Size	Minimum	Maximum	Straight pull	Over knot
7/0	0.025	0.064	0.25	0.125
6/0	0.064	0.113	0.5	0.25
5/0	0.113	0.179	1	0.5
4/0	0.179	0.241	2	1
3/0	0.241	0.318	3	1.5
2/0	0.318	0.406	5	2.5
0	0.406	0.495	7	3.5
1	0.495	0.584	10	5
2	0.584	0.673	13	6.5
3	0.673	0.762	16	8
4	0.762	0.864	20	10
5	0.864	0.978	25	12.5
6	0.978	1.105	30	15
7	0.105	1.219	35	17.5

Catgut and other absorbable sutures (e.g., polyglycolic acid, PGA: polylactic acid, PLA) invoke tissue reactions although the effect diminishes as they are being absorbed. This is true of other natural, nonabsorbable sutures like silk and cotton, which showed more reaction than synthetic sutures like polyester, nylon, polyacrylonitrile, etc. as shown in Figure 9-1. As in the case of the wound healing process (discussed in Chapter 10), the cellular response is most intensive one day after suturing and subsides in about a week.

As for the risk of infection, if the suture is contaminated even slightly the incidence of infection increases manyfold. The most significant factor in infection is the chemical structure, not the geometric configuration of the suture. Polypropylene, nylon, and PGA sutures developed lesser degrees of infection than sutures made of stainless steel, plain and chromic catgut, and polyester. The ultimate cause of infection is a pathogenic microorganism, not the biomaterial. The role of the suture in infection is to provide a conduit for ingress of bacteria, to chemically or

physically modify the body's immune response, or to provide an environment favorable to bacterial growth.

Figure 9-1. Cellular response to sutured materials.



9.1.2. Surgical Tapes and Staples

Surgical tapes are intended to offer a means of avoiding pressure necrosis, scar tissue formation, problems of stitch abscesses, and weakened tissues. The problems with surgical tapes are similar to those experienced with Band-Aids: (1) misaligned wound edges, (2) poor adhesion caused by moisture or dirty wounds, (3) late separation of tapes when hematoma, wound drainage, etc. occur.

The wound strength and scar formation in the skin may depend on the type of incision made. If the subcutaneous muscles in the fatty tissue are cut and the overlying skin is closed with tape, then the muscles retract. This in turn increases the scar area, resulting in poor cosmetic appearance compared to a suture closure. However, with the higher strength of scar tissue, the taped wound has a higher wound strength than the sutured wounds only if the muscles were not cut. Because

of this, tapes have not enjoyed the success that was anticipated when they were introduced.

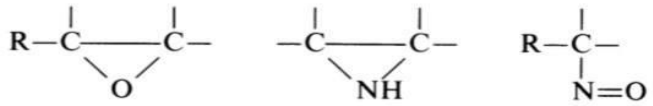
Tapes have been used successfully for assembling scraps of donor skin for skin graft, correcting nerve tissues for neural regrowth, etc.

Staples made of metals (Ta, stainless steel, and Ti-Ni alloy) can be used to facilitate closure of large surgical incisions produced in procedures such as cesarean sections, intestinal surgery, and surgery for bone fractures. The tissue response to the staples is the same as that of synthetic sutures but they are not used in places where esthetic outlook is important.

9.1.3. Tissue Adhesives

The special environment of tissues and their regenerative capacity make the development of an ideal tissue adhesive difficult. Past experience indicates that the ideal tissue adhesive should be able to be wet and bond to tissues, be capable of rapid polymerization without producing excessive heat or toxic by-products, be resorbable as the wounds heal, not to interfere with the normal healing process, have ease of application during surgery, be sterilizable, have adequate shelf life, and ease of large-scale production.

The main strength of tissue adhesion comes from the covalent bonding between amine, carboxylic acid, and hydroxyl groups oftissues, and the functional groups of adhesives such as



There are several adhesives available of which alkyl-a-cyanoacrylate is best known. Among the homologues of alkyl-cyanoacrylate, the methyl- and ethyl-2-

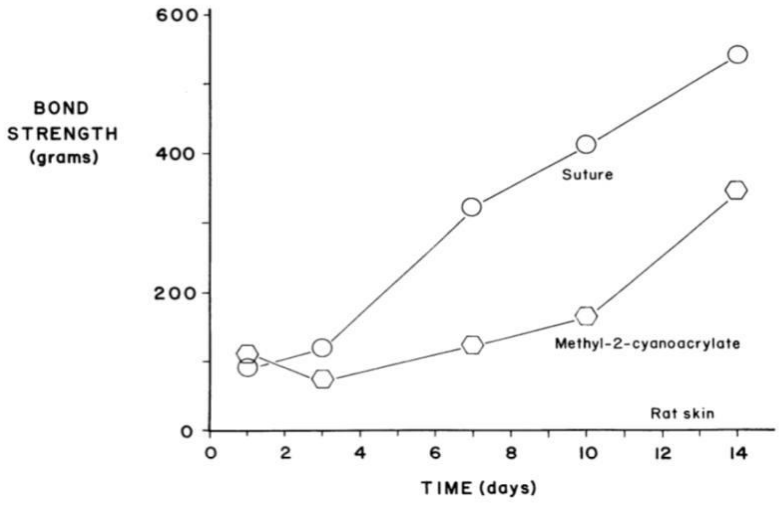


Figure 9-2 Bond strength of wounds with different closure material.

cyanoacrylate are most promising. With the addition of some plasticizers and fillers they are commercially known as Eastman 910®, Crazy Glue®, etc. An interesting comparison is illustrated in Figure 9-2, which shows that the bond strength of adhesive-treated wounds is about half that of sutured wounds after 10 days. Because of the lower strength and lesser predictability of in vivo perform- ance of adhesives, the application is limited to use after trauma on fragile tissues such as spleen, liver, and kidney or after an extensive surgery on soft tissues such as lung. The topical use of adhesives in plastic surgery and fractured teeth has been moderately successful. As with many other adhesives, the end results of the bond depend on many variables such as thickness, open porosity, and flexibility of the adhesive film, as well as the rate of degradation.

Some workers have tried to use adhesives derived from fibrinogen, which is one of the clotting elements of blood. This material has sufficient strength (0.1 MPa) and elastic modulus (0.15 MPa) to sustain the adhesiveness for the anastomoses of nerve, microvascular surgery, dural closing, bone graft fixation, skin graft fixation, and other soft tissue fixation. This material is available commercially in Europe and will be in the United States pending FDA approval.

9.2. PERCUTANEOUS AND SKIN IMPLANTS

The need for percutaneous (trans or through the skin) implants has been accelerated by the advent of artificial kidneys and hearts, and by the need for prolonged injection of drugs and nutrients. Artificial skin (or dressing) is urgently needed to maintain the body temperature of severely burned patients. Actual permanent replacement of skin by biomaterials is beyond the capability of today's technology.

9.2.1. Percutaneous Devices

The problem of obtaining a functional and a viable interface between the tissue (skin) and an implant (percutaneous) device is primarily due to the following factors. First, although initial attachment of the tissue into the interstices of the implant surface occurs, it cannot be maintained for a long period of time, since the dermal tissue cells turn over continuously and dynamically. Furthermore, downgrowth of epithelium around the implant (extrusion) or overgrowth of implant (invagination) occurs. Second, any openings large enough for bacteria to penetrate may result in infection even though initially there is complete sealing between skin and implant.

Many variables and factors are involved in the development of percutaneous devices. These are:

1. End-use factors: Transmission of information (biopotentials, temperature, pressure, blood flow rate), energy (electrical stimulation, power for heart assist devices), matter (cannula for blood), and load (attachment of prosthesis)

2. Engineering factors

a. Materials selection: polymers, ceramics, metals, and composites

b. Design variation: button, tube with and without skirt, porous or smooth surface, etc.

c. Mechanical stresses (soft or hard tissue interface, porous or smooth

interface)

3. Biological factors

a. Implant host: man, dog, hog, rabbit, sheep, etc.

b. Implant location: abdominal, dorsal, forearm, etc.

4. Human factors

a. Postsurgical care

b. Implantation technique c. Esthetic outlook

Figure 9-3 shows a simplified cross-sectional view of a generalized percutaneous device (PD), which can be broken down into five regions:

A. Interface between epidermis and PD should be completely sealed against invasion by foreign organisms.

B. Interface between dermis and PD should reinforce the sealing of (A), as well as resist mechanical stresses. Due to the relatively large thickness of the dermis, the mechanical aspect is more important at this interface.

C. Interface between hypodermis and PD should reinforce the function of (8). The immobilization of the PD against piston action is a primary function of (C).

D. Implant material per se should meet all of the requirements of an implant for soft tissue replacement.

E. The line where epidermis, air, and PD meet is called a three-phase line which is similar to (A).

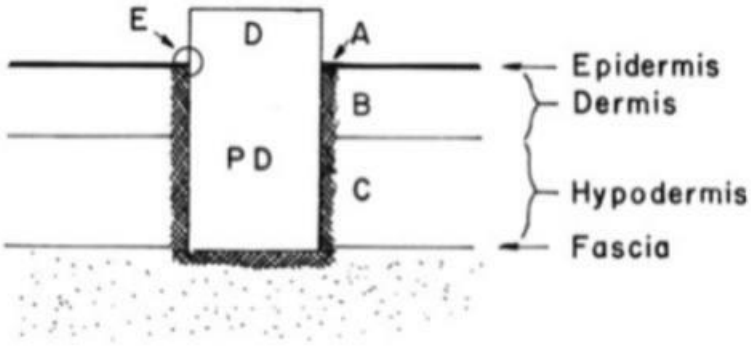


Figure 9-3

9.2.2. Artificial Skins

Artificial skin is another example of a percutaneous implant, and hence the problems are similar to those described in the previous section. Most needed for this application is a material that can adhere to a large (burned) surface and thus prevent the loss of fluids, electrolytes, and other biomolecules until the wound has healed. Although a permanent skin implant is needed, it is a long way from being realized for the same reasons given in the case of percutaneous implants proper. Presently, autografting and homografting (skin transplants) are the only methods available as a permanent solution.

In one study, wound closure was achieved by controlling the physicochemical properties of the wound-covering material (membrane). Six ways were suggested to improve certain physicochemical and mechanical requirements necessary in the design of artificial skin. These are shown schematically in Figure 9-4. Biomechanical and chemical analysis conducted in this study led to the design of a cross-linked collagen-polysaccharide (chondroitin 6-sulfate) composite membrane chosen for the ease in controlling porosity (5- to 150-JLm diameter), flexibility (by varying cross-link density), and moisture flux rate.

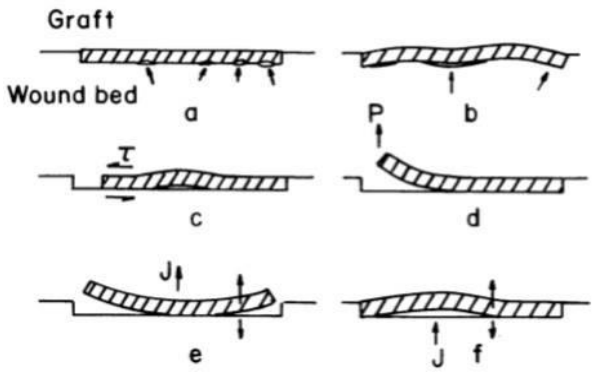


Figure 9-4

9.3. MAXILLOFACIAL AND OTHER SOFT-TISSUE AUGMENTATION

In the previous section we have dealt with problems associated with wound closing and wound/tissue interfacial implants. In this section we will study (cosmetic) reconstructive implants. Although soft-tissue implants can be divided into (l) space filler, (2) mechanical support, and (3) fluid carrier or storer, most have two or more combined functions. For example, breast implants fill space and provide mechanical support.

9.3.1. Maxillofacial Implants

There are two types of maxillofacial implant (often called prosthetics, which implies extracorporeal attachment) materials: extraoral and intraoral. The latter is defined as "the art and science of anatomic, functional or cosmetic reconstruc- tion by means of artificial substitutes of those regions in the maxilla, mandible, and face that are missing or defective because of surgical intervention, trauma, etc."

There are many polymeric materials available for the extraoral implant, which requires: (l) color and texture should be matched with those of the patient, (2) it should be mechanically and chemically stable, i.e., it should not creep or change colors or irritate skin, and (3) it should be easily fabricated. Polyvinyl chloride and acetate (5-20%) copolymers, polymethyl methacrylate, silicone, and polyurethane

rubbers are currently used. The requirements for the intraoral implants are the same as for other implant materials, since they are in fact implanted. For maxillary, mandibular, and facial bone defects, metallic materials such as tantalum, titanium, and Co-Cr alloys, etc. are used. For soft tissues like gum and chin, polymers such as silicone rubber, PMMA, etc. are used for the augmentation.

The use of injectable silicones that polymerize in situ has proven partially successful for correcting facial deformities. Although this is obviously a better approach in terms of the minimal initial surgical damage, this procedure was not accepted due to the tissue reaction and the eventual displacement or migration of the implant.

9.3.2. Ear and Eye Implants

The use of implants can restore the conductive hearing loss from otosclerosis (a heredity defect that involves a change in the bony tissue of the ear) and chronic otitis media (the inflammation of the middle ear, which may cause partial or complete impairment of the ossicular chain: malleus, incus, and stapes). Many different prostheses are available to correct the defects, some of which are shown in Figure 9-5. The porous polyethylene total ossicular replacement implant is used to obtain a firm fixation of the implant by tissue ingrowth. The tilt-top implant is designed to retard tissue ingrowth into the section of the shaft which may diminish sound conduction.

Many different materials have been tried in fabricating implants: polytetra-fluoroethylene, polyethylene, silicone rubber, stainless steel, and tantalum. More recently, polytetrafluoroethylene-carbon composite (Proplast®), porous polyethylene (Plastipore®), and pyrolytic carbon (pyrolite®) have been shown to be suitable materials for cochlear (inner ear) implants.

Artificial ear implants capable of processing speech have been developed and are undergoing clinical evaluation. These types of cochlear implants have electrodes that

stimulate the cochlear nerve cells. The implant also has a speech processor that transforms sound waves into electrical impulses that can be conducted through coupled external and internal coils as shown in Figure 9-5. The electrical impulses can be transmitted directly by means of a PD.

Eye implants are used to restore the functionality of the cornea and lens when they are damaged or diseased. Usually the cornea is transplanted from a suitable donor rather than implanted since the longevity of the cornea implant is uncertain because of fixation problems and infection. They are made from "transparent" acrylics, especially PMMA, which has a comparatively high refractive index (1.5). In cataract, the lens of the eye becomes cloudy; the lens can then be removed surgically. The lost optical power can be restored with thick-lens spectacles, but these cause distortion and restriction of the field of view, and some people object to their appearance. Intraocular lenses are implanted surgically to replace the original eye lens, and they restore function without the problems associated with thick spectacles.

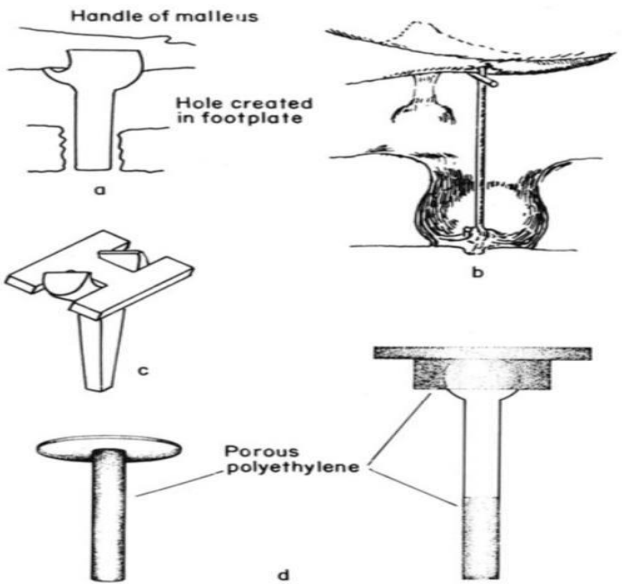


Figure 9-5

9.3.3. Fluid Transfer Implants

Fluid transfer implants are required for cases such as hydrocephalus, urinary incontinence, and chronic ear infection. Hydrocephalus, caused by abnormally high pressure of the cerebrospinal fluid in the brain, can be treated by draining the fluid (essentially an ultrafiltrate of blood) through a cannula as shown in Figure 9-6. The earlier shunt had two one-way valves at the ends while the Ames shunt has simple slits at the discharging end, which opens when enough fluid pressure is exerted. The Ames shunt empties the fluid in the peritoneum while others drain into the bloodstream through the right internal jugular vein or right atrium of the heart. The simpler peritoneal shunt showed less incidence of infection.

The use of implants for correcting the urinary system has not been successful because of the difficulty of joining a prosthesis to the living system to achieve fluid tightness. In addition, blockage of the passage by deposits from urine and constant danger of infection have been problematical. Many materials have been tried including glass, rubber, silver, tantalum, Vitallium@, polyethylene, Dacron@, Teflon®, polyvinyl alcohol, etc. without much long-term success.

The drainage tubes for chronic ear infection can be made from polytetra-fluoroethylene (Teflon®) or other inert materials. These are not permanent implants.

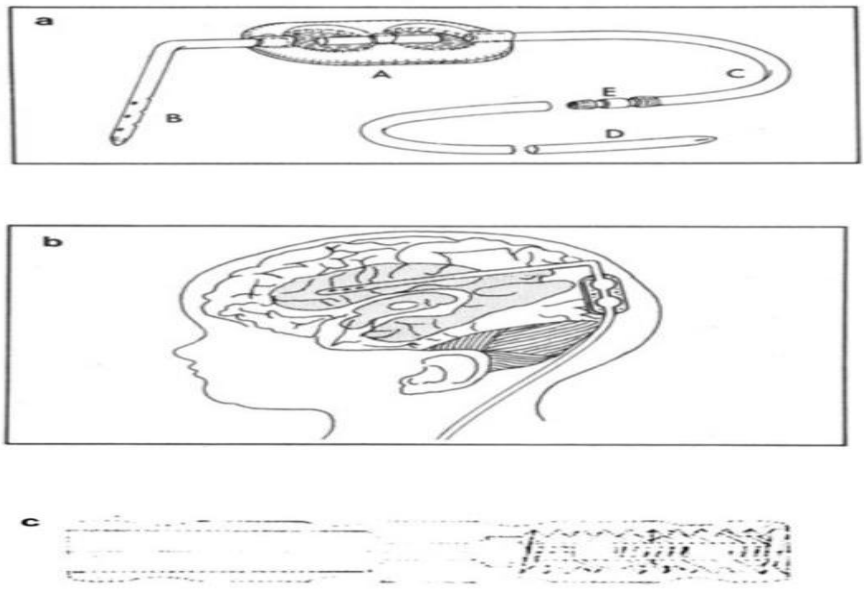


Figure 9-6

9.3.4. Space-Filling Implants

Breast implants are quite common space-filling implants. At one time, the enlargement of breasts was done with various materials such as paraffin wax, beeswax, silicone fluids, etc. by direct injection or by enclosure in a rubber balloon. There have been several problems associated with directly injected implants, including progressive instability and ultimate loss of original shape and texture, as well as infection, pain, etc. In the 1960s the FDA banned such practices by classifying injectable implants such as silicone gel, as drugs.

One of the early efforts in breast augmentation was to implant a sponge made of polyvinyl alcohol. However, soft tissues grew into the pores and then calcified with time and the so-called marble breast resulted. Although the enlarge- ment or replacement of breasts for cosmetic reasons alone is not recommended, prostheses have been developed for the patient who has undergone radical mastectomy or who has nonsymmetrical deformities. They are probably beneficial for psychological

reasons. In this case a silicone rubber bag filled with silicone gel and backed with polyester mesh to permit tissue ingrowth for fixation, is a widely accepted prosthesis as shown in Figure 9-7. The artificial penis, testicles, and vagina fall into the same category as breast implants in that they make use of silicones and are implanted for psychological reasons rather than to improve physical health.

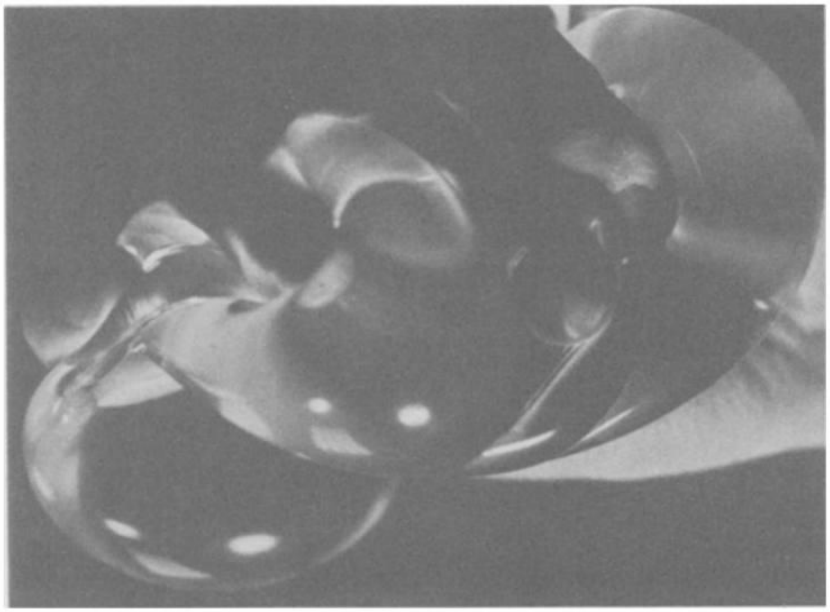


Figure 9-7