Module 5

Tracheal Replacement Devices

- Designs of Artificial Tracheae
  1. Nonporous Tube-Type Artificial Tracheae
  2. Mesh-Type Artificial Tracheae

End-to-end anastomosis has been one of the standard operations for tracheal reconstruction.

Reconstructive methods can be classified into the following three categories:

(1) reconstruction with autologous tissue

(2) reconstruction with nonautologous trachea (that is, transplantation)

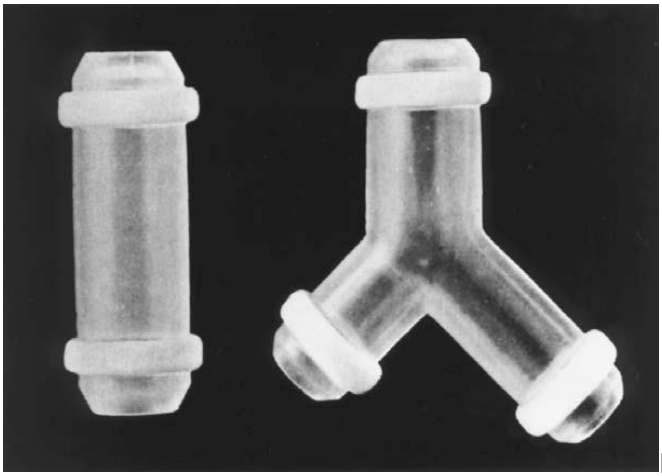
(3) reconstruction with artificial material.

The only one of these operative techniques which achieves good clinical results in the long term is the first (reconstruction with autologous tissue), particularly cervical tracheal reconstruction using an autologous skip flap conduit.

Designs of Artificial Tracheae:

The artificial tracheae developed previously were designed according to one of two concepts.

- One is that the implanted prosthesis alone replaces the resected area of trachea, and the inner surface of the reconstructed trachea is not endothelialized.
- The other is that the implanted prosthesis is incorporated by the host tissue and its inner surface is endothelialized. These two types of prosthesis are called *nonporous* and *mesh types*, respectively, which reflect the materials from which they are made.

 FIGURE 136.1

Neville artificial trachea constructed with a nonporous silicone tube with Dacron suture rings.

Nonporous Tube—Type Artificial Tracheae

- Only one prosthesis of this type remains on the market, the *Neville artificial trachea*, which comprises a silicone tube with two suture rings attached to each of its ends (Fig 136.1).
- late complications, such as migration of the artificial trachea and granular tissue formation at the anastomosis, were inevitable in many cases and occurred within several months and even as late as 2 years after implantation
- Neville prosthesis is not used for patients with benign tracheal disease

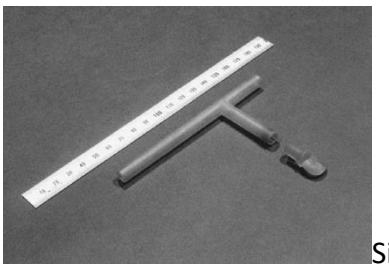
Tracheal replacement using the Neville artificial trachea requires the followingoperative procedure:

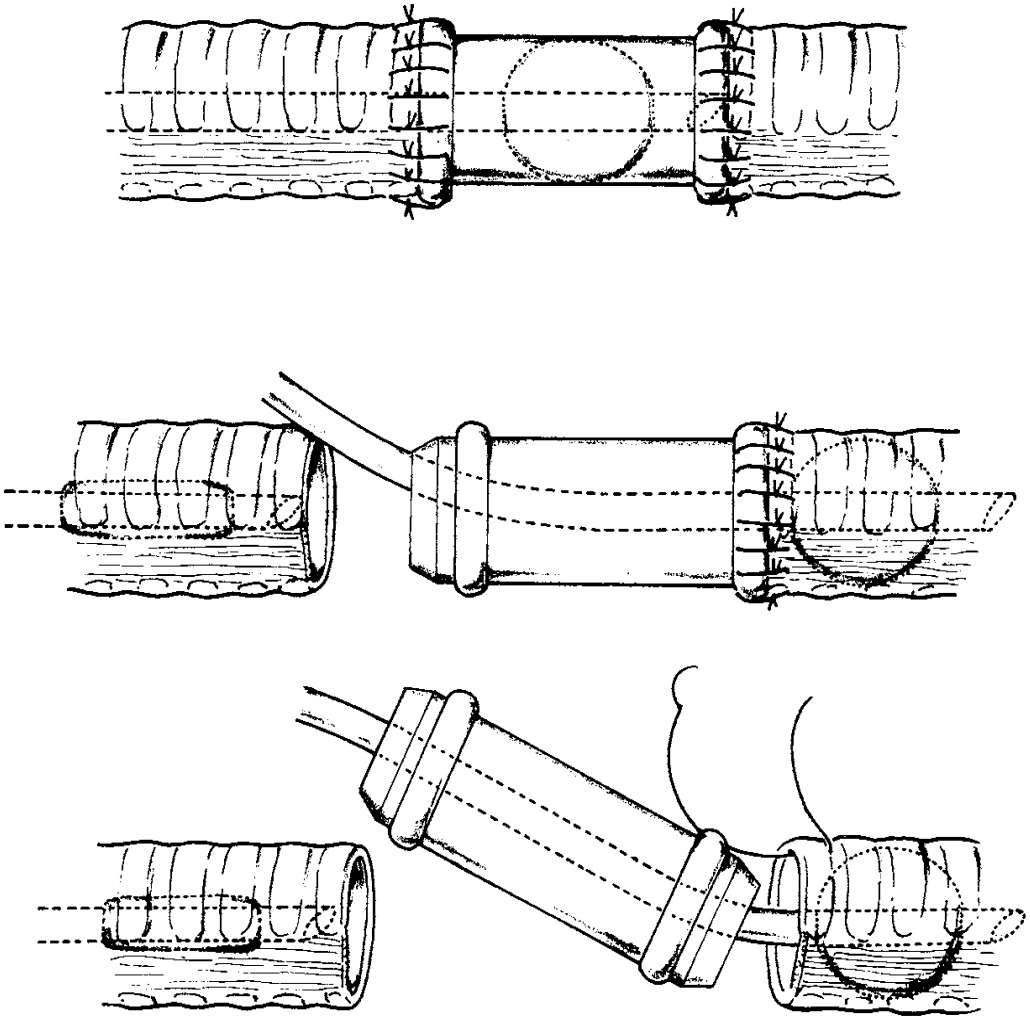
1. *Right-sided posterolateral skin incision and 4th or 5th intercoastal thoracotomy.* Up to the stage of tracheal resection, the operative procedure is similar to that for standard tracheal resection.

2.Reconstruction with an artificial trachea. After resection of the tracheal lesion, the oral intubation tube is drawn back, and the trachea is reintubated via the operative field (Fig. 136.3). In patients who require resection that reaches to near the bifurcation, the second intubation tube should be placed in the left main bronchus. An artificial trachea with a diameter similar to that of the tracheal end is used. Any small differences in their diameters can be compensated for by suturing. Anastomosis is carried out using 4–0 absorbable sutures, 2 mm apart, with interrupted suturing.

3. *Postoperative care* : Frequent postoperative boncofiberscopic checks should be performed to ensure sputum does not come into contact with the anastomosis sites. The recurrent laryngeal nerves on both sides are often injured during the operation, so the movement of the vocal cord should be checked at extubation.

Disadvantage: nonelasticity of the tube and suture rings. Anastomosis have not been conquered


Silicone T-Tube


Operation proceeding of tracheal reconstruction using an artificial trachea.

Mesh-Type Artificial Tracheae

Porous artificial tracheae are called *mesh-type* because the prosthetic trunk is made of mesh.

- In the 1950s, several trials of tracheal reconstruction using metallic meshes made of tantalum and stainless steel were conducted.
- In the 1960s, heavy Marlex mesh was used clinically for tracheal reconstruction, However, long-term observations showed that this mesh caused rupture of the adjacent graft vessels, which was fatal, so it fell gradually out of use for tracheal reconstruction.
- The pore size of materials conventionally used for artificial vessels, such as expanded PTFE (polytetrafluoroethylene, pore size of 15 ~ 30 μ m), is so small that the host tissue cannot penetrate the mesh, which is rejected eventually. The optimal pore size for tracheal replacement mesh is 200 ~ 300 μ m.
- Fine Marlex mesh is made of polypropylene with a pore size 200 ~ 300 μ m (Fig. 136.4).

It is now widely used clinically for abdominal wall reconstruction and reinforcement after inguinal herniation.

- Collagen-grafted fine Marlex mesh is air-tight, and clinically, good tissue regeneration is achieved when it is used to patch-graft of the trachea.
- The grafted collagen has excellent biocompatibility and promotes connective tissue infiltration into the mesh. However, the fine mesh alone is too soft to keep the tube open, so a tracheal prosthesis was made of collagen-grafted fine Marlex mesh reinforced with a continuous polypropylene spiral (Fig. 136.5).
- In dogs, complete surgical resection of a 4-cm length of trachea, which was replaced with a 5-cm long segment of this type of artificial trachea, was performed, and the prostheses were incorporated completely by the host trachea and confluent formation of respiratory epithelium on each prosthetic lumen was observed (Fig. 136.6) [2].
- These results indicate that this artificial trachea is highly biocompatible and promising for clinical application.

Laryngeal Replacement Devices

- Total laryngectomy is one of the standard operations for laryngeal carcinomas.
- As radiation therapy and surgery have progressed, the prognosis associated with laryngeal carcinoma has improved.
- The curability of total laryngeal carcinoma is now almost 70%
- Individuals who have undergone laryngectomy are called *laryngectomees* or *Laryngetomized patients :* laryngeal reconstruction is of the utmost importance.
- However, because the larynx is situated just beneath the oral cavity, where the danger of infection is high, successful reconstruction with foreign materials is very difficult.
- As yet, no total replacement device for the larynx has been developed, and laryngeal transplantation, although apparently feasible, is still at the animal experimental stage.
- The larynx has three major functions:

(1) phonation, (2) respiration, and (3) protection of the lower airway during swallowing.

- Of these, phonation is considered to be the most important.
- The conventional so-called *artificial larynx* can only substitute phonation.
- A variety of methods have been developed to recover phonation after total larygectomy, which is called *vocal rehabilitation*

.

- Methods for vocal rehabilitation are classified as

(1) esophageal speech, (2) artificial larynx, and (3) surgical laryngoplasty.

- The typical devices are the *pneumatic* and *electrical larynx* which are driven by the expiratory force and electric energy, respectively. Tracheoesophageal (T-E) fistula with voice prosthesis is the most popular method in surgical laryngoplasty. Fig. 136.7 illustrates the mechanical structures of typical artificial larynxes.
- The first pneumatic mechanical device was developed by Tapia in 1883.

- The pneumatic device uses expired air from the tracheo Stoma to vibrate a rubber band or reed to produce a low frequency sound, which is ransmitted to the mouth via a tube.
- Pneumatic transoral larynxes produce excellent natural speech, which is better than that with other artificial larynxes, but their disadvantages are that they are conspicuous and that regular cleaning and mopping of saliva leakage is necessary.

Electric Artificial Larynxes

- The *transcervical electrolarynx* is an electric, handheld vibrator that is placed on the neck to produce sound.
- The frequency used is 100 ~ 200 Hz. The vibrations of the electrolarynx are conducted to the neck tissue and create a low-frequency sound in the hypopharynx. This is the most popular artificial larynx.
- The *transoral artificial laryngeal device* is a handheld electric device that produces a low-pitched sound which is transmitted to the back of the mouth by a connecting tube placed in the patient's mouth.

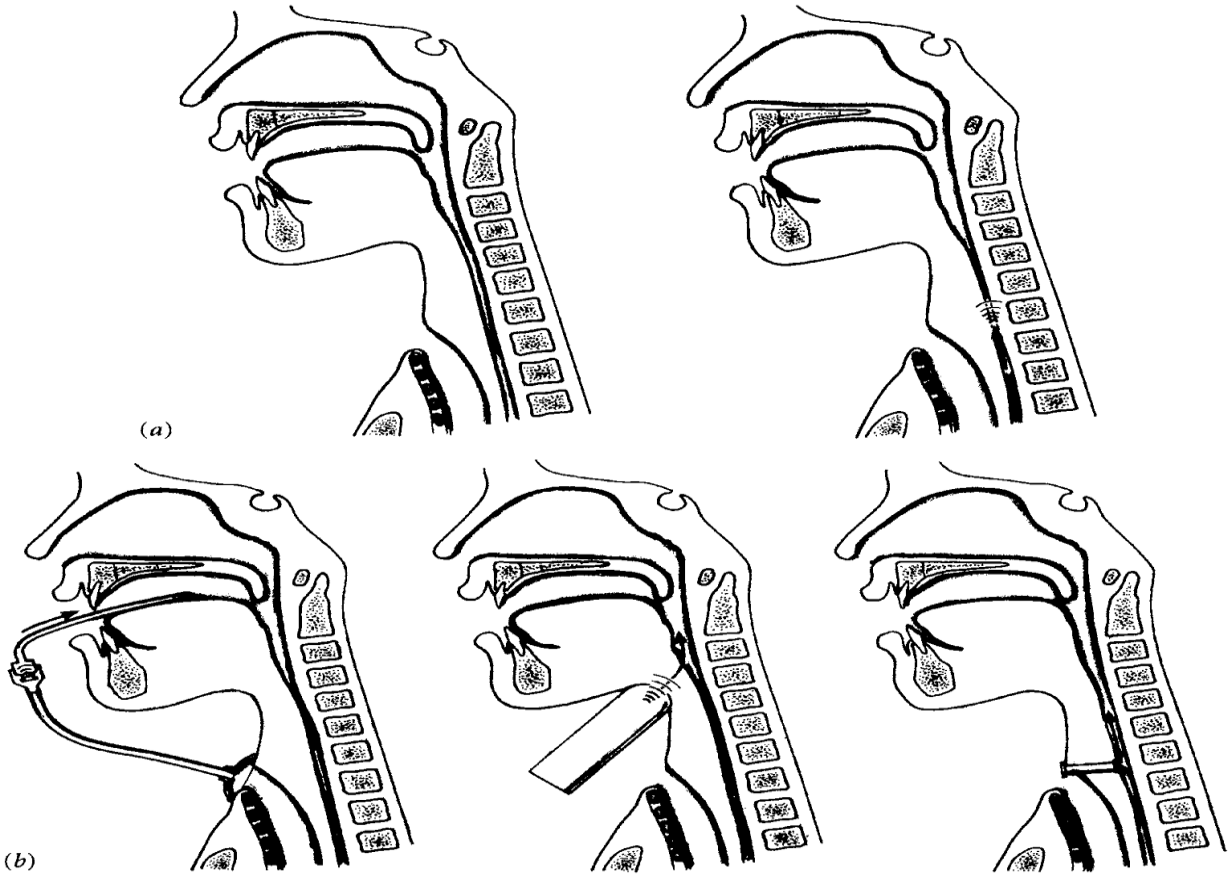


FIGURE 136.7

(*a*) Sagital views of the laryngectomee (left) and esophageal speech (right). Air flow from the esophagus makes the sound. (*b*) Pneumatic larynx (reed type) (left); electric artificial larynx (transcervical type), (center); voice prosthesis (T-E shut) of Blom & Singer method, right.

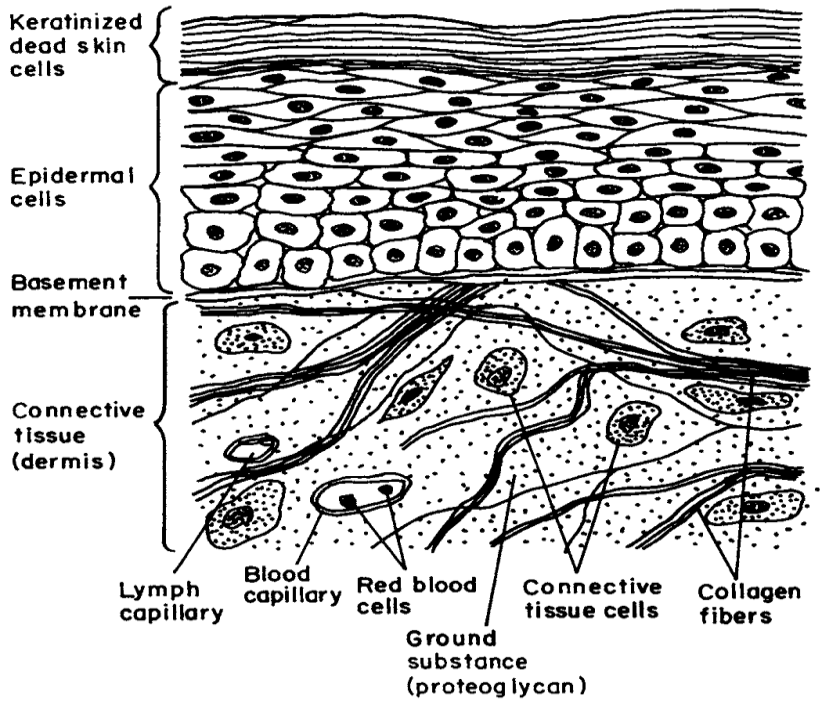
Voice Prostheses

- Tracheo-esophageal (T-E) fistula prostheses are now widely used for vocal rehabilitation, and excellent speech and voice results have been achieved.
- In 1980, Singer and Blom developed and introduced the first simple method, which is called Blom and Singer's voice prosthesis.
- The principle of the tracheo-esophageal fistula technique is to shunt expired pulmonary air through a voice prosthesis device into the esophagus to excite the mucosal tissue to vibrate.
- A fistula is made by puncturing the posterior wall of the trachea 5 mm below the upper margin of the tracheal stoma, and when a patient speaks, he/she manually occludes the stoma to control the expiratory flow through the fistula to the oral cavity.
- The voice prosthesis has a one-way value to prevent saliva leakage (Fig. 136.10).

Vital Functions of Skin

Skin is a vital organ, in the sense that loss of a substantial fraction of its mass immediately threatens the life of the individual. Such loss can result suddenly, either from fire or from a mechanical accident. Loss of skin can also occur in a chronic manner, as in skin ulcers. Irrespective of the time scale over which skin loss is incurred, the resulting deficit is considered life threatening primarily for two reasons: Skin is a barrier to loss of water and electrolytes from the body, and it is a barrier to infection from airborne organisms. A substantial deficit in the integrity of skin leaves the individual unprotected either from shock, the result of excessive loss of water and electrolytes, or from sepsis, the result of a massive systemic infection. It has been reported that burns alone account for 2,150,000 procedures every year in the United States. Of these, 150,000 refer to individuals who are hospitalized, and as many as 10,000 die. Four types of tissue can be distinguished clearly in normal skin. The *epidermis* , outside, is a 0.1-mmthick sheet, comprising about 10 layers of keratinocytes at levels of maturation which increase from the inside out. The *dermis*, inside, is a 2–5-mm-thick layer of vascularized and innervated connective tissue with very few cells, mostly quiescent fibroblasts. The dermis is a massive tissue, accounting for 15–20% of total body weight. Interleaved between the epidermis and the dermis is the *basement membrane*, an approximately 20–nm-thick multilayered membrane

(Fig. below). A fourth layer, the *subcutis*, underneath the dermis and 0.4–4-mm in thickness, comprises primarily fat tissue. In addition to these basic structural elements, skin contains several appendages (*adnexa*), including hair follicles, sweat glands, and sebaceous glands. The latter are mostly embedded in the dermis, although they are ensheathed in layers of epidermal tissue.



Current Treatment of Massive Skin Loss

The treatment of skin loss has traditionally focused on the design of a temporary wound closure. These include membranes or sheets fabricated from natural and synthetic polymers, skin grafts from human cadavers (homografts, or *allografts*), and skin grafts from animals (heterografts, or *xenografts*). Although a satisfactory temporary dressing helps to stem the tide, it does not provide a permanent cover. Polymeric membranes which lack specific biologic activity, such as synthetic polymeric hydrogels, have to be removed after several days due to incidence of infection and lack of formation of physiologic structures. Patients with cadaver allografts and xenografts are frequently immunosuppressed to avoid rejection; however, this is a stop-gap operation which is eventually terminated by removal of the graft after several days. In all cases where temporary dressings have been used, the routine result has been an open wound. Temporary dressings are useful in delaying the time at which a permanent graft, such as an autograft, is necessary and are therefore invaluable aids in the management of the massively injured patient.

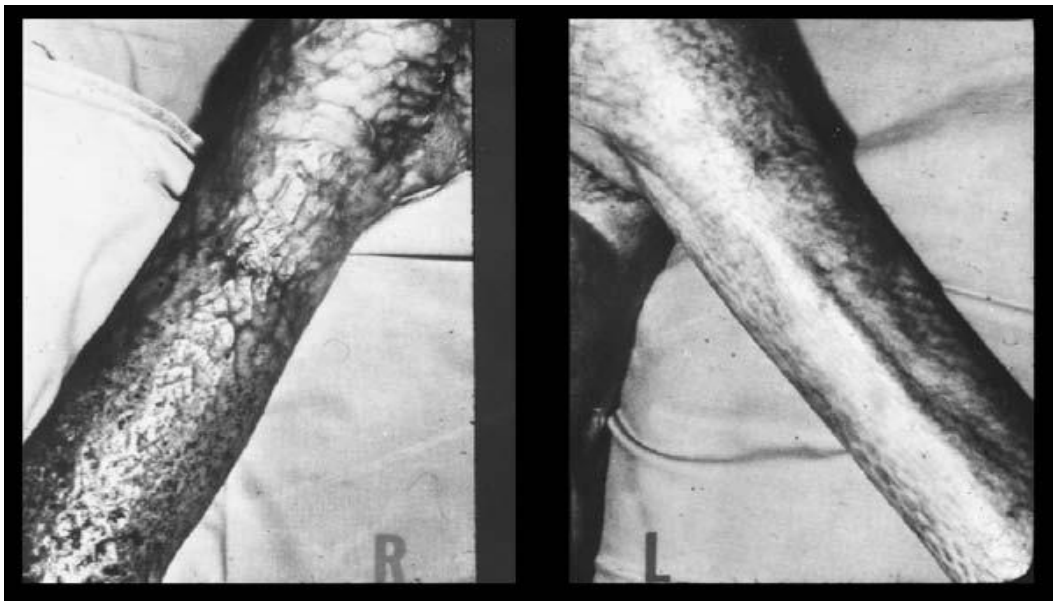


Fig 2 Comparision between treatment with the meshed autograft (R) and treatment with the artificial skin (L). Autograft is usually meshed before grafting; scar forms in areas coinciding with the open slits of the autograft. The artificial skin treatment consists of grafting the excised wound bed with a skin regeneration template, followed by grafting on about day 14 with a very thin epidermal autograft.

The use of an autograft has clearly shown the advantages of a permanent wound cover. This treatment addresses not only the urgent needs but also the long-term needs of the patient with massive skin loss. The result of treatment of a third-degree burn with a split-thickness autograft is an almost fully functional skin which has become incorporated into the patient's body and will remain functional over a lifetime. Autografts usually lack hair follicles and certain adnexa as well. However, the major price paid is the removal of the split thickness graft from an intact area of the patient's body: The remaining dermis eventually becomes epithelialized but not without synthesis of scar over the entire area of trauma (donor site). To alleviate the problem associated with the limited availability of autograft, surgeons have resorted to meshing, a procedure in which the sheet autograft is passed through an apparatus which cuts slits into the sheet autograft, allowing the expansion of the graft by several times and thereby extending greatly the area of use. An inevitable long-term result of use of these meshed autografts is scar synthesis in areas coinciding with the open slits of the meshed graft and a resulting pattern of scar which greatly reduces the value of the resulting new organ (fig 2).

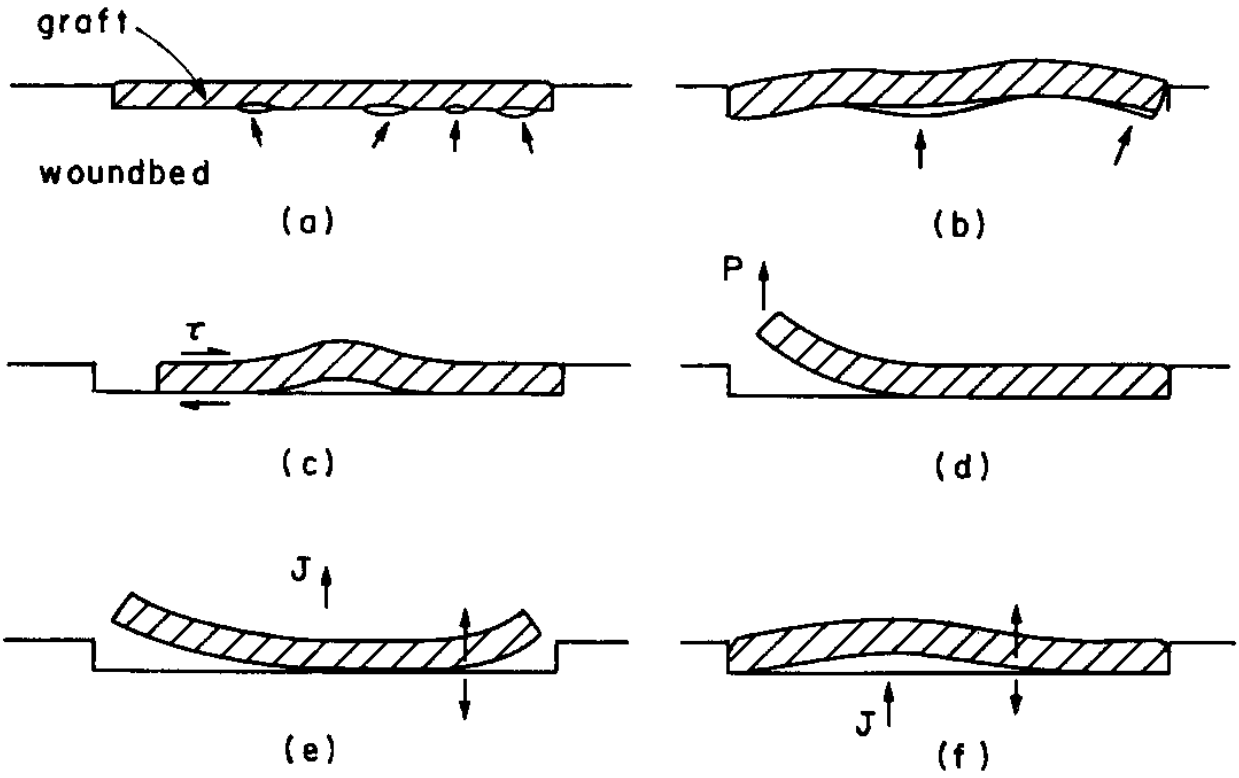
"Skin equivalent" (SE) refers to a collagen lattice which has been prepared by contraction of a collagen gel by heterologous fibroblasts ("dermal equivalent" or DE) and has subsequently been overlayed with a keratinocyte culture to induce formation of a mature, cornified epidermis *in vitro* prior to grafting of skin wounds. Cultured epithelial autografts (CEA) consist of a mature, cornified epidermis which has been produced by culturing keratinocytes *in vitro* , prior to grafting on skin wounds. The major goal of these treatments has been to replace definitively the use of the autograft in the treatment of patients with massive skin loss.

Design Principles for a Permanent Skin Replacement

The analysis of the plight of the patient who has suffered extensive skin loss, presented above, leads logically to a wound cover which treats the problem in two stages. Stage 1 is the early phase of the clinical experience, one in which protection against severe fluid loss and against massive infection are defined as the major design objectives. Stage 2 is the ensuing phase, one in which the patient needs protection principally against disfiguring scars and crippling contractures. Even though the conceptual part of the design is separated in two stages for purposes of clarity, the actual treatment is to be delivered continuously, as will be become clear below. The sequential utilization of features inherent in stages 1 and 2 in a single device can be ensured by designing the graft as a bilayer membrane (Fig. 138.3). In this approach, the top layer incorporates the features of a stage 1 device, while the bottom layer delivers the performance expected from a stage 2 device. The top layer is subject to disposal after a period of about 10–15 days, during which time the bottom layer has already induced substantial synthesis of new dermis. Following removal of the top layer, the epidermal cover is provided either by covering with a thin epidermal graft or by modifying the device (cell seeding) so that an epidermis forms spontaneously by about 2 weeks after grafting.

Stage 1 Design Parameters

The overriding design requirement at this stage is based on the observation that air pockets ("dead space") at the graft-wound bed interface readily become sites of bacterial proliferation. Such sites can be prevented from forming if the graft surface wets, in the physicochemical sense, the surface of the wound bed on contact and thereby displaces the air from the graft-tissue interface.



Certain physicochemical and mechanical requirements in the design of an effective closure for a wound bed with full-thickness skin loss. (*a*) The graft (cross-hatched) does not displace air pockets (arrows) efficiently from the graft-wound bed interface. (*b*) Flexural rigidity of the graft is excessive. The graft does not deform sufficiently, under its own weight and the action of surface forces, to make good contact with depressions on the surface of the wound bed; as a result, air pockets form (arrows). (*c*) Shear stresses τ (arrows) cause buckling of the graft, rupture of the graft-wound bed bond and formation of an air pocket. (*D*) Peeling force *P* lifts the graft away from the wound bed. (*e*) Excessively high moisture flux rate *J* through the graft causes dehydration and development of shrinkage stresses at the edges (arrows), which cause lift-off away from the wound bed. (*f*) Very low moisture flux *J* causes fluid accumulation (edema) at the graft-wound bed interface and peeling off (arrows). When the moisture flux exceeds the desired level, the graft is desiccated, and shrinkage stesses develop which pull the graft away from the wound bed. An estimate of the maximum normal stress can be obtained by modeling the desiccating graft in one dimension as a shrinking elastic beam bonded to a rigid surface.

Stage 2 Design Parameters

The leading design objectives in this stage are two: synthesis of new, physiologic skin and the eventual disposal of the graft. The lifetime of the graft, expressed as the time constant of biodegradation *tb* , was modeled in relation to the time constant for normal healing of a skin incision *th* . The latter is about 25 days. In preliminary studies with animals, it was observed that when matrices were synthesized to degrade at a very rapid rate, amounting to *tb* _*th* , the initially insoluble matrix was reduced early to a liquid like state, which was incompatible with

an effective wound closure. At the other extreme, matrices were synthesized which degraded with exceptional difficulty within 3–4 weeks, compatible with *tb_th*. In these preliminary studies it was observed that a highly intractable matrix, corresponding to the latter condition, led to formation of a dense fibrotic tissue underneath the graft which eventually led to loss of the bond between graft and wound bed. Migration of cells into the porous graft can proceed only if nutrients are available to these cells. Two general mechanisms are available for transport of nutrients to the migrating cells, namely, diffusion from the wound bed and transport along capillaries which may have sprouted within the matrix (angiogenesis). Since capillaries would not be expected to form for at least a few days, it is necessary to consider whether a purely diffusional mode of transport of nutrients from the wound bed surface into the graft could immediately supply the metabolic needs of the invading cells adequately.

The *dermis regeneration template*, a porous matrix unseeded with cells, induces synthesis of a new dermis and solves this old surgical problem. Simultaneous synthesis of a new, confluent epidermis occurs by migration of epithelial cell sheets from the wound edges, over the newly synthesized dermal bed. With wounds of relatively small characteristic dimension, e.g., 1 cm, epithelial cells migrating at speeds of about 0.5 mm/day from each wound edge can provide a confluent epidermis within 10 days. In such cases, the unseeded template fulfills all the design specifications set above. However, the wounds incurred by a massively burned patient are typically of characteristic dimension of several centimeters, often more than 20–30 cm. These wounds are large enough to preclude formation of a new epidermis by cell migration alone within a clinically acceptable timeframe, say 2 weeks. Wounds of that magnitude can be treated by seeding the porous collagen-GAG template, before grafting, with atleast 5 × 10 4 keratinocytes per cm 2 wound area. These uncultured, autologous cells are extracted by applying a cell separation procedure, based on controlled trypsinization, to a small epidermal biopsy.