United States Patent [19]

Sparks

[11] **3,707,958**

[45] **Jan. 2, 1973**

[54] **METHOD OF GROWING A GRAFT MEMBER IN A LIVING BODY**

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[22] Filed: **Aug. 30, 1971**

[21] Appl. No.: **175,915**

Related U.S. Application Data

[60] Division of Ser. No. 823,287, May 9, 1969, Pat. No. 3,625,198, which is a continuation-in-part of Ser. No. 655,838, July 25, 1967, Pat. No. 3,514,791.

[52] **U.S. Cl.** .....**128/1 R,** 128/334 R

[51] **Int. Cl.**.....**A61b 19/00,** A61f 1/24

[58] **Field of Search** .....3/1, DIG. 1; 128/334 R, 1 R, 128/92 R, 92 C, 92 G

[56] **References Cited**

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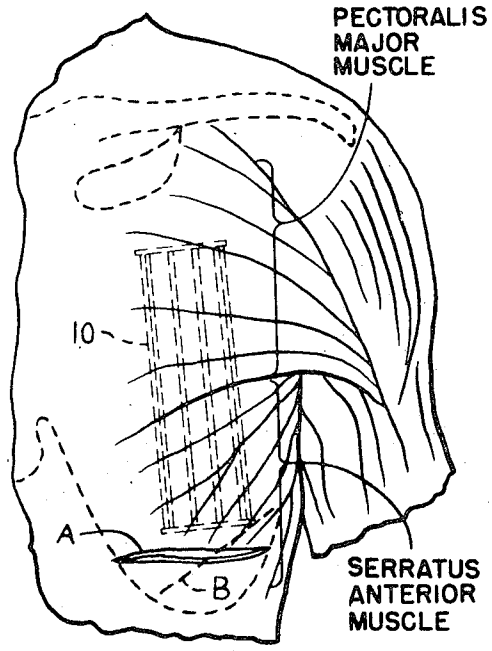
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[57] **ABSTRACT**

A cluster of tubular tissue dies in a die holder is inserted lengthwise in a stab wound. Each die tube is perforated and contains a cloth tube spaced outward from a central mandrel in the tube. Ingrowth of tissue encapsulates the cloth tube and fills the space between the cloth tube and mandrel forming a graft tube containing the cloth tube as a reinforcing member adjacent its outer surface and remote from the lumen formed by the mandrel. The die cluster containing the graft tubes is removed lengthwise from a second stab wound adjacent one end of the cluster.

6 Claims, 13 Drawing Figures



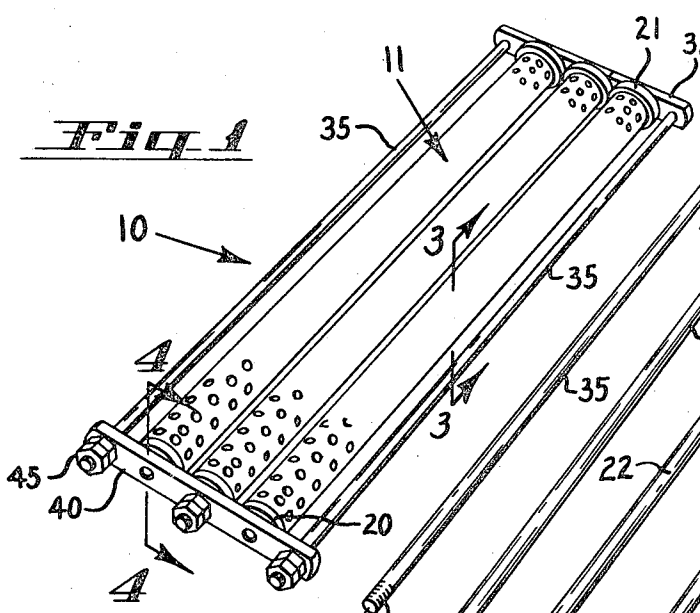


Fig 1

Fig 2

Fig 3

Fig 4

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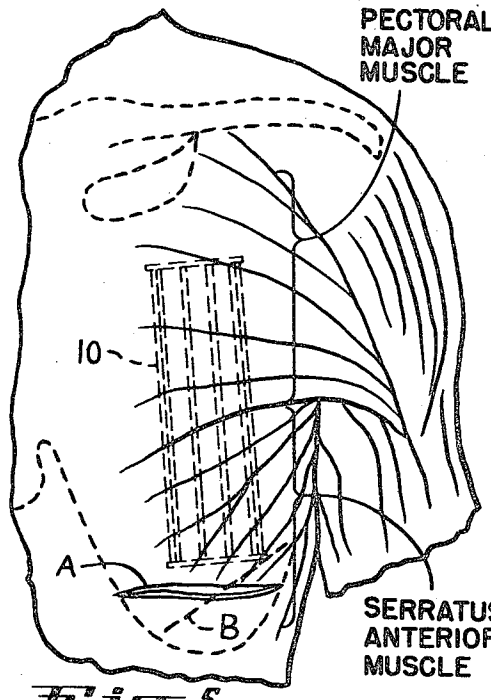


Fig 5

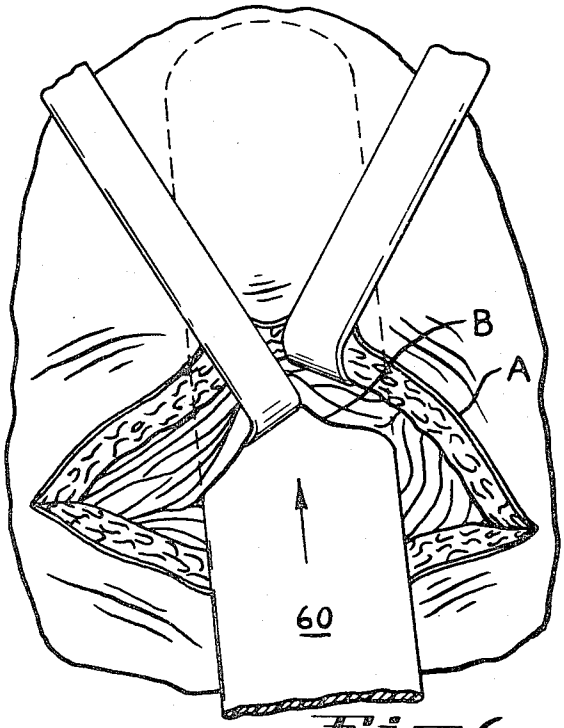


Fig 6

Fig 7

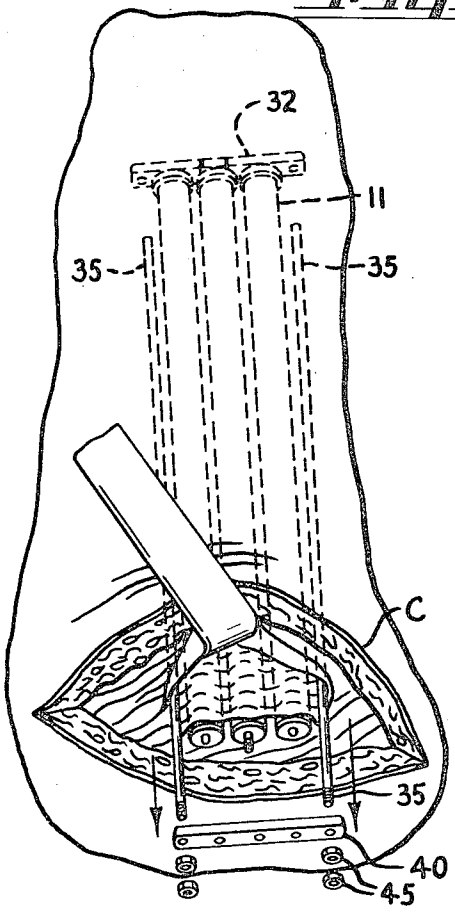


Fig 8

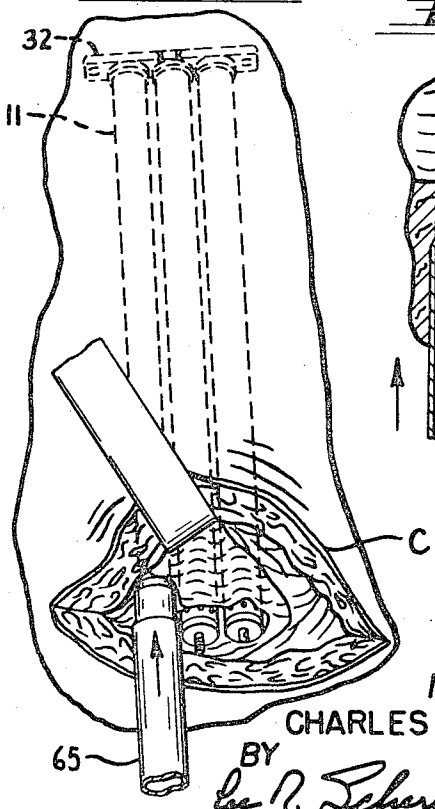
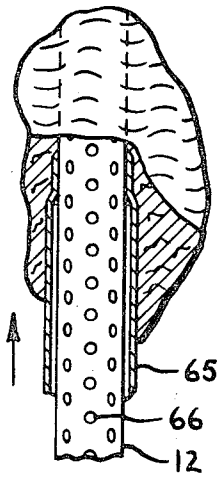


Fig 9



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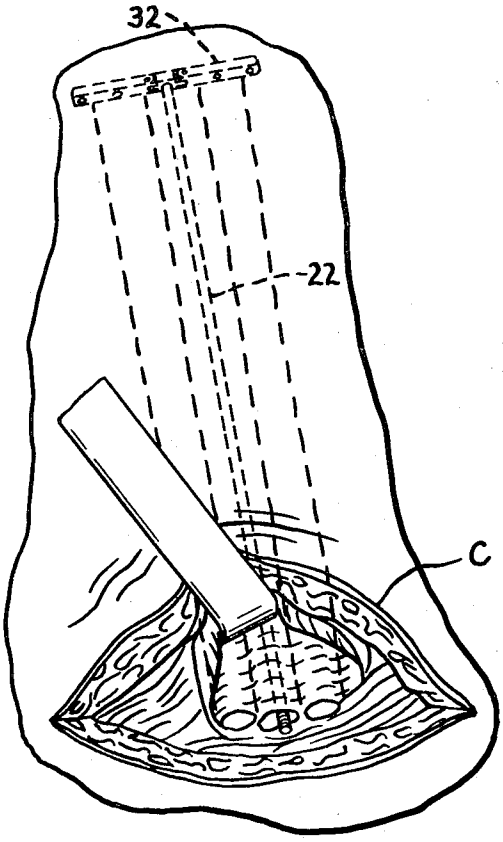


Fig 10

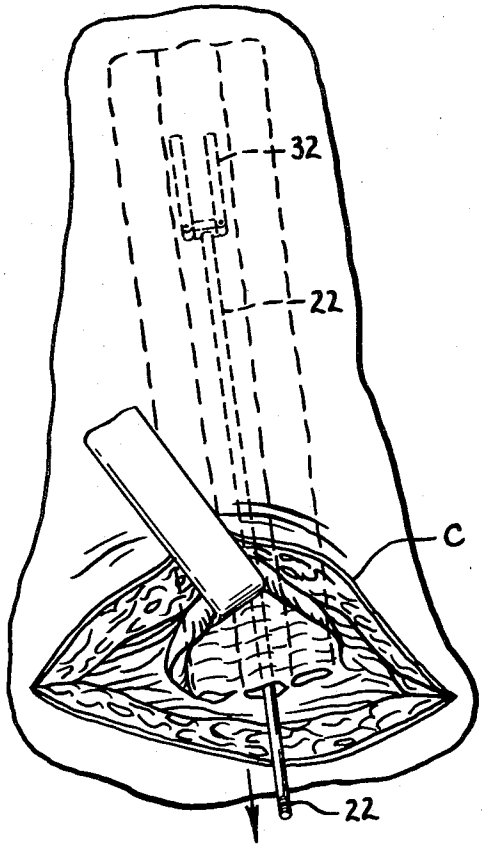


Fig 11

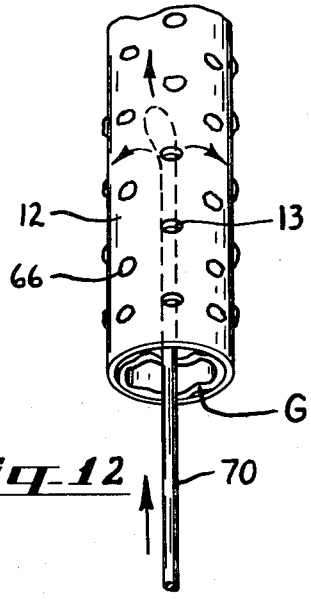


Fig 12

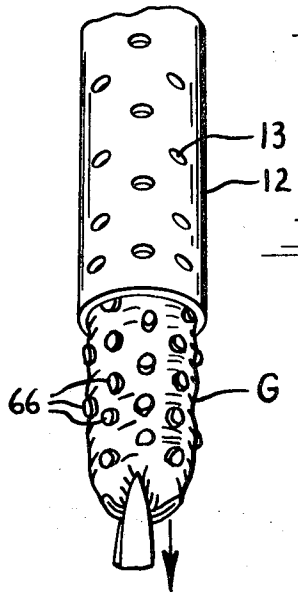


Fig 13

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METHOD OF GROWING A GRAFT MEMBER IN A LIVING BODY

CROSS REFERENCES TO RELATED APPLICATIONS

This application is a division of Ser. No. 823,287 filed May 9, 1969, now U.S. Pat. No. 3,625,198, which is a continuation-in-part of Ser. No. 655,838 filed July 25, 1967, now U.S. Pat. No. 3,514,791.

BACKGROUND OF THE INVENTION

This invention relates to a novel method of growing a graft member in a living body and has particular reference to an improved method of implanting dies in the body for growing the graft members.

My prior application, Ser. No. 655,838, discloses a number of individual dies for growing grafts for different purposes. It is often desired to grow a plurality of grafts at the same time, as for example, when a graft tube is needed of greater length than can be provided in a single implantable die. Also, the need may arise to grow different sizes or types of grafts simultaneously.

Further, an improved technique for implantation is desired. It would be advantageous to obviate the necessity for tying the die or dies to the bone structure of the body and to provide a method of implantation which would not require a large incision.

Objects of the invention are, therefore, to provide an improved tissue graft, to provide an improved cloth reinforcement for a tissue graft, to provide an improved arrangement of a cloth reinforcement within a die cavity, to provide an improved die for forming a tissue graft, to provide a novel die cluster for growing a plurality of tissue grafts simultaneously, and to provide an improved method for implanting a die or die cluster for growing grafts.

SUMMARY OF THE INVENTION

According to the present invention a cloth reinforcing member is impregnated with a stiffening agent so that the cloth may be pre-shaped and will maintain itself in a position in a die cavity where it will be located adjacent the outer surface of the graft tissue. When a plurality of grafts are needed, a number of dies are assembled in a die cluster for implantation as a unit.

Instead of tying the die or die cluster to the rib cage to avoid movement in the body, it is inserted under a layer of muscles overlying the rib cage. The muscles themselves hold the die or die cluster in fixed position against the ribs whereby the dies are easily insertable and removable through a relatively small incision.

Other objects and advantages will become apparent and the invention will be better understood with reference to the following description of the preferred embodiment illustrated in the accompanying drawings. Various changes may be made, however, in the details of the method and in the form of construction of the dies and certain features may be used without others. The invention is of particular advantage in growing autogenous grafts within the body of the same patient who is to receive the grafts but the invention may also be used in growing homografts and heterografts if desired.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a die cluster embodying the principles of the invention;

FIG. 2 is an exploded view of the die cluster in FIG. 1 with parts removed and parts broken away;

FIG. 3 is a sectional view on the line 3—3 in FIG. 1;

FIG. 4 is a sectional view on the line 4—4 in FIG. 1;

FIG. 5 is a fragmentary front elevation view of a patient, showing the die cluster of FIG. 1 implanted;

FIG. 6 is an enlarged view of a portion of FIG. 5 showing the use of a pathfinder for preparing an opening to receive the die cluster;

FIG. 7 is a view similar to FIG. 6 showing a first step in the removal of the dies;

FIG. 8 is a view similar to FIG. 7 showing a subsequent step in removal of the dies;

FIG. 9 is an enlarged view of a portion of FIG. 8 with parts in section;

FIGS. 10 and 11 are views similar to FIGS. 7 and 8 showing subsequent steps in removal of the die cluster;

FIG. 12 is a fragmentary perspective view showing a preliminary step in removal of a graft from a die; and

FIG. 13 is a similar view showing the final step in removal of a graft from a die.

DESCRIPTION OF THE PREFERRED EMBODIMENT

FIG. 1 shows a die cluster **10** containing a plurality of dies **11** for implantation as a unit. By way of example, tubular dies are illustrated for growing artery grafts and the like. Each die comprises essentially an outer cylindrical metal tube **12** containing perforations **13** and an inner cylindrical metal mandrel **14** of smaller diameter. The annular space between the outer surface of the mandrel and the inner surface of tube **12** forms a die cavity **15** for growing a tube graft. Tube **12** and mandrel **14** may be made of a suitable plastic if desired.

Each tube **12** and mandrel **14** is supported at its front end on a plastic ferrule **20** and at its rear end on a plastic ferrule **21**. In the middle die of the cluster these ferrules are mounted on an anchor rod **22** while in the two outside dies the ferrules are mounted on removable rods **23**. The two ferrules **21** on rods **23** are secured thereto by pins **24** while the other ferrules are not attached to their supporting rods. Each ferrule has a stepped end flange portion **25** to support tube **12** and an interior shoulder portion **26** supporting mandrel **14** in concentric position within tube **12**. Flange **25** on each ferrule **20** has the same diameter as the outside diameter of tube **12** while flange **25** on each ferrule **21** is of larger diameter for a purpose which will presently appear.

Mounted on the rear end of anchor rod **22** is a head **30** having hinge pins **31** for pivotal connection with cross bars **32**. The outer end of each cross bar **32** is provided with a threaded hole **33** and its intermediate portion is provided with a smooth hole **34**. The rear ends of rods **23** are received in the holes **34** and a pair of tie rods **35** have threaded engagement with the end holes **33**.

The assemblage thus far described is retained in the cluster by a front cross bar **40**. Cross bar **40** has a central hole **41** to receive anchor rod **22**, end holes **42** to receive tie rods **35**, and intermediate holes **43** to

receive the removable rods **23**, all of these holes being smooth bore. The front ends of rods **22** and **35** are threaded at **44** to receive nuts **45**. Nuts **45** hold all the parts in place and immobilize the hinged joints at **31** to form a rigid relatively flat unit for implantation. Cross bars **32** and **40** and rods **22** and **35** form a frame or die holder which contains the dies **11** in side by side relation.

In order to prevent adherence of the graft to the mandrel **14** the outer surface of the mandrel is preferably coated with a suitable release agent such as Dow Corning resin R–671 or Teflon. To strengthen the graft a cloth reinforcing member **50** is inserted in die cavity **15**. Member **50** is preferably made of woven or knitted seamless tubular construction having such diameter that it will lie against or substantially adjacent outer tube **12** in spaced relation to mandrel **14**. The structural advantages and disadvantages of both woven and knitted materials are well understood by persons skilled in the art. Tube **50** is preferably made of a suitable synthetic fiber such as Dacron. This reinforcement is most effective to prevent leakage or rupture of the graft under arterial blood pressure if the reinforcement is located adjacent the outer surface of the graft tube and relatively remote from the inner surface or lumen.

In order to make the cloth tube **50** support itself and lie substantially smoothly against the inside of tube **12**, the cloth is preferably impregnated with a suitable stiffening agent such as silicone rubber. A preferred procedure is to dip the tube several times in a 1:5 suspension of crude (unvulcanized) silicone rubber in xylene. The tube is hung to dry between dips. It is then stretched on a glass rod having a diameter equal to the inside diameter of tube **12** and vulcanized in stretched condition. This accomplishes a desirable sizing operation. When the cloth tube is removed from the glass rod it holds its diameter, and when installed in the die it automatically positions itself snugly against the inner surface of tube **12**. Impregnation and vulcanization in the manner described also causes the cloth tube to hold its length and causes the junctures of the threads to become locked together, both of which stabilizing factors are especially advantageous with a knitted type of cloth.

Before implantation of the die cluster the die cavities are preferably filled with a suitable nutrient. A preferred method of preparing the nutrient will be described. The quantities given in the following example are not intended to limit the invention but will serve to define the preferred proportions of the ingredients used. First, 50 cc. of the patient's blood is drawn from a vena-puncture into a syringe containing 2 cc. of a solution of 1 million units of penicillin and 1 gram of streptomycin dissolved in 20 cc. of normal saline solution. Then an assembled and sterile die cluster as shown in FIG. **1** is placed in a metal laboratory boat and covered with the blood solution just described. The die cluster is allowed to remain in the blood solution for about 25 minutes so that a strong, firm clot forms, filling the die cavities **15**.

FIGS. **5** and **6** illustrate the method of implantation of the prepared die cluster. A transverse incision A is made in the skin immediately above the costal margin across the mid-clavicular line as shown in FIG. **5**. This incision is carried down to the serratus anterior muscle. If the patient is right-handed this incision is made on the left side, as shown; if the patient is left-handed the incision would be made on the right side. In instances where two long graft tubes are needed, a die cluster is implanted on each antro-lateral chest wall.

After incision A has been made in the skin, the serratus anterior muscle is incised in the direction of its fibers as indicated at B in FIG. **5**. A flat spatula-shaped pathfinder **60** is inserted and passed on the rib cage supero-medially, aiming at the junction of the middle and medial thirds of the clavicle as shown in FIG. **6**. In the proximal one-half of the passage considerable resistance is met as a result of the origins of the serratus anterior muscle. These must be pushed forcefully off the ribs. Essentially no resistance is met as the instrument passes beneath the pectoralis major muscle in the upper half of the passage. Thus, the pathfinder forms a pocket to receive the die cluster. Then the pathfinder **60** is withdrawn.

The die cluster **10** prepared as above described is lifted from the boat and the back end having the jointed cross bar **32** is inserted in the same manner as pathfinder **60** in FIG. **6**. The die cluster is pushed up along the path made by pathfinder **60** until the lower end of the die cluster lies above incision A as shown in FIG. **5**. Finally, the incision is closed in layers using interrupted sutures and a light sterile dressing is applied. The patient is maintained on penicillin and streptomycin until hospital discharge. The patient is normally discharged from the hospital 1 or 2 days after implantation of the dies and resumes normal activity. The die cluster may be made to contain fewer or more than three dies if desired.

The serratus anterior muscle and the pectoralis major muscle clamp the die cluster firmly and rigidly against the ribs and prevent any movement of the die cluster, making it unnecessary to provide any mechanical attachment to the ribs. This makes it possible to insert and remove the die cluster endwise through a relatively small incision which heals quickly. While the die cluster is implanted, body tissue from the patient grows through holes **13** into the die cavity replacing the blood nutrient and encapsulating the reinforcing cloth tube **50**. This ingrowth of tissue completely fills the die cavity and forms the ultimate graft. Mandrel **14** casts a smooth surface on the lumen of the graft tube.

Two or three months later the patient is readmitted to the hospital for the grafting procedure. The grafts are usually complete in two months and are consistently complete at three months. The procedure for removing the dies is shown in FIGS. **7** to **11**. A 3 inch incision C is made over the lower end of the die cluster and perpendicular to its long axis. This incision is carried down through the muscle to the dies. Lower cross bar **40** and the lower 1 cm. of the dies are exposed by sharp dissection. Nuts **45** are removed and cross bar **40** is removed as shown in FIG. **7**, and tie rods **35** are unscrewed from threaded holes **33** in hinged cross bar **32**.

Then a cylindrical cutter **65** is passed onto the exposed end of a die and, using a rotary oscillating motion, is passed up over the entire length of the die as shown in FIGS. **8** and **9**. The larger diameter flanges **25** on plastic ferrules **21** provide stops for the cutter. This operation severs the necks of tissue **66** which have ingrown through the holes **13** in tube **12**. The cutter and

die are then removed and the die containing the graft is removed from the cutter. The remaining two dies are removed in the same manner. In removing the dies, rods **23** come out with the dies while anchor rod **22** remains in the patient.

At this stage only the center anchor rod **22** and the upper jointed cross bar **32** remain in the patient as shown in FIG. **10**. These parts are removed by firm traction on the anchor rod as shown in FIG. **11**, causing the ends of cross bar **32** to pivot back to trailing position, as shown. Incision C is closed in layers using interrupted silk sutures.

Using a surgical knife, the outer surface of each tube **12** is completely cleansed of all fragments of tissue and the mandrel **14** is extracted from each die. This is done by pushing the mandrel from one end to expose its other end which is then grasped with a small hemostat and extracted.

A gall bladder probe **70** is then passed between the graft G and the inner surface of tube **12** at several points around the circumference as shown in FIG. **12**. With each pass, it is passed throughout the length of the die, releasing the graft from the outer tube by withdrawing the necks of tissue **66** inwardly through the holes **13**. After the graft is completely freed from tube **12** in this manner, it may be grasped at one end with a hemostat and extracted as shown in FIG. **13**.

When a long graft tube is needed, the individual grafts from the three dies may be sutured together end to end over a glass rod, the ends of the grafts preferably being cut on a 45 degree angle for each anastomosis. In this manner a graft tube approximately 19 inches long may be made.

When only a short graft is needed, a single die similar to the central die is used with a modified form of die holder. In such case, cross bar **40** and hinged cross bars **32** are made shorter and holes **34** and **43** are omitted. This makes a narrower and more compact unit placing the tie rods **35** adjacent opposite sides of the single die on anchor rod **22**. When the die is round, the die holder prevents rotation in the body. When the die and die holder are of small size, the unit may simply be inserted in a stab wound directed as explained in connection with FIGS. **5** and **6**.

The invention is not limited to tube grafts. Dies for other graft members may also be implanted essentially as described in connection with FIGS. **5** and **6**. When the die is not round, the die holder may be eliminated if desired but a die holder may still be desirable for convenience in handling a single die or cluster of dies.

Having now described my invention and in what manner the same may be used, what I claim as new and desire to protect by Letters Patent is:

1. The method of forming a graft member comprising providing a perforated die having a die cavity; cutting an incision in the skin transversely immediately above the costal margin across the mid-clavicular line carrying the incision down to the serratus anterior muscle, incising said muscle in the direction of its fibers; inserting a flat, elongated pathfinder into said opening in an upward direction, passing said pathfinder on the rib cage supero-medially aiming at the junction of the middle and medial thirds of the clavicle and pushing the serratus anterior muscle forcefully off the ribs; and then withdrawing said pathfinder; inserting said die in the pocket formed by said pathfinder; said serratus anterior muscle clamping the die firmly against the ribs; closing said incision and leaving said die in said pocket for a time sufficient for connective tissue to grow into the die and form said graft member within the die cavity; making an incision for removal of said die; cutting said connective tissue on the outside surface of the die; removing the die containing said graft member; and then removing the graft member from the die.

2. The method of claim **1** wherein a cluster of dies in a die holder is implanted as a unit in said pocket.

3. The method of implanting a die in a living body for forming a graft member comprising cutting a transverse incision in the skin immediately above the costal margin across the mid-clavicular line carrying the incision down to the serratus anterior muscle, incising said muscle in the direction of its fibers; inserting a flat, elongated pathfinder into said incision in an upward direction, passing said pathfinder on the rib cage supero-medially aiming at the junction of the middle and medial thirds of the clavicle and pushing the serratus anterior muscle forcefully off the ribs; withdrawing said pathfinder and inserting said die in the position prepared by the pathfinder, said serratus anterior muscle clamping the die firmly against the ribs without mechanical anchoring means.

4. The method of implanting a die in a living body for forming a graft member in the die comprising cutting an incision in the skin, inserting a flat, elongated pathfinder into said incision separating the body tissues and forming a pocket to receive said die, withdrawing said pathfinder, inserting said die in said pocket, and closing said incision.

5. The method of claim **4** wherein said pathfinder is inserted under a layer of muscle so that the muscle will clamp said die in said pocket.

6. The method of claim **5** wherein said pathfinder is inserted between said layer of muscle and an underlying bony structure so that the muscle will clamp the die against said bony structure.

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