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(54) SURGICAL IMPLANT

CHIRURGISCHES IMPLANTAT

IMPLANT CHIRURGICAL

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Description

Field of Invention

[0001] The invention relates to the field of surgery and the provision of implants, particularly in neurosurgery.

Background

[0002] In response to various injuries and conditions surgeons often find it necessary to separate or remove tissue from a patient. In some procedures it is desirable that tissue does not grow onto or adhere to other tissue during healing.

[0003] Decompressive craniectomy is an example of such a case. This is a neurosurgical procedure in which part of the skull is removed to allow a swelling brain room to expand. It is performed on patients that have incurred a traumatic brain injury (TBI) such as following a car accident or a fall or in patients that have suffered a stroke.

[0004] When a neurosurgeon performs a decompressive craniectomy, part of the skull is removed and either a) stored in the patient's abdomen b) stored in a bone fridge or c) discarded.

[0005] Typically for a TBI, a 10-13cm round piece of bone is removed. The surgeon will cut along the hair line through the skin down to the bone and peel the 'skin flap' back. The surgeon will then remove bone (craniectomy) and not disturb the underlying layer of tissue, known as the dura mater.

[0006] The dura mater or dura is the outermost of the three layers of the meninges surrounding the brain and spinal cord. The other two meningeal layers are the pia mater and the arachnoid mater. The dura surrounds the brain and the spinal cord and is responsible for keeping in the cerebrospinal fluid. The bone is removed and the skin and periosteum (membrane covering the bone) is sutured back up and the patient is generally sedated in ICU to allow the brain to swell. A patient can then leave the hospital and function mindful of the area in their brain unprotected by bone.

[0007] The patient can return for surgery to restore the cranial vault in 6 weeks to 2 years. During this time, the dura will adhere and scar to the subcutaneous tissue.

[0008] To repair the cranium, the surgeon needs to reopen the same wound, and carefully separate the dura from the skin and subcutaneous tissue because the bone or implant is usually placed between these layers. This generally takes 45-60 minutes and can cause the dura to be nicked or torn.

[0009] While some surgeons improvise by using plastic bags and other *ad hoc* measures to minimize tissue adhesion, there are some basic flat silicone sheets, such as those by Bentec Medical, on the market which may be used.

[0010] Seprafilm® Adhesion Barrier (membrane) is an example of a basic flat sheet. This product is a sterile, bioresorbable, translucent adhesion barrier. Seprafilm Adhesion Barrier is indicated for use in patients undergoing abdominal or pelvic laparotomy as an adjunct intended to reduce the incidence, extent and severity of postoperative adhesions between the abdominal wall and the underlying viscera such as omentum, small bowel, bladder, and stomach, and between the uterus and surrounding structures such as tubes and ovaries, large bowel, and bladder.

[0011] Perthese ® by Mentor is yet another example of silicone sheeting that is flexible. This is a translucent silicone elastomer sheeting material designed for medical and laboratory applications. It is made from an enhanced tear resistant elastomer that consists of dimethyl and methyl vinyl siloxane copolymers which are available as non-reinforced, reinforced and non reinforced extra firm varieties.

[0012] GORE PRECLUDE® PDX Dura Substitute is also available. This product is a flat sheet of opaque white material composed of PTFE (polytetrafluoroethylene) and is indicated for use as a temporary or permanent prosthesis for repair of dura mater during neurosurgery. GORE PRECLUDE® PDX Dura Substitute is for staged procedures and those that may require re-operation, such as, decompressive craniectomies, brain electrode mapping for seizure disorders, recurrent brain and spinal tumors.

[0013] US 2005/0283256 discloses a collagen device having a plurality of pores. The device is designed to be in contact with bodily tissue and to be fully resorbable. The device is flat and may be curved in use.

[0014] US 2003/0204270 discloses an implant comprising a textured, discontinuous outer polymer layer, a second elastomeric layer and a third barrier layer. The textured layer is provided to encourage rapid incorporation and anchoring into surrounding tissue.

[0015] US 2006/0224242 discloses an implant made of a planar sheet of a thermoplastic resin having metal mesh or metal plates contained therein. The implant may be bent and retain its shape. However the implant is not elastic.

[0016] The above references to and descriptions of prior proposals or products are not intended to be, and are not to be construed as, statements or admissions of common general knowledge in the art.

Summary

[0017] In one aspect the present invention provides an elastic surgical implant comprising a biologically inert, curved, sheet of silicone or polytetrafluoroethylene, said sheet having a thickness of less than 0.5 mm, wherein the implant is pre-formed to conform to the anatomy of the cranium wherein, wherein in use, the implant provides a barrier between layers of tissue such that tissue on one side of the implant does not adhere to tissue on the other, and wherein, in use, the implant flexes to accommodate a swelling brain, the improvement comprising that the implant is made of suitably anatomically shaped surgi-

cally acceptable sheet material.

[0018] The surgical implant may be for temporary or permanent use. Preferably the implant is for temporary use.

[0019] The term "suitably anatomically shaped" refers to a shape which suits the anatomy of the body where the implant is to be used. Preferably the material is shaped to conform to a region of the human cranium. More preferably the material is shaped to conform to the temporo-parietal or frontal lobe of the cranium. Preferably the pre-contoured material is suitable for left and right sides of the frontal lobe (bi-frontal) or suitable for the temporo-parietal lobe. Conveniently the pre-contoured material for the left or right side of the frontal lobe is adjustable for the left or right side by inverting the material from one side to the other. More preferably the surgical implant is oversized enabling the surgeon to trim it to suit the required size of the cranial defect.

[0020] The term "surgically acceptable sheet material" refers to implant material that is biologically inert relatively thin material such as sheet material in the form of silicone or polytetrafluoroethylene. The sheet material may include a matrix, mesh, gauze and the like. The sheet material may also be transparent or opaque. The material may be biodegradable and/or resorbable.

[0021] Preferably the sheet material is thin and flexible. The sheet has a thickness of less than 0.5mm. Preferably the sheet material is around 0.5mm thick and is made of pre-shaped medical grade silicone film.

[0022] Optionally the sheet material is reinforced in certain areas to assist in suture retention; the reinforcement including increasing the material thickness or adding a second, more resilient material, such as woven polyester. Additionally the surgical implant may contain fixation sites, such as perforations, with or without reinforcement, that allow sutures screws or rivets to be used to secure the implant to the surrounding hard or soft tissues. Preferably the sheet material includes one or more areas of reinforcement adapted to prevent sutures from pulling out or cutting through the sheet.

[0023] Optionally the sheet material may have other useful properties. For example the sheet material may incorporate one or more pharmaceutical compositions, such as antibiotics and anti inflammatory compounds. Such agents may be introduced via material porosity or via the incorporation of a second material with such porosity that may or may not be biodegradable at a predetermined rate.

[0024] The present invention is pre-shaped/contoured to allow the implant to conform to the anatomy of the cranium. Other advantages include that the implant is thin and flexible and or elastic, allowing the brain to continue to swell after initial surgery. Further, the implant is modifiable which means that it can be trimmed intraoperatively. The implant may be permanent so that it will not resorb or be semi-permanent or slowly resorbable so re-implantation of the bone or another implant can be carried out at the best time to promote patient recovery.

[0025] In another aspect the invention provides an implant for use in a surgical method of providing a barrier between layers of tissue by use of the implant such that tissue on one side of the implant does not adhere to tissue on the other side, the improvement comprising appropriately inserting into a patient the implant wherein the implant is made of suitably anatomically shaped surgically acceptable sheet material.

[0026] Preferably the implant used is that according to the first aspect of the invention in a decompressive craniectomy or when a second stage cranioplastic procedure is likely to be necessary.

[0027] In another aspect, the invention provides an implant made of suitably anatomically shaped surgically acceptable biocompatible sheet material incorporating monitoring probes. Such probes may be incorporated into the invention at the time of manufacture or be attached to specially designed fixtures that allow such probes to be held in position such that they may be secured in direct contact with the underlying brain or associated structures by way of apertures within the implant. Such probes may have one or numerous monitoring functions such as intracranial pressure, temperature, electroencephalometric, blood gas saturation, pH, and microdialysis for biochemical monitoring.

[0028] In yet another aspect, the invention provides an implant made of suitably anatomically shaped surgically acceptable sheet material incorporating therapeutic delivery mechanisms or substances. Such mechanisms or substances may be incorporated into the implant at the time of manufacture by direct binding via porosity of the material or be bound to an incorporated delivery material. Alternatively, the mechanisms or substances may be attached to specially designed fixtures that allow such probes to be held in position such that they may be secured in direct contact with the underlying brain or associated structures by way of apertures within the implant. Such a mechanism may incorporate enclosed channels within the implant to deliver therapeutic substances to the brain and associated tissues via apertures or probes. Such substances may include antibiotic, anticonvulsant, stem cells or drugs that limit secondary neuronal damage. Such a mechanism may include slow release biodegradable substances that release therapeutic agents in a predictable time released way.

[0029] Another aspect of the invention relates to the provision of an implant made of suitably anatomically shaped surgically acceptable sheet material with an enclosed system of channels that allow the circulation of fluid to and from an external device incorporating a positive or negative pressure hydraulic pump. For example such a system could allow the circulation of fluid to modify the temperature of the brain. Such a system could induce regional hypothermia of the brain.

[0030] Yet another aspect of the invention relates to the provision of an implant made of suitably anatomically shaped surgically acceptable sheet material with a network of channels that allow the closed circulation of fluid

to and from an external device incorporating a positive or negative pressure hydraulic pump. A semi-permeable membrane may be used between such channels and the surface of the brain. The membrane may be designed so that only substances with specific molecular weights may cross. This would allow osmotic forces to be harnessed and allow substance or fluids to cross selectively to or from the brain for therapeutic purposes.

[0031] Still another aspect of the invention relates to the provision of an implant made of suitably anatomically shaped surgically acceptable sheet material with porosity or a scaffold and a network of channels to and from an incorporated port or reservoir. Such a port could be accessed percutaneously via injection or through access apertures so that therapeutic substances and stem cells could be introduced to promote the formation of new bone to integrate the invention with the surrounding skull.

Brief Description of the Figures

[0032] Figure 1 is a representation of implants suitable for procedures on the temporo-parietal and the frontal lobe of a human cranium.

Detailed Description of Illustrative Embodiment of the Invention

[0033] The invention will now be described with reference to the following non limiting illustration.

[0034] Figure 1 shows the implant of the invention suitable for temporo-parietal and frontal lobe use on a skull. The surgeon uses standard surgical techniques to fit the implant however it should be noted that compared to using a flat sheet the pre-shaped and contoured implant of the present invention is simpler to fit, saves operating theatre time and minimizes discomfort as a flat sheet may buckle or overlap. Further, the curved nature of the implant of the present invention means that it is more likely to remain in place in the defect. A flat sheet may buckle or overlap and cause discomfort and make a second procedure necessary.

[0035] Throughout this specification and the claims that follow, unless the context requires otherwise the words "comprise", "comprises", "comprising" will be understood to mean the inclusion of the stated integer, step or group of integers or steps but not the exclusion of any of other integer, step or group of integers or steps.

Claims

1. An elastic surgical implant comprising a biologically inert, curved, sheet of silicone or polytetrafluoroethylene, said sheet having a thickness of less than 0.5 mm, wherein the implant is pre-formed to conform to the anatomy of the cranium wherein, in use, the implant provides a barrier between layers of tissue such that tissue on one side of the implant does not adhere to tissue on the other and wherein, in use, the implant flexes to accommodate a swelling brain.

2. The implant of claim 1, wherein the sheet is pre-shaped to a contour of frontal or temporo-parietal regions of the cranium.

3. The implant of claim 1 or 2, wherein the sheet is medical grade flexible silicone film.

4. The implant of any preceding claim, wherein the sheet is reinforced in areas for suture retention, or the sheet contains fixation sites that allow sutures screws or rivets to be used to secure the implant to the surrounding hard or soft tissues.

5. The implant of any preceding claim, wherein the sheet incorporates one or more pharmaceutical compositions.

6. The implant of claim 5, wherein the one or more pharmaceutical compositions include antibiotics or anti inflammatory compounds.

7. The implant of any preceding claim, wherein the sheet incorporates monitoring probes.

8. The implant of claim 7, wherein the monitoring probes have one or numerous monitoring functions selected from intracranial pressure, temperature, electroencephalometric, blood gas saturation, pH and microdialysis for biochemical monitoring.

9. The implant of any preceding claim, wherein the sheet incorporates therapeutic delivery mechanisms or substances.

10. The implant of claim 9, wherein the sheet further includes enclosed channels to deliver therapeutic substances to the brain and associated tissues via apertures or probes.

11. The implant of any preceding claim, wherein the sheet further includes either, a closed system of channels that allow circulation of fluid or a network of channels that allow closed circulation of fluid, to and from an external device incorporating a positive or negative pressure pump.

12. The implant of claim 11, further including a semi-permeable membrane between the channels and the surface of the brain.

13. The implant of claim 12, wherein the membrane is designed so that only substances with specific molecular weights may cross.

14. The implant of any preceding claim, wherein the

sheet comprises a scaffold and a network of channels to and from an incorporated port or reservoir.

15. The implant of claim 14, wherein the implant is arranged such that, in use, a port is accessible percutaneously via injection or through access apertures so that therapeutic substances and stem cells can be introduced to promote the formation of new bone to integrate the implant with the surrounding skull.

Patentansprüche

1. Elastisches chirurgisches Implantat, umfassend eine biologisch inerte, gekrümmte Lage aus Silikon oder Polytetrafluorethylen, wobei die Lage eine Dicke von weniger als 0,5 mm aufweist, das Implantat vorgeformt ist, um sich der Anatomie des Schädels anzupassen, das Implantat bei Gebrauch eine Barriere zwischen Gewebeschichten bereitstellt, sodass Gewebe auf einer Seite des Implantats nicht an Gewebe auf der anderen Seite haftet, und wobei sich das Implantat bei Gebrauch biegt, um sich einem schwellenden Hirn anzupassen.

2. Implantat nach Anspruch 1, wobei die Lage auf eine Kontur der frontalen oder temporoparietalen Regionen des Schädels vorgeformt ist.

3. Implantat nach Anspruch 1 oder 2, wobei die Lage eine Folie aus flexiblem Silikon von medizinischer Qualität ist.

4. Implantat nach einem der vorhergehenden Ansprüche, wobei die Lage in Bereichen zur Nahtretention verstärkt ist oder die Lage Fixierstellen enthält, die die Verwendung von Nahtschrauben oder -nieten ermöglichen, um das Implantat an den umgebenden Hart- oder Weichgeweben zu sichern.

5. Implantat nach einem der vorhergehenden Ansprüche, wobei in die Lage eine oder mehrere pharmazeutische Zusammensetzungen eingebaut sind.

6. Implantat nach Anspruch 5, wobei die eine oder mehreren pharmazeutischen Zusammensetzungen Antibiotika oder antientzündliche Verbindungen einschließen.

7. Implantat nach einem der vorhergehenden Ansprüche, wobei in die Lage Monitoringsonden eingebaut sind.

8. Implantat nach Anspruch 7, wobei die Monitoringsonden eine oder zahlreiche Monitoringfunktionen ausgewählt aus intrakraniellem Druck, Temperatur, Elektroenzephalometrie, Blutgassättigung, pH-Wert und Mikrodialyse für biochemisches Monitoring aufweisen.

9. Implantat nach einem der vorhergehenden Ansprüche, wobei in die Lage Mechanismen zur Abgabe von Therapeutika oder Substanzen eingebaut sind.

10. Implantat nach Anspruch 9, wobei die Lage ferner umschlossene Kanäle zur Abgabe von therapeutischen Substanzen an das Hirn und assoziierte Gewebe mittels Öffnungen oder Sonden einschließt.

11. Implantat nach einem der vorhergehenden Ansprüche, wobei die Lage ferner entweder ein geschlossenes System von Kanälen, das Zirkulation von Fluid ermöglicht, oder ein Netzwerk von Kanälen, das geschlossene Zirkulation von Fluid ermöglicht, zu und von einer externen Vorrichtung einschließt, in die eine Positiv- oder Negativdruckpumpe eingebaut ist.

12. Implantat nach Anspruch 11, das ferner eine semipermeable Membran zwischen den Kanälen und der Oberfläche des Hirns einschließt.

13. Implantat nach Anspruch 12, wobei die Membran so konzipiert ist, dass nur Substanzen mit bestimmten Molekulargewichten hindurchgelangen können.

14. Implantat nach einem der vorhergehenden Ansprüche, wobei die Lage ein Gerüst und ein Netzwerk von Kanälen zu und von einem eingebauten Port oder Reservoir umfasst.

15. Implantat nach Anspruch 14, wobei das Implantat so angeordnet ist, dass bei Gebrauch ein Port perkutan über Injektion oder Zugangsöffnungen zugänglich ist, so dass therapeutische Substanzen und Stammzellen eingebracht werden können, um die Bildung von neuem Knochen zur Integration des Implantats in den umgebenden Schädel zu fördern.

Revendications

1. Implant chirurgical élastique, comprenant une feuille de silicone de polytétrafluoroéthylène courbe, biologiquement inerte, ladite feuille présentant une épaisseur inférieure à 0,5 mm, l'implant étant préformé pour s'adapter à l'anatomie du crâne, l'implant fournissant une barrière entre des couches de tissu pendant l'utilisation, de sorte que le tissu situé sur un côté de l'implant n'adhère pas au tissu situé de l'autre côté, et l'implant se courbant pendant l'utilisation pour s'adapter à un oedème cérébral.

2. Implant selon la revendication 1, dans lequel la feuille est préformée selon un contour de zones frontales ou temporo-pariétales du crâne.

3. Implant selon la revendication 1 ou 2, dans lequel la feuille est un film de silicone souple de qualité médicale.

4. Implant selon l'une quelconque des revendications précédentes, dans lequel la feuille est renforcée dans certaines zones pour la rétention de sutures, ou la feuille contient des points de fixation permettant d'utiliser des vis ou des rivets de suture pour fixer l'implant aux tissus durs ou mous environnants.

5. Implant selon l'une quelconque des revendications précédentes, dans lequel la feuille inclut une ou plusieurs compositions pharmaceutiques.

6. Implant selon la revendication 5, dans lequel les une ou plusieurs compositions pharmaceutiques comprennent des composés antibiotiques ou anti-inflammatoires.

7. Implant selon l'une quelconque des revendications précédentes, dans lequel la feuille inclut des échantillons de contrôle.

8. Implant selon la revendication 7, dans lequel les échantillons de contrôle présentant une ou plusieurs fonctions de contrôle sélectionnées parmi la pression intracrânienne, la température, l'électroencéphalométrie, la saturation en gaz dans le sang, le pH et la microanalyse pour un contrôle biochimique.

9. Implant selon l'une quelconque des revendications précédentes, dans lequel la feuille inclut des mécanismes ou substances de traitement thérapeutique.

10. Implant selon la revendication 9, dans lequel la feuille comprend en outre des canaux fermés destinés à délivrer des substances thérapeutiques au cerveau et aux tissus associés par des orifices ou des sondes.

11. Implant selon l'une quelconque des revendications précédentes, dans lequel la feuille comprend en outre soit un système fermé de canaux permettant une circulation de fluide, ou un réseau de canaux permettant une circulation fermée de fluide, vers à et à partir d'un dispositif externe comprenant une pompe à pression positive ou négative.

12. Implant selon la revendication 11, comprenant en outre une membrane semi-perméable entre les canaux et la surface du cerveau.

13. Implant selon la revendication 12, dans lequel la membrane est conçue de manière à ne laisser passer que des substances présentant des poids moléculaires spécifiques.

14. Implant selon l'une quelconque des revendications précédentes, dans lequel la feuille comprend un support et un réseau de canaux vers et à partir d'un orifice ou réservoir incorporé.

15. Implant selon la revendication 14, dans lequel l'implant est conçu de telle façon que pendant l'utilisation, un orifice est accessible par voie percutanée par injection ou à travers des orifices d'accès, de sorte que des substances thérapeutiques et des cellules souches peuvent être introduites pour favoriser la formation d'os nouveau afin d'intégrer l'implant dans le crâne environnant.

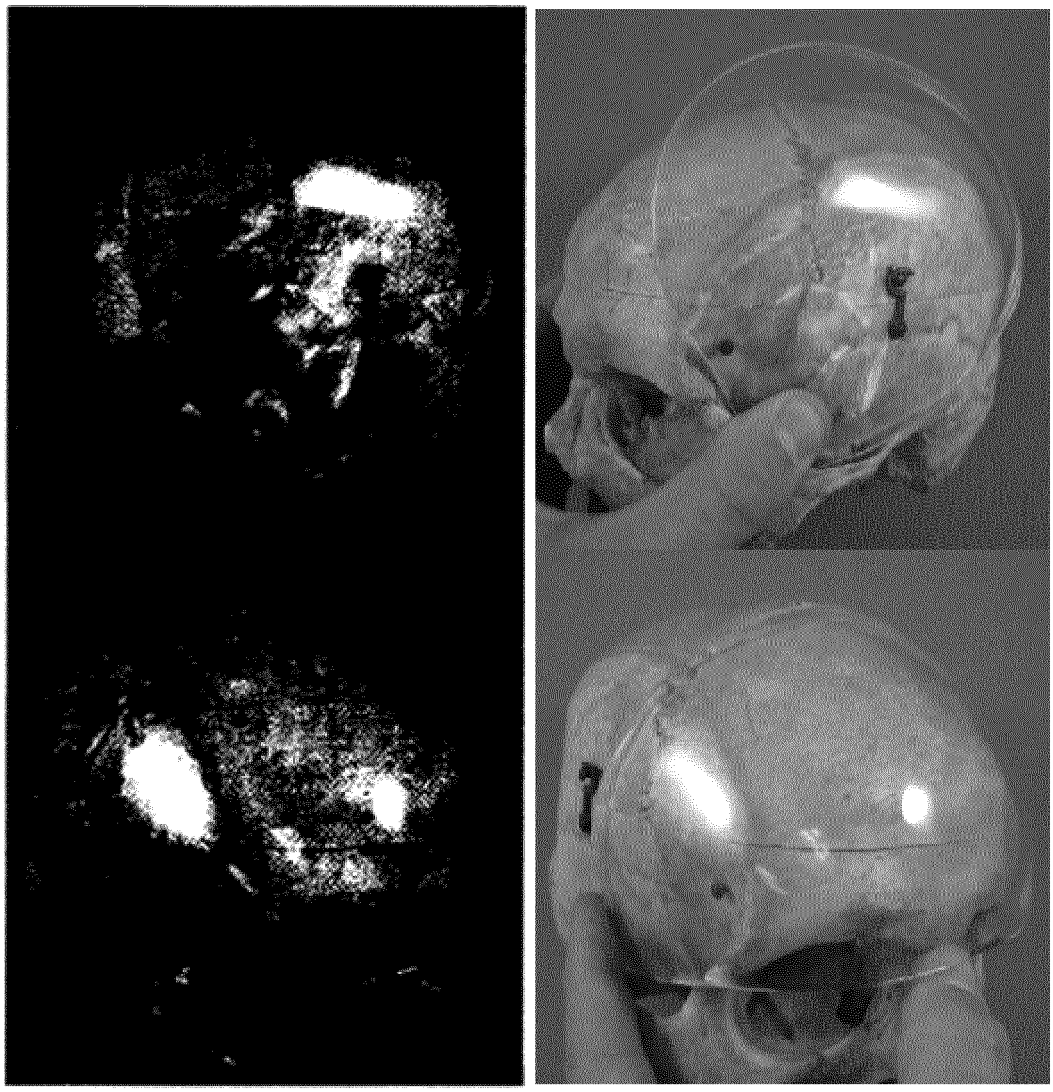

Figure 1

REFERENCES CITED IN THE DESCRIPTION

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摘要(译)

在使用中的外科植入物在组织层之间提供屏障，使得植入物一侧上的组织不粘附到另一侧上的组织，植入物由合适的解剖学形状的外科可接受片材制成。