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REVIEW ARTICLE

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Patches for carotid artery endarterectomy: Current materials and prospects

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Patch angioplasty is commonly performed after carotid endarterectomy. Randomized prospective trials and meta-analyses have documented improved rates of perioperative and long-term stroke prevention as well as reduced rates of restenosis for patches compared with primary closure of the arteriotomy. Although use of vein patches is considered to be the gold standard for patch closure, newer generations of synthetic and biologic materials rival outcomes associated with vein patches. Future bioengineered patches are likely to optimize patch performance, both by achieving minimal stroke risk and long-term rates of restenosis as well as by minimizing the risk of unusual complications of prosthetic patches such as infection and pseudoaneurysm formation. In addition, lessons from bioengineered patches will likely enable construction of bioengineered and tissue-engineered bypass grafts. (J Vasc Surg 2009;50:206-13.)

Since surgical repair of symptomatic carotid artery stenosis was first reported by Eastcott et al[1] in 1954, carotid artery endarterectomy (CEA) has remained the standard management strategy for significant carotid stenosis in both symptomatic and asymptomatic patients. Approximately 100,000 CEAs are performed annually in the United States.[2-4]

The standard surgical approach for CEA involves a longitudinal arteriotomy from the common to the internal carotid artery, allowing plaque removal. Unfortunately, closure of the longitudinal arteriotomy also allows for the possibility of narrowing the artery, either immediately or in delayed fashion, thus mimicking the stenosis for which the surgery was originally performed. Closure of the arteriotomy with a patch minimizes the effect of neointimal hyperplasia and scarring and maintains the arterial lumen diameter after the procedure. In addition, patches are commonly used to close arteriotomies in other vascular beds, such as after common femoral endarterectomy or profundaplasty.

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Eversion endarterectomy is an alternative surgical technique that allows plaque removal without longitudinal arteriotomy and potentially avoids placement of a patch; however, this technique is less frequently practiced.

To avoid restenosis after CEA, carotid patching was routinely used by Imparato[5] as early as 1965, and many articles have since supported the use of a patch.[6-11] Another early advocate of vein patching after CEA was Dr Thor Sundt, who was also a pioneer in his laboratory investigations examining the healing of carotid patches in a dog model.[12] Recent reviews continue to highly recommend patch angioplasty after CEA to avoid restenosis compared with primary arterial closure.[13] Patching is now thought to be part of optimal care of the patient undergoing traditional CEA.[14,15] In this review, we describe traditional and novel patch materials and review the characteristics and clinical results of these patches.

WHY PATCH AT ALL?

Important factors for all successful surgical procedures include simplicity, ease, safety, short duration, and cost-effectiveness. As such, primary closure for CEA can be seen as a good choice, with patch closure being somewhat more complicated and of longer duration. Therefore, it is a valid question to ask whether patching after CEA is a reasonable activity at all.

In 2004 Bond et al[10,11] reviewed the outcome of seven randomized trials comprising 1281 procedures in which primary closure was compared with patch angioplasty after CEA. Patch angioplasty was associated with reduced 30-day risk of ipsilateral stroke (1.6% vs 4.8%, $P = .001$), reduced risk of stroke or death (2.5% vs 6.1%, $P = .007$), reduced rates of return to surgery (1.1% vs 3.1%, $P = .01$),

Table I. Improved outcome after patch closure compared with primary closure after carotid endarterectomy

Study	Number		Stroke, %		Restenosis, %[a]	
First author, y	*Primary*	*Patch*	*Primary*	*Patch*	*Primary*	*Patch*
Hertzer,[16] 1987	483	434	3.1	0.7	31	9
Ranaboldo,[17] 1993	104	109	5.8	1.8	16	6
AbuRahma,[18] 1996	135	264	5.2	1.5	12	3
Katras,[19] 2001	97	107	2.8	1.0	9	6
Ali,[20] 2005	117	119	7.7	1.7	25	7
Rockman,[21] 2005	233	1377	5.6	2.2	. . .	. . .
Verhoeven,[22] 2005	83	236	6.0	2.5	11	7
Hertzer,[23] 2006	783	1479	2.8	1.4	29	15

[a]Time and degree of restenosis were defined by the authors of the referenced study.

and reduced rates of arterial occlusion (0.5% vs 3.6%, $P = .0001$) compared with primary closure. In addition, carotid patching was associated with reduced long-term rates of ipsilateral stroke (1.6% vs 4.8%, $P = .001$), reduced risk of stroke or death (14.6% vs 24.1%, $P = .004$), and reduced rates of recurrent stenosis (4.8% vs 18.6%, $P < .0001$) compared with primary closure.

This meta-analysis provides strong evidence that carotid patching provides both perioperative and long-term benefits for patient care and is consistent with standard use of patching during CEA. The benefit that is probably the most generally agreed upon is the reduced rate of restenosis in the long-term. Several important series are reviewed in Table I.[16-23] Although these series are heterogeneous, and reflect different patch materials and times of follow-up, the data nevertheless show that placement of a carotid patch is associated with fewer strokes and less restenosis compared with primary arterial closure.

Other accepted indications for patch angioplasty after CEA traditionally include a very small internal carotid artery (<4 mm), an extended, complex, or irregular arteriotomy, and concomitant repair of a distal internal carotid artery that contains a kink or coil. Patching may allow optimization of blood flow, vessel geometry, and biomechanics, although the influence of these physical parameters on long-term patient outcome is not well described.

TYPES OF PATCHES

The ideal requirements for any patching material are summarized in Table II. The following sections describe a variety of materials that are in common use for arteriotomy closure during CEA, each with advantages and disadvantages.

Prosthetic patches. The most commonly used prosthetic patching materials are polytetrafluoroethylene (PTFE) and Dacron. PTFE is a fluoride resin composed of only carbon and fluoride. Expanded PTFE (ePTFE) has a porous structure with 20- to 30-μm fibril distance and is also commonly used as a vascular graft. It has properties that include resistance to thrombosis and the ability to support re-endothelialization. More recently, an elastomeric coating such as polyurethane has been applied to the outside surface of ePTFE patches to minimize suture hole bleeding.[24]

Table II. Ideal requirements for a carotid patch material

- Long-term stability and durability
- Low risk of restenosis
- Compliance near that of the host artery
- Comfortable handling characteristics
- Easy harvest or ready to use
- Anticoagulant function
- Resistance to infection and late degeneration

Dacron is a polyester fiber, a condensation polymer of ethylene glycol and terephthalic acid, and shows high tensile strength and resistance to stretching. Woven or knitted sheets of Dacron are commonly used in vascular surgery, including use as vascular grafts.

An early Italian trial first showed the importance of prosthetic patch angioplasty in preventing restenosis after carotid endarterectomy.[25] Prosthetic patches have a significant advantage because they are ready-to-go (ie, available by just opening the package). In addition, outcomes of recent generations of various prosthetic materials show no differences compared with autologous vein patches.[26-28] For example, Naylor et al[28] reviewed the Leicester experience with 269 patients randomized to vein or thin-walled Dacron (Hemashield Finesse, Boston Scientific, Natick, Mass) patch closure. After 3 years, cumulative freedom from death or ipsilateral stroke was 93.0% in the Dacron-patched group compared with 95.5% in the vein-patched group ($P = .42$). Interestingly, cumulative freedom from recurrent stenosis (>70%) was 92.9% in the Dacron-patched group compared with 98.4% in the vein-patched group ($P = .03$).[28]

Similar results were reported from the Cleveland Clinic, with synthetic and vein patches having similar low rates of late stroke (2.1% vs 2.0%) and slightly higher but not statistically significant incidence of restenosis (>60%) in synthetic patches compared with vein patches (6.3% vs 4.8%, $P = .99$).[27] A recent Cochrane review suggested an odds ratio for risk of restenosis of 1.34 for PTFE patches

Table III. Outcome after patch closure–effects of different patch materials

Study	Number			Stroke, %			Restenosis, %[a]		
First author, y	*Vein*	*Dacron*	*ePTFE*	*Vein*	*Dacron*	*ePTFE*	*Vein*	*Dacron*	*ePTFE*
AbuRahma,[18] 1996	130	. . .	134	0.8	. . .	2.2	2.9	. . .	2.2%
Archie,[34] 2000	903	359	27	0.6	6.4	3.7	. . .	. . .	. . .
Jacobowitz,[35] 2001	159	90	. . .	2.0	2.2	. . .	2.2	8.5	. . .
Grego,[36] 2003	80	. . .	80	1.3	. . .	6.4	9.3	. . .	13.3
Naylor,[28] 2004	134	133	. . .	4.5	7	. . .	1.6	7.1	. . .
AbuRahma,[33] 2008	. . .	100	100	. . .	3	2	. . .	21	11

ePTFE, Expanded polytetrafluoroethylene.
[a]Time and degree of restenosis were defined by the authors of the referenced study.

compared with vein, but with a very wide 95% confidence interval (CI) of 0.71 to 2.51.[29]

Although PTFE patches were originally very commonly used for CEA, collagen-impregnated Dacron patches became more commonly used upon recognition of their advantage in hemostatic function (ie, reduced bleeding from the suture holes).[13] Carney et al[30] reported that PTFE patches showed significantly longer time to attain hemostasis after release of the clamps at the end of the operation, an increased incidence of blood loss >300 mL, and greater use of oxidized cellulose to stop the bleeding compared with vein or Dacron patches. In addition, AbuRahma et al[31] reported significantly longer hemostasis times in PTFE-patched patients compared with Dacron-patched patients (14.4 vs 3.4 minutes, $P < .001$). This group also reported that the long-term results of older collagen-impregnated Dacron patches compared unfavorably with ePTFE, with higher rates of postoperative stroke (7% vs 0%, $P = .02$) and carotid restenosis (12% vs 2%, $P = .013$).

Recent newer developments include sealing ePTFE patches (ACUSEAL; W. L. Gore & Assoc, Flagstaff, Ariz) and less thrombogenic Dacron patches (Hemashield Finesse), with each generation attempting to improve upon previous versions; for example, hemostasis times are typically shorter (3 to 4 minutes) and comparable between materials. AbuRahma et al[32] recently reported no significant differences in perioperative stroke (2% vs 2%, $P > .99$) and short-term restenosis risk (0% vs 4%, $P = .12$) between these patches. These results were recently confirmed in longer-term follow-up, with cumulative stroke-free rates of 98% for ePTFE and 97% for Dacron at 3 years ($P = .7$), whereas cumulative freedom from restenosis (>70%) was 89% for ePTFE and 79% for Dacron at 3 years ($P = .04$).[33]

In a recent Cochrane review, ePTFE and Dacron patches showed similar rates of arterial restenosis and occlusion compared with vein patches (OR, 1.01; 95% CI, 0.61-1.66).[29] Several large series have suggested increased rates of restenosis in Dacron patches (Table III).[18,28,33-36] It is likely that as additional materials are made available for clinical use, the results of these two prosthetic materials will converge. We believe that one advance in the reduction of bleeding time that is traditionally associated with ePTFE patches is the use of superiorly swagged needles, with the needle diameter not significantly larger than the suture diameter, creating less empty space for bleeding around the suture. Thus, time to hemostasis may be less patch-dependent with the use of newer sutures and needles.

Other significant long-term sequelae associated with prosthetic patches include pseudoaneurysm formation and development of infection.[37,38] Although both complications are unusual but treatable, this certainly suggests that use of prosthetic patch materials may require life-long surveillance in susceptible populations and thus are clearly not perfect materials. In particular, the rates of infection are unfavorably higher compared with other materials and remain as a point of improvement for future developments.

An early report by Branch and Davis[39] linked infection and pseudoaneurysm formation after CEA. This review of 57 cases estimated an incidence of 0.30% of pseudoaneurysm after CEA and estimated that CEA performed with primary closure had half this rate of postoperative infection.[39] One of the largest series of prosthetic patch infections was described by Cooley's group at the Texas Heart Institute.[40] This report of 13 cases of patch infections associated with pseudoaneurysms discussed a number of points from this group's extensive experience that remain critical for optimal patient management:

- Infection complicates patches, both prosthetic and vein, more frequently than primary arterial closures.
- Braided sutures such as silk can trap bacteria in their interstices, providing a nidus of infection in earlier series; the use of monofilament sutures, especially polypropylene, has eliminated this risk.
- Untreated patch infection can lead to patch blowout and massive hemorrhage, as well as sepsis, abscess formation, or stroke; these presentations must be treated urgently.
- *Staphylococcus* species were the most commonly cultured organism (29 of 30 patients), followed by gram-negative rods (7 of 30 patients).
- Surgical repair involves extensive dissection and usually needs general anesthesia.
- Use of a shunt is desirable but potentially hazardous due to the friable tissues and is usually impractical.

- Débridement of the arterial wall usually precludes safe primary closure; 75% of the patients treated by reclosure of the arteriotomy required early reoperation or died.
- Most repairs were treated by resection and saphenous vein replacement; treatment with autogenous tissue is thought to be mandatory in the presence of gross infection.
- Minor infections and pseudoaneurysms not associated with infection may be treated with partial aneurysmectomy and patch repair, although even saphenous vein patches can be reinfected.
- Ten percent of patients so treated developed postoperative strokes or died, most commonly patients needing carotid artery ligation (50%) and least frequently in patients in whom repeat patch placement was possible (12%).
- Recurrent patch infection was common in patients receiving Dacron patches.
- Donor vein site infection was also possible.
- Cranial nerve injury was less common in these procedures compared with primary CEA.

This series also estimated that infected patches and pseudoaneurysms occur in 0.18% of CEA.[40] A more recent review of prosthetic patch infections has estimated that patch infection occurs in approximately 0.37% of all patients, ranging from 0.26% to 0.71% in several reported series.[38] Repair of these prosthetic patch infections is associated with increased morbidity compared with the primary CEA procedure. Although the reported postoperative mortality rate was 2.6%, the postoperative stroke rate was 2.6%, the rate of cranial nerve injury was 12.8%, and the rate of recurrent infection was 7.7%, all of which were greater than rates associated for elective repair.[38] General recommendations from this group included reconstruction with a vein patch or an interposition graft, depending on the quality of the remaining artery after removal of all prosthetic and infection. The use of a muscle flap to cover the site has been reported,[41] although it is not possible to determine from the few overall number of case reports whether this adjunctive technique is popular or not.

Venous patches. Patching with autologous venous tissue remains the most commonly used option for arterial patching during CEA and continues to show superb results in the literature (Table III). This patch continues to enjoy popularity with surgeons: It is commonly used, has excellent handling, and is resistant to thrombosis and restenosis due to its endothelial lining on the luminal surface.[42] Many reports have compared results of CEA after use of autologous or synthetic patches.[6,11,13,27,29,35] Most analyses have shown no significant differences in early outcomes when comparing venous with prosthetic patches, with very low risk of any events.

O'Hara[27] reported the results from the Cleveland Clinic study that randomized 207 patients to vein or synthetic patch closure. The stroke rate in the vein patch group was 3.0% compared with 2.1% in the synthetic patch group (P = .99). Recurrent stenosis (>60%) was present in 4.8% of the vein patch group compared with 6.3% of the synthetic patch group (P = .99).[27] Similarly, Jacobowitz et al[35] reported the New York University experience. In 159 vein patches compared with 90 Dacron patches, similar rates were found for perioperative stroke (vein 1.3% vs Dacron 1.1%, P = NS) and late stroke (vein 2.0% vs Dacron 2.2%, P = NS). Restenosis of 50% to 79% was present in 2.2% of vein patches and 8.5% of Dacron patches (P = NS).

It is of interest that autologous vein was the first material to be used for CEA patching. Imparato and Weinstein[43] were early proponents for vein patches to be used routinely to prevent restenosis. Originally, surgeons used the proximal saphenous vein in the thigh, but patients and surgeons objected to the additional incision in the thigh for an operation that should be confined to the neck. This preference to avoid proximal saphenous vein harvest led to use of the distal saphenous vein at the ankle or the cervical veins harvested within the CEA incision. There was concern that these veins were weaker and could potentially lead to a catastrophic blowout.[44-48] Some authors have shown that veins >3.5 mm diameter are generally safe to use with reduced risk of rupture.[49,50]

A clever development deployed everted cervical vein (external jugular or facial vein), thereby creating a double-walled vein patch with increased tensile strength comparable with the saphenous vein. Because cervical veins are harvested within the CEA operative field, the additional leg incision is obviated.[51] The double-layered everted cervical vein patch has demonstrated durable outcomes compared with the traditional saphenous vein patch.[52]

Another option is the cryopreserved homograft saphenous vein patch. Plestis et al[53] reported a series of 1006 consecutive CEAs repaired with saphenous vein segments that were harvested from coronary artery bypass procedures and cryopreserved in 10% dimethyl sulfoxide at –120°C. Results were excellent, with 1.2% perioperative strokes and a 10-year cumulative freedom of 96% from ipsilateral stroke. Recurrence of severe (>75%) stenosis was 2%, and freedom from >20% restenosis was 84% at 10 years. These results suggest that modified vein may be a durable substitute for autologous vein.

There are few reports of infection after vein patch placement. In an early series, Thompson[54] reported no cases of vein patch infection in 1140 CEAs, although pseudoaneurysms occurred in seven Dacron patches (0.6%) in the series. A notable case report of a vein patch infection reported repair with resection, segmental replacement with a vein graft, topical irrigation for 2 weeks, and systemic antibiotics for 3 weeks.[55] Yamamoto et al[56] reported their experience with 2888 CEA closed with vein patches at the Mayo Clinic in 23 years; only three cases of infection occurred, all of which involved Dacron or Teflon mesh reinforcement of the site, without involvement of the vein patch itself. These were treated with removal of the synthetic material, without disturbance of the vein patch. This group also reported five patch ruptures of uninfected vein patches, three of which led to death or severe disability, and four cases of late (1 to 9 years) aneurysmal expansion. Interestingly, the group concluded that use of a synthetic material was preferable to a vein patch.[56]

Biomaterial patches. Bovine pericardium has served for many years as a popular option as a biomaterial patch for CEA.[57,58] Kim et al[59] reported their preliminary experience with this patch for CEA, with little differences in outcome compared with vein patches (no early strokes, >50% restenosis 3.3% vs 1.6%, P = NS). Hines et al[58] have recently confirmed these results, with excellent handling and early results; <50% restenosis occurred in 25% of cases by 2 years, but 16% of cases had 50% to 79% restenosis, and no cases were detected with >80% restenosis.

Bovine pericardium offers the benefits of off-the-shelf availability, durability, and biocompatibility, as well as the ability to ultrasound through the patch immediately after placement. In addition, the satisfactory use of bovine pericardial patches in infected fields has been reported. However, bovine pericardium has had reduced popularity after reports in the lay press of bovine spongiform encephalopathy in certain cattle herds, although bovine spongiform encephalopathy has never been reported after placement of a carotid patch.

When compared with outcomes after the use of polyester patches, bovine pericardial patches show comparable results but may have a lower incidence of recurrent stenosis. One study reported 4% restenosis in bovine patches compared with 7.6% restenosis in polyester patches, although the mean length of follow-up in the groups (bovine, 12 months; polyester, 24.5 months) was not comparable.[60]

Just as the newer prosthetic patches and standard vein patches show no significant differences regarding durability and outcomes, it is likely that bovine pericardial patches are also equivalent. Bovine pericardial patches have shown significantly decreased intraoperative suture line bleeding compared with prosthetic patches.[61] Although no reports have compared bovine pericardium with other conduits regarding rates of postoperative infection, bovine pericardium has been used in other infected cardiovascular fields.[62,63] The low risk of infection after autologous vein and biomaterial patches may be an important factor for the future development of tissue engineered vascular patches, although this assertion also awaits confirmation in large series.

One other biomaterial that has been reported after use in an animal study is a combination patch, with one side of the patch constructed from glutaraldehyde-fixed bovine peritoneum/fascia and the other side constructed from polyester.[64] This interesting patch was tested in femoral arteries of dogs, and at 6 months had no degeneration and complete re-endothelialization; the mechanical strength was superior to that of bovine pericardial patches. Other biomaterials for potential use include amnion,[65] decellularized bovine inferior vena cava,[66] and decellularized human pericardium.[67] Decellularized venous patches have similar burst and suture-holding strength as native veins.[68] As the tissue-engineering field matures, additional biomaterials for use as a carotid patch can be expected, such as patches with textured surfaces that promote cell migration and tissue healing.[69]

FUTURE DIRECTIONS

As excellent results are currently being obtained with available patch materials, directions for future development may lie in the prevention of unusual complications such as infection and pseudoaneurysm. However, additional benefits may become evident as the field develops.

An interesting option for carotid patching was reported by Jenkins et al[70] in which they used the superior thyroid artery. Use of this autologous vessel has the advantages of excellent material strength, reduction of surgical cost and possibly infection risk, excellent compliance match to the host artery, and availability within the operative field. The superior thyroid artery has limitations, however, including reduced patch size, focal arteriosclerosis, and limited follow-up data. Ultimately, the use of any artery is limited by its potential for creating distal ischemia in the original locus. Use of an endarterectomized occluded femoral artery has been reported, which eliminated the potential for distal ischemia[71]; nevertheless, this option has not become popular. However, the lessons derived in using autogenous artery suggest that strength and compliance matching are critical determinants for successful patch materials.

Tissue engineering, the combination of scaffolds and cells to develop neotissues, has recently become a popular field because the potential exists to create neotissues with both off-the-shelf availability as well as device alterations that can be customized to individual patient requirements. Novel synthetic conduits formed by tissue engineering will very likely replace structural arterial tissue after surgery. In the late 1980s, the concept of tissue engineering grafts with polymer scaffolds absorbed by newly replaced tissue was reported by Langer and Vacanti.[72] The first report of a tissue-engineered conduit applied in the human vascular system was the use of a tissue-engineered venous graft to repair congenital defects in the pulmonary artery.[73] Shin'oka et al[74] used autologous bone marrow cells to seed a scaffold copolymer of L-lactide and ε-caprolactone reinforced with a polyglycolic acid sleeve and reported satisfactory midterm clinical results in congenital pulmonary artery system repair. This tissue-engineered conduit has only been used in the venous system, but has potential as an arterial patch once its long-term strength and pathophysiologic changes to the arterial circulation are better understood.

Specific biologic cellular approaches for tissue engineering arterial grafts have started to be applied in clinical practice, with reports of dermal fibroblasts rolled into sheets and then used as tissue-engineered vascular grafts.[75-77] This method has focused on use of tissue-engineered vascular grafts as arteriovenous grafts for hemodialysis access and has shown fair prospects as a conduit. The advantage of this conduit, rolled sheets of dermal fibroblasts, for application as a carotid patch is the ability to be tolerated within the human arterial environment, including arterial pressure. In addition, this construct is based on autologous cells and thus is not likely to lead to rejection.

Another recent interesting approach to tissue engineering an arterial conduit has used cross-linked elastic salmon collagen as a vascular graft.[78] Although this particular conduit is not yet mature, the development of this graft shows that the concepts of using only biologic material that is gradually biodegradable and with similar wall compliance as native vessels may ultimately lead to the development of even better improved tissue-engineered devices.

Tissue-engineered grafts and patches still have obstacles to surmount. One of the major requirements of a tissue-engineered vascular patch is long-term stability. Another important requirement is to ensure a stable supply of cells within the neotissue. If the source of the cells for a tissue-engineered patch includes cells from middle-aged or elderly patients, then these cells may not grow well or very slowly, if at all. If these cells are taken from other humans or large animals, then infection and rejection need to be eliminated. The application of stem cells or novel types of stem cells, such as embryonic stem or induced pluripotent stem cells, for tissue engineered conduits has not yet been worked out; problems with ethical issues, accurate induction of specific cell types, carcinogenic gene transduction, and other problems still exist. For the potential of off-the-shelf use, hybrid biomaterials such as tissue-engineered conduits still have to surmount numerous obstacles.

CONCLUSIONS

Although minimally invasive carotid artery angioplasty and stenting preoccupies much discussion in the treatment of carotid artery stenosis, open surgery is still used to treat most patients with carotid disease.[4,13,79] As such, development of carotid patches, as well as patches for use in arteriotomy closure elsewhere, continues to remain a critical adjunct for vascular surgery. Reports comparing most synthetic and vein patches show acceptable satisfactory results after CEA, although problems such as infection, rupture, handling, stroke, cost, and others, remain.

Our preference is for biologic patches such as bovine pericardium, but we believe that the clinical results obtained with most available synthetic patches are currently similar enough to prevent clear recommendation of any particular one. Recent novel conduits are not yet mature enough for clinical use, although the future of biomaterials and tissue engineered patches, especially for use as vascular bypass grafts, is likely to be bright.

AUTHOR CONTRIBUTIONS

Conception and design: AM, AD
Analysis and interpretation: AM, TN, HD, AD
Data collection: AM, AD
Writing the article: AM, AD
Critical revision of the article: AM, TN, HD, AD
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