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Biological Materials in Vascular Surgery: Clinical Applications, Benefits, and Limitations

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ABSTRACT

Vascular grafting has progressed significantly in the pursuit of materials capable of achieving seamless biological integration with host tissue; however, an ideal graft that combines availability, durability, and biocompatibility remains elusive. This review provides a comprehensive overview of currently available biomaterials in vascular surgery, highlighting their clinical applications, benefits, and limitations. While autologous material (e.g., veins) remains the gold standard, its limited availability and harvesting-related morbidity, such as infection and thrombosis, have prompted the search for alternative biological grafts. Xenografts, derived from non-human donors (e.g., bovine, ovine, & porcine tissues), have demonstrated favorable patency rates and relatively low infection rates in vascular access, extremity revascularization, and aortic surgery. Human allografts have shown excellent performance in infected fields; however, their use is constrained by logistical challenges, including limited donor availability and labor-intensive preparation. Emerging tissue-engineered vascular grafts (TEVGs), often composed of biodegradable scaffolds seeded with biologically active cells, aim to replicate the structure and function of native vessels. Some TEVGs are designed to transform into native vasculature following biodegradation of the scaffold. However, further technical refinement and cost reduction are essential before TEVGs can be widely adopted as off-the-shelf solutions.

***Keywords*:** Allograft; Biomaterials; Polytetrafluoroethylene; Vascular surgery; Xenograft

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INTRODUCTION

Over the past eight decades, significant progress has been made in the development of graft materials used for vascular reconstruction, including arterial segment replacement and bypass procedures. Starting from the 1940s, the introduction and refinement of synthetic polymers—most notably polyethylene, polyurethane, polytetrafluoroethylene (PTFE), Terylene, and Dacron—revolutionized vascular surgery. Dacron emerged in the 1950s, followed by PTFE in the 1970s; both are frequently used due to their promising results in large diameter vessels. To this day, Dacron is often the graft material of choice in open aneurysmal aortic surgery.[1]

Nonetheless, synthetic grafts have demonstrated notable limitations in the surgery of small-diameter vessels (<6 mm), exhibiting lower patency rates and a higher incidence of complications (e.g., thrombosis).[2] Furthermore, adverse biological responses have raised concerns regarding the biocompatibility of these synthetic foreign materials.[3] These challenges have prompted a shift in focus toward biomaterials, which are derived from biological sources, with the aim of improving graft-associated outcomes, such as integration, healing, and function.

Since the 1960s, biomaterials have emerged as a promising alternative, and in recent years, the field has experienced substantial innovation. This review aims to provide a comprehensive historical and contemporary overview of the literature on biomaterials used in vascular surgery, examining their respective advantages and disadvantages while highlighting recent technological advancements.

LITERATURE SEARCH AND SELECTION CRITERIA

This review is a descriptive scoping review of biomaterials used in vascular surgery. We searched MEDLINE from inception to October 2025, combining Medical Subject Headings and keywords for "biomaterial/biological material," "xenograft," "allograft," and "vascular surgery." Eligible study designs included randomized trials, cohort studies, case series, reviews, and meta-analyses. Given our aim to provide a historical and contemporary clinical overview rather than a hypothesis-driven synthesis, we did not perform a formal systematic review or track exact query yields. We additionally screened reference lists of key papers to ensure thematic completeness. Retrieved articles were categorized based on the type of biomaterials and their applications in vascular surgery. The search was guided by three main objectives: (i) to identify relevant biomaterials used in vascular surgery, (ii) to gather information on the composition, clinical use, and background of these biomaterials, and (iii) to identify studies reporting clinical outcomes in patients treated with these biomaterials, including a description of outcome reporting methods.

RESULTS

An ideal vascular graft should closely mimic the properties of native arteries. It must be mechanically strong and reliable to withstand hemodynamic stress and arterial pressures, while also being non-toxic, non-immunogenic, biocompatible, and readily available.

Autologous material, typically autologous veins, technically qualifies as a biological material and demonstrates many, if not all, of these ideal properties. The first successful case of vascular reconstruction using autologous material was performed by Criado *et al.*[4] in 1905, in which a popliteal vein was successfully transplanted to repair a popliteal artery aneurysm.[4] Since then, autologous veins have become the gold standard whenever available, owing to their superior clinical outcomes. For example, in above-the-knee femoropopliteal bypass surgery, Klinkert *et al.*[5] reported a 74% patency rate using autologous saphenous vein compared to 39% with PTFE-grafts at the same anatomical site.[5] In more complex settings, such as the reconstruction of an infected aortic graft, autologous veins have demonstrated the lowest rates of infection and thrombosis (**Figure 1**).[6–8] Therefore, autologous material is currently preferred over any other graft type when feasible (**Table 1**).

However, despite these advantages, the primary limitation of autologous grafts is their availability. Depending on the clinical indication and vein quality, up to 30%–40% of patients may lack a suitable vein due to prior harvesting, systemic comorbidities (e.g., diabetes mellitus), phlebitis, hypoplasia, or unfavorable anatomy.[9,10] Additionally, vein harvesting carries inherent risks, with chronic venous insufficiency reported in up to 15%, deep vein thrombosis in 19%, and wound infection in 3% of patients.[6,8,11–14] Moreover, the procedure extends operating time by approximately 60 min.[14] These limitations underscore the need for alternative biocompatible graft materials in patients for whom autologous material is unavailable or carries a significant procedural risk (**Table 1**).

Biological materials in vascular surgery

Allografts

Allografts are human-derived vascular tissues, typically harvested from cadaveric donors and processed in a sterile manner for transplantation. The first successful landmark aortic repairs using allografts were performed by Jacques Outdot and Charles Dubost in 1950 and 1951, respectively.[15] However, allografts were soon abandoned due to significant mid- and long-term complications, including immune rejection and aneurysmal degeneration rates as high as 100%.[16,17] At the time, synthetic polyesters were more promising, prompting a shift toward their development and clinical use.

Since the 1990s, vascular allografts have regained attention in clinical practice due to improved understanding of immunologic rejection and the advent of cryopreservation (**Figure 2**).[18] Early indications included the treatment of abdominal aortic infections Klik of tik om tekst in te voeren.,[19,20] lower extremity revascularization,[21] and vascular reconstruction in patients undergoing chronic immunosuppression.[22] In a Spanish cohort of 171 patients undergoing lower extremity revascularization with arterial allografts, the majority (77.2%) had chronic limb ischemia as the primary indication. In this series, cryopreserved allografts demonstrated reliable 1-year primary patency rates, ranging from 53.5% to 86.7%, depending on the level of revascularization.[23]

Nevertheless, allografts have been largely overshadowed by the advent of other approaches, particularly endovascular techniques. Currently, clinical indications for their use are limited. Both the European Society for Vascular Surgery and the Society for Vascular Surgery guidelines recommend cryopreserved allografts primarily for the treatment or salvage of already infected grafts.[24] In the

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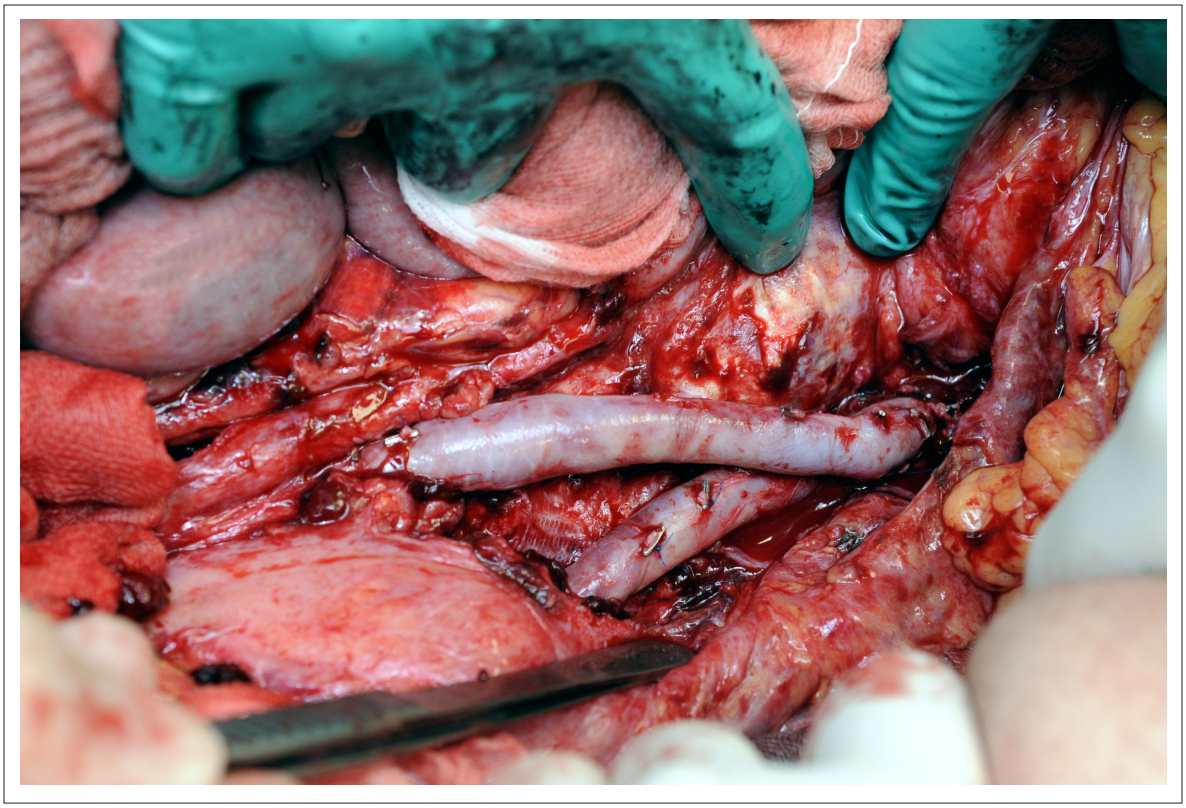

Figure 1. Intraoperative view of successful reconstruction of the aortic bifurcation using autologous vena femoralis superficialis in a 70-year-old patient at the authors' center.

Table 1. Overview of biologically derived graft materials used in vascular surgery

Biomaterial type	Indications (guidelines-supported)	Examples	Key advantages	Key limitations
Autologous	Vascular access Peripheral revascularization Aortic revascularization (Endo)graft infection Patch closure	Great saphenous vein Cephalic vein Basilic vein Pericardium	Clearly established in clinical practice Current gold standard Low (re-)infection rates Low complication rates High patency	Limited availability Morbidity-related harvesting
Allografts	Aortic and peripheral infection Graft infection	National transplantation registries CryoVein®	Human origin High biocompatibility Very low (re)infection rates	Availability Labor-intensive process Mixed results in research
Xenografts	Vascular access Peripheral revascularization Aortic revascularization (Endo)graft infection Patch closure	Artegraft® (bovine) Xenosure® (bovine) BioIntegral® (bovine) Omniflow® (ovine)	Availability through livestock Well researched Great results Ease of use	Expensive Degeneration Immunogenicity Informed consent needed
Tissue-engineered vascular grafts	Pediatric surgery Small-vessel surgery	Human acellular vessel® Biotube® Omniflow®	Potential for growth Remodeling Biodegradable Vascular regeneration	Experimental Complex Expensive Regulatory hurdles Research ongoing

setting of aortic reconstruction following graft infection, cryopreserved allografts demonstrated lower reinfection rates (ranging from 0% to 7%) compared to synthetic grafts (10%–20%).[25–27] For infected peripheral grafts, allografts also exhibited lower rates of reinfection and degeneration.[28] Reported primary and secondary patency rates were 56% and 73% at 1 year, and 17% and 38.5% at 5 years, respectively.[29]

However, significant concerns remain. A study by Touma *et al.*[30] expressed caution regarding the use of cryopreserved

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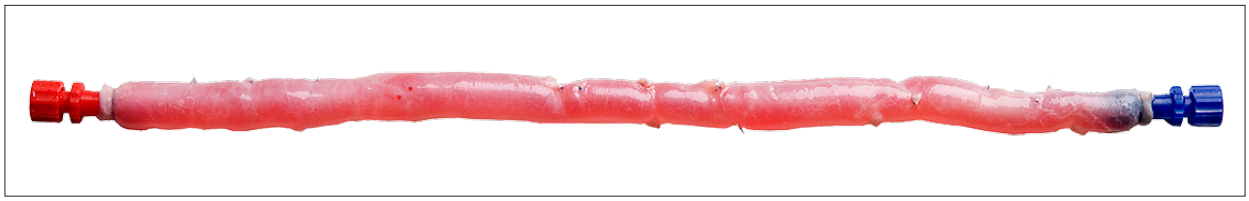

Figure 2. Human cryopreserved allograft (CryoVein Femoral Hero). Reprinted with permission of Artivion, Inc. Copyright© 2025, Artivion Inc.

allografts for *in situ* reconstruction of infected native aortic aneurysms or prosthetic grafts.[30] Although reinfection and limb salvage rates were satisfactory, early postoperative complications occurred in 52% of patients, with 35% being directly graft-related. Most notably, acute bleeding (20%), ischemic events (24%), and pulmonary complications (15%) were observed. Four of 54 patients (7.4%) died from graft-related causes.[30] These findings suggest that allograft degeneration may remain a significant concern, potentially leading to dilatation, aneurysm formation, or graft rupture.

The limitations of allografting are primarily related to donor scarcity and the labor-intensive nature of tissue preparation, which constrain availability. Tissue harvesting occurs within strict time frames to ensure viability and is not routinely incorporated into many national transplantation programs. Cryopreservation is performed at temperatures as low as −80°C or even −200°C, requiring specialized freezers. These processes introduce challenges related to transportation, thawing, handling, storage, and viability testing. Furthermore, the use of human tissue necessitates adherence to rigorous regulatory and documentation standards (**Table 1**).[20,31]

Xenografts

Xenografts are derived from non-human donor tissues and typically undergo processing, such as decellularization and sterilization, to enhance biocompatibility, improve host–tissue integration, and reduce immunogenicity. Bovine, porcine, and ovine tissues are commonly used, in part due to their widespread availability as byproducts of the livestock industry.

Various bovine-derived biomaterials, including bovine ureteral grafts, bovine mesenteric vein grafts, and small intestinal submucosa grafts, have been employed and evaluated for use in bypass surgery and vascular access.[32–34] However, concerns regarding late complications, such as aneurysmal degeneration and thrombosis, along with the development of more advanced graft materials, have led to a decline in the use of certain bovine grafts.[32,34–36] Others have demonstrated long-term durability and continue to be in clinical use.

Bovine pericardium, available in patch (e.g., Xenosure®) and graft form (e.g., BioIntegral®), has shown significant effectiveness as an alternative to autologous tissue in various applications, including reconstruction of infected native aortic aneurysms (**Figure 3**),[37] patch closure after carotid and femoral endarterectomy (**Figure 4**),[38–40] and venous or arterial reconstruction during abdominal surgery.[41–43] Its widespread use is attributed to its excellent mechanical strength, high biocompatibility, low infection rate, durability, low thrombogenicity, and consistent supply, making it a versatile option across several medical specialties.[39,44–46]

The Artegraft®, a bovine carotid artery graft, was initially introduced in the 1970s (**Figure 5**),[47] but fell out of favor due to late complications such as aneurysmal degeneration.[48] However, recent improvements in processing and design have led to improved outcomes. Emerging evidence suggests that modern iterations of Artegraft® may outperform PTFE grafts in hemodialysis access.[48] It has also shown excellent results in the limited number of studies evaluating its use for lower and upper extremity bypass surgery, with reported 12-month primary and secondary patency rates ranging from 78%–86% and 78%–88%, respectively.[49,50]

Porcine-derived materials, such as porcine small intestinal submucosa vascular grafts, have been studied in both preclinical and early clinical settings.[51,52] While their biocompatibility and structural properties are promising, further research is needed to determine their safety and long-term efficacy. Unlike bovine-derived xenografts, it remains uncertain whether any porcine materials will achieve widespread clinical adoption.

The Omniflow® graft is a unique xenograft that incorporates elements of tissue engineering to enhance biocompatibility. It consists of a glutaraldehyde-tanned ovine collagen conduit grown around a Dacron mesh template in a sheep bioreactor. Omniflow® grafts have demonstrated promising results in hemodialysis access (with primary and secondary patency rates of 60%–80% and 78%–82% at 12 months, respectively),[53,54] aortic reconstruction,[55] and lower extremity bypass procedures, where outcomes vary depending on anatomical site and indication.[56–58]

Xenografts may face limited acceptance due to cultural or religious objections to the use of animal-derived materials in healthcare.[59] Additionally, they are generally more expensive than synthetic alternatives. This raises the question of whether their clinical benefits justify the added cost, particularly in the absence of comprehensive cost-effectiveness analyses. Moreover, several xenografts currently lack long-term clinical outcome data. Nonetheless, xenografts remain among the most extensively studied and widely utilized biologically derived materials, with a long-standing record of safety and efficacy in various clinical applications (**Table 1**).

Tissue-engineered vascular grafts

Tissue-engineered vascular grafts (TEVGs) represent a promising and rapidly evolving technology in vascular surgery, integrating several of the biologically integrative principles discussed above. TEVGs are bioengineered constructs typically composed of biodegradable conduits (e.g., fibrin-based scaffolds) that are seeded with biologically active cells, such as smooth muscle cells or endothelial cells. These components aim to replicate the structural and functional characteristics of native vasculature, including growth capacity, self-repair, and reduced thrombogenic-

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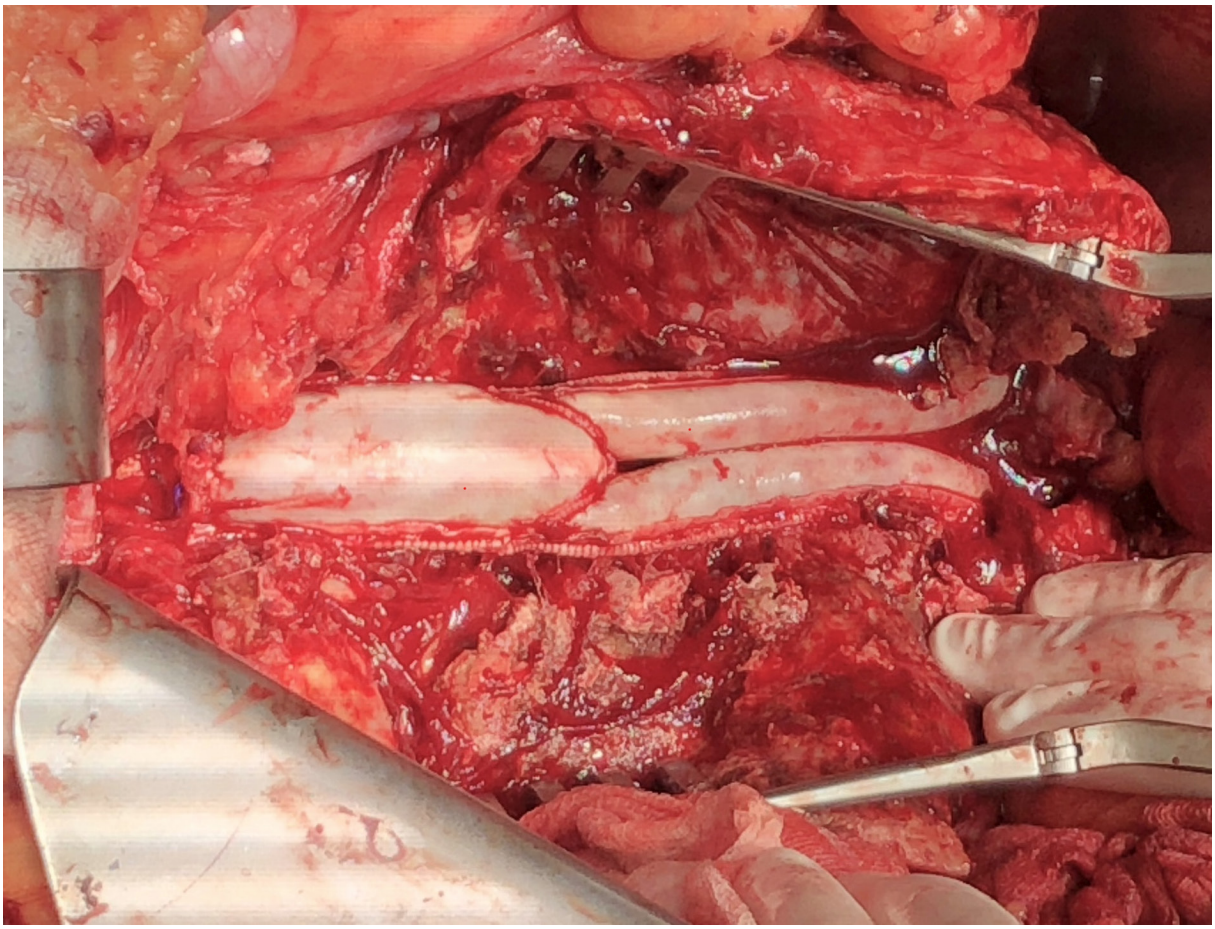

Figure 3. Intraoperative view of a BioIntegral® aortic bifurcation prosthesis replacing an infected endovascular aortic repair in an 80-year-old patient at the authors' center.

ity, making TEVGs particularly suited for the reconstruction of small-diameter vessels.[60,61] In addition, many TEVGs are biodegradable, allowing for gradual replacement by native tissue, typically within 26 weeks.[62] These properties are especially beneficial in pediatric patients, where vessel growth and remodeling are essential.[63]

The first tri-layered vascular construct, composed of intima, media, and adventitia, was engineered *in vitro* by Weinberg and Bell in 1986.[64] This model consisted of a polyester (Dacron) mesh coated with multiple layers of collagen and seeded with well-differentiated endothelial cells, which functioned as a permeability barrier and produced functional von Willebrand factor, demonstrating endothelial behavior similar to that of native vessels.[65]

A more recent innovation is the human acellular vessel (HAV; Humacyte®), a conduit made by seeding human vascular smooth muscle cells onto a polyglycolic acid mesh scaffold. The construct is matured in a bioreactor, after which the scaffold is repopulated by the recipient's cells while the biodegradable mesh dissolves, leaving behind an integrated, autologous-like vessel (**Figure 6**).[66] The HAV was recently evaluated in a phase II trial for peripheral arterial bypass with primary, primary-assisted, and secondary patency rates of 58%, 58%, and 74%, respectively, at 24 months.[67] No rejection or infection was observed, and the reintervention rate was low (5%).[67] Similar promising results were reported by Cifuentes *et al*.[66] Klik of tik om tekst in te voeren. However, a separate study by Lawson *et al*.[68] evaluating the HAV for hemodialysis access demonstrated lower primary (28%) and primary-assisted (38%) patency rates at 12 months, although secondary patency remained high at 89%.[68] These findings suggest that performance may vary depending on the clinical indication.

Another innovative approach is the "Biotube," which uses *in vivo* tissue transformation. A scaffold and mold are implanted subcutaneously, prompting the patient's body to naturally generate a fibrous tissue layer around the structure. Once matured, the scaffold is harvested. This technique, known as in-body tissue architecture, is designed to minimize immunogenicity.[69] Preclinical studies have shown favorable results in goats for use in lower extremity bypass and ascending aorta replacement.[70,71] Although still experimental, initial reports describe successful clinical applications in both lower extremity revascularization and hemodialysis access.[72,73]

The RestoreX™ from Xeltis is another TEVG-based innovative approach. It is a tubular graft, fabricated from a bioabsorbable polyester with a highly porous wall. It is also designed to completely remodel *in vivo*, yielding a fully functioning blood vessel composed of healthy, native autologous tissue.[74] The bioabsorbable, porous wall facilitates the attachment of blood cells, endothelial cells, smooth muscle cells, and extracellular matrix (ECM), all of

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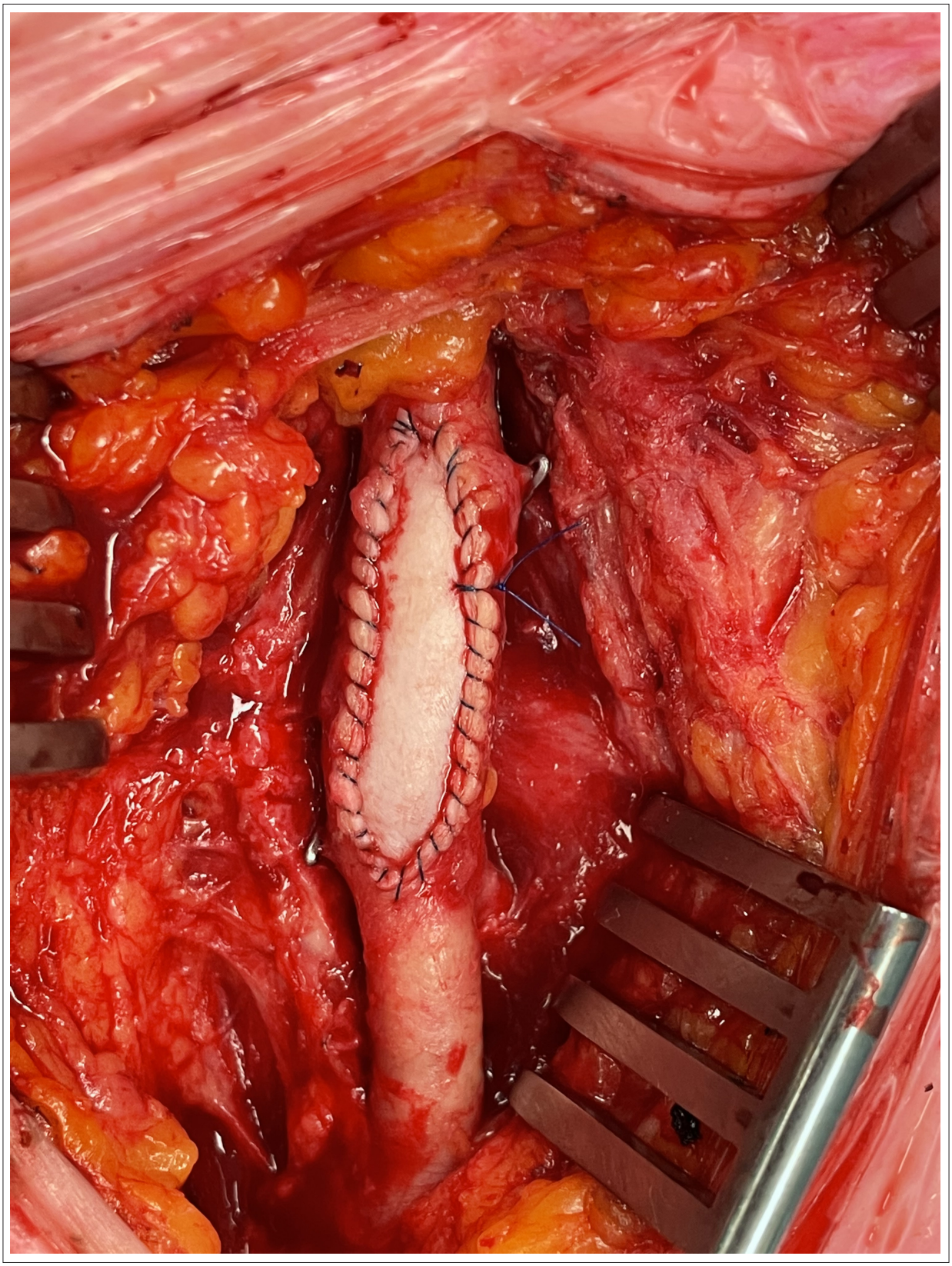

Figure 4. Intraoperative view of common femoral artery endarterectomy with bovine pericardium patch closure in a 90-year-old patient at the authors' center.

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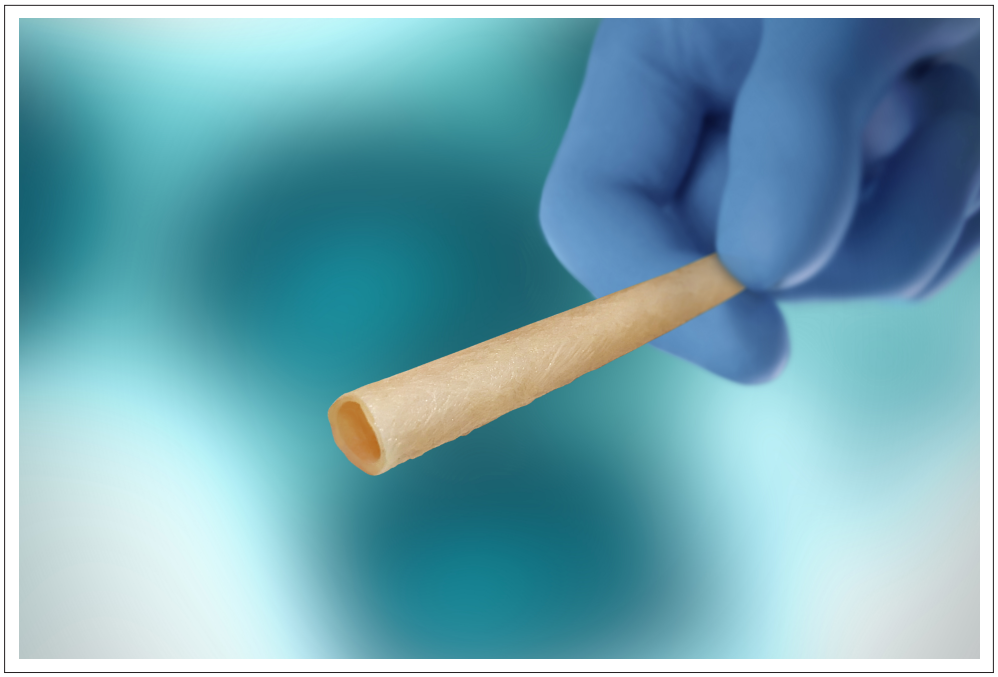

Figure 5. Bovine carotid artery graft (Artegraft®). Reprinted with permission of LeMaitre Vascular Inc. Copyright © 2025, LeMaitre Vascular Inc.

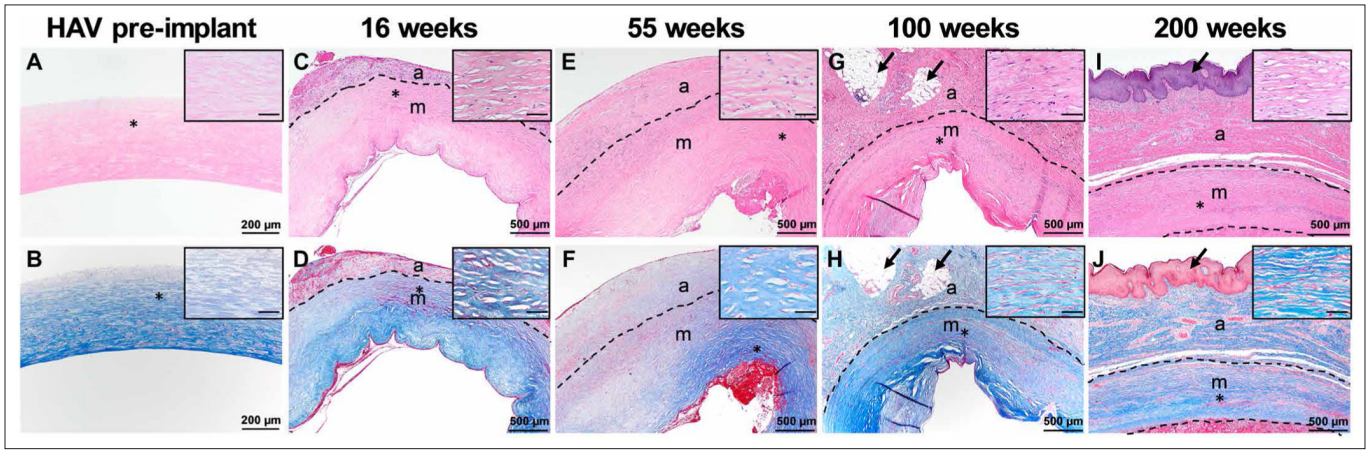

Figure 6. Representative routine staining of the human acellular vessel (HAV) before and after implantation (at 16, 55, 100 and 200 weeks). Explanted samples of the HAV (C through J) show transformation into autologous-like vessel; (a) (neo)adventitia, (m) tunica media , and (I and J; black arrow) ultimately epithelial. Scale bars: 200 µm, 500 µm. Reprinted with permission from Kirkton *et al.*[89] Copyright © 2019, The American Association for the Advancement of Science.

which are essential elements in creating native vascular tissue. Currently, the first clinical trials are ongoing, in which 20 patients are receiving RestoreX™ as a vascular access graft. The first 6-month results are promising,[75] with primary and secondary patency rates of 80% and 100% respectively, and no infection in all 20 patients. The first 2-year results are expected to be reported soon.

Despite their promise, TEVGs remain largely investigational. Limited data exists on their long-term interactions with host tissue.[76] Additionally, the complex composites of cells and biomaterials present significant regulatory hurdles, and current production capabilities are insufficient for widespread, affordable, off-the-shelf availability. Considering the limited availability of long-term data from clinical research, it is not yet possible to draw firm conclusions regarding clinical applicability; therefore, further research is required before widespread adoption can be recommended (**Table 1**).

Scaffolds

Scaffolds form the structural backbone of most TEVGs, aiming to replicate the biomechanical and biochemical functions of the native ECM. A vascular scaffold is generally defined as a three-dimensional platform that promotes cell adhesion, supports tissue remodeling, and degrades at a controllable rate aligned with tissue regeneration. Ideally, scaffolds should be low-thrombogenic, non-immunogenic, and mechanically robust.[77,78]

In the past, several scaffold materials have been investigated. Collagen-based scaffolds, such as those used in the Omniflow® and Artegraft® devices, have been in use since the 1980s due to their high tensile strength and structural integrity. However, collagen degradation can release thrombogenic amino acids, which may limit long-term biocompatibility.[77]

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Fibrin-based scaffolds offer more biologically integrative properties. Fibrin interacts with platelets, fibroblasts, leukocytes, and endothelial cells, aiding coagulation and facilitating tissue regeneration. These features allow for effective cell ingrowth and vascular remodeling.[79] Given that fibrin can be derived from the patient's blood, the risk of immunologic rejection is minimal. However, the mechanical strength of fibrin is relatively low, often necessitating reinforcement or combination with other scaffold materials.

Preclinical biomaterials

Biomaterials in vascular surgery extend beyond the aforementioned clinically applied examples, with ongoing research focusing on novel and experimental materials. Nanomaterials, such as nanofibers or nano-engineered polymers, are being explored for use in grafts and stents. While these materials offer promising surface properties and enhanced cell interactions, concerns remain regarding their long-term biocompatibility and stability.[80]

A key area of investigation focuses on identifying optimal scaffold materials for tissue-engineered vascular conduits. Decellularized ECM grafts offer the advantage of preserving the native ECM's architecture and mechanical properties. However, they have been linked to inflammatory responses and the potential transmission of viral diseases.[78,81] Other investigated scaffold materials include silk-based scaffolds,[82] alginate- and chitosan-based biomaterials, or hybrid materials combining natural and synthetic components.[82,83] These experimental biomaterials are currently limited to preclinical evaluation and are not yet considered viable for therapeutic use. Nonetheless, they represent promising avenues for future clinical application as the field of vascular tissue engineering continues to evolve.

DISCUSSION

Although biologically derived materials frequently outperform PTFE in small-caliber settings and infected fields, robust long-term durability data (≥ 5 years) remain scarce for many current xenografts and nearly all TEVG platforms. Historical experience with earlier bovine conduits, where late degeneration and thrombosis emerged, suggests the need for systematic, long-term follow-up of modern devices to confirm sustained safety and efficacy.

In the search for biological alternatives to synthetic grafts, numerous options have emerged over the past century. In many cases, biological materials have demonstrated superior patency rates compared to PTFE. This advantage is hypothesized to result from a closer match in compliance and elasticity at the anastomotic site.[84] PTFE grafts are associated with increased intimal hyperplasia, likely due to their mechanical stiffness and compliance mismatch at the vascular anastomosis.[85] By contrast, biologically derived materials, whether of human or animal origin, tend to preserve the native characteristics of functional vasculature and endothelium. To replicate these favorable traits, researchers have experimented with seeding PTFE grafts with endothelial progenitor cells, which has successfully reduced thrombogenicity and intimal hyperplasia in animal models.[86]

Human-derived grafts also have lower infection rates, making them particularly suitable for use in both infected and non-infected vascular beds.[24] Currently, xenografts represent the most extensively studied and widely used class of biologically derived materials, with applications across various anatomical and pathological indications. However, studies with follow-up times beyond 5 years are rare, limiting conclusions about long-term graft performance and host–graft interactions. This may in part be due to the relatively high mortality and poor survival among patients with vascular surgical pathology, such as peripheral arterial disease and vascular hemodialysis access (20%–30% per year and ~17% per year, respectively).[87,88] However, considering the history of long-term complications such as pseudoaneurysm and thrombosis in previous versions of xenografts,[34,36] long-term clinical studies are warranted to ensure the long-term safety of these current xenograft materials.

Looking forward, TEVGs may be the future of vascular reconstruction. These constructs combine beneficial properties of biologically derived materials, such as high biocompatibility, low thrombogenicity, and potential for regeneration, into a single platform aimed at functional remodeling and long-term integration. Autologous material currently remains the superior graft material for all surgical indications. Therefore, the concept of biodegradable scaffolds that ultimately transform into native vasculature may yield similar results to those of autologous material. However, TEVGs remain in early- or preclinical stages, and several challenges must be addressed before they can become a reliable, off-the-shelf alternative to existing graft options (**Table 1**).

CONCLUSION

In conclusion, material choice should be individualized by anatomic site, infection severity, host factors (e.g., diabetes mellitus, dialysis dependence), and conduit availability. Autologous veins remain the preferred option when feasible, while xenografts are valuable across multiple indications, particularly in contaminated fields; however, cost, availability, and long-term outcomes must be carefully weighed. TEVGs are promising for small-diameter reconstructions and have growth potential, yet remain investigational pending the development of scalable manufacturing and the collection of long-term data. Research priorities include ≥ 5-year patency/infection/degeneration endpoints, standardized reporting, cost-effectiveness analyses, and multicenter registries.

AUTHORS' DISCLOSURE

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