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Amniotic Membrane Transplantation: Clinical Applications in Enhancing Wound Healing and Tissue Regeneration

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Abstract

Chronic wounds and non-healing tissue defects pose significant clinical challenges, necessitating innovative therapeutic approaches. A comprehensive literature review of amniotic membrane transplantation for wound healing and tissue repair evaluates the efficacy and safety of amniotic membrane transplantation in enhancing wound healing and tissue repair. Amniotic membranes promote wound closure and reduce inflammation and scarring via abundant growth factors, cytokines, and extracellular matrix components, which foster conducive environments for tissue regeneration. Amniotic membrane transplantation is effective in various medical disciplines, including ophthalmology, dermatology, and orthopedics. Low immunogenicity and anti-microbial properties ensure their safe application. Amniotic membrane transplantation offers a promising therapeutic approach

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for wound healing and tissue repair, and further research is warranted to explore its regenerative potential fully.

Keywords

Amniotic membrane transplantation · Regenerative medicine · Tissue repair · Wound healing

Abbreviations

AMT	Amniotic Membrane Transplantation
bFGF	Basic Fibroblast Growth Factor
BMP	Bone Morphogenetic Protein
CXCR4	Chemokine Receptor Type 4
dHACA	Dehydrated Human Amnion/Chorion Allograft
DHAM	Dehydrated Human Amniotic Membrane
ECM	Extracellular Matrix
EGF	Epidermal Growth Factor
hAM	Human Amniotic Membrane
HAMS	Human Amniotic Membrane Scaffold
HGF	Hepatocyte Growth Factor
HSMA	Hypothermically Stored Amniotic Membrane
IVIG	Intravenous Immunoglobulin
MMP	Matrix Metalloproteinases
MMP	Mucous Membrane Pemphigoid
PDGF	Platelet-Derived Growth Factor
RFFF	Radial Forearm Free Flap
SDF-1α	Stromal Cell-Derived Factor 1 Alpha-
STSG	Split-Thickness Skin Graft
TGF-β	Transforming Growth Factor Beta
TNF-α	Tumor Necrosis Factor Alpha
VEGF	Vascular Endothelial Growth Factor

1 Introduction

The amniotic membrane, a component of the placenta, has gained significant attention in tissue and wound healing due to its unique properties (Leal-Marin et al. 2021). This biologically active membrane comprises multiple layers, including the amnion and chorion, rich in collagen, extracellular matrix, and various growth factors (Moreno et al. 2024a). These components contribute to its regenerative capabilities, making it an effective tool in promoting cell proliferation, reducing inflammation, and enhancing healing (Choi et al. 2009). One of the key advantages of using amniotic membrane in wound care is its ability to provide a natural scaffold for cell migration and tissue regeneration (Choi et al. 2009). It contains essential cytokines and growth factors that accelerate wound healing, reduce pain, and minimize scar tissue formation (Elkhenany et al. 2022). Additionally, its non-immunogenic nature ensures that the body does not reject it, making it a safe and effective option for various types of wounds, including chronic and hard-to-heal wounds (Naeem et al. 2023).

The application of amniotic membranes in clinical settings has shown promising results, particularly in treating diabetic foot ulcers, pressure ulcers, and surgical wounds (Laurent et al. 2017; Tettelbach et al. 2022a, b). Its antibacterial properties further enhance its effectiveness, providing a protective barrier against infections (Radwan and Nemr 2020). As research advances, amniotic membranes are expected to play an increasingly vital role in modern wound care and tissue engineering. This review paper sought to examine the literature on amniotic membrane use in wound healing while also assessing the ethical challenges, limitations, and future applications.

1.1 Definition of Amniotic Membrane Transplantation

During fetal growth and development, the amnion is an inner placental membranous multilaminar tissue surrounding the fetus; hence, the amniotic sac contributes to a prime microenvironment for fetal differentiation (Leal-Marin et al. 2021). Following adherence to proper medical ethics measures, including the due acquisition of patient consent, samples of amniotic membrane can be harvested from the human placenta around birth

via cesarean section (Leal-Marin et al. 2021; Sharma et al. 2023). These can then be dehydrated or cryopreserved, stored, and primed for various therapeutic medical uses (Svobodova et al. 2023).

Through years of research application, the human amniotic membrane (HAM) surface allograft has been found to possess significant anti-inflammatory, antifibrotic, and useful proliferative properties (Horvath et al. 2024; Wan et al. 2021). The hAM can be transplanted as a biodegradable scaffold over external wound sites of mucosal and non-mucosal morphology; its application can be particularly useful for larger wounds with delayed healing time, which portend significant functional limitations of native cellular health and integrity (Svobodova et al. 2023).

1.2 Importance in Normal Wound Healing and Tissue Repair

In the normal physiologic environment, platelets and macrophage cells release platelet-derived growth factor (PDGF); PDGF acts as a mediator of fibroblast activation. Migration of fibroblasts in the extracellular matrix (ECM) is strongly dependent upon chemotaxis and the bonding of fibrin/fibronectin components via integrin receptors: a key proliferative step involves fibroblast morphogenesis into collagen and several other granulation tissue components within the wound matrix (Schultz et al. 2011).

Amniotic membrane therapies promote wound healing and local tissue repair processes via either the upregulation or inhibition of several biochemical markers around sites of allograft transplantation (Svobodova et al. 2023). These mechanisms include the inhibition of proteases, matrix metalloproteinases, and pro-inflammatory cytokines. Conversely, amniotic membrane-based regenerative therapy potentiates the release of beneficial cytokines, such as transforming growth factor-beta (TGF-Beta): which counteracts enzymatic breakdown and lysis of collagenous substrate; this reaction contributes to the inhibition of tissue fibrosis and scarring. Transplanted amniotic membrane allografts also potentiate the release of epidermal/epithelial and nerve growth factors (Wan et al. 2021).

With normal tissue histology, an epithelial layer comprises the outermost covering; thus, the epithelium serves as a barrier which ensures complete integrity and protection of deeper tissues (Sharma et al. 2023). Profound loss of epithelial cells can occur via either ischemic, cytotoxic, or immunogenic mechanisms, resulting in wound formation. Without adequate re-epithelialization, subepithelial tissues are susceptible to microbial pathogens—consequences of which can include tissue necrosis with toxin release, cicatrization with loss of local function, and disability (Guest et al. 2021).

Delayed wound healing can also significantly hamper quality of life via induced pain, socioeconomic implications, and at times, functional limitations (Guest et al. 2021). Disease entities such as diabetes mellitus, deep venous thrombosis, drug-induced hypersensitivity syndrome, neurotrophic keratopathy, etc., which commonly result in indolent manifestations and delayed healing period, have been associated with severe sequelae such as limb amputation, sepsis, and blinding consequences (in cases with ocular involvement).

1.3 Search Criteria for Review

Using the National Library of Medicine database available at https://pubmed.ncbi.nlm.nih.gov/, a search criteria was tailored to include the terms "Amniotic membrane transplantation for wound healing and tissue repair," which spawned 607 results from 1954 to date. The records were then further stratified to include only papers published from 2020 to 2024, leaving 164 records.

The search string generated was "((("amnion" [MeSH Terms] OR "amnion" [All Fields] OR ("amniotic" [All Fields] AND "membrane" [All Fields]) OR "amniotic membrane" [All Fields]) AND ("transplantability" [All Fields] OR "transplantable" [All Fields] OR "transplantated" [All Fields] OR "transplantating" [All Fields] OR "transplantation" [MeSH Terms] OR "transplantation" [All Fields] OR "transplantations" [All

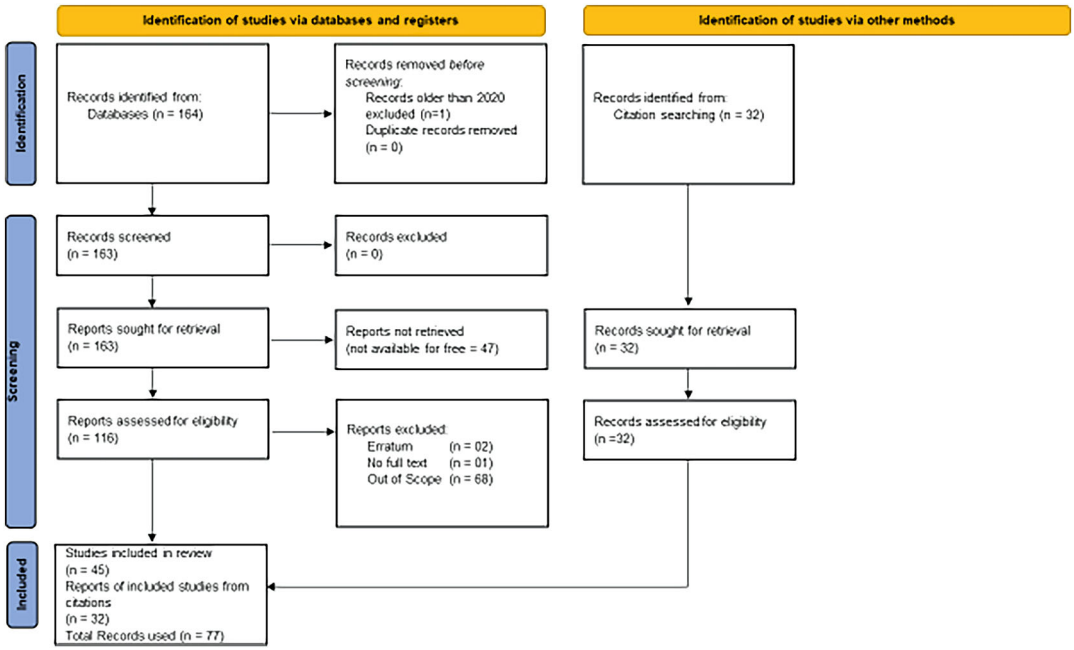

Fig. 1 PRISMA 2020 criteria and results of the selection of papers

Fields] OR "transplanted" [All Fields] OR "transplanting" [All Fields] OR "transplantation" [MeSH Subheading] OR "transplantations" [All Fields] OR "transplanter" [All Fields] OR "transplanters" [All Fields] OR "transplantion" [All Fields] OR "transplants" [MeSH Terms] OR "transplants" [All Fields] OR "transplant" [All Fields]) AND ("wound healing" [MeSH Terms] OR ("wound" [All Fields] AND "healing" [All Fields]) OR "wound healing" [All Fields]) AND ("wound healing" [MeSH Terms] OR ("wound" [All Fields] AND "healing" [All Fields]) OR "wound healing" [All Fields] OR ("tissue" [All Fields] AND "repair" [All Fields]) OR "tissue repair" [All Fields])) AND (2020: 2024[pdat])".

The search returned 164 records; one record was older than 2020 and was immediately excluded. One publication was included outside of the search string. 47 records could not be retrieved as they required a paid subscription. Two records were excluded because they were errata, another paper was excluded because it had no text, and a further 68 were excluded for being out of context. The references of the resulting 45 records were further searched for relevant papers, adding a further 32 records to this review (Fig. 1).

1.4 The Use of Amniotic Membrane Transplantation in Wound Healing and Tissue Repair

The amniotic membrane is an extraembryonic tissue that constitutes the inner lining of the fetal amniotic sac. It is an avascular and translucent thin tissue that plays a role in the absorption and production of amniotic fluid thus, aiding in the provision and maintenance of the required homeostatic environment required for the healthy growth and development of the embryo and later fetus. The amniotic membrane possesses several clinically fascinating and biological characteristics that encourage its use as a surgical and therapeutic agent in modern medicine.

The first documented therapeutic application of amniotic membrane in modern medicine was carried out at Johns Hopkins Hospital by Davis in 1910 (Malhotra and Jain 2014). This pioneering

work laid the foundation for the subsequent use of amniotic membranes as a therapeutic and surgical agent in modern medicine. Although marred by low success rates; approximately 30 years after Davis's astonishing work, De Rotth delineated and demonstrated for the very first time in ophthalmology. The effectiveness of amniotic membrane in managing ocular surface defects and conjunctival reconstruction. Amniotic membrane use in surgical reconstruction and wound healing was further popularized in ophthalmic practice in 1995 by the work of Kim and Tseng.

1.5 Properties of Amniotic Membrane

The general attributes of the human amniotic membrane which make it suitable to support the growth and development of an embryo and later fetus also make it highly invaluable in transplantation and reconstructive medicine (Bonvallet et al. 2022). During the gestation period, the human amniotic membrane alongside other extraembryonic tissue helps to provide a stable and relatively immune-neutral environment. Some of these properties include anti-fibrotic tendencies (Fiani et al. 2022; Fan et al. 2021); good oxygen permeability, homeostatic ability, moisture retention and hydration, analgesic effects (Panero et al. 2023); durability, elasticity, strength, anti-inflammatory and anti-microbial effects (Tasneem et al. 2024; Han et al. 2022; Dhall et al. 2021); low immunogenicity, high compatibility, immuno-regulatory, and tissue regenerative and rapid re-epithelialization ability (Koullias 2021; McDaniel et al. 2021; Ramasubramanian et al. 2024).

Although the human amniotic membrane has been popularized and is widely employed in tissue reconstruction and regenerative medicine, the technique used in preparing and preserving the human amniotic membrane can significantly impact the integrity of its structural configuration, biomolecular properties, its physicochemical qualities, and effectiveness (Hofmann et al. 2023; Gholipourmalekabadi et al. 2020). Thus, the importance of selecting the best and safest methods as well as the optimization of existing methods of collection, separation, cleaning, processing, sterilization, and quality control cannot be overemphasized, since the effectiveness of amniotic membranes in tissue engineering and wound healing is mostly dependent on its physicochemical and molecular properties (Radwan and Nemr 2020; Wang et al. 2023).

Abbasnezhad et.al suggested that the isolation process be carried out within a few hours after the cesarean section since a longer duration of storage resulted in contamination and altered desired results (Abbasnezhad et al. 2022). Furthermore, the human amniotic membrane can be tailored and augmented to meet specific needs and applications. This can be accomplished through the development of new and innovative processing strategies and tissue augmentation (Moreno et al. 2024b).

1.6 Amniotic Membrane Composition and Structure

In humans, the four extraembryonic membranes namely: the yolk sac, chorion, allantois, and the amnion are collectively also known as the fetal membrane (Verbruggen et al. 2017; Freyer and Renfree 2009). At the beginning of the second-week post-fertilization, the inner cell mass of the developing blastocyst begins to differentiate and reorganize into the two stratified embryonic cell discs, namely the dorsally located epiblast and the ventrally located hypoblast. At this phase of development, the structural arrangement is such that the amniotic cavity is located in between the two-layered embryonic cell disc and the trophoblast which is already implanted in the endometrial wall. This is closely followed by the encircling of the amniotic cavity by the dorsally located epiblast to form the amniotic membrane thus, yielding the amnion. Subsequently, the amniotic cavity becomes filled with amniotic fluid and completely envelops the developing embryo, later fetus.

The composition of the amniotic fluid varies with time. At the early stages of development, the amniotic fluid closely approximates the mother's plasma but as the fetus's kidneys and other organs

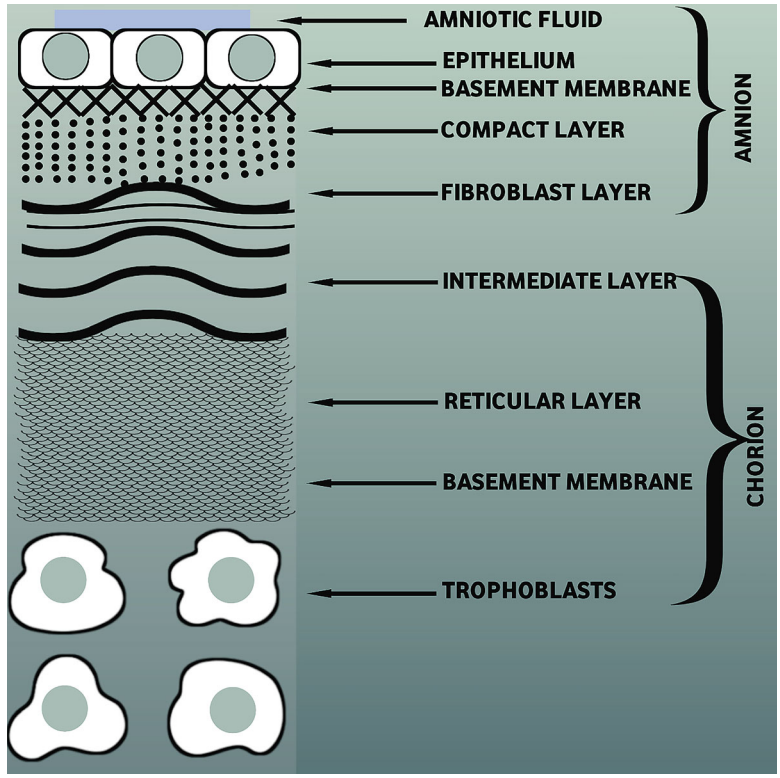

Fig. 2 A schematic representation of amniotic membrane layers. The compact layer is a dense fibrous acellular stratum that provides structural resistance to the membrane. It comprises types I, III, V, and VI collagen, and fibronectin. On the other hand, the fibroblast stratum comprises fibroblast-like cells, collagen types I, III, IV nidogen, and fibronectin, which enhances the membrane's structural integrity. The outer sponge layer consists of loosely organized cells and is rich in hyaluronan, collagen types I, II, IV, and proteoglycan. This stratum gives the amniotic membrane the deserved flexibility and elasticity

develop the composition is altered to include other substrates such as urea and phospholipids consequently altering the osmolarity of the amniotic fluid (Farrell et al. 1983; Whittle et al. 1981; Modena and Fieni 2004; Beall et al. 2007). Furthermore, elemental mineral concentration in amniotic fluid is altered with gestational age and fetal maturity (Sulibursk a et al. 2016).

The inner lining of the amnion or the amniotic membrane comprises three layers: the epithelium, the basement membrane, and the stroma. The epithelium is the innermost layer of the amniotic membrane and is in close contact with the amniotic fluid. It consists of a single layer of cuboidal epithelial cells, which can proliferate and differentiate rapidly and interestingly aid in the transport of fetal waste in and out of the amniotic fluid, and are involved in the production of amniotic fluid.

The basement membrane is a thin layer underlying the epithelium. It comprises collagen types IV, V, and VI, and other extracellular proteins such as fibronectin and laminin which appropriately anchor the epithelium and provide support (Malhotra and Jain 2014; Fukuda et al. 1999). The stroma is further divided into three layers, namely an inner compact layer, a middle fibroblast layer, and an outer spongy layer (Elkhenany et al. 2022). Figures 2 and 3 summarize these layers.

1.7 Biological Properties and Mechanisms of Action in Wound Healing and Tissue Repair

As shown by the image above, the biomolecular and tissue characteristics of the human amniotic membrane make it a therapeutic choice for many medical researchers and practitioners involved in stem cell research and tissue engineering. Although the anti-inflammatory properties of the human amniotic membrane can be attributed to several other biomolecular cascades such as the inhibition of pro-inflammatory proteins and

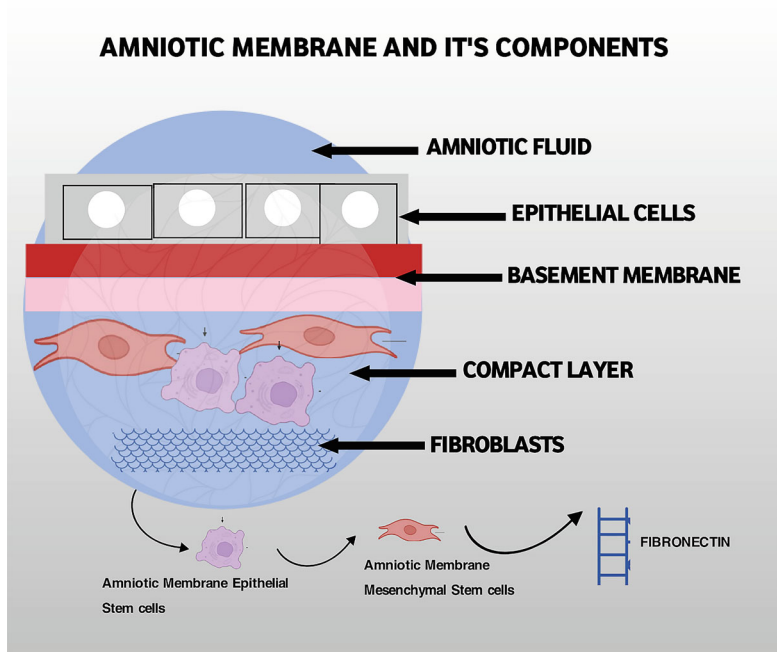

Fig. 3 A schematized representation of the micro-anatomy, biomolecular composition, processing, and preservation modes of the human amniotic membrane, as well as its application in surgical reconstruction and tissue engineering

cytokines (Moore et al. 2020); the release of growth factors by the human amniotic membrane plays an important role in diminishing inflammatory reactions. For instance, a substantial upregulated expression of growth factors like insulin-like growth factor 1 (IGF1), transforming growth factor beta 1 (TGFB1), and vascular endothelial growth factor (VEGF) were found in thermally injured rats that were treated with amniotic membrane impregnated with activated adipose tissue-derived stem cells (ASCs) (Tasneem et al. 2024).

Furthermore, it was also found that there was an increase in the deposition of collagen, the numerical population of basal cells of the epidermis, fibroblast, blood vessels, and the total count of proliferating cells when rats that had induced diabetic ischemic wounds were treated with a human amniotic membrane-scaffold (HAMS) incorporated with (SDF-1α) stromal cell-derived factor-1 alpha (SHAMS) used together with hyperbaric oxygen therapy (HBO). An upregulation of growth factors such as VEGF, TGF-B, and bFGF basic fibroblast growth factor was noted by the same researchers and it was proposed that the upregulation of the growth factors mentioned earlier diminished the expression of pro-inflammatory cytokines such as tumor necrosis alpha (TNF-α) and IL-1β and the cell population of macrophages and neutrophils consequently facilitating healing and diminishing inflammation (Tasneem et al. 2024).

More importantly, growth factors such as epithelial growth factor (EGF) have been known to facilitate proliferation, differentiation, cellular migration, and finally epithelialization thus decreasing inflammatory cascades (Zhao et al. 2020a; Moon et al. 2020). Other growth factors like hepatocyte growth factor (HGF) that have been known to be present in the human amniotic membrane inhibit inflammation by interfering with the signaling pathways of the transcription factor; nuclear factor kappa-light-chain enhancer of activated B cells (NF-kB) which is usually activated by TNF-α (Koizumi et al. 2000). Consequently, diminishing the expression of endothelial adhesion molecules such as E-selectin, eventually suppresses monocyte adhesion to the endothelial cells (Gong et al. 2006).

The amniotic membrane also maintains its anti-inflammatory and wound-healing properties via its anti-adhesive, anti-fibrotic, and immune

cell-trapping qualities (Zukawa et al. 2022; Endicott et al. 2023). The human amniotic membrane's anti-adhesive and anti-fibrotic features reduce inflammatory reactions and enhance wound healing by reducing the risk of fibrosis and scar development, minimizing mechanical friction and post-surgical pathologic irritation, reducing post-operative complication, and enabling appropriate tissue homeostasis (Endicott et al. 2023; Ebrahimi et al. 2022).

Pathological events such as injury, disease, and other inflammatory conditions impose significant physical stress, resulting in the recruitment of pro-inflammatory cytokines such as IL-1, TNF, and other acute phase proteins which further leads to the activation of the pro-fibrotic TGF-β1/SMAD pathway. However, certain proteins and extracellular matrix constituents present in the human amniotic membrane prevent the activation of TGF-β1 or downregulate its expression thus, preventing or reducing the chances of fibrosis. For instance, decorin a leucine-rich proteoglycan present in the amnion has been demonstrated to bind TGF-β1 and inhibit the downstream phosphorylation of the SMAD2 and SMAD3 consequently breaking the cascade of fibrosis at the biomolecular level (Meinert et al. 2001; Eremenko et al. 2024; Dudás et al. 2001; Zhang et al. 2009).

1.8 Clinical Applications of Amniotic Membrane

Amniotic membrane transplantation has gained popularity for its wound regeneration applications at multiple anatomic sites. The clinical usability of hAM therapies is diverse: with viable applications ranging from in-office to intraoperative and postoperative settings.

Dehydrated human amnion/chorion membrane: a cryopreserved derivative of hAM has been associated with fast healing times when utilized for postoperative care (Chen et al. 2021). Intraoperative amniotic membrane transplantation has also been employed with increased frequency. Although in the field of eye care, clinical uses of amniotic membrane transplantation have been applied mostly to ocular surface healing therapeutics (Hancox et al. 2020), its clinical applications have also been translated to improve surgical outcomes of high-stake vitreoretinal and glaucoma filtration procedures (Sharma et al. 2023). In this area, intraoperative placement of amniotic membrane onlay-grafts over the scleral flap site following trabeculectomy has been linked with longer periods of bleb patency and subsequent intraocular pressure control (Sharma et al. 2023).

1.9 Ophthalmologic Applications

The human amniotic membrane is a popular biological therapeutic tool in eyecare practice. Its unique physico-biochemical characteristics make it viable for treating ocular surface diseases (Zhao et al. 2020b); keratitis, persistent cornea epithelial defects (Dhillon et al. 2020; Riedl et al. 2021); corneal ulcers (Schuerch et al. 2020; Sakimoto et al. 2020); cornea perforations (Kate et al. 2023; Ke et al. 2020); aggressive necrotizing inflammatory diseases of ocular surface structures (Hwang and Kuo 2021); post-exenteration radiation-induced orbital wounds (Razlog et al. 2023); oculoplastic reconstruction and poorly healing post-surgical wounds (Kohlhaas et al. 2022; Malyugin et al. 2020; Gupta et al. 2020).

Although the outcome of the application of hAM in ophthalmology has been mostly satisfactory, several factors such as the stage of the disease and protracted dwelling of hAM on the affected tissue yield a more favorable outcome and reduce the overall duration a patient spends in the hospital from admission to discharge (Bulut et al. 2023).

The effectiveness of hAM in facilitating epithelialization and smooth wound healing without inducing fibrosis is why hAM is a good therapeutic choice in managing diseases of highly immune-sensitive tissues such as the cornea. Highly innervated tissues such as the cornea tend to lose some functionality even after the vascular infiltrations associated with inflammation have resolved. This smooth wound-healing quality of hAM has been demonstrated by Vojtech et.al to have a similar effect on the

healing of stubborn wounds. It was found that the average wound healing after 1 week was approximately 12.17% after the variability in wound healing of cryopreserved amniotic membrane grafts from nine placentae was investigated. Consequently, it was determined that the impact of inter-placental variability on the wound healing efficiency of hAM graft is negligible (Horvath et al. 2023).

It is no surprise that the human amniotic membrane works wonders in the management of severe symblepharon when combined with optimally performed symblepharon lysis and release (Venugopal and Ravindran 2022); and used to effectively manage a persistent cornea epithelial defect (PED) when adequately fixated on the ocular surface with augmented suturing methods such as modified continuous suturing technique (Baykara et al. 2022). Also, it may be applicable for reduction of cornea epithelial defects associated with orthopoxvirus (Uner et al. 2023). In addition, Kapp et al. in their case series, alluded to the effectiveness of amniotic membrane in managing hard-to-heal wounds when in an attempt to develop an alternative approach to managing post-Mohs surgical wounds. The study investigated the wound healing efficiency of hypothermically stored amniotic membrane (HSMA) in hard-to-heal wounds following Mohs micrographic surgery (Kapp and Pfendler 2024). Furthermore, the human amniotic membrane was effectively used to manage a 25-year-old female for cataract surgically, blebitis, and exogenous endophthalmitis caused by a long-standing bleb leakage following XEN stent implantation, bleb needling, and augmented trabeculectomy (Tang et al. 2023). Among the various characteristics of hAM, its anti-fibrotic, anti-inflammatory, and low immunogenicity qualities and the presence of growth factors and other important substrates contribute most to its effectiveness in ophthalmology practice.

Some researchers have demonstrated that the high-chain hyaluronic acid/pentraxin 3 (HC-HA/PTX-3) matrix complex derived from hAM inhibits tissue fibrosis mediated by TGF-B1 growth factor by repressing the TGF-B/SMAD pathway while simultaneously inducing the reversal of cornea fibroblast and myofibroblast to their earliest keratocyte state via the activation of CXCR4 signaling which results to the activation of bone morphogenetic protein (BMP) signaling and consequently leading to the consistent maintenance of the original morphologic state of the keratocytes (Zhu et al. 2020). This explains why it is very effective in managing pathologies of the cornea conjunctival and other susceptible neuro-ophthalmic tissues (Fogla and Indumathy 2021; Memmi et al. 2022; Yin et al. 2020; Khan et al. 2021). hAM has also been successfully employed in the surgical reconstruction of a case involving a traumatic soft tissue loss using a novel procedure in which a 2 mm X 2 mm full-thickness skin graft was sandwiched between two amniotic membrane grafts using cyanoacrylate tissue adhesive to attach the superficial amniotic membrane firmly (Reed et al. 2022).

The clinical effectiveness of amniotic membrane transplantation alongside minor ipsilateral simple limbal epithelial transplant (mini-SLET) in combination with tenonectomy, and mitomycin c in addressing recurrent pterygium was evaluated using the post-operative best correct visual acuity, restoration of the ocular surface, rate of recurrence and postoperative complication as the clinical factors upon which the outcome was defined. It was found that the ocular surface and other ocular variables affected by the recalcitrant pterygium were completely restored except in one case.

1.10 Dermatological Applications

The use of the human amniotic membrane (hAM) in dermatology and wound care has been well-established in the medical literature (Bn et al. 2024; Garcia et al. 2023). Various studies have shown hAM to be effective in managing burns (Sandora et al. 2022; Moreno et al. 2024c), chronic wounds such as diabetic foot ulcers and venous ulcers (Oropallo et al. 2021; Serena et al. 2022; Ditmars et al. 2022; Ahuja et al. 2020; Mohammed et al. 2022). Severe burns in diabetic patients are a life-threatening situation due to the altered or delayed immune reaction, neuropathy,

hyperglycemia, and ischemia resulting from suboptimal blood supply. As such, managing severe burns in patients with comorbid conditions like diabetes can be clinically challenging and resource-draining and carries a complicated prognosis when compared to third-degree burn patients without diabetes.

Some studies have reported a favorable outcome and enhanced wound healing with hAM, and may in no distant time be the preferred method of treating severe burns in diabetic patients (Arai et al. 2024; Nasiry et al. 2021; Huang et al. 2020; Kitala et al. 2020). Furthermore, the use of hAM in split-thickness skin graft (STSG) donor site healing has been demonstrated by some authors to be not only safe but also possesses a superior outcome when compared with routine dressing used in modern clinical practice (Liang et al. 2020; Babot-Pereña and Blanco-Blanco 2023). On the contrary, other authors have posited that the amniotic membrane does not necessarily possess a superior outcome in terms of the healing rate of the STSG site when compared to routine dressing techniques like petrolatum gaze but, attributes the greater acceptance and favorable outcome associated with the use of an amniotic membrane in wound care to its analgesic effect and re-epithelialization rate (Vaheb et al. 2020).

Despite the difference in opinions regarding the outcome of using human amniotic membrane in wound care, by some experts and researchers, available anecdotal evidence favors its application over other routine dressing techniques used in wound care thus, suggesting a superior outcome over others (Rahman et al. 2020; Hashemi et al. 2021; Ramakrishnan et al. 2022; Liu et al. 2020; Lakmal et al. 2021). hAM has also been applied in the successful management of skin lesions such as blisters, erosions, and sloughing of the skin associated with bullous skin diseases like Stevens-Johnson syndrome (Klama-Baryła et al. 2020; Ceylan et al. 2023). Its use has also been extended to manage TEN characterized by aggressive erosions and skin sloughing. There is enough anecdotal evidence to reinforce the fact that the prognosis of TEN syndrome can be further improved if a high-dose intravenous immunoglobulin is given early (IVIG) along with hAM as a combination therapy (Bashiri Aliabadi et al. 2023).

Aliabadi et al. posited that complications such as gastrointestinal bleeding pleural and infection of the involved areas of the skin were absent when a 61-year-old woman who presented with a generalized macular lesion on the trunk, upper extremities, and face was treated with early IVIG and amniotic membrane grafting, thus, demonstrating the safeness of hAM (Bashiri Aliabadi et al. 2023). hAM has also been applied in the management of congenital skin conditions like aplasia cutis congenital, an uncommon congenital developmental anomaly characterized by a localized or generalized absence of the epidermis, or dermis and results from an abnormal formation of the skin during the embryonic period of life (Kadivar et al. 2024). A cryopreserved amniotic membrane allograft has also been successfully employed in the management of traumatic tissue loss from Dog bite for which an excellent post-surgical outcome was reported thus, further demonstrating its effectiveness in tissue reconstruction and plastic surgery (Ye et al. 2024).

1.11 Other Fields of Application

In recent years, hAM application in wound care has extended to almost all specialties of medicine. Besides ophthalmology and dermatology, hAM has also been employed as a therapeutic agent in orthopedics, dentistry, cardiology, urology, obstetrics and gynecology, gastroenterology, oncology, and aggressive necrotic ulcerations such as pyoderma gangrenosum which requires a multispecialty intervention (Nejad et al. 2021; Doudi et al. 2022; Fridman et al. 2020). Oral soreness following surgical event results in significant discomfort to patients whose soft palate tissue was harvested for a free gingiva graft.

The pain-relieving and wound-healing efficacy of hAM after its grafting on a palatal donor site following a free gingival graft was investigated. It was found that it not only facilitated faster wound healing but also relieved pain and provided some

comfort (Kadkhoda et al. 2020). In maxillofacial surgery, hAM has been demonstrated to be effective in the surgical management of cleft palate, drug-related osteonecrosis of the jaw, oronasal fistula, oral mucosa, gingival recession defects, and gingival fenestration (Gomaa et al. 2022; Bhide and Tenenbaum 2020). Furthermore, both amnion and chorion when combined individually with decalcified freeze-dried bone allograft (DFDBA) gave a good clinical outcome in the management of mandibular molar furcation defects (Mallapragda et al. 2024).

There have been clinical reports of reduced post-surgical complications in patients who underwent lower extremity and bone reconstruction surgery following the application of aseptically processed dehydrated human amnion and chorion allograft (dHACA) or dehydrated human amniotic membrane (DHAM) (Tacktill et al. 2022; Horn et al. 2020). Furthermore, the radial forearm free flap (RFFF) donor site grafted with hAM has been shown to possess outstanding clinical and functional results (Hunger et al. 2020). In pediatrics, the use of a cryopreserved human umbilical cord and amniotic membrane allograft to surgically manage a dehisced abdominal wound that resulted from the surgical repair of a giant omphalocele was reported to yield a remarkable pot-surgical outcome (Boyar 2020).

1.12 Wound Healing and Tissue Repair Outcomes

Available evidence supports the cost-effectiveness of human amniotic membranes over other routine procedures for wound management (Carter 2020; Tettelbach et al. 2022a, b). Furthermore, augmented hAM has also been found to be cost-effective and a time-saving approach (Ceylan et al. 2023). Although the clinical outcome of hAM application in wound care and surgical reconstruction has been largely satisfactory, its application in the management and surgical reconstruction of the conjunctival fornix and cicatricial entropion repair in mucous membrane pemphigoid (MMP) patients has been mostly short-lived (Au et al. 2021; Khan et al. 2024).

Age has been indicated as a variable linked with time-to-healing in response to amniotic membrane therapy (Chen et al. 2021). In the setting of acute moderate to severe ocular burns, outcome measures narrowly based on corneal epithelial healing time and reduced corneal neovascularization do not demonstrate vast quantitative differences between standalone medical therapy and a combination of amniotic membrane transplantation with medical therapy (Clare et al. 2022).

1.13 Comparison with Other Treatment Modalities

Abbasnezhad et al. reported on a combined therapy comprising low-level laser and amniotic membranes to manage wounds in rats. These diabetic murine models showed better wound healing when managed with low-level diode laser irradiation amniotic membrane grafts than using the grafts alone (Abbasnezhad et al. 2022). Nasiry et al. took a different comparative approach, pairing amniotic membrane graft with hyperbaric oxygen in a group of test rats, while another group received amniotic grafts alone. Again, they reported that hyperbaric oxygen-enriched amniotic membrane graft therapy outperformed the standalone amniotic membrane graft-treated wounds in diabetic rats (Nasiry et al. 2022).

On the other end of the spectrum, Tandon et al. conducted a randomized controlled trial to assess healing in patients being managed strictly with standard medical therapy (including the occasional need to release adhesions that developed in areas of contact mechanically), and another group that had an extra adjunctive amniotic membrane-derived therapy (Tandon et al. 2011). While final visual outcomes and clarity were not significantly different, the researchers concluded that the group with standard medical treatment alone performed better ($p = 0.0004$).

1.14 Safety and Complications

While amniotic membrane transplantation opens a new forte in managing wound healing and tissue repair, it has safety requirements and complications. Chief among these are:

Infection: Reviewing relevant literature reveals case reports and opinions on infective processes after amniotic membrane transplantation. Alreshidi and Al-Swailem reported on a late-onset intra-amniotic membrane infection in an adult male being managed for epithelial defects following corneal surgery (Alreshidi and Al-Swailem 2021). They opined that gram-positive isolates were the most common microbial agents responsible for post-amniotic transplant membrane infection. Marangon et al. examined 326 case files of patients who underwent amniotic membrane transplantation over the 7 years leading up to 2001 (Marangon et al. 2004). They discovered 11 cases of microbial infection (3.4%), all due to gram-positive bacteria.

Tissue rejection: graft rejection occurs when the recipient's innate immune system attacks the transplanted tissue, destroying and rendering it ineffective (Justiz Vaillant and Mohseni 2024). Schmiedova et al. reported on the failure of amniotic graft transplantation in patients treated with lyophilized amniotic membranes due to possible tissue rejection.

1.15 Research Gaps and Areas for Further Investigation

Amniotic membrane transplantation has seen significant advancements in wound healing in recent years. The amniotic membrane, derived from the innermost layer of the placenta, is rich in growth factors, cytokines, and extracellular matrix components that promote tissue regeneration and repair. The following research gaps and areas for further investigation still exist.

Enhanced Preservation Techniques: Recent developments in the preservation and processing of amniotic membranes have greatly improved their bioavailability and shelf life. Cryopreservation and dehydration methods have been refined to maintain the biological activity of the membrane, ensuring that its healing properties are retained over longer periods. Preclinical research suggests that micronized amniotic membranes may integrate well with umbilical cord-derived mesenchymal stem cells by providing a scaffold for better delivery and protection of stem cells at diabetic wound sites (both in vivo and in vitro) (Zheng et al. 2015, 2017). Better preservation will result in optimum viability of amniotic membrane grafts and derivatives.

Clinical Applications and Efficacy: Amniotic membrane transplantation has been successfully applied in various clinical settings, including chronic wounds, burns, and surgical wounds (Schuerch et al. 2020). Studies have shown that amniotic membranes can accelerate epithelialization, reduce inflammation, and minimize scarring (Sharma et al. 2023; Röck et al. 2018). For instance, in chronic wound management, applying amniotic membranes has led to faster wound closure and improved patient outcomes. Its clinical applications continue to be an area of interest for researchers and clinicians alike.

Combination Therapies: Combining amniotic membranes with other regenerative therapies has shown promising results. For example, using amniotic membranes alongside amnion-conditioned media has effectively treated chronic wounds, promoted granulation tissue formation, and restored normal blood flow (Seong et al. 2023; Kim et al. 2023). This synergistic approach enhances the healing process and offers new avenues for complex wound management.

Innovative Forms and Delivery Methods: Advances in biotechnology have led to the development of various forms of amniotic membrane products, such as gels, powders, and sheets. Tissue engineering of amniotic membranes presents a new frontier to its use in medicine (Langer and Vacanti 2016). These different forms cater to specific wound types and conditions, providing tailored solutions for optimal healing. The gel form, for instance, offers a hydrating barrier that can control the release of therapeutic components, making it particularly useful for wounds requiring moisture balance (Rahman et al. 2019). Amniotic membranes can now be bioengineered to drops

and allied preparations, allowing their application in novel techniques (Lacorzana 2020). Bioengineered tissue preparations can also be easier to preserve when compared to their original extracted form (Jirsova and Jones 2017).

These advancements in amniotic membrane transplantation highlight its potential as a versatile and effective tool in modern wound care, offering hope for improved healing outcomes and quality of life for patients with challenging wounds.

1.16 Limitations

Despite the promising benefits of amniotic membranes in wound healing and tissue repair, several limitations must be considered. One significant challenge is the cost associated with the procurement, processing, and storage of amniotic membranes. These processes require stringent sterilization and preservation techniques to maintain the membrane's biological properties, which can be expensive and limit accessibility, especially in resource-constrained settings (Tettelbach et al. 2022a, b; Ramakrishnan and Jayaraman 1997).

Another limitation is the variability in the quality and efficacy of amniotic membranes. Factors such as the donor's health, age, and the method of membrane preparation can influence the membrane's therapeutic potential. This variability can lead to inconsistent clinical outcomes, making it difficult to standardize treatment protocols. Horvath et al. looked at this and concluded that the source of the graft did not significantly affect its efficacy (Horvath et al. 2023).

Regulatory and ethical concerns also pose challenges. Using human-derived tissues necessitates rigorous regulatory oversight to ensure safety and ethical compliance (Sridhar and Tripathy 2024; Chen et al. 2022). This can result in lengthy approval processes and restrict the adoption of amniotic membrane therapies.

Additionally, there is a need for more comprehensive clinical studies to fully understand the long-term effects and potential complications associated with amniotic membrane use. While short-term benefits are well-documented, long-term data is limited, and further research is essential to establish the safety and efficacy of these treatments over extended periods. In summary, while amniotic membrane offers significant advantages in wound healing and tissue repair, addressing these limitations through continued research, innovation, and regulatory advancements is crucial for its broader application in clinical practice.

2 Conclusion

The utilization of amniotic membranes in wound healing and tissue repair has demonstrated significant promise due to its unique properties. The membrane's rich composition of cytokines, growth factors, and extracellular matrix components enhances the healing process by promoting cell proliferation, reducing inflammation, and minimizing scar tissue formation. Its non-immunogenic nature ensures compatibility and reduces the risk of rejection. Clinical applications have shown that amniotic membranes can effectively treat chronic and hard-to-heal wounds, such as diabetic foot ulcers, pressure injuries, and surgical wounds. The membrane's ability to provide a biological barrier, reduce pain, and accelerate tissue regeneration makes it a valuable adjunctive therapy in modern wound care. Despite its benefits, challenges, such as the cost of treatment and the need for standardized protocols, remain. Future research should optimize the preparation and application methods of amniotic membrane to maximize its therapeutic potential. In conclusion, the amniotic membrane stands out as a potent tool in the arsenal of wound healing and tissue repair strategies. Its continued integration into clinical practice, supported by ongoing research and innovation, holds the promise of improved outcomes for patients with complex wound healing needs.

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