

Uterine Factor Infertility: Current Therapeutic Frontiers and the Promise of Uterine Bioengineering

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Abstract: Absolute uterine factor infertility (AUFI), resulting from congenital absence or non-functionality of the uterus, affects approximately 1 in 500 women of reproductive age and remains one of the most challenging forms of female infertility. While uterine transplantation has enabled successful pregnancies, it is associated with substantial limitations including donor scarcity, long-term immunosuppression, and ethical concerns. As a promising alternative, uterine tissue engineering aims to restore reproductive function using biocompatible scaffolds, often combined with stem or progenitor cells. This review summarizes current experimental and clinical evidence on scaffold-based and stem cell-driven approaches to uterine regeneration. Various cell sources have been explored, including mesenchymal stem cells (MSCs), embryonic stem cells (ESCs), and induced pluripotent stem cells (iPSCs), with MSCs emerging as the most clinically feasible due to their immunomodulatory properties and accessibility. Scaffold types range from natural biomaterials (e.g., collagen) to synthetic polymers and decellularized extracellular matrices. Recent preclinical and clinical studies demonstrate promising outcomes in regenerating endometrial tissue and restoring fertility in conditions such as Asherman's syndrome. Nonetheless, challenges remain in standardization, long-term safety, and translation to widespread clinical use. Continued multidisciplinary research and advances in 3D bioprinting and personalized regenerative strategies may soon redefine the therapeutic landscape for AUFI.

Keywords: uterine factor infertility, uterine tissue engineering, uterine regeneration, stem cells, scaffold, uterine bioengineering, endometrial repair, 3D bioprinting.

1. Introduction

Absolute uterine factor infertility (AUFI) is defined as a condition resulting from either congenital absence of the uterus or the presence of a non-functional uterus. The latter may arise from severe intrauterine pathology or as a consequence of hysterectomy. AUFI affects approximately 1 in 500 women of reproductive age and remains a significant clinical challenge, with uterine transplantation currently representing the only definitive therapeutic option [1,2,3].

The first successful live birth following uterine transplantation occurred in 2014. The recipient was a 35-year-old woman diagnosed with congenital uterine agenesis, specifically Mayer-Rokitansky-Küster-Hauser (MRKH) syndrome. The donor was a 61-year-old postmenopausal woman. Throughout the treatment, the recipient was maintained on immunosuppressive therapy. The first embryo transfer took place one year after transplantation. The pregnancy was complicated by preeclampsia and was

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concluded by an emergency cesarean delivery at 32 weeks of gestation. A healthy neonate was delivered, weighing 1,775 grams with an APGAR score of 9/9/10 [4].

While uterine transplantation has opened a new frontier in reproductive medicine, it is not without limitations. The scarcity of suitable donors, the necessity for prolonged immunosuppression, and the inherent risk of graft rejection all present significant clinical and ethical challenges. Moreover, long-term immunosuppressive therapy carries considerable risks, including nephrotoxicity, diabetes mellitus, hypertension, accelerated atherosclerosis, and increased susceptibility to severe infections [2].

Emerging advances in uterine bioengineering offer a promising alternative. This approach involves the implantation of a biocompatible scaffold into the patient, potentially seeded with autologous or donor-derived cells prior to transplantation. These tissue-engineered constructs aim to restore reproductive function in patients affected by uterine factor infertility or recurrent pregnancy loss [5,6,7].

The following article presents a comprehensive overview of scaffold materials and cell types under investigation in the field of uterine tissue engineering. It explores the biological, technical, and translational aspects that may one day enable regenerative solutions to overcome the limitations of traditional transplantation.

2. Experimental Section

A systematic literature review was conducted using the PubMed, databases to identify relevant peer-reviewed publications addressing therapeutic approaches to absolute uterine factor infertility (AUI), with particular emphasis on uterine tissue engineering and regenerative strategies.

The search strategy employed combinations of specific Medical Subject Headings (MeSH) and keywords, including: *"uterine factor infertility"*, *"uterine tissue engineering"*, *"uterine regeneration"*, *"stem cells"*, *"scaffold"*, *"uterine bioengineering"*, *"endometrial repair"*, and *"3D bioprinting"*.

The primary objective was to evaluate and synthesize existing preclinical and clinical evidence supporting the feasibility, safety, and efficacy of cell- and scaffold-based regenerative techniques in the context of AUI.

Tissue Engineering Approach to Uterine Regeneration

Tissue engineering seeks to develop functional

tissues or entire organs to restore or replace damaged structures, particularly in cases of uterine infertility resulting from either structural defects or complete uterine loss.

Cell Sources

The ideal cell source for uterine bioengineering consists of stem or progenitor cells due to their self-renewal capacity and potential to differentiate into multiple cell types relevant to uterine tissue architecture. The three most commonly investigated cell types include mesenchymal stem cells (MSCs), embryonic stem cells (ESCs), and induced pluripotent stem cells (iPSCs).

a) Mesenchymal Stem Cells (MSCs)

MSCs are non-hematopoietic, multipotent progenitor cells that can be isolated from bone marrow, adipose tissue, or umbilical cord tissue. Among these, umbilical cord-derived MSCs are particularly attractive due to their non-invasive harvest, high cell yield, and enhanced proliferative potential compared to bone marrow-derived MSCs. MSCs may be administered locally or intravenously for their paracrine and juxtacrine effects, which include immunomodulation, angiogenesis, and promotion of endogenous tissue repair. Current clinical applications include cardiac repair post-myocardial infarction, autoimmune disorders such as type 1 diabetes and Crohn's disease, and graft-versus-host disease. Prior to transplantation, MSCs can also be pre-differentiated into target cell types and implanted with a biocompatible scaffold to enhance integration and functionality [8].

Umbilical cord-derived MSCs (UC-MSCs) have a higher yield and less invasive collection method compared to adipose-derived MSCs (ADSCs). UC-MSCs show a broader differentiation potential into bone, cartilage, and adipose tissue, and ADSCs have a stronger differentiation potential into adipocytes and osteoblasts. Uterine tissue repair is ensured by the rapid proliferation of UC-MSCs and the increased proangiogenic potential of ADSCs [9,10,11].

b) Embryonic Stem Cells (ESCs)

ESCs are derived from the inner cell mass of blastocyst-stage embryos and possess unlimited proliferative capacity and pluripotency, allowing differentiation into a wide range of specialized cells. Despite these advantages, their use is ethically and clinically controversial due to the destruction of embryos, risk of immune rejection, and potential for tumorigenesis, especially from residual

undifferentiated cells [12].

c) Induced Pluripotent Stem Cells (iPSCs)

iPSCs are reprogrammed somatic cells rendered pluripotent through the enforced expression of key transcription factors [8]. The benefits are relatively simple extraction from cutaneous sources, such as dermal fibroblasts, compared to invasive extraction from bone marrow or adipose tissues; and autologous transplantation which avoids immunogenicity [13]. Although they offer reduced immunogenicity and ethical advantages over ESCs, challenges remain in terms of low reprogramming efficiency and variable differentiation potential [14]. A landmark clinical application was the transplantation of iPSC-derived retinal pigment epithelium for the treatment of age-related macular degeneration [15].

Due to the lack of long-term clinical trial results, the outcome of therapeutic use is still uncertain. Informed consent is an essential part of treatment, in which the patient must be informed of the potential risk of tumorigenicity. The primary risk of tumorigenicity stems from the inherent self-renewal and pluripotency of stem cells. Even after controlled differentiation of ESCs and iPSCs, a small number of residual undifferentiated cells may persist and potentially form teratomas, which are benign tumors containing cells from all three germ layers. In order to eliminate the risk of tumorigenicity, it is necessary to ensure complete removal or differentiation of all pluripotent cells before transplantation. A disadvantage of using ESCs is the risk of immune rejection, which must be suppressed by long-term immunosuppression [16, 17, 18, 19].

Scaffold Materials

The scaffold is a three-dimensional matrix designed to support cell adhesion, proliferation, and differentiation. An ideal scaffold must be biocompatible, non-immunogenic, mechanically stable, and biodegradable at a rate conducive to tissue regeneration [20]. The biocompatibility is basically the tolerance of different substances in biological environment. It is evaluated according to interactions between the given material and the organism (tissue), or between the environment, it is placed into. If the implant is incompatible with the organism, the organism will not adopt the implant, thus the implantation itself is not suitable [21]. Scaffolds may be classified into three main categories: natural biomaterials, synthetic polymers, and decellularized extracellular matrices (ECM).

Natural Materials

Natural scaffolds such as collagen, hyaluronic acid-based hydrogels, fibrin, alginate, silk, and gelatine are valued for their high biocompatibility, mechanical flexibility, and cell-adhesive properties. However, issues with batch-to-batch variability, purification challenges, and rapid degradation limit their scalability [22].

Synthetic Materials

Synthetic scaffolds, including polymers (PLA, PLGA, PCL), metals, ceramics, and graphene, offer controllable mechanical properties and tunable degradation kinetics. Biodegradable polymers like PLA and PLGA have found wide use in reconstructive surgery and exhibit favourable biocompatibility and low immunogenicity. Composites, such as PCL-PLA blends, can be engineered for enhanced thermal stability and structural integrity [22, 23].

The use of synthetic materials also has its limitations. These include, for example, inflammatory reaction, poor bioactivity and integration problems. Inflammatory reaction: the body's reaction to synthetic materials is the formation of a fibrous capsule that physically isolates the implant from the surrounding tissue, which prevents direct interaction and integration of the implant with the host tissue. Macrophages are activated and the subsequent release of inflammatory substances with cytokines occurs. If the condition is not addressed, the inflammation becomes chronic, which can cause the breakdown of the synthetic material and the need to remove the implant. Poor bioactivity: synthetic materials do not have inherent properties that would allow the body's cells to recognize and interact with them. The absence of these properties leads to improper cell adhesion, failure of cell proliferation and differentiation, which ultimately prevents the integration of the implant [24, 25, 26].

Decellularized Matrices

Decellularization involves the removal of cellular components from native tissues or organs, leaving behind an ECM scaffold rich in collagen, elastin, fibronectin, glycosaminoglycans, and growth factors, while preserving organ-specific architecture and vascular conduits [27, 28]. Effective decellularization must eliminate immunogenic DNA and proteins without compromising the ultrastructure or biomechanical properties of the ECM [29]. Decellularization protocols typically involve physical

(freeze-thaw, agitation, electroporation), chemical (detergents, acids, bases, solvents), and enzymatic (nucleases, trypsin) methods. A successful scaffold should contain <50 ng of dsDNA per mg dry ECM, DNA fragment lengths <200 bp, and no histologically visible nuclear material [28].

The interaction of stem cells with the ECM is a complex mechanism that involves the process of signalling and mechanotransduction. In ECM signalling, stem cells bind to ECM proteins via integrin receptors. Mechanotransduction ensures the conversion of the strength and stiffness of the ECM into a biochemical signal, which leads to the differentiation of stem cells. To create a functional vasculature in artificially created tissues, endothelial cells are seeded within a scaffold with supporting cells. These cells form capillary structures by proliferation, migration and mutual association [29].

Currently, scaffolds are used for uterine regeneration, which can be divided into 2 categories. Category 1 consists of scaffolds obtained from uterine tissue that has undergone a decellularization process. This process involves physical, chemical or enzymatic treatments. Category 2 scaffolds consist of synthetic or natural materials. The scaffolds can be transplanted alone or first seeded with stem cells before transplantation.

3. Results and Discussion

Most of experimental and clinical studies in uterine tissue engineering have targeted the

endometrial layer, both in animal models and human subjects. Natural scaffold materials, particularly those derived from collagen, have been most employed due to their favourable biocompatibility and structural resemblance to native extracellular matrix (ECM).

Despite encouraging preliminary results, uterine tissue engineering remains in the early stages of development. Most available data are derived from small-scale animal studies or pilot human trials with limited follow-up. The variability in scaffold materials, cell sources, and implantation techniques complicates comparison across studies and hinders standardization.

One notable example is the study by Zhao et al., which investigated the therapeutic application of collagen-based scaffolds seeded with autologous bone marrow-derived mononuclear cells (BMNCs) in patients with severe Asherman's syndrome. The bioengineered construct was transplanted into five women with extensive intrauterine adhesions. During the three subsequent menstrual cycles, the patients underwent diagnostic hysteroscopy and endometrial biopsy to assess tissue regeneration. Remarkably, all five patients achieved successful pregnancies and delivered live-born infants, demonstrating the clinical viability of this strategy [31].

A second clinical trial by Cao et al. focused on patients with recurrent intrauterine adhesions (IUAs). The authors utilized a collagen scaffold

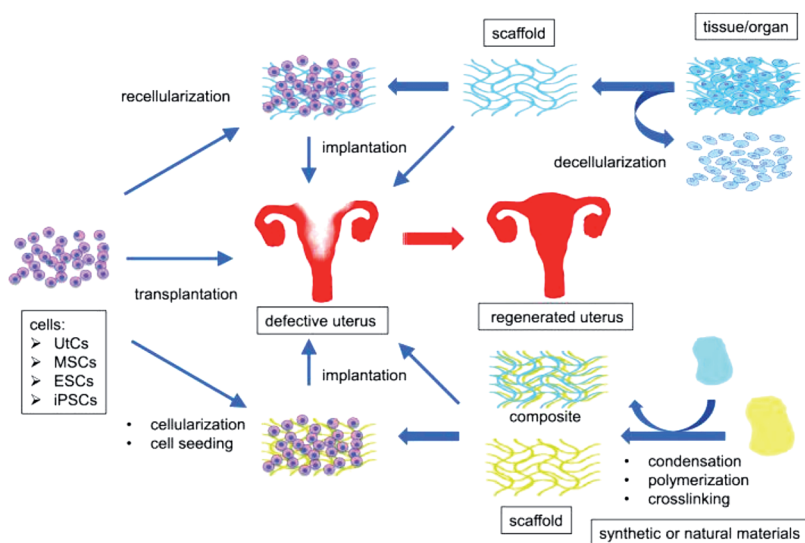


Figure 1: Therapeutic strategies for uterine bioengineering [30]

seeded with umbilical cord–derived mesenchymal stem cells (UC-MSCs). Out of 26 participants, 10 patients conceived following the intervention, and 8 went on to deliver live-born infants without evidence of placental abnormalities or congenital anomalies. These findings further validate the regenerative potential of MSC-based therapy in uterine pathologies associated with fibrosis and scarring [32].

In a pivotal preclinical study, Olalekan and colleagues developed a three-dimensional endometrial model through sequential decellularization and recellularization of human uterine tissue. Decellularization was achieved using a combination of Triton X-100 and sodium deoxycholate (SDC), followed by treatment with ribonuclease to reduce viral contamination risk. Histological evaluation using Hematoxylin and Eosin (H&E), trichrome staining, and dsDNA quantification confirmed successful removal of nuclear material while preserving ECM integrity. Electron microscopy further validated the scaffold's ultrastructural preservation, showing collagen-rich, acellular architecture. Immunohistochemistry confirmed the presence of laminin, collagen IV, elastin, and fibronectin, essential for cellular signalling and structural integrity. The recellularization phase involved seeding the decellularized scaffold with endometrial cells derived from a different patient. Over a period of four weeks, the cells successfully repopulated the scaffold, maintaining their phenotypic and functional characteristics. This study provided compelling evidence that decellularized endometrial scaffolds can support functional tissue regeneration in vitro [33]. Among decellularization techniques reviewed across published studies, chemical processing was the most frequently employed, particularly using ionic and non-ionic detergents. Non-ionic agents such as Triton X-100 demonstrated gentler processing conditions, preserving ECM proteins and reducing the risk of denaturation. While ionic detergents like sodium dodecyl sulphate (SDS) offered more thorough cell removal, they were associated with greater ultrastructural disruption and protein degradation [34, 35].

Overall, these studies highlight the promising potential of cell-scaffold constructs in the regeneration of functional endometrial tissue. Clinical outcomes such as successful pregnancies,

improved endometrial thickness, and reduced recurrence of adhesions support the feasibility of translational applications. However, significant challenges remain, including standardization of scaffold fabrication, ensuring cell viability and differentiation, and optimizing immunologic safety.

The path toward full uterine reconstruction, whether partial or complete, will likely depend on advances in 3D bioprinting, vascularized scaffold design, and integration of multiple cell types, including epithelial, stromal, vascular, and immune-regulatory cells. Continued interdisciplinary collaboration between reproductive medicine, regenerative biology, and bioengineering will be essential to advance this field from bench to bedside.

4. Conclusions

Tissue-engineered approaches have the potential to transform the clinical management of uterine factor infertility. Unlike uterine transplantation, which remains limited by donor availability and immunologic risk, bioengineered uterine constructs could offer off-the-shelf solutions or autologous grafts derived from the patient's own cells. These therapies may be particularly relevant in regions or countries where surrogacy is restricted or prohibited, as in many parts of Europe.

Furthermore, the successful regeneration of functional endometrium in patients with Asherman's syndrome or recurrent intrauterine adhesions opens new therapeutic avenues beyond infertility—potentially addressing recurrent pregnancy loss, abnormal placentation, or even uterine malformations. However, for these applications to reach the clinic, rigorous preclinical validation and regulatory approval will be essential.

The future of uterine bioengineering lies in the integration of advanced biomaterials, stem cell technologies, and 3D bioprinting to develop anatomically and functionally accurate uterine constructs. Future research should focus on optimizing vascularization strategies to support tissue perfusion and implantation, as well as on refining scaffold architecture to mimic the complex biomechanical properties of the uterus. The development of multi-cellular, compartmentalized uterine models incorporating stromal, epithelial, endothelial, and immune cells will be critical for functional regeneration.

Further challenges include insufficient long-term outcome data, limited understanding of host-graft interactions, and risks of tumorigenicity, particularly with pluripotent stem cell-based therapies. There is also a lack of robust immunologic profiling, especially in allogeneic constructs, and little is known about how these grafts behave during subsequent pregnancy or in the hormonal milieu of the reproductive cycle.

To overcome these limitations, future studies must adopt standardized protocols, incorporate larger, well-characterized patient cohorts, and address the translational gap between experimental success and clinical application. Only through methodologically rigorous, multidisciplinary research can uterine bioengineering move from a promising concept to a reliable clinical intervention.

Continued progress will require a multidisciplinary effort involving reproductive biologists, material scientists, surgeons, and regulatory agencies. As 3D bioprinting technologies and patient-specific regenerative strategies evolve, uterine bioengineering may one day offer a scalable, ethical, and immunologically safer alternative to organ transplantation—marking a paradigm shift in the management of uterine factor infertility.

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