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Uterus Transplantation as an Innovative Therapeutic Strategy for Absolute Uterine Factor Infertility: Implications for Women's Health and Quality of Life

Natalia Trędotą [NT]

ORCID <https://orcid.org/0009-0008-0052-6308>
naiilaan@gmail.com

Independent Public Health Care Facility in Bochnia, District Hospital of Blessed Marta Wiecka, Krakowska 31, 32-700 Bochnia, Poland

Julia Chmielowiec [JC]

ORCID <https://orcid.org/0009-0000-5033-8059>
julieta.chmiel@gmail.com

Multi-Specialty District Hospital S.A. Pyskowicka 47-51, 42-612 Tarnowskie Góry, Poland

Zuzanna Czyżewicz [ZC]

ORCID <https://orcid.org/0009-0005-8809-2708>
zuzannace@gmail.com

5th Military Hospital with Polyclinic in Cracow, u. Wrocławska 1/3, 30-901 Kraków, Poland

Kinga Dworak [KDW]

ORCID <https://orcid.org/0009-0002-1551-6686>
kingadworak98@gmail.com

Specialist Hospital of Edmund Biernacki in Mielec, Żeromskiego 22, 39-300 Mielec, Poland

Dominika Posid [DP]

ORCID <https://orcid.org/0009-0000-3578-3912>
dominika.posid@gmail.com

Faculty of Medical Sciences in Katowice, Medical University of Silesia, Katowice, Poland

Michał Lewczuk [ML]

ORCID <https://orcid.org/0009-0001-2267-1871>

michal.lewczuk00@gmail.com

National Medical Institute of the Ministry of the Interior and Administration, ul. Wołoska
137, 02-507 Warszawa, Poland

Karol Dańda [KD]

ORCID <https://orcid.org/0009-0001-6182-0462>

karoldanda@gmail.com

Complex of Municipal Hospitals in Chorzów, ul. Strzelców Bytomskich 11, 41-500 Chorzów

Aleksandra Chludek [AC]

ORCID <https://orcid.org/0009-0006-4536-7537>

ola.chludek@poczta.fm

Complex of Municipal Hospitals in Chorzów, ul. Strzelców Bytomskich 11, 41-500 Chorzów

Barbara Chobot [BC]

ORCID <https://orcid.org/0009-0009-3133-8446>

barbarachobot97@gmail.com

Municipal Hospital in Zabrze, ul. Zamkowa 4, 41-803 Zabrze, Poland

Marta Wachowska [MW],

ORCID <https://orcid.org/0009-0000-0221-1862>

mail: martaw590@gmail.com

Piekary Medical Center, ul. Szpitalna 11, 41-940, Piekary Śląskie, Poland

Corresponding Author

Natalia Trędota, E-mail: naiilaan@gmail.com

Abstract

Background: Uterus transplantation (UTx) is currently the only therapeutic option for women with absolute uterine factor infertility (AUI) caused by congenital or acquired absence of the uterus or impaired uterine function. Experimental studies in animal models provided the foundation for the successful clinical introduction of UTx. Until the first live birth following UTx in 2014, this form of infertility was considered untreatable. Since then, significant advances have been achieved, making UTx one of the few transplant procedures performed primarily to improve quality of life rather than prolong survival.

Aim: This review summarizes the current evidence on uterus transplantation as a treatment for AUI, focusing on clinical outcomes, surgical techniques, donor and recipient selection, immunosuppressive management, obstetric outcomes, and procedure-related complications.

Material and Methods: A narrative literature review was conducted using publications indexed in PubMed and Google Scholar. The search included the following terms and their

combinations: absolute uterine factor infertility, AUFI, uterus transplantation, UTx, Mayer–Rokitansky–Küster–Hauser syndrome, MRKH, uterine agenesis, hysterectomy, living donor uterine transplant, deceased donor uterine transplant, immunosuppression after UTx, and pregnancy after UTx.

Conclusions: Uterus transplantation is a promising therapeutic option that enables selected women with AUFI to achieve pregnancy and childbirth. However, it remains a technically demanding procedure associated with significant surgical and immunological challenges. Further research is needed to optimize donor and recipient selection, minimize perioperative risks, and confirm the long-term safety and efficacy of UTx to support its broader clinical application.

Key words : absolute uterine factor infertility, AUFI, uterus transplantation, UTx, Mayer–Rokitansky–Küster–Hauser syndrome, MRKH, uterine agenesis, hysterectomy, living donor uterine transplant, deceased donor uterine transplant, immunosuppression after UTx, pregnancy after UTx.

1. Introduction

Despite remarkable advances in the treatment of infertility since the birth of the first child conceived by in vitro fertilization in 1978, infertility caused by uterine factor, referred to as absolute uterine factor infertility (AUFI), has remained untreatable [1,2,47].

Contemporary research on uterus transplantation began shortly after the first human hand transplantation in 1998 a procedure that opened a new era in transplant surgery by extending its scope to non-life-saving tissues and organs whose transplantation could significantly improve patients' quality of life [3]. Uterus transplantation (UTx) has since been successfully introduced as a potential therapeutic option for women with uterine factor infertility. AUFI, affecting approximately 3–5% of the female population, is associated with congenital uterine agenesis, such as Mayer–Rokitansky–Küster–Hauser (MRKH) syndrome, severe congenital uterine malformations (including hypoplastic uterus and unicornuate or bicornuate uterus), surgical absence of the uterus, or acquired conditions resulting in impaired uterine function, such as intrauterine adhesions and leiomyomas. These conditions lead to implantation failure or placental abnormalities [4].

Uterus transplantation is currently the only therapeutic approach that enables women with AUFI to achieve both genetic and gestational motherhood. Although the demand for this treatment is substantial, only a limited number of candidates may currently benefit from UTx, as the procedure remains in an early stage of clinical development [5]. Alternative options for motherhood in this population include adoption or gestational surrogacy to achieve genetic parenthood followed by legal adoption. However, surrogacy is prohibited in many countries for ethical, legal, or religious reasons [6].

Successful uterus transplantations have demonstrated that women with AUFI may achieve both genetic and gestational motherhood. In contrast to other types of transplantation, UTx may involve both deceased donors and living donors. Moreover, UTx is currently the only ephemeral transplant that remains in situ in the recipient for a limited period of time. Planned hysterectomy is usually performed approximately five years after transplantation, preferably after the birth of

two healthy children. This limited graft duration significantly reduces the risk of well-known long-term adverse effects associated with chronic immunosuppression [4,7].

The pioneering work in the field of uterus transplantation, which initiated multiple clinical trials worldwide, was conducted by the Gothenburg group under the leadership of Mats Brännström [8].

Uterus transplantation involves retrieval of the uterus from the donor followed by implantation into the recipient. Both procedures are complex and technically demanding, and are associated with considerable surgical risk and potential complications. Donor hysterectomy may last between 6 and 10 hours. The uterus, together with its vascular pedicles, is subsequently transplanted into the recipient. Postoperatively, the recipient requires immunosuppressive therapy to prevent graft rejection, which entails potential health risks. Approximately 12–18 months after transplantation, an embryo—obtained through in vitro fertilization prior to the transplant procedure—is transferred into the transplanted uterus. The pregnancy is closely monitored and is delivered by cesarean section. If the woman does not plan another pregnancy, hysterectomy is performed approximately six weeks postpartum, allowing discontinuation of immunosuppressive therapy [8,46].

2. Methods

This article is based on a comprehensive narrative review of the current scientific literature concerning uterus transplantation (UTx) as a therapeutic option for absolute uterine factor infertility (AUI). Relevant peer-reviewed publications were identified through systematic searches of the PubMed and Google Scholar databases from inception through the present. The following search terms and their combinations were used: absolute uterine factor infertility, AUI, uterus transplantation, UTx, Mayer–Rokitansky–Küster–Hauser syndrome, MRKH, uterine agenesis, hysterectomy, living donor uterine transplant, deceased donor uterine transplant, immunosuppression after UTx, pregnancy after UTx. The search strategy aimed to capture studies presenting clinical trials, case series, observational studies, consensus statements, and relevant review articles regarding both experimental and clinical aspects of uterus transplantation. Articles were screened initially by title and abstract for relevance to the topic. Full-text evaluations were subsequently performed on selected articles to extract detailed data.

3. Literature Review

3.1. Historical Overview

The first, albeit unsuccessful, attempt at uterus transplantation was performed in 2000 using a uterus retrieved from a living donor [10], followed by a second attempt in 2011 with an organ obtained from a deceased donor [11]. These early procedures were conducted without prior structured research preparation and were not aligned with the IDEAL framework (Innovation, Development, Exploration, Assessment, Long-term follow-up) for the introduction of surgical innovations, nor with international ethical guidelines for UTx [1]. In 2011, a research group in Turkey reported a successful transplantation from a deceased donor. However, to date, this procedure did not achieve the ultimate goal of UTx, which is the successful completion of a healthy, uneventful pregnancy. Building on extensive preclinical experience in various animal models, including non-human primates, the Gothenburg group led by Mats Brännström reported the first live birth following UTx from a living donor in 2014. This milestone not only

demonstrated the feasibility of uterus transplantation but also helped define appropriate areas for clinical research and protocol development [4].

3.2. Animal Studies

Modern experimental research on uterus transplantation (UTx) in animals began in the early 21st century [12,13]. Studies were conducted in rodents, including mice and rats, domestic species such as pigs and sheep, and non-human primates, including the cynomolgus macaque. The first live offspring following UTx were reported in 2003 in a mouse model [14]. Subsequent experiments in rodents demonstrated that the transplanted uterus tolerated up to 24 hours of cold ischemia [15]. Larger animals, such as pigs and sheep, were subsequently utilized due to the advantages of their larger uterine and vascular structures, which more closely approximate human anatomy. Initial ovine experiments employed autologous UTx with anastomosis to the external iliac vessels, also resulting in live offspring. The porcine UTx model was initially developed as an autologous transplant to study reperfusion and vascular patency [1]. In further preclinical studies, baboons and cynomolgus macaques were employed as models for UTx. The first pregnancy and live birth following autologous UTx in a non-human primate were demonstrated in the cynomolgus macaque, establishing the feasibility of transplantation in species phylogenetically closer to humans [16].

3.3. Indications for Uterus Transplantation

Absolute uterine factor infertility (AUI) remains the only major type of female infertility that is still considered untreatable [6]. The underlying causes include congenital uterine agenesis, such as in Mayer–Rokitansky–Küster–Hauser (MRKH) syndrome, or other severe congenital uterine malformations, as well as acquired uterine dysfunction or previous hysterectomy. When considering indications for uterus transplantation, it is important to distinguish between congenital anomalies and the absence of the uterus resulting from surgical removal. This differentiation has significant implications for patient selection, surgical planning, and anticipated clinical outcomes [17].

3.3.1. Mayer–Rokitansky–Küster–Hauser (MRKH) Syndrome

Mayer–Rokitansky–Küster–Hauser (MRKH) syndrome, also known as Müllerian aplasia, is the second most common cause of primary amenorrhea [44]. It is characterized by congenital absence of the uterus, cervix, and upper portion of the vagina, or by the presence of a rudimentary, solid, bicornuate uterus in women with a normal female karyotype (46,XX). MRKH syndrome accounts for less than 3% of all Müllerian developmental anomalies and occurs in approximately 1 in 4,500–5,000 live female births [20].

The female reproductive system in humans comprises the fallopian tubes, uterus, cervix, and vagina. The fallopian tubes, uterus, cervix, and upper two-thirds of the vagina are derived from the Müllerian ducts, whereas the lower portion of the vagina originates from the urogenital sinus [21]. The development of the Müllerian ducts begins around the 5th to 6th week of gestation, when bilateral cranio-caudal invaginations of the intermediate mesoderm grow caudally toward the Wolffian ducts and the urogenital sinus [22]. The caudal portions of the two Müllerian ducts fuse to form the uterus, cervix, and upper vagina, while their cranial segments give rise to the fallopian tubes [19].

Current evidence suggests multiple possible etiologies of MRKH syndrome, including monogenic, oligogenic, polygenic, multifactorial, and environmental factors. Regulatory mechanisms, such as epigenetic factors, and somatic genetic events during development may

also contribute. Familial clustering of MRKH syndrome and associated anomalies increasingly supports a potential monogenic genetic basis [19,23,24].

Two types of MRKH syndrome are recognized:

- **Type I** – involving the upper vagina, cervix, and uterus.
- **Type II** – associated with additional developmental anomalies, including renal and skeletal defects, and the MURS (Müllerian Renal Cervical Somite) phenotype, characterized by cervicothoracic malformations.

The reported prevalence of Type I and Type II MRKH ranges from 56–72% and 28–44%, respectively [20,25,26].

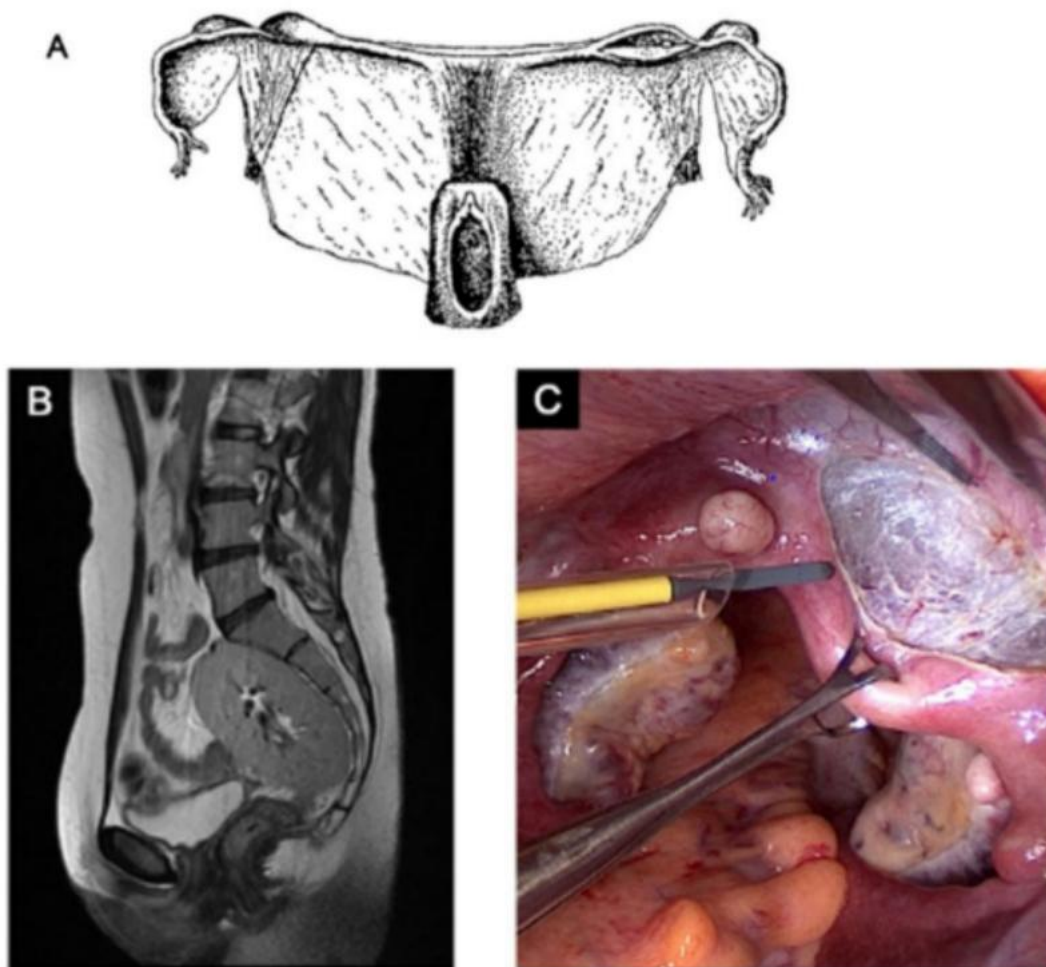


Figure 1. **A** – Original illustration by Carl von Rokitansky (1838) depicting the morphology of the uterus and vagina in MRKH syndrome, showing a shortened, blind-ending vagina and rudimentary uterine remnants. **B** – Sagittal T2-weighted MRI demonstrating complete uterine-vaginal agenesis in Type II MRKH syndrome associated with renal agenesis and a solitary pelvic kidney. **C** – Pelvis of a patient with MRKH syndrome during surgical preparation for uterus transplantation. Forceps hold the fibrous uterine remnant along the midline while it is being dissected from the bladder. The ovaries are positioned medially toward the pouch of Douglas.

3.3.2. Hysterectomy

Hysterectomy is the most frequently performed gynecological surgery in women. Approximately 600,000 hysterectomies are performed annually in the United States and around 60,000 in Poland [27]. More than 40% of women undergoing hysterectomy are under 44 years of age. Excluding malignant tumors, the main indications for surgical removal of the uterus include uterine fibroids, abnormal uterine bleeding, endometriosis, pelvic organ prolapse, and chronic pelvic pain syndrome. Acute indications include postpartum hemorrhage and severe uterine bleeding that cannot be controlled by other means. Hysterectomy due to malignant tumors is considerably less common in women of reproductive age.

The most frequent malignant indications for hysterectomy are cervical cancer, endometrial cancer, epithelial ovarian cancer, and non-epithelial ovarian cancer. Rare indications include the treatment of leiomyosarcoma, endometrial stromal sarcoma, and chemo-resistant gestational trophoblastic tumors localized in the uterus [7].

Different types of hysterectomy are illustrated in Figure 2.

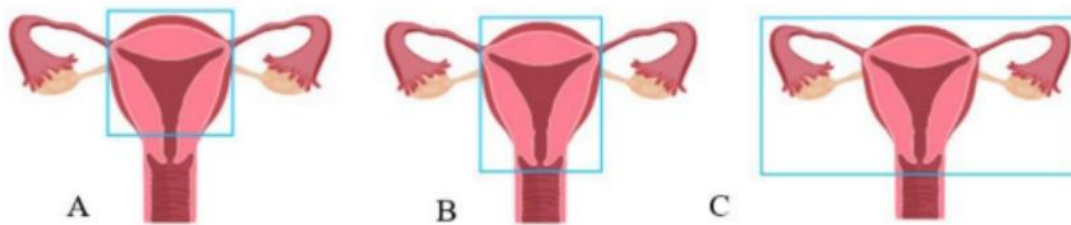


Figure 2. A – Partial hysterectomy: only the uterine body is removed. B – Total hysterectomy: the uterus along with the cervix is removed. C – Radical hysterectomy: the uterus, cervix, adnexa, and a portion of the vagina are removed.

3.4. Procedure

Uterus transplantation represents the first introduced ephemeral type of transplant, in which the graft is not intended for lifelong use. The uterus is typically removed after the birth of one or two children, thereby reducing the long-term adverse effects associated with immunosuppressive therapy [6]. Most currently performed organ and tissue transplants involve deceased donors; the concept of a living donor has been well established in kidney and liver transplantation [3]. In contrast to other transplant types, UTx may involve either deceased or living donors [7]. Donors are screened for high-risk human papillomavirus infection, as treatment of such infections is limited in immunocompromised recipients, and the risk of cervical neoplasia is significantly increased [4,28]. The UTx procedure involves isolation of the uterus along with bilateral long vascular pedicles, including arteries and veins. The complexity of the surgery is largely due to extensive vascular dissection, encompassing distal segments of the internal iliac veins and arteries [6]. Ischemia–reperfusion injury (IRI) in the uterus has been studied in animal models; however, clinical data in humans remain limited. Human uterine tissue preserved in Perfadex solution showed no significant histological changes after prolonged cold ischemia of up to 24 hours. Myometrial contractility, however, was better preserved after 6 hours of cold storage compared with 24 hours [4]. In an ex vivo clinical study, eight uteri retrieved from brain-dead donors showed no histological changes after 12 hours of

cold ischemia [29], although histological endometrial shedding has been reported after 24 hours of cold storage in some cases [30].

Assessment of UTx success is justified only after more than 18 months post-transplantation, as attempts to achieve pregnancy are generally delayed until approximately 12 months after UTx. Three components are typically used to evaluate UTx efficacy:

- Early favorable surgical outcome within 3 months following living-donor UTx.
- Graft function up to 1 year, evidenced by regular menstrual cycles over several months.
- Successful pregnancy resulting in the live birth of a healthy child [4].

3.4.1. Uterus Transplantation from a Living Donor (LD UTx)

A common surgical approach for LD UTx involves a midline incision [10,31,32]. The uterus is retrieved with the longest possible vascular pedicles, a substantial portion of the round and uterosacral ligaments, and an extensive bladder peritoneal flap [46]. Vascular dissection of the cervix and uterine vessels is feasible only after complete hysterectomy. The vagina is transected below the cervix to obtain a cuff sufficient for anastomosis with the recipient's vaginal canal. In some studies, the ovaries were also removed [31,33]. Both the Swedish group and Wei et al. have reported UTx procedures performed using robotic-assisted surgery [34]. Two LD UTx attempts outside the MRKH population have been reported in the literature. The first case, performed in 2000 in Saudi Arabia, involved a uterus from an unrelated, perimenopausal donor transplanted into a woman who had undergone emergency peripartum hysterectomy. Graft necrosis occurred, and the uterus was removed 99 days after transplantation due to bilateral thrombosis of the uterine vessels [7,10]. The second attempt, in 2017, involved a 26-year-old woman with severe Asherman's syndrome who received a uterus from her mother via a combined laparoscopic and open approach [36]. In a clinical study initiated in 2012 in Sweden by M. Brännström et al., the cohort included eight women with MRKH syndrome [31]. Six of the eight donors were related (five mothers and one sister), one was a family friend, and one was a mother-in-law. Four donors were postmenopausal, and all had previously experienced uncomplicated pregnancies. Uterine retrieval via a midline incision involved dissection of the uterus along with the bilateral uterine arteries and deep uterine veins, including segments of the internal iliac vessels. Deep dissection of the uterine veins and ureters is technically demanding and time-consuming, with total donor surgery lasting 10–13 hours [31]. Recipient surgery was less complex, lasting 4–6 hours, and included bilateral end-to-side anastomoses of the internal iliac arteries and veins of the graft with the recipient's external iliac vessels. After restoration of uterine blood flow, the graft was anastomosed to the vagina and fixed to the pelvis via the uterosacral and round ligaments, as well as the residual lateral uterine tissue. Six of eight transplanted uteri remained viable after six months [7]. The two graft losses were due to bilateral uterine vessel thrombosis within one week post-transplant in one patient and persistent intrauterine infection progressing to uterine abscess three months after UTx in the other patient [7].

One of the eight recipients had previously undergone radical hysterectomy seven years prior for cervical cancer. At age 25, she was diagnosed with a 3 cm cervical tumor. UTx was performed according to the standard Swedish protocol. She achieved pregnancy on the fourth embryo transfer and delivered a healthy boy via cesarean section in November 2014. In January 2016, she delivered a healthy daughter, becoming the first UTx recipient worldwide to have

two successful post-transplant births. The uterus was removed during the second cesarean section, and immunosuppression was immediately discontinued [7].

Since 2014, approximately 60 uterus transplants have been performed in clinical trials, resulting in 13 live births [8,37,38]. Among donors reported in the literature, one intraoperative and two postoperative complications occurred. Other complications included urinary tract infections, fecal impaction, leg pain, and nocturia. Most donors experienced uncomplicated postoperative courses and were discharged 5–7 days after surgery [33].

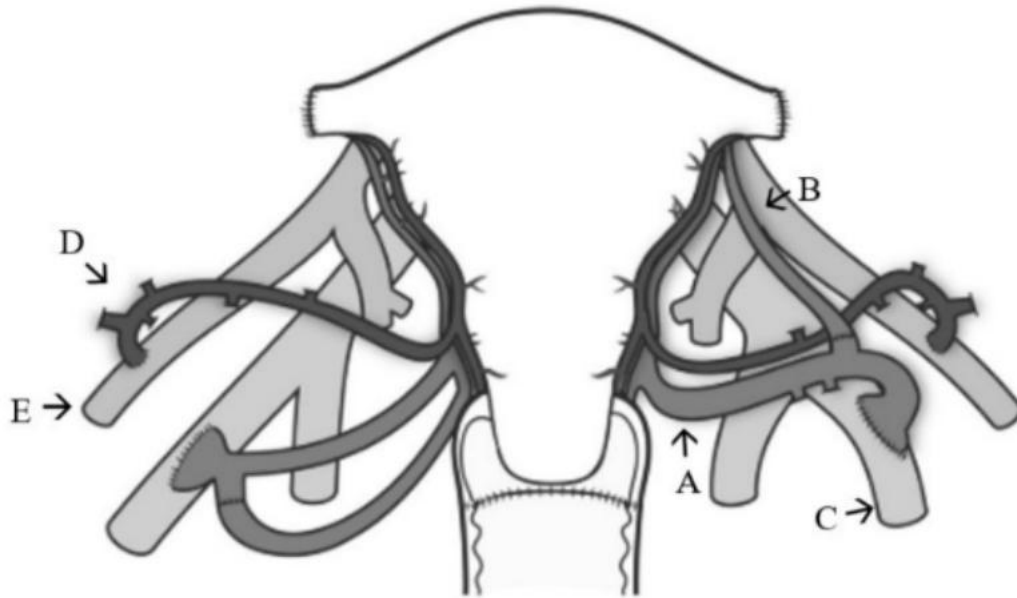


Figure 3. Schematic representation of vascular anastomoses in uterus transplantation from living donors. Both uterine and ovarian veins were used for venous outflow. On the left side, the uterine vein (A), which anatomically joins the ovarian vein (B), was anastomosed to the external iliac vein (C). On the right side, one ovarian vein was transected prior to organ retrieval to allow extraction of the graft without compromising the ureter. The transected vein was subsequently re-anastomosed end-to-end. The uterine arteries (D) were bilaterally anastomosed to the external iliac arteries (E) [1,4].

3.4.2. Uterus Transplantation from a Deceased Donor (DD UTx)

Uterus transplantation from a deceased donor differs somewhat from the procedure using a living donor. To date, seven cases of DD UTx have been reported. The first attempt was performed in 2011 in Turkey, where a 21-year-old patient with MRKH syndrome received a uterus from a 22-year-old nulliparous brain-dead donor [11]. The uterus was removed as the first organ among other retrieved organs for transplantation. No live birth resulted from this procedure.

Another DD UTx attempt occurred in China in late 2015 [35]. A daughter with MRKH received a uterus from her 42-year-old mother. The procedure involved a fully laparoscopic, robot-assisted donor surgery, with ovarian veins used as the only venous outflow. Utilizing the ovarian veins simplified surgical preparation but required oophorectomy, which carries potential risks of long-term cardiovascular complications. One year after transplantation, the uterus remained viable, but no pregnancies have been reported [35].

In 2016, a DD UTx attempt was performed in the USA in a patient with MRKH. Prolonged cold ischemia due to long transport distance between donor and recipient sites led to graft removal two weeks post-transplantation because of fungal infection of the uterine vessels [39]. Also in 2016, Czech researchers conducted DD UTx attempts, dividing the procedure into six phases [40]:

1. Transvaginal ultrasound to exclude uterine, tubal, or ovarian pathology.
2. Macroscopic in situ evaluation of the uterus, assessing color, homogeneity, firmness, scarring or trauma, and presence of endometriosis.
3. Preparation of the uterus and vessels, including dissection of the uterine-groin ligament along the pelvic wall, preparation of ovarian veins, separation of the uterus from the bladder, and separate dissection of the uterine artery and vein, along with ureterolysis.
4. Flushing of vessels with preservation solution via cannulation of both external iliac arteries after distal ligation; venous drainage via cannulation of the inferior vena cava.
5. Organ retrieval following macroscopic assessment of uterine perfusion.
6. Ex vivo graft assessment, including perfusion quality and vascular integrity.

In this study, recipients were four women, while donors included two postmenopausal women with prior uncomplicated pregnancies and two premenopausal nulliparous women. One graft was removed one week post-transplant due to thrombosis, and another after seven months due to endometrial degeneration secondary to primary herpes simplex virus infection. No live births have been reported to date from these cases [41].

The first successful DD UTx was performed in Brazil in September 2016. A 32-year-old patient with MRKH received a uterus from a 45-year-old donor who died of subarachnoid hemorrhage [42]. Recipient surgery included bilateral anastomosis of the uterine vessels with the external iliac vessels. Following clamp release, significant flow was observed through preserved ovarian veins, which were subsequently anastomosed to the recipient's external iliac veins. Six months after transplantation, conception occurred. A planned cesarean section was performed at 35 weeks and 3 days, resulting in the birth of a healthy female infant. The uterus was removed postpartum. Histological examination revealed prominent fibrous thickening of the uterine artery intima; the cause remains unclear and has not been reported in post-delivery LD UTx hysterectomies. Infant growth and development during the first seven months postpartum were normal. This case is of pivotal significance, demonstrating that uterus transplantation from deceased donors represents a viable alternative to living donor transplantation.

3.5. Immunosuppression

Immunosuppressive therapy in uterus transplantation is similar to that used in kidney transplantation [33]. The most recent protocol includes intraoperative administration of thymoglobulin and prednisone [31,33,35,36]. Postoperatively, patients receive tacrolimus,

mycophenolate mofetil (MMF), and prednisone. Maintenance immunosuppression typically consists of triple or dual therapy with calcineurin inhibitors (CNI), most commonly tacrolimus, in combination with MMF [4]. Antibiotic prophylaxis commonly includes piperacillin-tazobactam or ceftriaxone with ornidazole, and trimethoprim-sulfamethoxazole is administered to prevent *Pneumocystis carinii* infection [11,35]. If the donor tests positive for cytomegalovirus, ganciclovir is administered for three months postoperatively. CNIs, corticosteroids, and azathioprine are considered safe for immunosuppression, whereas rituximab (anti-CD20 antibody) and MMF have been associated with teratogenic effects [4]. Therefore, rituximab and MMF are discontinued at least two months prior to embryo transfer and replaced with azathioprine to minimize potential teratogenic risk [6].

3.6. Pregnancy and Delivery

Recipients are placed under close surveillance throughout pregnancy. Immunosuppressive therapy is maintained during gestation, typically consisting of tacrolimus, azathioprine, and prednisone. Patients are monitored every 2–3 weeks with comprehensive ultrasonographic assessment of uterine and umbilical artery pulsatility indices, as well as fetal growth. Cervical biopsies are performed monthly to assess graft integrity. Delivery is performed via cesarean section [6,33].

3.7. Ethical Considerations

Uterus transplantation combines assisted reproductive technologies with transplant medicine. It represents the only ephemeral transplant performed primarily to improve quality of life rather than to prolong survival [9,33,43]. In 2008, the FIGO Committee on Ethical Aspects of Human Reproduction and Women's Health outlined ethical considerations for uterus transplantation. In 2012, the Montreal Criteria for the ethical feasibility of UTx were introduced and subsequently updated in 2013. These criteria define requirements and guidelines for the recipient, donor, and the healthcare team involved in the procedure [33].

4. Conclusions

Infertility is a condition affecting a significant number of women and substantially reducing their quality of life. Despite considerable advances in infertility treatment, therapeutic options for women with absolute uterine factor infertility (AUI) remain limited. Recent years have seen substantial progress in the field of uterus transplantation, which was preceded by extensive animal studies validating the rationale for this type of transplant. Uterus transplants have been performed using both living and deceased donors. Deceased donor uterus transplantation represents a promising alternative, with documented successful outcomes; however, a standardized protocol for postmortem organ retrieval is still required. Based on current experiences, there is strong potential for integrating uterus transplantation into routine clinical practice for infertility treatment, although numerous challenges remain unresolved. Future research should focus on strategies to reduce perioperative risks for both donors and recipients. Given the occurrence of graft acceptance without restoration of fertility in some cases, the underlying causes must be investigated, and methods to enhance post-transplant fertility should be developed. Long-term effects of maternal immunosuppression on offspring development also require careful evaluation, as well as potential strategies to mitigate immunosuppressive

side effects in this population beyond graft removal and cessation of immunosuppressive therapy.

Author's Contribution:

Conceptualization: NT,KDW,BC,JC,KD,AC,MW,,DP,

Methodology: NT,KDW, BC,MW,

Formal analysis: KDW, ZC, AC,

Investigation: MW,AC,BC,ZC

Supervision: NT,KD,AC,JC,

Writing-rough preparation: NT,AC,KD,ZC, DP

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