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Review

UTERUS TRANSPLANTATION: CURRENT STATUS IN 2024

Andrew Jacques[1], Giuliano Testa[1], Liza Johannesson[1,2]

[1] Annette C. and Harold C. Simmons Transplant Institute, Baylor University Medical Center, Dallas, Texas, USA; [2] Department of Obstetrics and Gynecology, Baylor University Medical Center, Dallas, Texas, USA

Summary

Uterus transplantation (UTx) has evolved as an effective treatment for women with absolute uterine-factor infertility (AUFI). From its tentative beginnings, this approach now has demonstrated success in two published multicentre reports – with a combined 78 recipients and 40 live births. Clinical and ethical considerations remain, with the requirement for a specialised multidisciplinary team to guide patient care as the procedure transitions from experimentation to a more widely accepted treatment reality. The majority of recipients are women with a congenitally absent uterus, receiving grafts predominantly from living donation, but as the procedure is adopted more broadly an expansion in both donor and recipient selection is anticipated. The goal of this review is to describe the current status of UTx, including an exploration of surgical technique, postoperative complications, graft and pregnancy assessment, and long-term outcomes. The review concludes with an optimistic outlook for the future of UTx, with an emphasis on the need for ongoing patient protection through regulatory oversight and long-term outcome reporting.

Key words: uterus, transplantation, infertility, living donor, *in vitro* fertilization

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Correspondence
Liza Johannesson
E-mail: liza.johannesson@bswhealth.org

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INTRODUCTION

For women with absolute uterine-factor infertility (AUFI), uterus transplantation (UTx) provides an effective treatment modality for an otherwise untreatable affliction. The aetiology of AUFI can be either congenital or acquired – with Mayer-Rokitansky-Küster-Hauser (MRKH) syndrome (congenital AUFI) affecting approximately 1 in 4500 women [1], and hysterectomy (acquired AUFI) occurring over 150,000 times per year in fertile-aged women across the United States [2]. UTx is currently positioned in a unique clinical phase, both at the intersection of multiple medical specialties and reproductive ethics, and at a transition from experimentation to broader acceptance and clinical adoption as a viable treatment. A multidisciplinary team remains essential to navigate the current clinical and ethical considerations in UTx – which include donor and recipient selection, surgical technique, assisted reproduction, graft and pregnancy monitoring, and long-term follow-up. The aim of this review is to provide an overview of the current state of UTx, with a historical perspective on how the current landscape has been realised, and to explore areas of both opportunity and caution for the future.

HISTORY OF UTERUS TRANSPLANTATION

The first human UTx was performed in Saudi Arabia in 2000 [3]. Despite being an initial technical success, the procedure was ultimately unsuccessful due to vascular thrombosis and graft loss 99 days after transplantation. The second case occurred in Turkey in 2011 and eventually led to a successful live birth in 2020 [4,5]. The first live birth, however, occurred earlier in 2014 [6] as part of the Swedish Uterus Transplant Trial, which included nine recipients who received a transplant from living donors [7]. The Swedish team was the first to establish the success of UTx as a clinical approach to AUFI. The definition of success, however, requires further consideration and incorporates not only the technical success of the transplant surgery, but also the birth of a healthy and appropriately developing infant with minimal harm to the mother and donor (if living donation was pursued). Success has been further defined by the United States Uterus Transplant Consortium into seven discrete and progressive stages (Tab. I) [8]. In the Swedish trial, seven of the nine transplants were technically successful – with two hysterectomies required secondary to thrombosis or hypoperfusion [9]. For the seven recipients with technically successful transplants, three had two live births, three had one live birth (a total of nine live births), and one had recurrent miscarriage.

Subsequent to the initial success, new UTx programs were established internationally – with various programs in the United States, Europe, and Asia all reporting outcomes following multiple transplants at their respective institutions [10-14]. In addition, there is a growing number of isolated cases, both published and unpublished, by various UTx programs across the globe [15-19]. The first multi-institutional case series was published from the United States in 2022, representing more than half the live births that have ever resulted from UTx [20] (Tab. II). From this cohort of 33 recipients, 94% had MRKH syndrome, 64% received a uterus from a living donor, and no donor or recipient mortality was reported. One-year graft survival was 74%, and 19 of 33 recipients (58%) had 21 live-born children at a median gestational age of 36 weeks 6 days, with no congenital malformations detected. Based on this published report, the authors assert the safety of the approach and advocate for the acknowledgement of UTx as a clinical option for patients with AUFI wishing to pursue parenthood. Subsequently, the International Society of Uterus Transplant published its first report of combined results from 13 non-US centres, representing a further 45 recipients and 19 live births to date [21] (Tab. II).

RECIPIENT AND DONOR EVALUATION AND SELECTION

Recipient selection

Based on the international experience published to date, common inclusion criteria for UTx have included an absent or nonfunctioning uterus, in the absence of severe comorbidity, and the willingness to undergo or receive a) *in vitro* fertilization (IVF) with cryopreservation prior to transplantation; b) general anaesthesia and major gynaecological surgery; c) potential high-risk pregnancy, caesarean section, and eventual hysterectomy; and d) immunosuppressive medication, prophylaxis protocols, and standard vaccinations [7,22]. The Swedish and US experience have both required recipients to have a body mass index < 30 kg/m^2, with upper age limits of 38 and 45 years, respectively. A psychosocial assessment is also mandatory to ensure that adequate support structures are in place for all participants given the intensive nature of the

Table I. Stages of success in uterus transplantation (adapted from Johannesson et al, 2020) [8].

Stage	Success	Assessment	Failure
1. Technical	Establishment of inflow and outflow to graft	Doppler ultrasound Biopsy	Graft hysterectomy
2. Menstruation	Commencement of withdrawal bleeding	Clinical review Cyclical bleeding	No menstrual bleeding
3. Embryo implantation	Successful implant of an embryo	Positive pregnancy test	Negative pregnancy test
4. Pregnancy	Fetal growth and development	Fetal ultrasound	Miscarriage
5. Delivery	Live birth (via caesarian section)	Healthy newborn and healthy mother	Maternal or infant morbidity or mortality
6. Graft hysterectomy	Removal of graft (following live birth[s])		Maternal morbidity or mortality
7. Long-term follow-up			

Table II. Donor and recipient characteristics, postoperative and reproductive outcomes: combined results from the International Uterus Transplant Registry and United States Uterus Transplant Consortium.

		ISUTx Registry[21]	USUTC[20]	Combined
Donor characteristics				
Living	Total (n)	35	21	56
	Age (years; mean)	49.7	37.7	45.2
	Body mass index (kg/m^2; mean)	25.4	25.0	25.3
	Directed donor (n)	34 (97%)	1 (5%)	35 (63%)
Deceased	Total (n)	10	12	22
	Age (years; mean)	37.8	31.5	34.4
	Body mass index (kg/m^2; mean)	24.5	25.0	24.8
Recipient characteristics				
	Total (n)	45	33	78
	Age (years; mean)	29	31	29.8
	Body mass index (kg/m^2; mean)	22.2	24	23
	MRKH syndrome (n)	44 (98%)	31 (94%)	75 (96%)
Postoperative outcomes				
Living donor	Clavien-Dindo grade 3 (n)	3 (9%)	5 (19%)	8 (14%)
Recipient	Clavien-Dindo grade 3 (n)	8 (18%)	3 (1%)	11 (14%)
	Graft loss (n)	12 (27%)	8 (24%)	20 (26%)
Technical success	Total (n)	33 (73%)	25 (76%)	57 (73%)
	Acute rejection (n)	16 (48%)	10 (40%)	26 (46%)
	Vaginal stricture (n)	-	18 (72%)	-
Reproductive outcomes				
Live births	Total (n)	19	21	40
	Technical success ⩾ 1 live birth (n)	16 (48%)	19 (75%)	35 (61%)
Pregnancy	Gestational diabetes (n)	1 (5%)	5 (24%)	6 (15%)
	Gestational hypertension (n)	1 (5%)	3 (14%)	4 (10%)
	Preeclampsia (n)	1 (5%)	3 (14%)	4 (10%)
	PROM (n)	1 (5%)	1 (5%)	2 (5%)
Delivery	Birth weight (g; median)	2620	2860	2746
	Gestational age (weeks; median)	35	36.9	36
	Earlier than protocol (n)	6 (32%)	13 (62%)	19 (48%)
	< 32 weeks (n)	-	2 (10%)	-

ISUTx: International Society of Uterus Transplantation; MRKH: Mayer-Rokitansky-Küster-Hauser; PROM: premature rupture of membranes; USUTC: United States Uterus Transplant Consortium.

care provided. The overwhelming majority of published cases are in women with MRKH syndrome – while recognising the opportunity to expand beyond this indication in the future.

Donor selection

Both advantages and disadvantages exist for the utilisation of living and deceased donors for UTx (Tab. III). Common to all donors, known uterine pathology, active or chronic infection, and active malignancy are considered contraindications to donation. Protocols for donor selection, however, vary between institutions. Age, menopausal status, a history of term live births, and body mass index are all examples of potential donor factors for which there is no current consensus. Relatively strict protocols, however, have historically been employed during the experimental phase of clinical UTx. While a history of childbearing in women who are premenopausal may be preferred, successful live births have occurred from both nulliparous and postmenopausal donors [12].

Living donors

Adopting a living donor model allows for a more thorough evaluation of any potential donor and facilitates a more controlled schedule for a complex and multidisciplinary operation. These aspects are significant advantages during the development phase of the technique but inevitably introduce a risk of harm to the donor. The risk of harm

Table III. Advantages and disadvantages of living and deceased donor uterus transplant.

Donor	Advantages	Disadvantages
Living	Comprehensive donor evaluation	Potentially older grafts (e.g., mother)
	Minimized donor ischemic time	Psychological harm following complications
	Elective scheduling of complex procedure	Risk of coercion or undue influence
		Surgical risk to donor (e.g., ureteric injury)
		Limitations to vascular pedicle resection
Deceased	No harm to donor	Limited donor evaluation
	More radical resection of vascular pedicle	Multidisciplinary scheduling difficulties
	Potentially younger grafts	Potential geographic challenges
		Increased bleeding with rapid procurement
		Challenges with next-of-kin consent

may be further compounded when involving related donors, with the potential for significant psychological impact when complications arise in either the donor or recipient. The initial Swedish experience, for example, was exclusively from directed donors – most commonly mothers donating to daughters. In contrast, however, the combined US experience has been overwhelmingly from nondirected (i.e., altruistic) living donors [20].

Living donation remains the most common method of donation in the published literature. A significant majority of potential related donors, however, are at risk of not meeting more stringent selection criteria [23]. Exclusion criteria such as nulliparity, previous caesarean section, a history of smoking, and obesity may preclude many individuals from pursuing living-related UTx.

Deceased donors

A key advantage of using deceased donor grafts is the opportunity for more "radical" procurement and greater accessibility to vascular pedicles. There is also the potential for younger donors, but challenges persist with the extent of preoperative assessment, next-of-kin consent, and surgical scheduling. Overall, the use of deceased donor grafts (exclusively from brain-dead donors at this stage) is an area of ongoing investigation given the modest numbers and relatively small proportion of deceased donor transplants. The experience in the United States, however, has not shown a difference in graft survival or live-birth rate between grafts from living and deceased donors [20], with the understanding that significantly more experience is needed to statistically determine noninferiority.

Donor-recipient matching

ABO compatibility and the presence of donor-specific antibodies remain the primary criteria for donor-recipient matching. Epstein-Barr virus and cytomegalovirus (CMV) also require consideration, with mismatches accepted by some teams. Given the risk of CMV to both recipient and future pregnancies, many teams have avoided transplanting CMV-positive grafts into CMV-negative recipients. Unique to UTx, further consideration is required for the herpes-simplex virus and human papillomavirus status.

SURGERY

Living donor surgery

Uterus procurement from a living donor can be performed with either an open or minimally invasive approach (i.e., laparoscopic or robotic). The complexity and associated complication profile is not dissimilar to that of a radical hysterectomy. The procedure begins with identifying and ligating the round ligaments and accessing the retroperitoneum down to the vesico-uterine peritoneum. Ensuring an adequate venous outflow for the procured graft is critical – particularly as venous thrombosis is a significant cause of graft loss – with isolation of the superior and inferior (i.e., utero-ovarian and uterine) veins for future use. Complexity is associated with the dissection and isolation of these veins, given the number of branches and their association with both paracervical tissue and the ureters. The uterine arteries with either a whole segment or patch of the internal iliac artery are also procured for implantation bilaterally.

The most frequently reported Clavien-Dindo grade 3 or greater complication in the living donor has been ureteric injury (5-14%) [24]. Special attention has therefore been warranted to reduce the risk of donor harm and to ensure the ongoing sustainability of living donation as a safe approach to UTx. The use of pre- and postoperative ureteric stents, reduced thermal energy usage during ureterolysis, and accurate vessel identification with intraoperative indocyanine green angiography are all methods that may reduce the risk of ureteric injury [25].

Deceased donor surgery

The key advantages of deceased donor surgery relate to

the more radical resection that can be performed without harming the donor. Larger vessels, including internal arteries and veins, can be procured, and the ureters can be divided in close proximity to the bladder, but superior to the ureteric tunnel, making ureterolysis unnecessary. Deceased donor surgery does, however, result in longer cold ischaemic times (which has not been demonstrated to impact outcome) and may result in a greater bleeding risk following reperfusion, as many smaller vessels are unsealed during the procurement process.

Preservation strategies

As with other solid organs for transplantation, the donor uterus undergoes both warm and cold ischaemia following procurement, and an appropriate preservation solution is of great importance (e.g., HTK solution). Established limits of permissible ischaemic times are not currently defined and remain an area of research. This has particular relevance in the context of deceased donor transplantation, where the challenges of coordinating unplanned surgery are more evident. There is the future potential for machine perfusion technologies to improve deceased donor transplant logistics, as well as modulate ischaemic-reperfusion injury and allow for viability assessment, as has been performed in other organ systems [26].

Recipient surgery

The steps of the implantation surgery are less variable than those of the donor operation and are traditionally performed in an open fashion. The initial steps involve the separation of the vaginal vault from the rectum and bladder, with subsequent exposure of the external iliac vasculature in preparation for implantation. An orthotopic position is utilised for the graft, with end-to-side anastomoses performed between donor uterine or internal iliac to recipient external iliac vessels. After vascular reperfusion, the vaginal vault of the recipient is opened in preparation for an end-to-end anastomosis with the vaginal rim of the donor graft.

Vascular complications and thrombosis remain the major causes of graft loss, having been reported in multiple centres and occurring in approximately 20% of cases [14]. Most frequently this occurs in the early postoperative phase and necessitates graft hysterectomy. To mitigate this risk, the use of both systemic heparinisation and intraoperative ultrasound has been adopted. Graft positioning may also play a role – with donor and recipient round and uterosacral ligaments reapproximated to secure the graft and prevent prolapse.

Vaginal stenosis, likely secondary to a combination of size discrepancies and the use of end-to-end circumferential anastomoses, is a common complication. Adequate vaginal length is also critical to create an adequate anastomosis with the donor uterus. Ensuring adequate access and visualisation is also essential to facilitate the flow of menstrual effluent, to perform cervical biopsies to monitor for rejection, and to allow for the subsequent transfer of embryos. From the US experience, 72% of recipients developed vaginal strictures with dilation successfully completed either nonoperatively or operatively (approximately 50% for both) [20].

GRAFT MONITORING AND REJECTION

Graft assessment

The technical success of initial UTx surgery can be established by confirming vascular inflow, outflow, and graft viability with early postoperative ultrasound. In cases where perfusion concerns are present, further assessment with serial ultrasound, computed tomography, or magnetic resonance angiography is possible. Unique to UTx, the graft can also be accessed via noninvasive examination to assess the uterine cervix for biopsy and assess for rejection in a protocolised fashion [27].

Immunosuppression and rejection

Immunosuppressive protocols currently employed mirror those used in kidney transplantation. Induction therapy typically incorporates thymoglobulin, mycophenolate, and methylprednisolone, with tacrolimus commenced on the first day postoperatively and a transition to maintenance tacrolimus and prednisone. Mycophenolate is fetotoxic, and before embryo transfer can either be exchanged for azathioprine or discontinued entirely.

The risk of rejection following UTx appears high, and the use of protocol biopsy is essential. Most cases have been of the cellular-mediated type, the majority responding to pulse corticosteroids, with thymoglobulin reserved for the rare and more severe scenarios. While acute cellular rejection remains common, to date no cases of rejection resulting in the need for graft hysterectomy have been reported.

Infection

As with transplantation of other solid organs, prophylactic antimicrobial therapy can prevent most infections, particularly in the early months after transplantation. As previously discussed, key infections to consider with donor-recipient mismatch are Epstein-Barr virus, CMV, human papillomavirus, and herpes-simplex virus – with the potential to influence immunosuppressive regimens, risk of rejection, complications associated with pregnancy, and posttransplant lymphoproliferative disorders. Unlike acute rejection, however, cases of graft hysterectomy resulting from infective complications have been reported (e.g., uterine abscess) [7,11,28].

PREGNANCY

In vitro fertilization

IVF is mandatory for a live birth, as intercourse will not lead to pregnancy following division of the oviducts during UTx [29]. The first IVF cycles are always performed prior to transplantation. This is to avoid any complications that may arise secondary to changes in pelvic vascular anatomy or immunosuppressive medication and to ensure sufficient embryos can be frozen to justify subsequent transplantation. The initial ovarian stimulation, oocyte retrieval, and ultimate embryo transfer all occur as they would for standard fertility treatment. Some women may require treatment for vaginal strictures prior to transfer.

Initial trials waited 12 months after transplantation before embryo transfer. However, motivated by a desire to reduce the recipient's exposure to immunosuppressive therapy, the time has been reduced to 6 months and now to 3 months by the Dallas team [30]. This reduction has not resulted in any detrimental outcomes in either recipient or foetus and has offered notable psychological advantages, given the reduced time to pregnancy, and medical advantages, with the reduced time from UTx to graft hysterectomy limiting the time of immunosuppressive therapy. Prior to embryo transfer, hysteroscopic assessment of the uterine cavity is common, and single embryo transfer remains mandatory to avoid multiple pregnancies.

Gestation and delivery

The antenatal care schedules following UTx have largely been shaped by guidelines for pregnancy following other solid organ transplants [31]. Tacrolimus, prednisone, and azathioprine are most commonly used. The monitoring of immunosuppression levels, blood pressure, and renal function, assessment for infections with vaginal swabs, and surveillance for foetal growth are all mandated. In the initial Swedish trial, three women (of six) developed preeclampsia from a total of eight live births; all of these women had unilateral renal agenesis, which is associated with MRKH [32]. From the US experience, the most common pregnancy-associated complications included hypertension (24%), gestational diabetes (12%), and preeclampsia (12%), and all were successfully managed through standard obstetric care [20].

Close monitoring during the later stages of pregnancy is mandated given the risk of preterm labour. Uterine contractions are not felt by the recipient given the denervation following transplantation. Protocols in the US plan for delivery at 37 to 38 weeks; however, more than half of the deliveries have occurred before that target window (median 36 weeks 6 days), and two of 21 live births occurred between 30 and 32 weeks. Vaginal delivery is contraindicated due to concerns for vaginal anastomotic dehiscence and injury to surrounding structures during delivery. Caesarean section is mandatory and can potentially be combined with graft hysterectomy if no further children are desired. At present, a maximum of two children have been attained following UTx.

LONG-TERM FOLLOW-UP

Graft hysterectomy remains a key component of UTx protocols after one or two pregnancies at all current institutions. Immunosuppression is immediately withdrawn and long-term follow-up is required. Renal toxicity has been reported following UTx but has been reversed after graft hysterectomy and immunosuppression cessation [33]. Neonatal outcomes from Dallas have not identified any cases of foetal malformation or organ dysfunction, with normal attainment of developmental and physical milestones at 2 years of life [34,35].

At present, long-term outcomes are incompletely defined. This is an area of ongoing monitoring and active research. Beyond physiological outcomes, psychological and quality of life assessments are also critical for all parties involved – recipient, donor, partner, and child.

FUTURE CONSIDERATIONS

Transition from experimental to clinical treatment

UTx is uniquely positioned at the cusp of wider clinical adoption after appropriately cautious and experimental beginnings. This transition comes with both profound opportunity and a need for ongoing consideration and vigilance. The expansion of clinical activity undoubtedly will require an expansion of individual institutions with active UTx programs. The complex and novel nature of the procedure will require a multidisciplinary team with appropriate skill sets and UTx experience. We encourage the formation of collaborative relationships with more established centres for any institutions with a view of commencing a UTx program. Furthermore, expansion will require deliberation for regulatory oversight within defined jurisdictions, creation of regional uterus registries, and establishment of long-term reporting standards. The United States Uterus Transplant Consortium has already proposed guidelines for standardized reporting nomenclature in UTx to further strengthen the quality of published evidence [8].

With clinical expansion also arises concerns surrounding patient access and cost. Varying health care systems, with differing societal perspectives and distinct funding structures (e.g., public versus insurance based), will need to assess both the clinical need and acceptance of UTx as

a fertility treatment modality. Growth in deceased donor UTx activity will also necessitate consideration of waiting list management and the most equitable approach to donor graft allocation.

Donor and recipient expansion

Despite cautious beginnings, future clinical growth will undoubtedly come with the expansion of both the recipient and donor pools. For potential recipients, there will be an inevitable move to consider not only those with MRKH but also those with other forms of AUFI or even relative forms of infertility (e.g., Asherman's syndrome, uterine malformations). With growing experience, there is likely an opportunity for less stringent donor criteria, particularly relating to donor age, nulliparity, menopausal status, and donor-recipient matching. Deceased-donor UTx remains less common, but given the limited access to suitable live donors for many patients, this may change as the procedure becomes more common.

While there are both ethical and societal implications for UTx, a discussion around the role of UTx in the transgender community has begun [36]. While not yet a clinical reality, there remains the potential for transgender UTx to be adopted in the future, as well as for this community to be a source of nondirected living donation.

CONCLUSIONS

The current status of UTx in 2024 is both strong and optimistic. This remains a critical time for UTx as it makes the transition from experimentation to a clinical reality for select patients with infertility. Almost a decade after the first live birth, the ever-developing evidence base for the approach provides reason for a cautious but positive outlook. Long-term outcome reporting remains essential for the accurate evaluation of treatment efficacy, as well as the establishment of mature regulatory bodies for patient protection. Ongoing international collaboration and multidisciplinary engagement remain essential for the safe and timely adoption of UTx for patients who could benefit from the procedure.

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