American Society for Reproductive Medicine position statement on uterus transplantation: a committee opinion

Practice Committee of the American Society for Reproductive Medicine

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Following the birth of the first child from a transplanted uterus in Gothenburg, Sweden, in 2014, other centers worldwide have produced scientific reports of successful uterus transplantation, as well as more recent media reports of successful births. The American Society for Reproductive Medicine recognizes uterus transplantation as the first successful medical treatment of absolute uterus factor infertility, while cautioning health professionals, patient advocacy groups, and the public about its highly experimental nature. (Fertil Steril® 2018;110:605–10. ©2018 by American Society for Reproductive Medicine.)

KEY POINTS

- Uterus transplantation is an experimental procedure for the treatment of absolute uterus-factor infertility (UFI).
- Uterus transplantation should be performed within an Institutional Review Board (IRB)–approved research protocol.
- Uterus transplantation teams should be well-coordinated and multidisciplinary.
- Surgical training with animal models and/or cadaver labs is necessary prior to attempting transplantation in human subjects.
- The organ used during uterus transplantation can be from living or deceased donors.
- Transparent inclusion and exclusion criteria should guide selection of transplantation recipients.
- Standardized reporting on outcomes of uterus transplantation is desirable to assess the true risks, benefits, and outcomes associated with this procedure.
- Consistent with all organ transplantations, the Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS) is the supportive organization for data collection. However, neonatal and long-term pediatric outcomes need to be collected.

BACKGROUND

Until the first live birth after uterus transplantation in Sweden in 2014, there were no treatment options available for women with an absent or nonfunctional uterus to carry their own child. Internationally, an attempt at uterus transplantation in 2000 resulted in the uterus being removed and another attempt in 2011 did not produce a live birth (1, 2). Women with UFI who have a nonfunctional or absent uterus historically have been advised to explore in vitro fertilization (IVF) with a gestational carrier (where legal), adoption, foster parenting, or to lead a life without children. The number of women with UFI is significant. In the United States, UFI affects 1%–5% of reproductive-aged infertile women and may result from major congenital uterus malformations (e.g., Mayer-Rokitansky-Küster-Hauser syndrome); benign, obstetrical, or oncologic hysterectomy; or an acquired uterus condition that leaves the uterus in situ but renders it nonfunctional such as severe Asherman syndrome (3, 4). It is not clear what percentage of these patients have an irreversible cause of UFI. Some women with UFI find adoption or the use of a gestational carrier impossible or unacceptable due to legal, religious, financial, or ethical concerns. Although the surgical approach to uterus transplantation is still in its infancy, there is widespread public interest and support for uterus transplantation and gestational

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surrogacy (5–12). More than 30 uterus transplantations have been performed worldwide (13) as of the publication of this document, indicating the rapid tempo of developments in this field. There are several programs initiating or conducting clinical trials of uterus transplantation using both living and deceased donor models in the United States (14). There have been 11 reported deliveries worldwide, all through IVF, with 8 in Sweden, 2 in the United States, and 1 in Brazil (the first reported birth from a deceased donor), at the time of this writing. The mean gestational age at delivery in the Swedish trial of eight births was 35 weeks and 1 day with a birth weight of 2.5 kg. No birth defects were reported. The main obstetrical complications were preeclampsia and cholestasis. Follow-up between 2 months and 3 years has not revealed any significant infant disorders.

Composition of an Appropriate Research Team

Uterus transplantation is currently considered an experimental procedure and should not be performed outside of an IRB–approved research protocol. These trials should be listed on Clinicaltrials.gov. Due to the medical and surgical complexity of uterus transplantation as well as the need for long-term maternal-fetal-neonatal follow-up, these protocols appear to be most appropriate for tertiary medical centers. Teams embarking upon such protocols should be multidisciplinary with recommended representation as listed in Table 1. The primary surgeon/physician for the program should be clearly identified. This concept applies solely to the transplantation component and others will take the lead for the reproductive and obstetrical aspects of the procedure.

Uterus transplantation is unique in its temporary nature; the graft is not intended to last for the life of the recipient, only for as long as necessary to achieve childbearing goals. However, institutions must be prepared to follow a uterus transplantation recipient through four or more abdominal surgeries, including initial implantation of the uterus, one or more cesarean deliveries, and ultimate hysterectomy once childbearing is complete. For an individual recipient, this cycle may take several years to complete; therefore, ensuring the infrastructure for long-term follow-up is essential. Follow-up of the offspring will take even longer.

As a surgical team prepares for transplantation attempts in human subjects, surgical practice specific to uterus transplantation is required. Teams in both Sweden and the United States have prepared for human clinical trials with prior surgical training in rats, sheep, pigs, and nonhuman primates (15, 16). Surgical training and preparation may involve either large animal research or cadaver practice to optimize the surgical approach and team training for obtaining and implanting a uterus graft. The surgical complexity surrounding uterus transplantation lies mainly with the highly difficult dissection of the uterus vein, if used, to provide optimal drainage of the graft (17). As with all innovative surgical procedures, adaptations may be necessary to obtain optimal results (18, 19). Surgeons should possess considerable expertise in vascular dissection and anastomosis as well as navigating the pelvic, vaginal, and retroperitoneal pelvic anatomy. Transplantation teams and recipients must understand that postoperative complications such as graft thrombosis and infection may necessitate hysterectomy in the immediate postoperative period. In addition, other complications, such as graft rejection, may also occur prior to the recipient completing any pro creative treatment and childbearing. Psychosocial team members should have experience either with the psychosocial assessment and care of solid-organ transplant candidates and solid-organ donors or be willing to be mentored by psychosocial team members from existing uterus vascularized composite allograft (VCA) programs.

Issues of Ethics, Consent, and Subject Selection

Human uterus transplantation is considered a VCA, similar to transplantation of the face, limbs, abdominal wall, and other non-lifesaving organs. These transplants can be substantially life-enhancing. However, they do present unique ethical and logistical considerations. VCAs are regulated in a manner similar to other solid organs and require specialized consent to allow removal of the specified organ as well as its use in research. UNOS provides oversight for organ procurement organizations, which obtain the appropriate consent for VCAs from either the donor in living-donor transplants or the donor's family in deceased-donor transplants. Living donors should be specifically counseled regarding the risks of injury, as the hysterectomy required for a living-donor uterus transplantation approximates a radical hysterectomy and injuries have been reported to donors in all series of living donors to date (18, 19). Care should be taken to avoid undue emotional and psychological pressure in living donors, who are often family members of the recipient seeking transplantation. Recipients must be counseled carefully and thoroughly, as women hoping to achieve pregnancy are considered a vulnerable population. Counseling must highlight the experimental nature of this type of clinical research rather than potential pregnancy as the central focus. Recipients must be advised of both known and unknown risks of transplantation and the

TABLE 1

Recommended composition of the uterus transplantation team.

Team member
Reproductive endocrinologist
Transplant surgeon
Gynecologic surgeon
Maternal-fetal medicine specialist
Anesthesiologist
Infectious disease specialist
Psychiatrist or psychologist
Neonatologist
Pathologist
Radiologist
Bioethicist or professional with bioethics expertise
Social worker
Living donor advocate as described by UNOS regulations
Research nurse/coordinator
Transplant medicine specialist

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accompanying anti-rejection medical treatments. As bioethical issues in uterus transplantation (including reproductive and obstetrical components) are a foremost concern, bioethicists or those with bioethics expertise should be included in research protocols from the outset (20, 21).

Careful consideration should be given to inclusion of appropriate subjects. Common inclusion and exclusion criteria for recipients are listed in Table 2. As most protocols in IVF and embryo cryopreservation (freezing) prior to transplantation require, recipients should be excellent IVF candidates. The need for routine use of preimplantation genetic testing in this patient population has not been defined. The optimal number of cryopreserved embryos necessary prior to proceeding with the uterus transplant is undefined, but it seems reasonable that it would be the total number of embryos that would result in at least one live birth (based on the recipient's age, embryo quality, and the statistics of the IVF program). A single embryo should be transferred each time.

Inclusion and exclusion criteria for donors have not been well established and will depend on whether living or deceased donors are used. All donors must be blood-type compatible with their intended recipient. All recipients should be screened for preformed anti-human leukocyte antigen (HLA) antibodies prior to transplantation using single-antigen beads or other solid-phase methodology as currently performed by the transplant center's HLA laboratory. When living-donor liver transplantation is performed, the HLA donor-recipient compatibility can be tested electively. Strong B and T cell crossmatch positivity should be avoided, as the effects of a strong immunological reaction on graft outcomes are unknown. The use of virtual crossmatch can be used to optimize donor-recipient HLA matching in cadaveric uterus transplantation, where the actual cross match result can be available for logistical reasons only after the transplant has occurred.

Deceased donors of reproductive age will have met criteria for brain death or donation after cardiac death. It is unclear whether increased-risk donors should be used (such as those who have died from intravenous drug overdose). Living donors should be medically healthy before donation, parous, and have a favorable obstetric history. Donors should not have a history of gynecologic conditions that would impact reproductive outcomes such as submucous, intracavitary, or large intramural leiomyomas; clinically significant adenomyosis; uterus anomalies; or endometrial pathology. Donors should not have active human papillomavirus or active cervical dysplasia present. Importantly, donors should be free of conditions associated with vasculopathy, such as diabetes, hypertension, and significant lipid abnormalities. Critical infectious diseases must be ruled out in all donors.

Immunosuppression

State-of-the-art immunosuppression should be provided based on the principles established in solid-organ transplantation and composite-tissue transplantation.

Surveillance of Rejection

Cervical punch biopsies from the ectocervix are used to monitor rejection and can also be used in pregnancy (22). Periodic biopsies will be performed at scheduled intervals as well as at the discretion of the program.

Surgical Considerations and Future Directions

It is currently unknown whether living-donor or deceased-donor uterus transplantation represents the superior approach. It is possible that both surgical techniques will be relied upon, similar to what has been recognized in liver

TABLE 2

Suggested inclusion and exclusion criteria for recipients of a uterus transplant.

Inclusion	Exclusion
Meets criteria for an absent or a nonfunctional uterus	Age >45 y or poor reproductive status of embryos
Reproductive-aged female (18–45 y) with sufficient number of good-prognosis embryos	History of hypertension, diabetes, or significant systemic illness, including serious abnormalities of the heart, liver, kidney, hematologic, or central nervous system
Willing and able to undergo criteria of the study including psychiatric and social-work evaluation	Any medical diagnosis placing the subject at high risk of surgical complications based on the transplantation team's review of medical history
Willing and able to undergo general anesthesia, in vitro fertilization, major gynecologic surgery, pregnancy with potential high-risk complications, cesarean delivery, and eventual hysterectomy to remove the graft	Smoker within 3 mo of study enrollment
Willing and able to receive immunosuppressive medications	History of prior malignancy (excluding early-stage cervical cancer or other cancers at low risk for recurrence)
Willing to receive standard vaccinations	History of human immunodeficiency virus or any history of mycobacterial infection (treated or untreated)
Social support and ability to sign informed consent	Presence of active documented systemic infection or recent systemic infection within the past 3 mo
Nonsmoker	Active chemical and/or alcohol dependency or abuse
Approval of multidisciplinary treatment team	Anatomical abnormality which would make the pelvic transplantation surgery unlikely to be successful
Willing and able to follow infection prophylaxis protocols associated with solid-organ immunosuppression practice, including but not limited to cytomegalovirus and pneumocystis pneumonia prophylaxis	Body mass index >30 kg/m^2
	Relative or absolute contraindication to immunosuppression
	Untreated hepatitis C or active hepatitis B viremia or carrier state

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TABLE 3

Living- versus deceased-donor models.

Donor type	Advantage	Disadvantage
Living	• Opportunity to obtain detailed medical/surgical history • Donor and recipient in close geographic proximity • Convenient scheduling and assessment	• Procedural risks associated with pelvic surgery • Undue pressure to donate • Possible "donor guilt" if unsuccessful • Potential risks with older uteri/vascular grafts • Use of ovarian vessels may require oophorectomy
Deceased	• No donor risks • Grafts from younger-aged donors • Greater variety of vascular pedicles available, including ovarian vessels	• Limited preoperative assessment • Scarcity of suitable organs and inconvenient scheduling/geography • Possible difficulties in obtaining consent from next of kin

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and kidney transplantation. Each approach has distinct advantages and disadvantages, as outlined in Table 3. At this stage, it appears ethically sound to pursue both deceased- and living-donor approaches based on the experience and preferences of the institution and research team.

Ischemia-reperfusion injury is a significant concern in both living- and deceased-donor protocols and neither optimal cold nor warm ischemic times for uterus transplantation have been determined to date. Although several studies have demonstrated resistance to cold ischemia in uterus myometrial cells (23, 24), consideration should be given to limiting both cold and warm ischemia times. Deceased-donor programs may benefit from approximating living-donor techniques as closely as possible. This may include selecting donors in close geographic proximity to the recipient in order to limit transit and ischemia time for the graft. It may also be advantageous to have two different teams for organ procurement and implantation, as is commonly coordinated in solid-organ living-donor models. Postoperative surveillance for both infection and thrombosis should be intensive as these appear to be the leading causes of immediate post-transplantation hysterectomy (13). Ideal graft monitoring and follow-up should include a combination of laboratory studies, imaging, and cervical biopsies; however, an optimal strategy for either short- or medium-term post-transplant surveillance has not been established to date.

As the technique of uterus transplantation is quickly evolving, several key issues remain to be determined. Foremost is whether a uterus obtained through minimally invasive techniques can result in a live birth and mitigate some of the risks associated with open living-donor surgery (25). Robotic and laparoscopic approaches have been described recently (26, 27). The use of ovarian or utero-ovarian vessels for venous outflow has been a novel application to circumvent the dissection and use of the uterus veins (19P). However, it is generally not recommended to use the ovarian vessels if this results in the loss of ovaries in premenopausal women. Techniques have been established to use the utero-ovarian veins that allow preservation of the ovaries. In addition, although fetal exposure to immunosuppressive medications is similar in uterus transplantation to other well-studied solid-organ transplants such as kidney, neonatal assessment and future strategies to decrease potential harm to the offspring should be investigated.

As uterus transplantation becomes a more common therapeutic procedure in the United States, there is a need for uniform reporting and evaluation of outcomes. At a minimum, surgical centers should report the short-term parameters listed in Table 4 to their IRB. As longer-term follow-up on a greater number of procedures becomes available, a cautious assessment will be necessary to determine the appropriateness and impact of this procedure on the physical and mental health of recipients and offspring as well as of donors. Although an international registry is planned, programs in the United States are obligated by OPTN/UNOS to carefully track and report on data related to ongoing uterus function, safety, and reproductive outcomes. Established research programs are encouraged to maintain transparency and cooperation both with each other as well as with newly established centers. It should be noted that, as a uterus transplant is classified as a VCA, reporting is mandated by UNOS to allow for data to be submitted and analyzed by the Scientific Registry of Transplant Recipients. The breadth of the

TABLE 4

Standards for consistent reporting for uterus transplantation surgeries.

Information source	Data to collect
Donor	Age and body mass index of donor Surgical times for uterus procurement Route of surgery (abdominal versus laparoscopic or robotic) Living-donor complications and length of stay
Graft	Cold and warm ischemia times for the graft
Recipient	Surgical times for uterus reimplantation Blood transfusion Length of stay post-transplantation Postoperative complications Outcome of surgery (i.e., graft in situ versus post-transplantation hysterectomy) If hysterectomy is performed, what was the indication (thrombosis, infection, etc.) Presence of vaginal stenosis Episodes of rejection based on cervical biopsy and method of management Pregnancy Long-term follow-up Outcomes for offspring

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data mandated and reported should be extensive enough to allow the needed analysis of the effectiveness, risks, and overall utility of this emerging and rapidly proliferating organ transplant.

SUMMARY

- Uterus transplantation is an experimental procedure for the treatment of absolute uterus-factor infertility.
- Uterus transplantation should be performed within an IRB-approved research protocol.
- A uterus transplant program requires a multidisciplinary team experienced with the technique prior to attempting transplantation in human subjects.
- The organ used during uterus transplantation can be for living or deceased donors; each approach has its own challenges and strengths.

CONCLUSION

Uterus transplantation is an experimental procedure that may allow women with absolute uterus factor infertility to achieve a pregnancy.

UNANSWERED QUESTIONS

- Is a living- or deceased-donor approach superior for uterus transplantation?
- In living donors, can the utero-ovarian veins be used in place of the uterine veins for the entire venous return of the uterus?
- What are the long-term consequences of transplant and anti-rejection drugs on the mother and her baby?

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