Original Research

Twelve Live Births After Uterus Transplantation in the Dallas UtErus Transplant Study

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OBJECTIVE: To describe aggregated pregnancy outcomes after uterus transplantation from a single, experienced center.

METHODS: This prospective study reports on live births among 20 women who received a uterus transplant from 2016 to 2019 at Baylor University Medical Center at Dallas. These live births occurred between November 2017 and September 2020. The main measures were live birth, maternal complications, and fetal and newborn outcomes.

RESULTS: There were six graft failures (four surgical complications and two with poor perfusion postoperatively). Of the 14 technically successful transplants, at least one live birth occurred in 11 patients. Thus far, the live birth rate per attempted transplant is 55%, and the live-birth rate per technically successful transplant is 79%. Ten uteri were from nondirected living donors and one uterus was from a deceased donor. In vitro fertilization was performed to achieve pregnancy. Ten recipients delivered one neonate, and one recipient delivered two neonates. One organ rejection episode was detected during pregnancy and was resolved with steroids. The median birth weight was 2,890 g (range 1,770–3,140 g [median 68th percentile]). Maternal weight gain was higher than Institute of Medicine recommendations. Maternal medical complications were observed in five recipients (elevated creatinine level, gestational diabetes, gestational hypertension [n=2], and preeclampsia). In five recipients, maternal medical or obstetric complications led to an unplanned preterm delivery (elevated creatinine level, preeclampsia; preterm labor [n=3]). The median gestational age at delivery was 36 6/7 weeks (range 30 6/7–38 weeks). All neonates were liveborn, with Apgar scores of 8 or higher at 5 minutes.

CONCLUSION: Over the first 3 years, our program experienced a live-birth rate per attempted transplant of 55% and a live-birth rate per technically successful transplant of 79%. In our experience, uterus transplantation resulted in a third-trimester live birth in all cases in which pregnancies reached 20 weeks of gestation. Maternal medical and obstetric complications can occur; however, these were manageable by applying principles of generally accepted obstetric practice.

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Mayer-Rokitansky-Küster-Hauser syndrome is a developmental abnormality that results in absence of the uterus. Women with this condition are infertile but develop normal secondary sexual characteristics because ovarian function is not affected. Uterus

transplantation is the only treatment that restores reproduction and the ability to experience gestation in women with absolute uterine-factor infertility, such as Mayer-Rokitansky-Küster-Hauser syndrome. Uterus transplantation is costly and requires the recipient and donor to undergo major surgery. Once our uterus transplantation protocol was approved, we received inquiries from close to 1,500 potential recipients and 700 potential donors. Our protocol was approved for 20 recipients. The first live birth to a woman after uterus transplantation was reported in 2014.[1] Since then, the number of uterus transplantation procedures has increased, and births have occurred in multiple centers.[1–6] Of the 20 live births after uterus transplantation that were mentioned in media outlets worldwide, only 10 were reported in the medical literature.[1–4,7] These reports often were incomplete. This limits conclusions regarding pregnancy outcomes and safety. Our aim was to describe the outcomes of the first 12 pregnancies that led to live births at our center.

METHODS

DUETS (the Dallas UtErus Transplant Study) was a prospective cohort study of the first 20 women undergoing uterus transplantation at a single center. The study was approved by the Baylor University Medical Center ethics committee and institutional review board in 2015. It was listed on clinicaltrials.gov (NCT02656550) before the first transplant.

Our initial experience ascertaining recipients and donors for uterus transplantation (n=272 and 79, respectively), the screening protocol, and demographic data were published previously.[8] Forty-five potential recipients and 36 potential donors were evaluated.[8–10] Potential living donors were excluded if they had a history of obstetric complications, including recurrent pregnancy loss, spontaneous abortion in their most recent pregnancy, or any prior dilation and curettage. Pregnancy history information for deceased donors was incomplete. Potential recipients with preexisting hypertension requiring medications, diabetes requiring pharmacologic therapy, or any ongoing serious medical complication were excluded from uterus transplantation in our protocol.[8]

Our protocol allows for recipients to experience a maximum of two pregnancies, and then a graft hysterectomy is performed. The hysterectomy is performed after either the first or second delivery, depending on the patient's wishes or medical and obstetric considerations. Between September 2016 and August 2019, 20 women were transplanted with uteri from living donors (n=18) or deceased donors (n=2). A uterine transplantation procedure was considered technically successful when there was a vital graft 3 months postoperatively.

Before uterus transplantation, recipients underwent in vitro fertilization. The DUETS protocol required good-quality day 5–6 expanded blastocysts (Society for Assisted Reproductive Technology [SART] grading). All recipients underwent single embryo transfer of an expanded blastocyst. Early in the program (cases 4, 5), embryo transfer was planned 6–8 months after uterus transplantation. In subsequent cases, to minimize recipient graft time, which we defined as time from uterus transplantation to hysterectomy,[11] we individualized the timing of embryo transfer after uterus transplantation based on postoperative recovery, graft function (eg, established menses), immunosuppression regimen, and infectious disease susceptibility.[11] This allowed us to shorten the time interval from uterus transplantation to embryo transfer.

An induction regimen with thymoglobulin (total dose 4.5 mg/kg), and 500–1,000 mg of methylprednisolone was used at the time of uterus transplantation. Maintenance immunosuppression was achieved with oral tacrolimus. The goal of trough tacrolimus levels was 9–11 ng/mL during months 1–3 post–uterus transplantation and 4–8 ng/mL thereafter. Drug levels were monitored, and doses adjusted at 1- to 2-week intervals after uterus transplantation and throughout pregnancy. Mycophenolate mofetil was used for cases 4, 5, and 7, and embryo transfer was performed after a 3-month washout. After the ninth recipient, mycophenolate mofetil was eliminated from the regimen and replaced with azathioprine or everolimus, which allowed us to consider embryo transfer 3 months after induction therapy. All recipients received low-dose aspirin (81 mg) daily from uterus transplantation throughout pregnancy and the postpartum period.

After uterus transplantation, patients were monitored according to our protocol. This included cervical biopsies to monitor for rejection. For 3 months after uterus transplantation, biopsies were done at approximately 14-day intervals. Afterwards, monthly biopsies were performed until embryo transfer. Prenatal visits occurred every 2 to 3 weeks. Routine care included fetal growth, biophysical profiles, and umbilical artery Doppler studies. Rejection episodes were managed with intravenous SoluMedrol, 1 g on day 1 and 500 mg on days 2 and 3. A repeat cervical biopsy was done 1 week after rejection treatment. During pregnancy, cervical biopsies were performed twice (12–14 and 24–26 weeks of gestation).

Uterus transplantation is performed at multiple centers around the world, and the delivery modality is universally cesarean delivery owing to concern that the vaginal anastomosis could dehisce during labor. In addition, a circumferential stricture at the anastomosis site is common, and this creates a small diameter of the upper vagina. To prevent descent of the fetal head, many centers plan for a preterm delivery before the onset of labor. Our protocol allowed for delivery timing to be at the discretion of the obstetrician and maternal-fetal medicine subspecialist. Our initial protocol was to deliver patients at 35–36 weeks of gestation. However, as we gained experience, our protocol was modified to deliver at 37–38 weeks of gestation. In all cases in which there was a maternal medical or obstetric complication, delivery time was individualized.

The primary outcomes were live birth, pregnancy complications, fetal growth and development, and newborn weight. Pregnancy complications were divided into three categories: maternal medical, obstetric, and fetal. Maternal medical complications included preeclampsia with and without severe features and gestational diabetes. Preeclampsia with and without severe features were defined according to standard American College of Obstetricians and Gynecologists' criteria.[12] All patients were screened for gestational diabetes between 26 and 28 weeks of gestation with a 50-g oral glucose load (140 mg/dL or higher); a 3-hour diagnostic test (100 g) was performed if needed (95 mg/dL or less, 180 mg/dL or less, 155 mg/dL or less, and 140 mg/dL or less at fasting, 1 hour, 2 hours, and 3 hours, respectively). A diagnosis of gestational diabetes was made with two or more abnormal values on the 3-hour test.[13] Maternal weight was recorded at each obstetric visit. At the end of pregnancy, maternal weight gain was compared with the Institute of Medicine's (now known as the National Academy of Medicine) recommendation for weight gain during pregnancy based on starting body mass index (BMI, calculated as weight in kilograms divided by height in meters squared).[14]

Obstetric complications included preterm birth (less than 37 weeks of gestation), conditions of abnormal placentation after 28 weeks, cervical shortening (24 mm or less before 28 weeks), and abnormal amniotic fluid volume as determined by either an amniotic fluid index[15] or a single deepest pocket of less than 2 cm or more than 8 cm on a biophysical profile. The amniotic fluid index was defined as abnormal when the value was less than the 5th percentile or more than the 95th percentile for gestational age.[15] Vaginal bleeding was considered an obstetric complication when it spanned two trimesters (trimesters: 14 weeks of gestation or less, 14 1/7 weeks to 28 weeks or less, and 28 1/7 weeks to delivery). This decision was made a priori, because bleeding in two consecutive trimesters has been associated with adverse pregnancy outcomes.[16] A severe obstetric complication was one that led to a surgical procedure or delivery before the planned date.

Fetal complications included congenital anomalies or abnormal fetal growth. Fetal growth abnormalities were defined as either biometric measures or estimated fetal weight less than the 10th percentile or greater than the 90th percentile. Doppler flow was considered abnormal when there was absent or reverse end diastolic velocity in any umbilical artery. A fetal echocardiogram was performed between 22 weeks and 24 weeks of gestation in all pregnancies. Apgar scores, umbilical artery pH, and birth weight were recorded at delivery. Birth weight was adjusted for age and neonatal sex using Fenton growth charts for preterm births[17,18] and World Health Organization charts for full-term infants.[19]

RESULTS

Of the 20 uterine transplants performed (Fig. 1), 14 were technically successful.[20] Graft failures were attributed to surgical complications (four cases) and poor graft perfusion (two cases). The majority of the graft losses were seen among the first 10 uterus transplants (cases 1–3, 8, 10). Of the 14 technically successful transplants, at least one live birth occurred in 11 patients. At the time of this report, the success rate (ie, live birth) per attempted transplant is 55%, and the live birth rate per technically successful transplant is 79%.

With the 10 most recent transplants, the technical success rate was 90%, and the live-birth rate per technically successful transplantation is currently 67% among these women. There was also one patient that at preparation of this article was carrying a pregnancy (delivered November 2020). There also is one patient carrying a second pregnancy in this cohort (case 11), and two patients are proceeding with additional embryo transfers (cases 12 and 17).

Among the 11 recipients with live births, the indication for uterus transplantation was absolute uterine-factor infertility (Mayer-Rokitansky-Küster-Hauser syndrome) in 10 and hysterectomy in early adulthood owing to a leiomyomatous uterus in one (case 15). At the time of uterus transplantation, participants had a median age of 30 years (range 20–36 years) and a median BMI of 25 (range 21–31) (Table 1). One recipient (case 9) with Mayer-

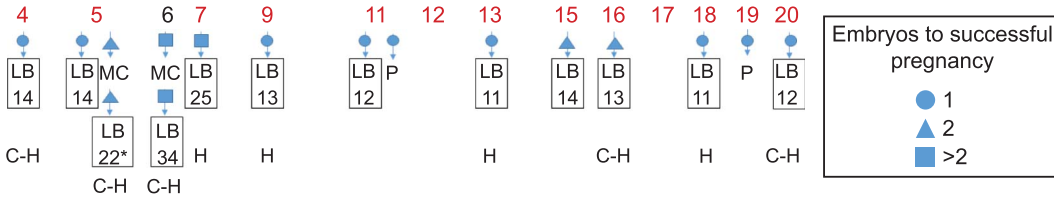

Fig. 1. Schematic overview of the 14 technically successful uterus transplantations in DUETS (the Dallas UtErus Transplant Study). Numbers are recipient case numbers. Live births, embryo transfers, time from uterus transplant to live birth, and graft hysterectomy are shown. Patient numbers not shown are those with a nonvital graft at 3 months after transplant. Patients 12 and 17 have thus far had multiple embryo transfers and no live births; neither patient has proceeded beyond 20 weeks of gestation. Patient 6 was a deceased donor. Numbers beneath live birth (LB) indicate completed months from uterine transplant or *previous live birth. MC, miscarriage; P, ongoing pregnancy; C-H cesarean hysterectomy; H, delayed hysterectomy.

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Rokitansky-Küster-Hauser syndrome had a single kidney. The median serum creatinine level before uterus transplantation was 0.76 mg/dL (range 0.63–0.99 mg/dL). Ten of the donors were living nondirected (eg, the organ is intended for an individual neither named nor specified by the donor), and one was deceased. The donors each had at least one full-term live birth (median 3, range 1–7) and not more than two cesarean deliveries (Table 1). Three donors (cases D7, D11, D15) had prior cesarean deliveries. One donor was a grand multipara (case D9).

Four recipients had a single episode of mild rejection before pregnancy (cases 4, 5, 11, 13). In three of these four patients, the rejection episodes occurred with hormonal priming of the uterus before embryo transfer. In each case the rejection episode resolved before embryo transfer, using steroid administration as described previously. One recipient had a rejection episode that was detected during pregnancy (case 20). The rejection episode resolved after steroid treatment.

In this cohort (Fig. 1), seven patients achieved a live birth after their first embryo transfer and two patients after two embryo transfers; two patients required multiple embryo transfers to achieve live birth. One patient had a second live birth (case 5). After the first delivery, she miscarried after two embryo transfers and subsequently achieved a second live birth after two additional embryo transfers.

Seven patients had weight gain during pregnancy exceeding the Institute of Medicine's recommendations.[21] The average weight gain during gestation was a 12.6 kg (range 4.5–19.5). Six patients had BMIs at delivery in a nonobese category.

Table 1. Demographics and Baseline Values for the 11 Recipients and Donors at Uterus Transplantation

	Recipient					Donor				
Case No.	Indication for UTx	Age (y)	BMI (kg/m^2)	SCr Level (mg/dL)	Renal Malformation	Type	Age (y)	Gravidity	Parity	No. of Deliveries (Vaginal/Cesarean)
4	MRKH	30	25	0.88	None	LNDD	34	2	2	2/0
5	MRKH	28	23	0.72	None	LNDD	36	4	4	4/0
6	MRKH	36	21	0.8	None	DD	33	3	3	NA
7	MRKH	25	31	0.67	None	LNDD	39	331/2		
9	MRKH	24	25	0.85	Single kidney	LNDD	35	7	7	7/0
11	MRKH	20	25	0.99	None	LNDD	32	4	5	3/2
13	MRKH	31	30	0.76	None	LNDD	39	6	4	3/0*
15	Hysterectomy	31	29	0.82	None	LNDD	43	2	2	0/2
16	MRKH	31	26	0.73	None	LNDD	30	1	1	1/0
18	MRKH	33	21	0.63	None	LNDD	38	2	2	2/0
20	MRKH	30	21	0.66	None	LNDD	38	4	2	2/0
Median		30	25	0.76			36	3	3	2/0

UTx, uterus transplantation; BMI, body mass index; SCr, serum creatinine; MRKH, Mayer-Rokitansky-Küster-Hauser syndrome; LNDD, living nondirected donor; DD, deceased donor.
* One twin delivery included.

When all categories of pregnancy complications (maternal medical, obstetric, and fetal) were considered, 8 of 12 (67%) pregnancies were noted to have at least one complication (Table 2). Five patients had at least one maternal medical complication, and seven had at least one obstetric complication. None had a fetal complication.

Three recipients had a blood pressure measurement of 140 mm Hg or higher systolic or 90 mm Hg or higher diastolic. One of these three had an unplanned delivery owing to preeclampsia without severe features, which was diagnosed the same day as delivery. The recipients, in aggregate, showed a blood pressure decline during the end of the second trimester of pregnancy (Fig. 2). Tacrolimus levels were kept at target trough levels of 4–7 ng/mL in all participants. The serum creatinine concentrations in this cohort remained stable during pregnancy. However, one recipient had elevated prepregnancy serum creatinine levels, and these remained above the median value throughout pregnancy (1.1–1.4 mg/dL) (case 4). This recipient had an unplanned delivery owing to acute kidney injury attributed to exposure to tacrolimus.

One recipient was diagnosed with gestational diabetes. This was managed with diet and metformin starting at 30 weeks of gestation. Insulin was started at 32 weeks of gestation owing to side effects from metformin. Delivery timing was not altered by this maternal medical complication.

Preterm birth occurred as planned in two women (17%), but delivery timing was unplanned in five cases (42%) (Table 3). In two cases (cases 4 and 15), the unplanned preterm delivery was indicated owing to maternal medical complications, and in three cases the cause was preterm labor. One of these had an examination-indicated cerclage at 23 4/7 weeks of gestation for suspected cervical insufficiency. The patient delivered at 30 6/7 weeks of gestation owing to spontaneous preterm labor. The median gestational age for the entire cohort was 36 6/7 weeks of gestation (range 30 6/7–38 weeks) (Table 3).

All participants had estimated fetal weight by ultrasonography across pregnancy between the 10th and 90th percentiles. Umbilical artery Doppler flow was normal across the pregnancy for all patients.

The median time interval from uterus transplantation to delivery was 417 days (range 345–760). Neonates had a median birth weight of 2,890 g (range 1,770–3,140 g), which was between the 18th and 88th percentile (Table 3). All neonates were liveborn, with Apgar scores of 8 or higher at 5 minutes (Table 3). The median umbilical artery pH was 7.26 (range 7.16–7.29) (Table 3).

All pregnancies concluded with cesarean delivery per protocol. In four cases, the uterine graft was removed at the time of the first delivery and in one case at the time of the second delivery (Fig. 1). Hysterectomy and discontinuation of tacrolimus resulted in resolution of serum creatinine elevation in one patient (case 4).[3] Four patients had delayed postpartum hysterectomies. The delay of hysterectomy was due to patient preference; in some cases, consideration was given to having a second pregnancy, as allowed by our protocol. All hysterectomies were performed without complications.

The median estimated blood loss at delivery for the entire cohort was 943 mL (range 500–2,600 mL). Estimated blood loss for the patients who underwent cesarean hysterectomy was 1,040 mL (range 500–2,600 mL). One patient (case 20) received a transfusion (2 units of packed red blood cells) postoperatively owing to heavy bleeding before cesarean hysterectomy.

DISCUSSION

More than half of the first 20 uterus transplant participants at our center have now had successful live births. We searched PubMed using the following terms: uterus transplantation OR uterine transplantation AND live birth OR pregnancy, on November 11, 2020. Our search generated 136 citations (starting timeframe 1990) that included original cohort studies, case reports, and reviews. To our knowledge, this is the first detailed report of a series of live births after uterus transplantation from a single center. All recipients underwent uterus transplantation owing to absolute uterine-factor infertility caused by congenital agenesis of the uterus (Mayer-Rokitansky-Küster-Hauser syndrome) or hysterectomy in early adulthood. This is consistent with worldwide experience.[5]

Before uterus transplantation, patients with Mayer-Rokitansky-Küster-Hauser syndrome and other causes of absolute uterine-factor infertility had only two options for reproduction: adoption and surrogacy. Gestational surrogacy laws are complex. In some countries, there is complete prohibition; in the United States, state laws are not uniform, with some states prohibiting surrogacy. Although uterus transplantation is costly and can require major surgery for two patients (donor and recipient), women with absolute uterine-factor infertility participated in our protocol.

In our cohort, uterus transplantation resulted in third-trimester live births once pregnancies reached 20 weeks of gestation. All live births concluded with a delivery at or beyond 30 6 /7 weeks of gestation. All

Table 2. Maternal, Obstetric, and Fetal Complications in the 11 Uterus Transplant Recipients With Live Births*

	Maternal Medical Complications		
Case	Gestational Hypertension	Preeclampsia	Gestational Diabetes Mellitus
4			
5 (1st pregnancy)			
5 (2ndpregnancy)			
6	✓		
7			✓
9			
11			
13			
15		✓	
16	✓		
18			
20			

* Renal complications such as rising serum creatinine level, poor creatinine clearance, or proteinuria.
† Vaginal bleeding spanning at least two trimesters (less than 14 weeks of gestation, 14–28 weeks, more than 28 weeks).
‡ Delivery for a maternal medical, obstetric, or fetal indication.

neonates were born without congenital anomalies. We had two maternal medical complications that led to unplanned early deliveries. We attribute one (case 4) to exposure to immunosuppressive agents and the other (case 15) to preeclampsia. We consider both maternal medical complications to be unavoidable but easily recognized, followed, and managed.

Prior obstetric history was considered in the donor selection process. Examination-indicated cerclage was performed in one patient (case 9) who went on to deliver spontaneously preterm (30 6/7 weeks of gestation). This patient delivered earliest among the patients in our cohort. Importantly, the live uterus donor was a grand multipara but had no history of cesarean delivery,

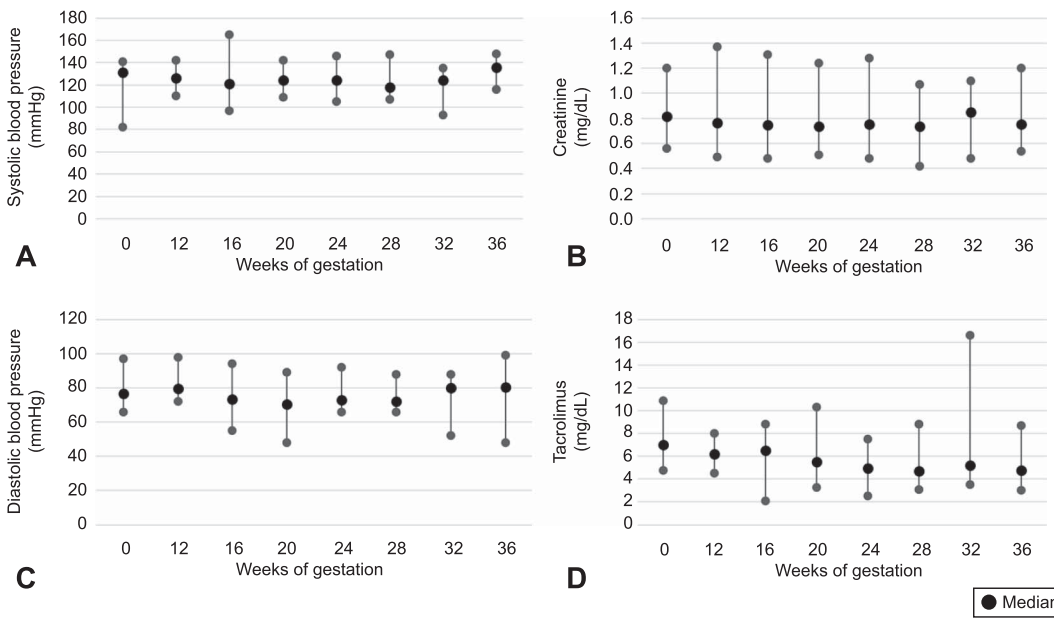

Fig. 2. Maternal outcomes during pregnancy. Aggregated systolic blood pressure (mm Hg) (**A**), creatinine level (mg/dL) (**B**), diastolic blood pressure (mm Hg) (**C**), and measured tacrolimus blood levels (ng/mL) (**D**). Values shown as median (*trend line*) and range (*vertical line*).

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Obstetric Complications							
Renal*	Vaginal Bleeding†	Placenta Previa	Cervical Insufficiency	Polyhydramnios	Oligohydramnios	Preterm Labor	Preterm Delivery‡
✓	✓						✓
	✓						
			✓			✓	✓
		✓					
				✓			
	✓	✓				✓	✓
						✓	✓

cervical insufficiency, or prior preterm births. It is unclear whether relaxing the selection process would result in less favorable obstetric outcomes for the recipients.

Most reports of uterus transplantation have used an immunosuppression regimen based on tacrolimus maintenance therapy as a single agent or in combination with mycophenolate mofetil, antimetabolites, protein kinase inhibitors, or corticosteroids.[2,5,22–24] Because the use of mycophenolate mofetil has to be stopped before embryo transfer owing to its teratogenic nature, we opted to abandon use of mycophenolate mofetil. Instead, tacrolimus and azathioprine were used as maintenance therapy. This alteration enabled earlier embryo transfer, which decreases cumulative immunosuppression exposure.

Table 3. Newborn Outcomes Among Live Births to Uterus Transplant Recipients

Case	Recipient Age at Delivery (y)	Birth Weight (g)	Gestational Age (wk)	Birth Weight Percentile(s)*	Apgar Score (1-min/5-min)	Umbilical Artery (pH)	Sex	Indication for Delivery
4	31	1,995	33 1/7	44	8/9	7.26	Male	Elevated SCr level
5 (1st pregnancy)	29	2,920	36 6/7	76	9/9	7.26	Female	Per protocol
5 (2nd pregnancy)	31	3,370	38 0/7	74/54	9/9	Not done	Female	Per protocol
6	39	3,470	37 6/7	82/62	9/9	Not done	Female	Per protocol
7	28	2,860	35 6/7	74	8/8	7.29	Female	Per protocol
9	25	1,770	30 6/7	83	7/8	7.29	Female	Preterm labor
11	21	3,140	37 2/7	62/30	8/8	7.25	Male	Per protocol
13	32	2,960	37 0/7	51/23	8/9	7.24	Male	Per protocol
15	32	2,400	36 6/7	18	8/9	7.26	Female	Preeclampsia
16	32	3,025	37 0/7	57/23	4/8	Not done	Male	Per protocol
18	34	2,350	32 4/7	88	7/8	7.16	Male	Preterm labor
20	31	2,325	35 6/7	29	8/8	7.27	Female	Preterm labor
Median	31	2,890	36 6/7	68	8/9	7.26		
Range	21–39	1,770–3,140	30 6/7–38 0/7	18–88	4–9/8–9	7.16–7.29		

SCr, serum creatinine.

* Measured birth weight for age. Sex-specific percentiles are derived from Fenton growth charts for preterm births and the World Health Organization charts for full-term infants.[17–19]

Studies of female solid organ transplant recipients (not uterus) during pregnancy have shown an association with preterm delivery and small-for-gestational-age neonates.[25,26] In our protocol, delivery was initially recommended at 35–36 weeks of gestation. As we gained experience, we delivered patients at later gestational ages and observed a correspondingly greater birth weight. The median gestational age in our study (36 6/7 weeks) was higher than the world experience reported after uterus transplantation (34 5/7 weeks).[1–5] Our mean birth weight (2,890 g, 68th percentile) compares favorably to that reported by others (2,890 g, 52nd percentile, vs 2,576 g, 31st percentile, respectively).[1–5] Umbilical artery Dopplers were normal throughout pregnancy in all recipients. Similarly, all neonates were appropriate for gestational age at delivery. Low birth weight after uterus transplantation is likely due to preterm delivery and not poor fetal growth after exposure to immunosuppressive agents or uteroplacental insufficiency.

In normal pregnancies, serum creatinine level declines in the second trimester and slowly rises during the third trimester.[27] Serum creatinine level as a surrogate for renal function in uterus transplantation recipients before and during pregnancy is of great importance, because it can affect the recipients' perinatal and long-term health. We did not observe a clinically significant change in serum creatinine level.

Rates of preeclampsia are reported to be increased after uterus transplantation.[5] In these reports, preeclampsia led to unplanned delivery at 31–35 weeks of gestation.[5] These patients had type 2 Mayer-Rokitansky-Küster-Hauser syndrome, which includes abnormalities in kidney development, and one had a single kidney. One of our patients developed preeclampsia, and, interestingly, that was the only patient not diagnosed with Mayer-Rokitansky-Küster-Hauser syndrome. It may be that exposure to daily low-dose aspirin contributed to the infrequent observation of preeclampsia in our cohort.

The primary limitation of our study is its small sample size. Although we report on 12 live births after uterus transplantation, this is the largest experience from a single center. A major strength of our report is that it is detailed and offers a framework of clinical care for others embarking on a uterus transplantation program. We hope presentation of our data can bring uterus transplantation centers together for data sharing to improve patient care.

In our experience, uterus transplantation resulted in a third-trimester live birth once pregnancies reached 20 weeks of gestation. Maternal medical and obstetric complications can occur; however, these were manageable by applying principles of generally accepted obstetric practice. Uterus transplantation only should be performed at centers with the capability of assembling a multidisciplinary team that can identify and respond to unforeseen complications during pregnancy.

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Will individual participant data be available (including data dictionaries)? *No.*
What data in particular will be shared? *Not available.*
What other documents will be available? *Not available.*
When will data be available (start and end dates)? *Not applicable.*
By what access criteria will data be shared (including with whom, for what types of analyses, and by what mechanism)? *Not applicable.*

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