Three-year follow-up results of two children born from a transplanted uterus

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Aims. To evaluate the 3-year follow-up results of two children delivered at our institution in 2019 from mothers with a transplanted uterus.
Methods. Observational data on pregnancy outcomes, neonatal course, and growth trajectory in two children born to mothers after uterus transplantation, including 3-year follow-up and neurodevelopmental status assessed using the Bayley Scales of Infant and Toddler Development, third edition (Bayley-III).
Results. Both children were born prematurely via uneventful caesarean sections, to mothers with Mayer-Rokitansky-Küster-Hauser syndrome and a transplanted uterus. An acute caesarean section was performed in one mother because of the onset of regular uterine contractions at 34 weeks and 6 days of pregnancy; in the other mother, an elective caesarean section was performed at 36 weeks and 2 days of gestation. The children were born healthy with no congenital malformations. They had an uneventful postnatal course and showed a normal growth trajectory during 3 years of follow-up. The Bayley-III neurodevelopmental scores of both children were within the normal ranges at ages 2 and 3 years.
Conclusion. Though pregnancy after uterus transplantation is associated with the risk of premature delivery, no abnormalities were observed in the neonatal course and 3-year follow-up results, including the neurodevelopmental status, of two children born prematurely to mothers with a transplanted uterus. This is the first report on neurodevelopmental outcomes in children born after uterus transplantation. More data on children born after this radical procedure of uterine factor infertility treatment are required to support our promising results.

Key words: absolute uterine factor infertility, assisted reproduction, Bayley-III scales, neurodevelopment, uterus transplantation

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INTRODUCTION

The first clinical trial of living-donor human uterus transplantation (UTx) for the treatment of absolute uterine factor infertility (AUFI) was started in Gothenburg, Sweden, in 2012; since then, there has been considerable progress and expansion in this experimental treatment, which involves, among other things, the processes of ovarian hyperstimulation, ovum pick-up, in vitro fertilisation, embryo cryopreservation, uterine graft procurement and transplantation, immunosuppression induction, and post-transplant embryo transfers[1,2]. The first successful birth of a child after living-donor UTx occurred in Sweden in 2014, and this was followed by several other livebirths, including in two UTx recipients who each had two offspring[3-5]. In 2017, the first pregnancy after deceased-donor UTx was successfully completed in Brazil[6].

Only a few studies reporting neonatal data and short-term paediatric outcomes after UTx have been published thus far. A recent publication has described the neonatal outcomes and 2-month postpartum follow-up results of 12 children born from transplanted uteri[7]. A further follow-up on this group was published later and this described the children's growth and physical, neurological, and cognitive outcomes at ages 6, 12, 18, and 24 months. Within the first 2 years of life, all parameters were age appropriate based on 'Bright Futures: Guidelines for Health Supervision of Infants, Children, and Adolescents' from the American Academy of Pediatrics[8]. Other studies also reported normal paediatric outcomes at the 12-month follow-up; however, there was no neurodevelopmental assessment[9,10]. The 2-year follow-up outcomes in the first Swedish UTx study, which included an assessment of the children's development, were published recently[11].

The primary aim of UTx is the birth of a healthy child; therefore, detailed monitoring of the reproductive aspects and long-term follow-up outcomes of children born from a transplanted uterus is crucial. In this article, we report the pregnancy outcomes, neonatal course, 3-year follow-up results, and neurodevelopmental status of two children born at our institution in 2019 to mothers with a transplanted uterus.

MATERIALS AND METHODS

Recipients and donors of uteri

Child 1's mother, a 25-year-old woman with Mayer-Rokitansky-Küster-Hauser syndrome (MRKHS) type I and a neovagina created using the dilation technique, received a uterus from a living donor in January 2017. Child 2's mother, a 26-year-old woman with MRKHS type I and a neovagina surgically created using the Vecchietti technique, received a uterus from a living donor in November 2017 (ref.[12]). Both recipients were in good general health status, with no history of chronic illness, any medication use, cardiac or kidney anomaly, malignancy, or infectious diseases. The deceased donor was a 20-year-old nulliparous, blood-compatible, and brain-dead woman with no history of chronic illness, cancer, infection, or uterine damage. The living donor (the recipient's mother) was a 49-year-old blood-compatible, healthy woman without any uterine abnormalities.

In vitro fertilisation and embryo transfers

Ovarian hyperstimulation based on the long gonadotropin-releasing hormone agonist protocol and in vitro fertilisation with embryo cryopreservation was performed before UTx to exclude infertility factors that might affect the success of post-transplant fertilisation. All oocytes were fertilised via intracytoplasmic sperm injection. Preimplantation genetic testing was not performed because both candidates for UTx had a low risk for aneuploidy. On the basis of the ground-breaking first Swedish UTx study, the first single embryo transfer was scheduled at post-transplant month 12 (ref.[3]).

Before embryo transfer, endometrial preparation with oral oestradiol hemihydrate (6 mg daily) was initiated on cycle day 1. Transvaginal ultrasonography was performed on day 10, and embryo transfer was scheduled when the endometrial thickness was at least 7 mm and no growing follicles were present; otherwise, the transfer was cancelled. Progesterone (600 mg daily) was administered vaginally, and 5 days later, embryo transfer using a soft catheter was performed under abdominal ultrasound guidance. During pregnancy, progesterone was administered until the end of week 12.

Children's data

The children's characteristics, including neonatal and anthropometric data at ages 2, 12, 24, and 36 months, were assessed. At age 2 and 3 years, the children's neurodevelopmental status was evaluated using the Bayley Scales of Infant and Toddler Development, third edition (Bayley-III), which is a tool designed to assess the developmental functioning of infants, toddlers, and young children aged between 1 and 42 months. The Bayley-III is based on a series of play tasks and parent-report questionnaires for assessing a child's level of functioning across various developmental domains, including cognitive (sensorimotor development, concept formation, and object relatedness), language (receptive and expressive), motor (fine and gross), social-emotional development (relationships and useful interactions), and adaptive behaviour (application of developmental skills to daily living) (ref.[13]). These domains are critical to the comprehensive assessment of young children, as they are fundamentally important for documenting developmental delays and early intervention efforts. The composite score in the Bayley-III is based on the comparison of a child to a normative age-matched sample[14]. The Bayley Scales are the gold standard tool for assessing a child's early development[15]. All outpatient preventive examinations were performed in accordance with the American Academy of Pediatrics guidelines[16].

Table 1. Characteristics of pregnancies and caesarean deliveries in mothers with a transplanted uterus.

	Mother of child 1	Mother of child 2
Donor of the uterus	Brain-dead	Living
Maintenance oral immunosuppression in pregnancy	Tacrolimus	Tacrolimus, azathioprine, and prednisolone
Weight gain in pregnancy, kg	10	12
Initial haemoglobin (g/L)	120	130
Predelivery haemoglobin (g/L)	103	94
Ferrous sulphate intake in pregnancy	No	Yes
Nuchal translucency at week 12 (mm)	1.8 at crown–rump length 50 mm	2.3 at crown–rump length 57 mm
Non-invasive prenatal testing	Normal, male sex	Normal, female sex
Complications in pregnancy	Gestational diabetes	Hypertension
Cervical length at week 20 (mm)	35	45
Cervical length before delivery (mm)	20	30
Type of hysterotomy/anaesthesia	Transversal/epidural	Transversal/epidural
Foetal presentation	Head	Head
Total surgical time (min)	47	120
Estimated blood loss (mL)	300	1000
Surgical complications	None	Extensive adhesiolysis with partial omentectomy
Postoperative transfusion	None	2 units of packed red cells

RESULTS

Ultrasound examinations were performed at 2-week intervals throughout the pregnancies, which revealed normal flow parameters in the uterine arteries and normal foetal growth. Additionally, the results of umbilical Doppler studies were normal. The characteristics related to pregnancy and caesarean delivery in both UTx recipients are shown in Table 1. Both mothers continued immunosuppressant therapy postpartum because the transplanted uterus was not removed during the caesarean section. Postnatal ultrasound examinations of the head, heart, and abdomen revealed no anomalies in either child. In the first week of life, all laboratory parameters, including complete blood count, serum glucose, C-reactive protein, and serum biochemistry profile, were within the normal ranges. No history of a higher occurrence of respiratory infections in either child was recorded during the 3-year follow-up.

Child 1

Pregnancy and caesarean section

Child 1's mother, the recipient of a uterus from a deceased donor, developed clinically insignificant post-transplant stenosis of the vaginal-neovaginal anastomosis and conceived after the fourth single frozen embryo transfer[17]. She was diagnosed with gestational diabetes at week 28, and treatment with low doses of insulin lowered her serum glucose levels to within the normal range. At 34 weeks and 6 days of an otherwise uneventful pregnancy, prompt caesarean section was performed because of regular (3-min intervals) uterine contractions, which the mother did not feel at all. Antenatal steroids for inducing foetal lung maturation were not administered before the caesarean section because the plan was to deliver the baby 10 days later. The incision-to-birth interval, including the release of omental adhesions to the anterior uterine wall, was 9 min. The mother's postoperative recovery was uneventful.

Postnatal course

The male infant had a birth weight of 2740 g (65th percentile, Fenton growth charts) (ref.[18]), length of 47 cm (60th percentile), and head circumference of 33.5 cm (65th percentile). The Apgar scores were 7, 9, and 9 at 1, 5, and 10 min, respectively. Because of mild respiratory distress, the newborn received nasal continuous positive airway pressure from the first hour of life, with a maximum FiO_2 of 0.3. This support was discontinued 48 h after birth. The serum tacrolimus level decreased from 5.2 μg/L on the day of birth to < 1.5 μg/L on day of life 5. Oral feeding was initiated on day of life 1, and parenteral nutrition was not required. The newborn started to gain weight on day of life 9. The fully breastfed neonate required no treatment and was discharged on day of life 16. The neonatal characteristics are shown in Table 2.

In further follow-up assessments at ages 2 months (3 weeks corrected to gestational age), 1 year (postnatal age 13 months, 12 months corrected to gestational age), 2 years (postnatal age 25 months, 24 months corrected to gestational age), and 3 years (postnatal age 35 months, 36 months corrected to gestational age) (ref.[19]), the anthropometric parameters were normal (Table 3). The neurodevelopmental scores (Bayley-III) are presented in Table 4. The child's growth was proportional to a lower quartile of the growth charts, in accordance with the size of the parents. He exhibited neurodevelopment corresponding to his postnatal age, with a mild deficit in expressive communication.

Child 2

Pregnancy and caesarean section

Child 2's mother, the recipient of a uterus from a living donor, did not develop post-transplant stenosis of the

Table 2. Neonatal characteristics of two children born to women with a transplanted uterus.

	Child 1	Child 2
Birth (month, year)	August, 2019	November, 2019
Prepartum betamethasone administration	No	Yes, on week 35
Group B *Streptococcus* status in pregnancy	Negative, on week 34	Positive, on week 35
Timing of caesarean section (gestational age in weeks + days)	34+6	36+2
Mode of delivery	Acute caesarean section because of onset of regular uterine contractions	Elective caesarean section
Sex	Male	Female
Birth weight, g (percentile)	2740 (65th)	2300 (30th)
Length, cm (percentile)	47 (60th)	45 (30th)
Head circumference, cm (percentile)	33.5 (65th)	33 (50th)
Apgar scores at 1/5/10 min	7/9/9	10/10/10
Respiratory support (mode, days)	Yes (continuous positive airway pressure, 2 days)	No
Phototherapy for neonatal hyperbilirubinaemia	Yes, 1 day	No
Parenteral nutrition	No	No
Nutrition at discharge	Breast milk	Breast milk
Discharge from hospital (day of life)	16	9

vaginal-neovaginal anastomosis and conceived after the third single embryo transfer[17]. After the second unsuccessful embryo transfer, an endometrial receptivity array was performed to increase the probability of conception. From gestational week 19, oral methyldopa 250 mg once daily was administered because of repeated increase in blood pressure to 155/95 mmHg. The results of blood and urine tests ruled out pre-eclampsia. The mother's blood pressure values later became < 135/85 mmHg. However, 1 week before giving birth, her blood pressure increased again, and the methyldopa dosage was adjusted to 250 mg three times daily. Even at that time, the results of laboratory and clinical examinations did not suggest pre-eclampsia. Elective caesarean section was performed at 36 weeks and 2 days of gestation. The incision-to-birth interval was relatively long (was 24 min) because of the presence of extensive and firm adhesions of the omentum and sigmoid colon to the left ovary and left uterine margin. Partial omentectomy was performed after uterotomy closure.

Postnatal course

The female infant had a birth weight of 2300 g (30th percentile), length of 45 cm (30th percentile), and head circumference of 33 cm (50th percentile). The Apgar scores were 10, 10, and 10, at 1, 5, and 10 min, respectively. No respiratory support was required after delivery. Oral feeding was initiated on day of life 1. The serum tacrolimus level decreased from 6.9 μg/L on the day of birth to < 1.5 μg mcg/L from day of life 6. The newborn started to gain weight on day of life 7. The fully breastfed neonate was discharged on day of life 9. The neonatal characteristics are shown in Table 2.

In further follow-up examinations at ages 2 months (4 weeks corrected to gestational age), 1 year (postnatal age 13 months, 12 months corrected to gestational age), 2 years (postnatal age 25 months, 24 months corrected to gestational age), and 3 years (postnatal age 35 months, 36 months corrected to gestational age), the anthropometric parameters were within the normal ranges (Table 3). The neurodevelopmental scores (Bayley-III) are presented in Table 4. The child's growth was proportional to the second and third quartiles of the growth charts. She exhibited neurodevelopment corresponding to her postnatal age, with higher-than-average fine motor skills.

At age 18 months, the girl was examined outside of the regular visit schedule because of signs of idiopathic

Table 3. Anthropometric data at 2, 12, 24, and 36 months corrected to gestational age.

	Child 1	Child 2
Weight, kg (percentile)		
2 months	4.51 (50th)	4.35 (55th)
12 months	9.0 (30th)	9.0 (50th)
24 months	11.2 (25th)	12.0 (60th)
36 months	12.8 (25th)	13.5 (50th)
Length, cm (percentile)		
2 months	55 (60th)	53 (40th)
12 months	74 (25th)	73 (40th)
24 months	83 (15th)	86 (50th)
36 months	93 (25th)	94 (50th)
Head circumference, cm (percentile)		
2 months	37.5 (55th)	37.5 (55th)
12 months	45.5 (20th)	46.5 (60th)
24 months	47.5 (20th)	48.0 (50th)
36 months	49.0 (25th)	50.0 (80th)

Table 4. Neurodevelopmental status assessed using the Bayley Scales of Infant and Toddler Development, third edition (Bayley-III) at age 24 and 36 months.

Bayley-III (normal range, 85–125)	Child 1		Child 2	
	24 months	36 months	24 months	36 months
Cognitive composite score	90	95	110	100
Language composite score	79	83	91	91
Receptive communication scale score	7	8	9	9
Expressive communication scale score	6	6	8	8
Motor composite score	91	97	110	94
Fine motor scale score	8	10	14	9
Gross motor scale score	9	9	9	9

The composite scores are interpreted as follows: ≥100 (standard deviation [SD]=15) – standardised mean score 50th percentile, mid-average functioning; <85 = (1 SD below the mean) – 16th percentile, mild impairment/at 'risk' of developmental delay; <70 = (2 SD below the mean) – moderate/severe impairment.

premature thelarche. Her nipples were pigmented, and vaginal cytology revealed early proliferation. Therefore, a luteinisinghormone-releasing hormone test was performed, which ruled out the suspicion of premature puberty. A follow-up examination after 3 months confirmed benign thelarche.

DISCUSSION

The aim of UTx is to cure AUFI and enable the birth of a healthy offspring. In this article, we report the pregnancy outcomes and 3-year follow-up results of two children born to mothers with MRKHS and a transplanted uterus. Both newborns had birth weights within the normal range, and neurodevelopmental assessment revealed no abnormalities at ages 2 and 3 years. The growth trajectories at 2 years and beyond were normal for both weight and length and were consistent with those of 2-year-old children in the first Swedish UTx study.[11] Similar to other children born after UTx, both fully breastfed infants in our study showed a decrease in serum tacrolimus to subtherapeutic levels on DOLs 5–6 (ref.[7]).

The vascular anatomy of a transplanted uterus differs from that of the native uterus: the blood inflow in a transplanted uterus relies on only two uterine arteries, and the blood outflow relies on two to four veins (uterine and/or ovarian) (ref.[7,20,21]). This two-artery vascular supply of the transplanted uterus instead of the normal anatomical supply of the native uterus may cause asymmetrical blood distribution in the myometrium[22], which could affect embryo implantation, placental development, and, theoretically, foetal growth. In both mothers in this study, the blood inflow was via two uterine arteries and the blood outflow was via two uterine veins and two ovarian veins. All ultrasound examinations after transplantation and during pregnancy showed a homogeneous myometrium (indicating symmetrical blood distribution in the uterus) with normal pulsatility index and peak systolic velocity in the left and right uterine arteries.

Previous data on foetal exposure to immunosuppressants were derived from solid organ transplant studies and showed an increased incidence of pregnancy-related complications (e.g. pre-eclampsia, gestational hypertension) and neonatal complications (e.g. preterm birth, low birth weight) (ref.[23]). However, pregnant women with solid organ transplants usually have a pre-transplant long-term failing kidney, liver, or heart, whereas the mothers of the two children in our study were otherwise healthy. Pregnancy after UTx can itself be a risk factor for preterm delivery for various reasons (e.g. pre-eclampsia, premature rupture of membranes, and onset of uterine contractions).

Newborns without birth defects, a low incidence of complications during pregnancy, near-term caesarean delivery, and uneventful postnatal development should be the main parameters of reproductive success in the treatment of AUFI. However, long-term follow-up of children, up to school age or later, is required to assess the true success of the entire UTx program[7,9,24]. Both children born at our institution in 2019 underwent regular paediatric examinations and detailed neurodevelopmental assessments at ages 2 and 3 years. In child 1, the anthropometric measurements at 1, 2, and 3 years were consistent with the growth charts and were around the 30th percentile for all parameters. The neurodevelopmental assessment according to the Bayley-III scales at ages 2 and 3 years showed normal results for four out of five items (cognitive and motor). The total language composite score was slightly below the normal range, with an excellent receptive language score and an expressive language score that was below the normal range but which slightly improved at age 3 years (Table 3). However, this deficit is observed in boys younger than 3 years with no additional developmental changes, and usually improves with age[25]. In child 2, all scores in the Bayley-III scales were within the normal ranges. The girl presented with idiopathic premature thelarche; the prevalence of this rare symptom at age 18 months is 1.6 in 1000, with most girls showing only benign symptoms[26].

Neurodevelopmental assessment using the Bayley-III scales at ages 2 and 3 years provides appropriate data for predicting neurological outcomes and intelligence quotient at ages 4 and 6 years in preterm and late-preterm infants[27,28]. Our results showed Bayley-III scale scores within the normal ranges in both children; however, we can only speculate whether the children will have satisfactory neurodevelopmental outcomes at the preschool and early school ages.

A limitation of this study is the fact that there were only 2 cases. However, UTx is still in the experimental stage, and long-term data on the development of children born from transplanted uteri are lacking. The strength of this study lies in the 3-year follow-up of neonatal and other developmental data, as well as the neurodevelopmental assessment at ages 2 and 3 years using specialised validated instruments.

CONCLUSION

Herein, we report satisfactory pregnancy courses, early neonatal lives, and 3-year follow-up outcomes, as well as normal neurodevelopmental status at ages 2 and 3 years (based on the Bayley-III scales) in two children born from a transplanted uterus. To our knowledge, this is the first report on neurodevelopmental outcomes in children after UTx. Although this promising method of AUFI treatment is in its infancy, the future availability of long-term data on children born from a transplanted uterus worldwide could enable UTx to become the standard infertility treatment method in women with a missing uterus who desire having biological children.

ABBREVIATIONS

AUFI, Absolute uterine factor infertility; MRKHS, Mayer-Rokitansky-Küster-Hauser syndrome; UTx, Uterus transplantation.

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