ORIGINAL ARTICLE

Long-term outcome of kidney transplant by using restored kidney grafts after tumour *ex vivo* excision – a prospective study

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SUMMARY

The aim of this study is to report long-term outcomes of kidney transplantation by using the kidney graft after a small tumour *ex vivo* excision. A structured programme was established to use the restored kidney graft from urological referral after radical nephrectomy. The criteria were defined as tumour size ≤3 cm, margin clear on frozen section and recipients aged ≥60 years or those on the urgent list for transplantation as a result of imminent lack of dialysis access. The recipients were followed up regularly for surveillance of tumour recurrence. Between February 2007 and February 2018, 28 recipients had kidney transplantation by using the restored kidney grafts. The tumour size was 2.6 ± 0.7 cm. The follow-up was median 7 years without evidence of tumour recurrence. The patient and graft survival was satisfactory. Kidney transplantation by using restored kidneys after a small tumour excision is a novel source for selected recipients. The long-term patient and graft survival is satisfactory. Although there is a risk of tumour recurrence, it is rare event. Together with literature review, we would support use of kidney graft after a small tumour excision for selected recipients.

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Key words
kidney graft, kidney transplant, live donors, small kidney tumour, tumour *ex vivo* excision

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Introduction

Kidney transplant is the preferred treatment for patients with end-stage kidney disease, as it not only improves quality of life, but also patient's life expectancy compared with dialysis treatment [1-6]. Compared to dialysis treatment kidney transplantation is associated with an average annual savings of $AUD 80 000 [2]. Elderly patients have a poor quality of life and are vulnerable to developing medical comorbidities if they remain on dialysis, and the mortality rate is higher [7–9]. On the other hand, organ shortage is a global issue and the demand for kidneys continues to exceed supply [10]. Consequently, older patients who may be medically or surgically eligible for transplantation may not always receive a kidney transplant and therefore are not considered in many transplant programmes. Many strategies have been implemented to increase the kidney transplantation, including a greater utilization of expanded criteria donors, ABO incompatible kidney

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transplants, the paired kidney exchange programme and the use of machine perfusion [11–14]

Several transplant programmes have described the utilization of kidneys after a small tumour was excised as a novel source for kidney transplantation [15–19]. This situation usually occurs during deceased organ procurement or during live donor workup. On many occasions, this type of kidney graft was discarded due to the uncertainty of consequence after transplantation. On the other hand, the elderly patients may miss the opportunity for transplant due to developing comorbidities as the long-term waiting on the list. In 1996, Dr. Nicol et al from Queensland (Australia) established a programme with the intention to use the kidney graft after *ex vivo* excision of a small tumour for transplant to selected elderly recipients, in the context of treating urology patients after radical nephrectomy [20]. Subsequently, there are a few more transplant centres that have implemented this programme including our unit (Western Australia) [21–23]. The aim of this study is to review the long-term graft and patient outcomes of kidney transplant in our cohort by using a restored kidney after a small tumour *ex vivo* excision.

Materials and methods

The study includes all recipients who have received a restored kidney graft transplant from live–unrelated donor at Sir Charles Gairdner Hospital, Perth, Australia, between February 2007 and February 2018. The criteria for acceptance of donor kidneys (with a small renal tumour) and potential recipients have been previously reported [21]. Briefly, the kidney graft with a small tumour of ≤3 cm was referred by urologists to our transplant programme after an independent decision between the urologist and patient was made to pursue radical nephrectomy in the treatment of the renal tumour. This decision was made after rigorous discussion between the patient and treating urologist as per urology usual practice. In some occasions, the choice for radical nephrectomy was made predominantly by the patient with the fear of tumour recurrence, while in some cases the decision was made for radical nephrectomy due to the difficult location for laparoscopic partial nephrectomy. The potential donor is then assessed by the surgical and medical transplant teams to determine whether the kidney is suitable for transplantation. The donation is altruistic without any financial or other gains. The programme is targeted to potential transplant candidates aged ≥60 years or those on the urgent list for transplantation as a result of imminent lack of dialysis access. The patients were fully informed about the risk of tumour recurrence and metastasis, increased risk of urological complications such as urine leak after transplantation, and consent form was obtained prior to listing. The patients were also informed there is a risk that the transplant may not go ahead on the day if the kidney is deemed not suitable for transplant after nephrectomy and tumour *ex vivo* excision. On the day of surgery, the transplant team went to the urology operating theatre and prepared a back table for kidney perfusion, which was the same as for live donor nephrectomy. The tumour was then excised completely and sent for frozen section. The kidney was only considered suitable for transplantation if the margin was clear on frozen section. The small vessel stumps and open areas of the collecting system were sutured closed with 5/0 PDS (polydioxanone) and the renal parenchyma was closed by 2/0 Vicryl sutures prior to transplant.

Recipients were given standard immunosuppression of basiliximab induction, followed by the maintenance of prednisolone (starting at 30 mg daily reducing to 5 mg daily by 3 months), tacrolimus (target trough of 10–15 ng/ml in the first 1 month and 8–12 ng/ml between 2 and 3 months) and enteric-coated mycophenolate sodium (720 mg twice daily).

The recipients were routinely followed up in the transplant clinic according to unit protocol, but all recipients underwent pre-specified tumour surveillance of the transplant allograft with ultrasound 3 monthly for the first 2 years and 6 monthly up to 5 years, then annually, and chest X-rays 6 monthly for first 2 years, followed by annually. The local institutional human research ethic committee of Sir Charles Gairdner Hospital approved the study.

Graft and patient survivals were compared between patients who have received restored kidney transplants (study group) and an age-matched group of patients who have received live donor kidney transplants (i.e. non-restored kidneys) undertaken in the same centre between January 2010 and February 2017 [24].

Data collection

Data extracted from prospective collected database included donor characteristics of gender, age and tumour size and recipient characteristics of gender and age. The primary outcome was kidney graft function immediately post-transplant and kidney graft function at follow-up. The secondary outcomes included tumour

Transplant International 2020; 33: 1253–1261

recurrence, peri- and post-transplant surgical complications, and allograft and patient survival.

Statistical analysis

Data were expressed as number (proportion), mean ± standard deviation for normally distributed continuous variables and as median (Interquartile range (IQR)) for non-normally distributed data. Comparisons between groups (restored kidney transplants vs. age-matched kidney transplants) were made by chi-square test, analysis of variance (ANOVA) or Mann–Whitney *U* test where appropriate. Unadjusted overall allograft and patient survivals and 95% confidence intervals (95% CI) at 1, 3, 5 and 10 years post-transplant were calculated by Kaplan–Meier method, and a log rank test was performed to compare patient and graft survival with age-matched cohort of normal live donor kidney transplant. (R Core Team 2019). A P value of < 0.05 was considered significant.

Results

Study population

Between February 2007 and February 2018, 32 urology patients were referred by urologists to the transplant programme for consideration of kidney altruistic donation. Twenty-eight patients who had a small renal tumour were willing to donate a kidney altruistically after radical nephrectomy. The donor age was 55.6 ± 12.2 (31–75) years and male to female ratio was 13:15. The tumour size was 2.6 ± 0.7 cm. On histopathology, there were 20 cases of renal clear cell carcinoma, 1 case of chromophobe, 3 cases of papillary renal cell carcinoma and 4 cases of benign. The warm ischaemic time was 5 min 24 s (3–20 min). The cold ischaemic time was 270 (155–340 min). The recipient age was 64.8 ± 7.1 years at the time of transplantation. The male to female ratio was 16:12.

Outcome data

The recipients were followed up for a median of 7.5 (IQR 6–10) years. The age at the time of the last follow-up assessment was 70.7 ± 6.7 years. Of the 28 patients who have received restored kidneys, 2 (7%) grafts were lost (one graft experienced primary non-function and one graft was lost on transplant day + 6 from dehiscence at the arterial anastomosis site, in which three renal arteries were reconstructed with a venous patch). The first three cases developed urine leakage from the excision site, which was resolved by interventional drainage and prolonged placement of an indwelling urethral catheter. There was no more urine leakage after modification of the surgical technique [21]. One kidney graft developed pseudoaneurysm at the tumour excision site. Interventional embolization was performed, and there was no further sequela. Three kidney grafts had delayed graft function. There was no tumour recurrence in the kidney grafts on follow-up images. The creatinine level at the final follow-up was 149.6 ± 60.5 μmol/l. Ten recipients died of medical comorbidities, not related to the kidney tumour. Patient and graft survival decreased during the follow-up period (Figs 1 and 2).

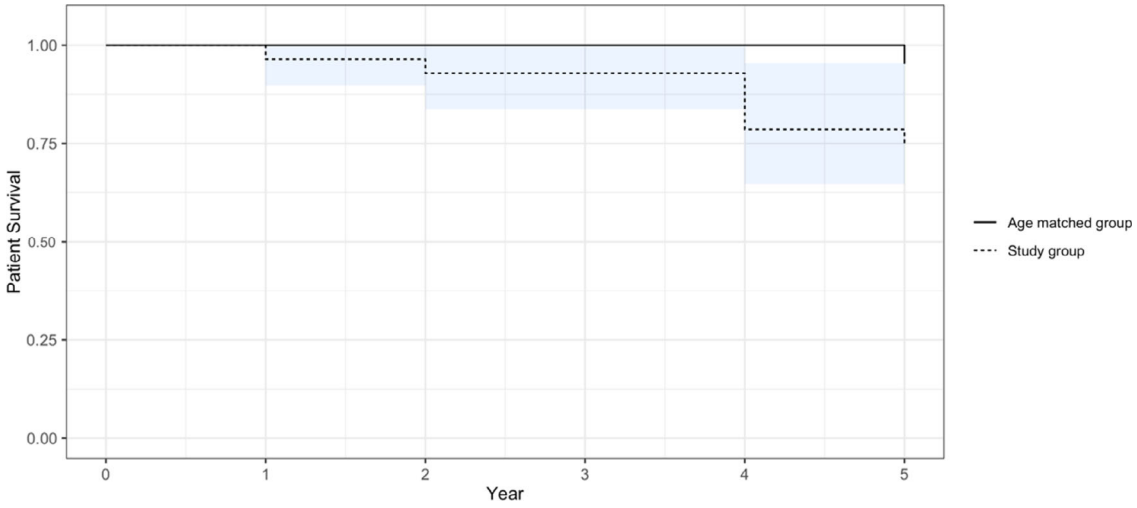
Comparison to age-matched cohort

Table 1 shows the baseline characteristics and early surgical complications between patients who have received restored kidney transplants and age-matched standard kidney transplants. In the age-matched cohort of 23 patients who have received standard live donor kidney transplants, patients were aged between 56 and 73 years (mean ± SD 60.7 ± 4.7 years). Male to female ratio was 17:6. The updated creatinine level at 5 year was at 141.4 ± 60.1 μmol/l. The donor age was from 26 to 66 years (mean ± SD 54.7 ± 10.5 years), and male to female ration was 9:14. The patient and graft survival at 1, 3 and 5 years were shown in (Figs 1 and 2). There was no statistically significant difference between the two groups up to 5 years post-transplant (Table 2).

Discussion

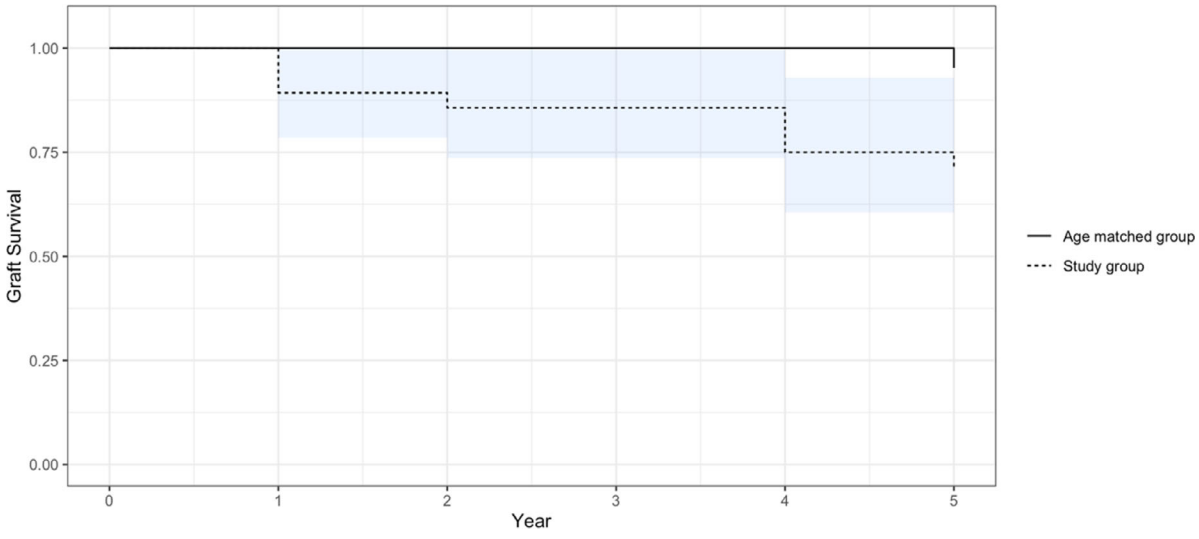
Kidney transplant by using a restored kidney graft after *ex vivo* excision of a tumour has been reported as a novel source [16,19–22,25]. The tumour was usually an incidental finding during deceased donor kidney procurement or live donor workup. As early as 1982, Stubenbord reported the first case of using a kidney graft after excision of a tumour. The case was followed up for 8 years without evidence of tumour recurrence [15]. Over last three decades, there were increased reports from different countries and over all 152 cases were reported with satisfactory patient and graft survival [16,17,19,21,22,26,27]. There were few tumour recurrences over median 3-9 years follow-up [16,17,19,21,22,26,27].

Most importantly, some transplant centres have implemented a structured programme with the



Number at risk:						
Study group	28	28	27	26	25	20
Age-matched group	23	23	21	20	17	12

Figure 1 Patient survival at 1, 3 and 5 years for study group and age-matched group.



Number at risk:						
Study group	28	28	25	25	24	19
Age-matched group	23	23	21	20	17	12

Figure 2 The kidney graft survival at 1, 3 and 5 years for study group and age-matched group.

Transplant International 2020; 33: 1253–1261

Table 1. Baseline characteristics and early surgical complications of the restored and age-matched kidney transplant patients.

	Study group restored kidney after tumour excision (n = 28)	Age-matched group from live donor (n = 23)	P value
Donor age (years, mean ± SD)	55.6 ± 12.2	54.7 ± 10.5	0.78
Donor sex: Male (n, %)	13 (46.4)	9 (39.1)	0.81
Left donor kidney (n, %)	20 (71.4)	22 (95.7)	0.06
Tumour size (cm, mean ± SD)	2.6 ± 0.7	-	-
Recipient age (years, mean ± SD)	64.8 ± 7.1	60.7 ± 4.7	0.05
Recipient sex: Male (n, %)	16 (57.1)	17 (73.9)	0.34
Delayed graft function (n, %)	3 (10.7)	0 (0.0)	0.31
Primary non-function (n, %)	1 (3.6)	0 (0.0)	1.00
5-year creatinine (μmol/l, mean ± SD)	128.1 ± 47.4*	141.4 ± 60.1	0.44
5-year eGFR (ml/min/1.73 m^2, mean ± SD)	51.2 ± 18.5*	50 ± 18.5	0.85
Urine leak (n, %)	3 (10.7)	0 (0.0)	0.31
Ureteric stenosis (n, %)	0 (0.0)	0 (0.0)	0.48
Intra-parenchymal pseudoaneurysm (n, %)	1 (3.6)	0 (0.0)	1.00
Renal artery stenosis (n, %)	1 (3.6)	1 (4.3)	1.00

Data expressed as number (proportion) or mean (standard deviation [SD]).

eGFR = estimated Glomerular filtration rate calculated using formula of CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration).

intention to expand using the restored kidney grafts after radical nephrectomy for treating kidney tumour from urological referral [20-23]. A pioneer group was Nicol et al, who have performed 56 cases of transplant by using restored kidney grafts since 1996. In their cohort, there was only one renal cancer recurrence 9 years after transplantation in an elderly recipient. The recipient insisted to keep the kidney graft for a better quality of life as he was having difficulty in dialysis access [20,27,28]. Our unit has adopted the programme since 2007, and early results were reported satisfactory [21]. This study is a subsequent long-term follow-up and shows that the patient and graft survival is comparable to those received kidney transplant from deceased donors [4,6], as well as comparable to those of live donor kidney transplant in the age-matched cohort of recipients (age ≥ 55 years old) by ad hoc analysis [24]. There was no tumour recurrence with median follow-up over 7 years.

Another structured programme in Australia for using restored kidney grafts is from Sprott et al. [22] who have reported 23 cases. In their study, the recipients were divided into two groups based on tumour size: one group received a small tumour (size ≤ 3 cm), while another group received the tumour size between 3 cm and 5 cm. There was one tumour recurrence in the small tumour group after 2 years of transplantation. The tumour was a clear cell carcinoma at Fuhrman grade IV.

From Australian structured programme of three transplant centres, there were overall 107 cases (including 28 cases of this study), and the incidence of tumour recurrence was 1.87% over median 7 years follow-up [20,22,27,28], whereas the tumour recurrence would be 1.3% if all reported 152 cases of kidney transplant after tumour excision were counted as denominator from the literature [16,17,19,21,22,26,27]. In partial nephrectomy *in vivo* for treating a small renal tumour, the incidence of tumour recurrence was reported 1–4% [29,30]. The tumour recurrence usually occurred in the first 3 years after surgery [31,32]. In one study of 3651 patients, the recurrence was reported 29.8% at median 1.9 years (IQR, 0.6 to 5.5 years) after partial or radical nephrectomy for renal cell carcinoma in median 9.0 years (IQR, 5.7 to 14.4 years) follow-up [33]. Furthermore, the incidence of renal tumour after transplant from a normal kidney graft (without a tumour at the time of transplantation) was reported from 0.1% to 0.5% [34-36] and the duration was about 7–10 years after transplant [37,38].

The incidence of tumour recurrence is associated with the tumour size and its Fuhrman grade. The kidney graft with a tumour at Fuhrman grade IV should not be recommended for transplantation as the high risk of tumour recurrence [21,25,33].

It should be mentioned that there was an increased risk of surgical complications associated with tumour excision including haemorrhage, arterial–venous fistula

Table 2. Patient and graft survival at 1, 3, 5 and 10 years after kidney transplantation

Study	Patient survival (95% CI)(95% CI)			Graft survival (95% CI)(95% CI)		
Survival	Study group Restored kidney transplant	Age-matched group*	*P* value	Study group Restored kidney transplant	Age-matched group*	*P* value
Year 1	96.4 (89.8–100)	100 (100–100)	0.36	89.3 (78.5–100)	100 (100–100)	0.11
Year 3	92.9 (83.8–100)	100 (100–100)	0.20	85.7 (73.7–99.7)	100 (100–100)	0.06
Year 5	75 (60.6–92.9)	95.2 (86.6–100)	0.26	71.4 (56.5–90.3)	95.2 (86.6–100)	0.29
Year 10	64.3 (48.8–84.7)	-	-	60.7 (45.1–81.8)	-	-

Data expressed as patient and graft survival with 95% confidence interval (95% CI).

*Refers to ref. [24].

or pseudoaneurysm and urine leakage [20–22], although these were not statistically significant. However, these surgical complications could be prevented after modification of surgical technique with delicate suture closure of all vessel stumps and collecting system [21]. In this cohort, the first 3 cases had urine leakage and the 6th case had pseudoaneurysm formation. After surgical technique modification, we did not encounter any more urine leakage or pseudoaneurysm. The other complications of ureter stenosis and renal artery stenosis are comparable in both groups, which are in line with literature reports [24,39,40].

In the era of increasing demand for kidney transplantation, using this novel source of restored kidney grafts would overcome the organ shortage and provides benefits to the selected patients, otherwise they have to stay on dialysis. However, this novel source remains arguable as the fear of tumour recurrence. Many pioneers have advocated the implementation of this novel source for kidney transplantation [19–22,25,41–44]. Cohn *et al* have campaigned a decade ago: 'We encourage urologic oncologists to open discussions with transplant surgeons about considering transplantation of kidneys after *ex vivo* excision of small renal masses, from very selected donors (who prefer radical to partial nephrectomy) and into very selected (high-risk) recipients' [42]. From our study and literature review, the tumour recurrence is in fact a very rare event after *ex vivo* tumour excision for transplantation, despite the recipients were under immunosuppression. This outcome could be due to the delicate excision of the tumour on the back table and clear margin on frozen section prior to transplant. Most interestingly, Yu et al have conducted a study aiming to test the viability of tumour cell after cold perfusion and preservation. It was found that the viability of tumour cell is much lower than normal renal tubular cell after cold perfusion and preservation [41]. Nevertheless, the tumour recurrence is always a risk after tumour excision and a strict protocol is mandatory for surveillance. If a tumour recurrence does occur, then transplant nephrectomy should be considered and immunosuppression is ceased. It was reported that an episode of rejection after immunosuppressant withdrawal may result in complete regression of the tumour in approximately 50% of cases [45].

Taking together, we would support use of the restored kidney grafts for transplantation after *ex vivo* excision of a small tumour as a novel source. Our study will provide additional supporting evidence to the recent literature review by Hevia et al that kidney transplant by using kidneys after excised low-grade small renal tumours appears to be safe in terms of overall survival, graft survival and oncological outcomes in appropriate selected recipients [46]. Establishment of a structured programme would facilitate expanding utilization of this type of kidney grafts. It should be emphasized that the patient was only accepted to transplant programme after the decision is made for radical nephrectomy. The key point of this decision-making for radical nephrectomy is after rigorous discussion purely between the patient and treating urologist. Whenever possible, Mammalian target of rapamycin (mTOR) inhibitors should be considered in the immunosuppression regimen as its dual effect as immunosuppressive and anti-tumour effect [47,48]. In our cohort, some patients were unable to convert to mTOR due to other contraindications. Further study is necessary to evaluate the role of mTOR in the context of kidney transplant by using a restored kidney graft after excision of a small tumour.

It is understood that partial nephrectomy has been increasingly implemented in urology clinical practice for T1 renal cell carcinoma and been recommended in most of urology guidelines as a result of equivalent oncology outcome and survival benefit to radical nephrectomy [49–51]. In particular, it would be a better approach for

patients with a solitary kidney, pre-existing chronic kidney disease or those with bilateral kidney lesions. Furthermore, a common question one may ask is whether the kidney graft can be transplanted after tumour excision, why do not consider partial nephrectomy for the donor patients themselves. This is arguable as the decision is purely made after thorough discussion between the treating urologist and patient. The patient is only accepted to transplant programme as a potential altruistic donor after decision is made for radical nephrectomy.

In addition, we have learnt the live kidney donors have similar life expectancy and cardiovascular risk after donation in comparison with age-matched people [52]. Therefore, on the other hand a radical nephrectomy seems unlikely predispose any harm for the patient long-term survival with rigorous assessment [53,54]. In the current urological practice, it is also observed that radical nephrectomy is still a viable option for a small renal tumour in some cases. This is usually due to either the patient's demand as the fear of tumour recurrence or a difficult location for *in vivo* laparoscopic partial nephrectomy. In United States, about 3000 kidneys with a small renal mass could be made available for transplantation after radical nephrectomy [43,53,55,56]. In UK, given increased implementation of partial nephrectomy over last decade, there was about 45% of patients underwent radical nephrectomy for T1a renal cell carcinoma, yielding about 3000 kidney grafts and some of these might have been suitable for transplantation [51,57-59].

In Australia, there were 1401 procedures performed for renal lesions <10 cm in 2012. Of these, 876 (63%) were radical nephrectomies; some of these kidneys with a small renal mass might have been suitable for transplantation after tumour excision. These kidney grafts would be a valuable resource to provide an opportunity for selected dialysis patients to receive a kidney transplant. As a result, the patient quality of life and life expectancy would be improved as well as cost-effective.

In conclusion, a major barrier to kidney transplantation is the shortage of the organ supply. In urology practice, if the kidney with a small tumour is decided for radical nephrectomy, then this kidney graft should be considered for a restored kidney graft transplantation. This concept is also applied to the kidneys with an incidental finding of a small tumour at deceased organ procurement or live kidney donor workup. This is a novel source for overcoming the organ shortage for kidney transplantation. This study together with literature has shown that the tumour recurrence is a rare event in selected candidates. It should be encouraged to establish a structured programme with an intension to expanding use of the restored kidney grafts for transplantation. Further studies are necessary to continue providing further information for future clinical practice and broad implementation.

Authorship

BH: contributed to study design, participated in the programme, performing the surgeries, data collection, literature review and writing of the manuscript. ZQN: contributed to literature review, data collection and help writing the manuscript. LM: participated in the programme and critically reviewed of the manuscript. LD: contributed to study design, implementation and participation of the programme and critical review the manuscript. BJ: contributed to participation of programme and critically reviewed the manuscript. JT: contributed to statistical analysis of the data and critically reviewed revised the manuscript. GM: contributed to statistical analysis of the data and critically reviewed revised the manuscript. WL: contributed to participation of the programme, renal review of patients, and critically reviewed and revised the manuscript.

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Conflict of interest

All authors have no conflict of interest or financial disclosure to declare.

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