Case Study

Using OmniGraf to Monitor Immunosuppression Modification

- 59-year-old male patient
- 2 years post-transplant
- Stable serum creatinine (1.3-1.5 baseline)
- Immunosuppression: everolimus and mycopehnolate mofetil
- Calcineurin inhibitor toxicity on recent biopsy

Goal

Modify immunosuppression regimen to minimize side effects without increasing risk of rejection.

Approach

Monitor immune status at baseline and following modifications with OmniGraf.

Results

OmniGraf confirmed immune quiescence following immunosuppression modification.

The Challenge and Opportunity of Immunosuppression Modification

The challenge with immunosuppressive medication is that patients could become over immunosuppressed, leading to increased risk of infection and other adverse side effects, or under-immunosuppressed, leading to rejection episodes — beginning with subclinical acute rejection (subAR) and potentially progressing to graft loss.

To minimize the potentially significant side effects of immunosuppressive medications, post-transplant management may include strategies to modify immunosuppression dosage while maintaining therapeutic effectiveness.

Case Study: 59-Year-Old Kidney Recipient

This kidney transplant recipient is a 59-year-old male patient, who received his kidney graft two years ago. A year later, a routine surveillance biopsy revealed calcineurin inhibitory (CNI) toxicity with elevated serum creatinine levels. The patient was converted from tacrolimus to everolimus based on the one-year post-operative biopsy findings.

The patient received an OmniGraf biomarker rejection panel (combining TruGraf gene expression profiling (GEP) and Viracor TRAC donor-derived cell-free DNA (dd-cfDNA) assays) at the time of the one-year biopsy:

- TruGraf: Negative / TX (“Transplant eXcellence”): low risk of rejection
- Viracor TRAC: 0.6%: low risk of rejection

Monitoring the Effects of Medication Changes with OmniGraf

OmniGraf Kidney is a non-invasive panel of two novel biomarkers; it is the only combination panel available today that offers the earliest possible detection of “silent” subclinical acute rejection. It is a powerful tool to use in quickly assessing the adequacy of immunosuppression regimens.

OmniGraf Results Validate Immunosuppression Reduction

Following the initial immunosuppression modification, the patient was monitored with the OmniGraf rejection biomarker panel:

- TruGraf: Negative / TX: low risk of subclinical acute rejection
- Viracor TRAC: 0.3%: low risk of clinical acute rejection
- Serum creatinine result: Stable
- Interpretation: Immune system quiescent

In this particular case, OmniGraf was able to confirm that following immunosuppressant regimen changes, the patient’s immune system remained in a state of quiescence in addition to other monitoring tools. The patient’s new immunosuppression regimen may be maintained, and repeated OmniGraf can be utilized to continually monitor the equilibrium between over- and under-immunosuppression.

OMNIGRAF™

The first and only non-invasive panel that combines genetic biomarker tests for the earliest and most accurate view of kidney transplant rejection.

	Combination Panel	Gene Expression	Donor-Derived Cell-Free DNA
	OmniGraf™	**TruGraf®**	**Viracor TRAC®**
Type of Biomarker	Blood gene expression (120 genes) & dd-cdDNA (~100,000 SNPs)	Blood gene expression (120 genes)	dd-cfDNA (~100,000 SNPs)
Context of Use	Earliest[1] and most accurate[2] detection of subclinical and clinical rejection in transplant patients with stable kidney function	Rules out subclinical rejection in kidney transplant recipients with stable kidney function	Rules out acute rejection in kidney transplant recipients with suspicion of clinical acute rejection
Validation	Surveillance	Surveillance	For-cause biopsy
When to Start Testing	90 days post-transplant	90 days post-transplant	Suspicion of clinical rejection
Blood Draw Required	6ml / 1 tube	5ml / 2 tubes	10ml / 1 tube
Result Measurements	Gene Expression (***TruGraf***): TX (Transplant eXcellence) or Not-TX dd-cfDNA (***Viracor TRAC***): % of dd-cfDNA	TX or Not-TX	% of dd-cfDNA
Interpretation of Results	Negative / TX & <0.7 = low risk of rejection Positive / Not-TX & ≥0.7 = high risk of rejection	Negative / TX: low risk of rejection Positive / Not-TX: at risk of rejection	< 0.7% clinical rejection unlikely ≥ 0.7% clinical rejection should be considered
Negative Predictive Value (NPV)	94%	92%	92%
Positive Predictive Value (PPV)	89%	65%	40%
Suggested Testing Frequency	Quarterly monitoring	Quarterly monitoring	Clinical suspicion of rejection
Rejection Type Targeted	TCMR & ABMR	TCMR	ABMR

[1]OmniGraf and TruGraf are the only tests that detect subclinical acute rejection, before the onset of clinical acute rejection.
[2] OmniGraf has the highest Positive Predictive Value of currently-available biomarker-based rejection tests.

Learn more at
transplantgenomics.com/omnigraf-kidney

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