

ENSURING ETHICAL APPROACHES TO VASCULARIZED COMPOSITE ALLOTRANSPLANTATION

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Disclosure Statement

I have no conflicts of interest to disclose.



Presentation Overview

- 1) Ethics of VCA vs. Solid Organ Transplantation (SOT)
- 2) Goals of Vascularized Composite Allotransplantation (VCA)
- 3) Ethical Approaches to Surgical Innovation: Whole-Eye Transplantation
- 4) Shifting Toward Equity



ETHICS OF VCA VS. SOT

Ethical Principles in Transplantation

- Organs as Scarce Resource
- Balancing Utility and Equity

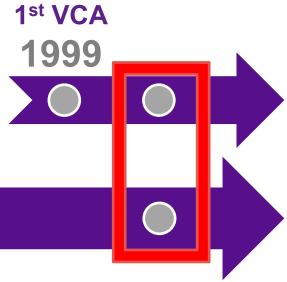




SOT / VCA Timeline

1st SOT 1954





2022

SOT: ~130K/yr

VCA:<300





Ethically Relevant Differences: SOT vs. VCA

- Life Saving vs. Life Enhancing
- Standard of Care vs. Experimental
- Degree of Variation Among and Across Types



Variation Across VCA Types as of 2023

VCA TYPE	VOLUME	1 ST SUCCESS
Hand	< 150	1999
Face	< 50	2005
Uterus	> 100	2013
Penis	4	2014



Informed Consent for Hand and Face Transplant

- Autonomy
 - Decisional capacity
 - Severity of injury/condition
 - Availability of alternative treatment options
- Informational Needs and Limited Outcomes Data
- Informed Consent for Research vs. Clinical Care
- Role of Shared Decision-Making



GOALS OF VCA

Purpose of VCA: To Improve Quality of Life

World Health Organization (WHO) defines QoL as:

"an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns. It is a broad-ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships, and their relationship to salient features of their environment."



Quality of Life and Lived Experience

AMA Journal of Ethics®

November 2019, Volume 21, Number 11: E980-987

MEDICINE AND SOCIETY: PEER-REVIEWED ARTICLE

How to Integrate Lived Experience Into Quality-of-Life Assessment in Patients Considering Facial Transplantation

Laura L. Kimberly, MSW, MBE, Allyson R. Alfonso, Rami S. Kantar, MD, Elie P. Ramly, MD, Arthur L. Caplan, PhD, and Eduardo D. Rodriguez, MD, DDS



Which Facets of Quality of Life Matter to VCA Recipients?

 Perceptions of Quality of Life among Face Transplant Recipients: A Qualitative Content Analysis

Greenfield, Jason A.; Kimberly, Laura L.; Berman, Zoe P.; More

Plastic and Reconstructive Surgery - Global Open. 8(8):e2956, August 2020.





FT Quality of Life Research: Perennial Challenge

Purpose: To understand the impact of facial transplantation (FT) on quality of life (QoL) for FT recipients.

Why?

To enhance QoL assessment and outcomes for FT recipients



Alternative Strategy

Knowledge Gap: FT Recipients' Perspectives on QoL

Opportunity: Publicly Available Transcripts of Media Interviews with FT Recipients



ETHICAL SURGICAL INNOVATION: WHOLE-EYE TRANSPLANTATION









American Journal of Bioethics

Target Article

First-in-Human Whole-Eye Transplantation: Ensuring an Ethical Approach to Surgical Innovation

Matteo Laspro 📵, Erika Thys, Bachar Chaya, Eduardo D. Rodriguez & Laura L. Kimberly 💌 📵

Published online: 05 Jan 2024

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Ethical Issues in First-in-Human WET

- Balancing Risks and Benefits Combining FT-WET
- Psychosocial Considerations Identity, Technology, Social Support,
 Media Exposure
- Transparency Pros and Cons



Ethics of Surgical Innovation

- Surgical Learning Curve
- Managing Optimism Bias
- Optimal Care for WET Recipients
- Demonstrating Readiness



SHIFTING TOWARD EQUITY

Some Equity and Justice Questions in VCA

- Who has access to VCA? Who doesn't? Who should have access?
- What factors influence disparities in VCA access and outcomes?
- How do we center patients' perspectives in VCA, including shared decision-making?
- How can individuals' lived experience of health and illness be incorporated into standardized VCA measures?



Navigating Geographic Distance and/or Institutional Changes

- Monitoring for graft rejection
- Delegating long-term follow-up to local providers
- Implications for quality/continuity of care
- Relationship with care team
- Financial and logistical considerations
- Care team members and recipient must be able to relocate

Journal of Plastic, Reconstructive & Aesthetic Surgery (2018) 71, 1383-1391





Review

Long-distance care of face transplant recipients in the United States



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Privacy for VCA Recipients and Families

- Very challenging for face transplant
 - Public interest
 - Institutional incentives to publicize
- Stances on expectations for privacy have been program-specific
- For hand transplant, interest early on but privacy easier to assure now



Further Ethical Considerations in VCA

- Shifting toward equity
 - Standardizing VCA measures
 - Addressing disparities in access and outcomes
 - Securing a sustainable funding model



FUTURE DIRECTIONS

Conclusion and Future Directions

- One size does NOT fit all in VCA
- Opportunity to address equity proactively
 - Learn from SOT
 - Empirical evidence: cross-institutional collaboration, multistakeholder involvement



Selected References

- Kimberly, Laura L, Michelle W McQuinn, Arthur L Caplan, and Nomi C Levy-Carrick. 2019. 'The Ethics of Psychosocial Assessment in Vascularized Composite Allotransplantation: A Call for Transparency of Process to Support the Equitable Selection of Patients.' *The Journal of Clinical Ethics* 30 (4): 318–30.
- Rifkin, W., Manjunath, A. K., Kantar, R. S., Jacoby, A., Kimberly, L. L., Gelb, B. E., Diaz-Siso, J. R., Rodriguez, E. D. (2021). A comparison of immunosuppression regimens in hand, face, and kidney transplantation. *Journal of surgical research*, *258*, 17-22.
- Laspro M, Thys E, Chaya B, Rodriguez ED, Kimberly L. L. First-in-Human Whole-Eye Transplantation: Ensuring an Ethical Approach to Surgical Innovation. *The American Journal of Bioethics*. 2024 Jan 5:1-5.
- Kimberly, L. L., Alfonso, A. R., Ramly, E. P., Kantar, R. S., Caplan, A. L., & Rodriguez, E. D. (2019). How to integrate lived experience into quality-of-life assessment in patients considering facial transplantation. *AMA journal of ethics*, *21*(11), 980-987. doi: 10.1001/amajethics.2019.980
- Cherikh, Wida S., Linda C. Cendales, Christopher L. Wholley, Jennifer Wainright, Vijay S. Gorantla, David K. Klassen, Sue v. McDiarmid, and Lawrence Scott Levin. 2019. 'Vascularized Composite Allotransplantation in the United States: A Descriptive Analysis of the Organ Procurement and Transplantation Network Data'. *American Journal of Transplantation* 19 (3): 865–75. doi:10.1111/ajt.15062.
- Jowsey-Gregoire, Sheila, and Martin Kumnig. 2016. 'Standardizing Psychosocial Assessment for Vascularized Composite Allotransplantation'. Current Opinion in Organ Transplantation 21 (5): 530–35. doi:10.1097/MOT.00000000000351.



Selected References

- Kumnig, Martin, and Sheila G Jowsey-Gregoire. 2016. 'Key Psychosocial Challenges in Vascularized Composite Allotransplantation.' *World Journal of Transplantation* 6 (1): 91–102. doi:10.5500/wjt.v6.i1.91.
- National Academies of Science, Engineering, and Medicine; Health and Medicine Division; Board on Health Sciences Policy; Committee on A
 Fairer and More Equitable, Cost-Effective, and Transparent System of Donor Organ Procurement, Allocation, and Distribution. 2022.
 Confronting and Eliminating Inequities in the Organ Transplantation System. Edited by Meredith Hackmann, Rebecca English, and Kenneth
 Kizer. Realizing the Promise of Equity in the Organ Transplantation System. Washington, D.C.: National Academies Press.
- Greenfield, J., Kimberly, L. L., Alfonso, A., Ramly, E., Diep, G., Berman, Z., Lee, O., Rodriguez, E. D. (2020). Perceptions of quality of life among face transplant recipients: a qualitative content analysis. *Plastic and reconstructive surgery global open, 8*(8).
- Moore, F. Ethics in New Medicine: Tissue Transplants. Medical College of Virginia Quarterly (MCV/Q) 1, 19–23 (1965).
- Miller, M. E., Siegler, M. & Angelos, P. Ethical Issues in Surgical Innovation. World J Surg 38, 1638–1643 (2014).
- Gupta, S., Muskens, I. S., Fandino, L. B., Hulsbergen, A. F. C. & Broekman, M. L. D. Oversight in Surgical Innovation: A Response to Ethical Challenges. World J Surg 42, 2773–2780 (2018).
- Kimberly, L. L., Ramly, E. P., Alfonso, A. R., Diep, G. K., Berman, Z. P., & Rodriguez, E. D. (2021). Equity in access to facial transplantation. *Journal of medical ethics*, *47*(12), e10-e10.
- Eyers, T. & Krastev, Y. Ethics in Surgical Innovations from the Patient Perspective. Yearb Med Inform 29, 169–175 (2020).
- Zahra, J. et al. Discussing surgical innovation with patients: a qualitative study of surgeons' and governance representatives' views. BMJ Open
 10, e035251 (2020).



THANK YOU



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