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Vascularized Composite Allotransplantation: Military Interest for Wounded Service Members

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Abstract Vascularized composite allotransplantation (VCA) is an extrapolation of the considerable knowledge gained over the past five decades of solid organ transplantation (SOT)—kidneys, livers, hearts, and lungs, among other organs—applied as a novel strategy for catastrophic loss of vital composite tissues, particularly those of the face and hands. Department of Defense (DoD) funding of the VCA field is substantial, reflecting the DoD commitment to making innovative approaches to caring for catastrophic injuries available to wounded service members. This article is an articulation of the ideals, goals, unknowns, challenges, and risks facing the DoD in the context of this investment.

Keywords Transplantation · Vascularized composite allotransplantation · Combat injury · Amputation · Severe facial injury

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Introduction

The men and women who serve in the armed forces, in the words of Major General Joseph Caravalho, "sign a blank check, co-signed by their families, payable to the Army, Navy, Air Force, or Marines, up to and including their lives" [1]. In order to follow orders into harm's way, and to honor the commitment he or she made in signing that blank check, a Service Member (SM) must *know* that should he or she suffer grievous injury, military medicine will use every product, technology, or technique available to restore them to health and wholeness. But the conflicts in Iraq and Afghanistan have demonstrated medicine's limitations in the ability to fully heal some wounds. Therefore, to keep faith with SMs, military medicine and research must do more, must do better, and must work faster, to find solutions to the most challenging combat injuries.

Vascularized composite allotransplantation (VCA) is described in the Health Resources and Services Administration, Department of Health and Human Services (HRSA, DHHS) Final Rule as, "the transplant of intact vascularized body parts, such as hands and faces" [2••]. The VCA is an extrapolation of the considerable knowledge gained over the past five decades of solid organ transplantation (SOT)—kidneys, livers, hearts, and lungs, among other organs—applied as a novel strategy for catastrophic loss of vital composite tissues, particularly those of the face and hands. Department of Defense (DoD) funding of the VCA field is substantial, at more than $30M and growing, reflecting the DoD commitment to making innovative approaches to caring for catastrophic injuries available to wounded SMs. It also makes the DoD the largest single investor in the field.

Below is an articulation of the ideals, goals, unknowns, challenges, and risks facing the DoD in the context of this investment.

Background

Insurgent tactics in the conflicts in Iraq and Afghanistan changed in 2004–2005, escalating the use of improvised explosive devices (IEDs) and, consequently, the number of US casualties. At the same time, lessons learned from previous casualties and conflicts regarding the use of personal protective equipment, field care, evacuation, and trauma resuscitation meant casualties were surviving ever more severe injuries. Unfortunately, the ability to save those wounded warfighters outstripped medicine's ability to heal their wounds. Conventional reconstructive surgeries exhausted, some wounded warriors have been left with residual function and appearance that are unacceptable.

The technology capabilities can be divided into discrete solution types. The first type includes current practices and technologies. The second type represents incremental improvements to existing products, procedures, or technologies. The third type is "exquisite capabilities"—those that entirely disrupt the practice of medicine by offering solutions where none previously existed [3]. These solutions embody the definition of exquisite: "marked by flawless craftsmanship or by beautiful, ingenious, delicate, or elaborate execution" [4]. For wounded warriors surviving catastrophic injuries that in previous wars would have killed them, exquisite capabilities represent their best chance at a full and meaningful recovery.

In 2006, DoD leadership acknowledged the need to find exquisite capabilities for combat injuries and identified novel treatments, such as regenerative medicine and VCA, which held tremendous promise for the most challenging clinical problems facing military surgeons. In 2008, the Armed Forces Institute of Regenerative Medicine (AFIRM) was the first regenerative medicine effort funded by the DoD to partner with a consortium of private academic institutions and industry in an effort to translate such products into the clinic as rapidly as possible. Since 2008, numerous other awards have built on the success of AFIRM, expanding the number of products in development and pushing other technologies further along the development pathway.

VCA, previously known as composite tissue allotransplantation (CTA) or reconstructive transplantation (RT), was supported from the start of AFIRM. While regenerative technologies hold the promise of regrowing what was lost, the reality is that most of the products are years—or decades—from US Food and Drug Administration (FDA) approval and widespread clinical use. VCA offers an interim solution for those whom conventional strategies have failed and whose residual deficits preclude a satisfactory quality of life. The techniques, options, and approaches with hand and face transplants share many technical similarities, but there are significant and unique differences that lead to modified considerations for patient selection, immunosuppression therapy, and rehabilitation.

Population of Interest

While the primary interest of the DoD is to restore wounded SMs to health, the benefit to civilians of medical advances devolving from armed conflict has a long history. Approximately 1600 wounded warriors sustained amputations from the wars in Iraq and Afghanistan; close to 500 of those suffered amputations of more than one limb. Four thousand service members sustained facial injuries; conservative estimates suggest 50 of those injuries were catastrophic. While the number of SMs who sustained these catastrophic combat injuries to the face and limbs is unacceptably high, in truth, the number of civilians who suffer similar injuries is even greater.

Two million people are living with limb loss in the USA [5]; 185,000 undergo amputations each year [6]. Approximately 100,000 of those patients have vascular disease and/or diabetes; roughly 83,000 are due to trauma [5]. The remaining amputations are due to cancer or other causes, such as acute infection with sepsis. Amputation for vascular disease or diabetes heralds long-standing and very advanced, disseminated arterial disease, with a consequently poor prognosis; fewer than half survive for 5 years after amputation [7]. Given the extent of their disease and other comorbidities, these chronically ill patients have very low functional demands and may never use a prosthetic limb. Amputees due to trauma, however, are likely to be a population that is younger and premorbidly more active than the vascular amputees, putting much higher functional demands, over a much longer duration, on whatever limb substitute is employed.

Catastrophic facial injuries—those not amenable to satisfactory reconstruction with conventional procedures—are rare events, though exact statistics are difficult to obtain. Three million facial injuries are treated in emergency rooms in the USA each year [8]. Conservative estimates suggest that if even 0.5 % of those are catastrophic injuries, then 15,000 patients each year suffer dramatically life-changing disfigurement and disability. If only 1 % of those 15,000 catastrophically injured patients are suitable for a face transplant, there may be as many as 150 new candidates for the procedure each year.

Status of the Field

Procedures

The world experience with VCA is limited in number and quite varied in scope. Transplantation of a wide variety of

tissues has been attempted, with varying success: larynx, trachea, uterus, penis, abdominal wall, and knee joint, in addition to the most commonly attempted transplants of the hand and face. There are 20 programs in hand or facial transplantation in the USA. Thirteen of those programs have received DoD funding for some type of VCA research, as seen in Table 1. VCA transplant programs in the USS had performed 31 VCAs, as of November 2014: 21 hand transplants and 10 facial transplants.

The first attempt at hand transplantation was performed in South America in 1964; an unsophisticated antirejection regimen, by today's standards, resulted in rejection of the graft 2 weeks later. More than three decades elapsed before the next unilateral hand transplant was performed in France in 1998, followed by a unilateral hand transplant at the University of Louisville in 1999; worldwide, more than 100 have been done in the intervening years, more than 20 of those in the USA [9, 10]. To date, overall 5-year graft survival is 90 %. In comparison, the next best SOT survival rate is for kidneys at 75 %. An analysis of hand transplants done in transplant centers outside of China presented at the 2013 American Transplant Congress revealed a 1-year graft survival of 84 % overall and 90.5 % for isolated hand transplants (i.e., those not combining hand transplant with face or lower limb transplant). There were three causes of graft loss: vascular complications, sepsis, and chronic rejection [11].

The first face transplant was performed in France in 2005. More than 30 have been done in the world since, 10 of those in the USA [12••]. To date, five patients have died: two from infection; one from immunosuppression noncompliance and graft loss; one from a recurrence of cancer, possibly due to immunosuppression; and one from a self-inflicted gunshot wound 4 years after transplantation [13].

Ethical Issues

There are several ethical issues related to VCA, but the primary concern is about subjecting otherwise healthy VCA recipients to lifelong, immunosuppression therapy, with all of its attendant risks, for a transplant that is not life-saving.

VCA is like any other organ transplant in that the major long-term risk is rejection and chronic changes of the graft. In order to reduce the risk of rejection, VCA recipients, like organ transplant recipients, require lifelong immunosuppression with several powerful medications that are associated with a wide variety of side effects and risks such as severe infection, cancer, kidney failure, high blood pressure, diabetes, and significant weight gain, which may ultimately shorten recipients' lives by as much as 10 years [14]. When considering an immunosuppression regimen for SOTs of the kidneys, heart, lungs, or liver, the long-term risks of

Table 1 VCA centers in the USA

	Institution	Hand Transplant Team Leader	IRB	Face Transplant Team Leader	IRB
Active Centers	Brigham and Women's Hospital	Simon Talbot	Yes	Bohdan Pomahac	Yes
	Massachusetts General Hospital	Curt Cetrulo	Yes		
	University of Pennsylvania	L. Scott Levin	No		
	Johns Hopkins University	W.P. Andrew Lee	Yes	W.P. Andrew Lee	Yes
	University of Pittsburgh	Vijay Gorantla	Yes	Joseph Losee	Yes
	University of Louisville	Christina Kauffman	Yes		
	Mayo Clinic	Steven Moran	No		
	Wilford Hall	Dmitry Tuder	Yes		
	UCLA	Kodi Azari	Yes	Kodi Azari	Yes
	New York University			Eduardo Rodriguez	Yes
	Cleveland Clinic			Frank Papay	Yes
	U of Chicago			Maria Siemionow	Yes
	Duke University	Linda Cendales	Yes		
	U of Maryland			Branko Bojovic	Yes
	U of Texas Southwestern	Tae Chong	Yes		
	U of Southern Illinois	Michael Neumeister	Yes		
Proposed Centers	MD Anderson/U of Texas Houston	J Selber/R Andrassy	Yes	J Selber/R Andrassy	Yes
	Northwestern University	Gary Dumanian			
	U of Arizona	Warren Breidenbach III			
	U of Washington	Peter Neligan			

Orange indicates the program received funding from the DoD

immunosuppression pale in comparison to the short-term and very real risk of imminent death without the transplant. But when the transplant is life-changing, *not* life-saving, the balance in the equation shifts, or so ethicists thought when the first VCAs were considered.

The answer to this question, particularly for face transplant recipients, has evolved slowly, as the number of cases has grown. It has become clear even to an early, vocal opponent of the procedure, NYU ethicist Dr. Art Caplan, that face transplants offer relief from the underappreciated suffering of patients with catastrophic facial injuries. Patients who have suffered injuries severe enough for consideration of face transplantation are grotesquely disfigured; are often unable to speak, breathe, chew, or swallow normally; and often are in constant physical pain. The psychological distress stemming from the stigma of disfigurement and the consequent self-imposed isolation from friends, relatives, and the public in general is equally agonizing. Such suffering is impossible to ignore when the state of the science has advanced to the point of making the procedure available to carefully chosen recipients [15].

The ethical issues of hand transplantation are slightly more nuanced, in that the risk/benefit balance includes another variable—whether the transplant is for one limb or two in the same recipient. Many unilateral upper extremity amputees are able to adapt to a prosthesis or to using the residual limb as an assist to the remaining limb. However, disability following bilateral upper extremity amputation is much more profound than after unilateral amputation, and adaptation to bilateral upper extremity prostheses is much more difficult. As a result, many investigators at VCA centers believe that bilateral upper extremity amputations tip the balance toward a more acceptable risk profile for hand transplantation, although those with a significant impairment in function with a unilateral amputation are also considered. The other way to tip the balance of this dilemma in favor of VCA is to find ways to reduce the risk and burden of immunosuppression.

Immunosuppression

During early attempts of the procedure, both hand and face transplant recipients were treated with standard immunosuppression regimens used to prevent rejection in life-saving SOTs such as thymoglobulin or another induction agent and long-term maintenance with a calcineurin inhibitor (i.e., tacrolimus), mycophenolate mofetil, and steroids [12••]. Initial expectations were that the highly antigenic skin component of a composite graft would induce more frequent or more severe rejection episodes. Experience has shown that skin rejection is reversible in most cases and interest has turned to finding ways to reduce the risk of immunosuppression in an effort to make the procedure more acceptable for young, otherwise healthy, patients.

Graft loss has very different implications for face transplant recipients than for hand transplant recipients. Loss of the facial graft would represent a life-threatening risk to the patient and would require extensive autologous grafting to provide soft tissue coverage for wound closure to those who survive. The patient would be left with a defect and disfigurement at least as severe as their pretransplant state. For this reason, VCA centers performing face transplants have chosen the most conservative approach, using immunosuppression regimens with well-proven histories of efficacy in SOTs.

Hand transplantation represents an extraordinary opportunity to closely monitor rejection in a setting that may be higher risk to the graft, but is not life-threatening for the recipient. Other SOTs (i.e., kidney, liver, lung, heart) are hidden from view, requiring indirect measures of function, or invasive biopsies, to indicate rejection. Typically, by the time these indirect measures register dysfunction, the rejection episode may be well advanced. In contrast, transplanted hands allow for visual surveillance at any time and early detection of acute rejection episodes.

Several hand transplant investigators have taken advantage of this opportunity. Some clinical trials are investigating methods for reducing immunosuppression: bone marrow infusions around the time of the transplant, substances which "cloak" the antigenic markers of the graft, biomarker-guided withdrawal of immunosuppressants, exogenous induced chimerism between donor and recipient immune cells, and other strategies. Other investigators are looking at whether immunosuppression medications proven effective in SOT are as effective in VCA. Still others are searching for more accurate, less invasive means of doing graft surveillance to catch and treat rejection episodes as early as possible. All of these investigations are still ongoing, and it will be some years before one or more prove superior.

Patient and Outcome Considerations

"The most important decision determining the success of facial transplantation remains patient selection" [12••]. In order to give the patient the best chance at the best outcomes, there must be a convergence of factors: an operatively favorable deficit, an immunologically favorable profile, patient resilience, commitment to postoperative demands, characterologic suitability, and substantial psychosocial support [16, 17]. This requires very careful patient selection, not only for physical characteristics but also just as importantly for the characteristics without clear metrics or biomarkers. These include grit, resilience, commitment to a long-term goal, determination, adaptive coping skills, and initiative, which will be important for the arduous process of rehabilitation and to overcome risks and complications. The prospect of undergoing a VCA procedure is formidable, with perhaps the surgical technique being the more straightforward aspect of it. Reestablishing function

of either a facial graft or an arm/hand graft requires extensive physical, speech, and/or occupational therapy. Similar to other settings, the more compliant and committed the patient is to the therapy, the better the outcome. The corollary is that patients who are noncompliant and unwilling to engage in rehabilitation are unlikely to recover optimal function and ultimately may experience graft loss.

At the time this article was written, there was no nationally agreed-upon set of outcome measures for hand and face transplantation gathered consistently across the various VCA centers. In a Federal Register Notice published July 3, 2013, the US Department of Health and Human Services announced that VCA was added to the definition of organs covered by federal regulation. Following the announcement, the United Network for Organ Sharing (UNOS) recruited members for the Organ Procurement and Transplant Network (OPTN) VCA committee. The committee was charged with the initial development of guidelines for implementation. This standardization of guidelines and data collection will provide a better understanding of patient outcomes and comparisons among the different VCA programs.

Challenges of Reimbursement

VCA is currently considered experimental and not covered by insurers without case-by-case consideration and exception. At present, costs are borne by the performing institution, the clinicians who do the surgery and follow-up at no cost, and any research grants awarded to the project. The benefits of performing a procedure under experimental status are numerous: to insure capture of outcomes and systematic data for an emerging technique and to insure the procedure is done under the most carefully controlled circumstances, and so the effort is based on a research question. A limitation is that until a new procedure is proven cost-effective and reimbursed widely, availability of the procedure will be limited, representing potential barriers to access some patients may be unable to overcome.

There is debate among those in the field of VCA as to when the procedure may reasonably be considered standard of care and, therefore, subject to reimbursement by insurers. Some argue that hand transplantation *with standard triple therapy immunosuppression* (as is given for SOTs) should no longer be considered experimental. Two programs, the Mayo Clinic and the University of Pennsylvania, have gone so far as to establish hand transplant programs without approval of the procedure by an institutional review board (IRB). Any IRB approval obtained by those programs is for capturing some type of data related to the procedure, not about the procedure itself. The argument for a nonexperimental stance is twofold; first, the surgical portion is essentially identical to replantation, a procedure that has been performed successfully, not considered experimental, and reimbursed successfully, since the early 1960s. Secondly, the immunosuppression regimen is identical to regimens used successfully with SOTs, and reimbursed for those transplants, for decades. The American Society for Reconstructive Transplantation (ASRT) has gone so far as to develop Guidelines for Medical Necessity Determination for both hand and face transplant candidates [18].

Proponents on the other side of the argument strongly believe that with the small numbers of VCA procedures done to date, the evidence to support its acceptance as standard of care and its cost-effectiveness is lacking, and in order to continue to insure the safe conduct of the procedures, as well as continued data accumulation, it should remain in an experimental status.

Nevertheless, some programs have negotiated with public and private insurers for coverage of posttransplant care after the initial postoperative period. The negotiations occurred in anticipation of transplantation, as a precondition for the patient being put on the waiting list for a suitable donor.

At present, VCA is not a generally accepted medical practice and consequently not included in the care and services provided by the Veterans Health Administration under the Department of Veterans Affairs Medical Benefits Package (see title 38 Code of Federal Regulations (CFR) 17.38) [19], . Therefore, any costs of the procedure not covered by the performing institution or by research funding cannot be charged to the VA. However, any veteran who is eligible for (VHA Handbook 1601A.02, Eligibility Determination) [20], and enrolled in, VA services elects to undergo transplantation, the VA will provide necessary postoperative follow-on care and treatment [21].

Patient Access

The VCA process or patient eligibility requirements are managed by the VCA program directly and the center's information can be found on www.clinicaltrials.gov by searching the institution and/or investigator name. Members of each VCA center's team are the most appropriate individuals to determine suitability/eligibility of transplant candidates for their program. Potential VCA patients or care providers may contact the VCA center's team lead for further information regarding detailed inclusion/exclusion criteria, the evaluation process, and how the center works with referring physicians.

Active duty service members (SMs) interested in pursuing transplantation must obtain a waiver letter for the use of Supplemental Healthcare Program funds to cover transplant costs not included under institutional or research umbrellas. The process is outlined in Table 2.

Those SMs who choose not to pursue VCA for catastrophic facial or upper extremity injuries through the use of SHCP prior to separation from active duty may choose to pursue transplantation from the VA system. However, VCA is not a generally accepted medical practice and consequently not

Table 2 Approval process for Active Duty Service Member VCA candidates

- Active Duty Service Member (ADSM) and Primary Care Manager (PCM) determine VCA is an option
- AD SM visits VCA sites
- AD SM deemed candidate by VCA site
- Supplemental Health Care Program (SHCP) waiver packet initiated by care team through Service-specific Surgeon General's (TSG) office
- Care team requests Transplant Advisory Board (TAB) meeting for candidate review
- Service-specific TSG reviews SHCP waiver packet and TAB minutes
- If TSG approves, waiver forwarded to TRICARE Management Activity Office of the Chief Medical Officer (TMA OCMO)
- TMA OCMO reviews SHCP waiver and board recommendation. Requests TMA OCMO board review
- If approved, AD SM letter of approval signed and sent to Service-specific Surgeon General and PCM, at which point listing for transplant may proceed

included in the care and services provided by the Veterans Health Administration under the Department of Veterans Affairs Medical Benefits Package (see title 38 Code of Federal Regulations (CFR) 17.38)." Therefore,,any costs incurred preoperatively or in the immediate postoperative period that are not covered by research funding may not be eligible for VA coverage. However, the VA provides long-term coverage of immunosuppression medications as well as other services necessary to maintain the health of the transplant, which may include physical, occupational, speech therapy, or other interventions to eligible and enrolled Veterans.

Future Directions

As noted above, VCAs were included under the definition of organ transplantation. At the time this review was written, guidelines for membership requirements for VCA programs, VCA allocation, and data collection were being developed. The federal regulation recognizes VCA as a field of transplantation and provides a standard assessment of the safety and quality of the grafts. In addition, it provides assurance that all programs carrying out VCA procedures will be governed by the same policies and regulations [22].

While the draw-down from the conflicts in Iraq and Afghanistan will result in fewer acute casualties for consideration as VCA candidates, the SMs who suffered catastrophic injuries in the midst of those conflicts are still in need of better solutions. Therefore, the DoD will continue to pursue VCA as an available procedure for severely injured SMs. Recent efforts for funding consideration included expanded clinical trials, preclinical trials for immunosuppression, immunomodulation, immunocloaking technologies, graft surveillance, and standardization of processes and protocols. As knowledge in the field of VCA grows, DoD-funded research opportunities will co-evolve, continuing to support the leading edge of research in this field.

Conclusion

The DoD has made a solemn commitment to honor the debt owed to SMs who willingly put themselves in harm's way by pursuing promising avenues to innovative solutions for the most challenging combat wounds. VCA holds great promise for those who have suffered unimaginable injuries and represents an opportunity for research in different areas that could benefit all transplant candidates, military and civilian, VCA and SOT alike. While the risks are considerable, if one person with catastrophic injury returns to a meaningful life as a result of this technology, it is work worth pursuing.

Compliance with Ethics Guidelines

Conflict of Interest The authors declare that they have no competing interests.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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