



FEP Medical Policy Manual

FEP 7.03.13 Composite Tissue Allotransplantation of the Hand and Face

Annual Effective Policy Date: January 1, 2024

Original Policy Date: June 2013

Related Policies:

None

Composite Tissue Allotransplantation of the Hand and Face

Description

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Composite tissue allotransplantation (also referred to as vascularized composite allotransplantation) is defined as transplantation of histologically different tissues. This type of transplantation is being proposed for facial transplants in patients with severely disfigured faces, and for hand transplants in patients dissatisfied with prosthetic hands. The treatment has potential benefits in terms of improving functional status and psychosocial well-being. It also has potential risks, most notably those associated with a lifelong regimen of immunosuppressive drugs.

Composite tissue allotransplantation refers to the transplantation of histologically different tissue that may include skin, connective tissue, blood vessels, muscle, bone, and nerve tissue. The procedure is also known as reconstructive transplantation. To date, primary applications of this type of transplantation have been of the hand and face (partial and full), although there are also reported cases of several other composite tissue allotransplantations, including that of the larynx, knee, and abdominal wall.

Hand and face transplants have been shown to be technically feasible. The first successful partial face transplant was performed in France in 2005, and the first complete facial transplant was performed in Spain in 2010. In the U.S., the first facial transplant was done in 2008; it was a near-total face transplant and included the midface, nose, and bone. The first hand transplant with short-term success occurred in 1998 in France. However, the patient failed to follow the immunosuppressive regimen, which led to graft failure and removal of the hand 29 months after transplantation. The first hand transplantation in the U.S. took place in 1999.

Composite tissue allotransplantation procedures are complex and involve a series of operations using a rotating team of specialists. For face transplantation, the surgery may last 8 to 15 hours. Hand transplant surgery typically lasts between 8 and 12 hours. Bone fixation occurs first, and this is generally followed by the artery and venous repair and then by suture of nerves and/or tendons. In all surgeries performed to date, the median and ulnar nerves were repaired. The radial nerve was reconstructed in about half of the procedures.

Unlike most solid organ transplantations (eg, kidney and heart transplants), composite tissue allotransplantation is not life-saving, and its primary aim rests mainly in a patient's cosmetic satisfaction and quality of life. In the case of facial transplantations, there is immense potential for psychosocial benefits when surgery is successful. Moreover, the goal of composite tissue transplantation is to improve function (eg, grasping and lifting after hand transplants, blinking and mouth closure after face transplants) without alternative interventions such as prosthetics. Additionally, in the case of face transplantation, the procedure may be less traumatic than "traditional" facial reconstructive surgery using the patient's own tissue. For example, traditional procedures often involve dozens of operations, whereas facial transplantation only involves a few operations.

Composite tissue allotransplantation is associated with potential risks and benefits, and patients who undergo face or hand transplantation must adhere to a lifelong regimen of immunosuppressive drugs. Risks of immunosuppression include acute and chronic rejection, an opportunistic infection that may be life-threatening, and metabolic disorders such as diabetes, kidney damage, and lymphoma. A review of 115 facial or upper extremity transplants found an overall acute rejection rate of 89% with 11% of recipients with chronic rejection.¹ Other challenges include the need to participate actively in intensive physical therapy to restore functionality and the potential for frustration and disappointment if functional improvement does not meet expectations. Moreover, there is the potential for allograft loss, which would lead to additional procedures in hand transplant patients, and there are limited reconstructive options for facial transplantation. Furthermore, in the case of hand transplants, there is a risk that functional ability (eg, grasping and lifting objects) may be lower than with a prosthetic hand, especially compared with newer electronic prosthetic devices. Due to the importance of selecting candidates who can withstand these physical and mental challenges, potential hand and face transplant recipients undergo extensive screening for both medical and psychosocial suitability.

OBJECTIVE

The objective of this evidence review is to determine whether composite tissue allotransplantation of the hand and/or face improves the net health outcome compared with standard management without transplantation.

POLICY STATEMENT

Composite tissue allotransplantation of the hand and/or face is considered **investigational**.

POLICY GUIDELINES

Currently, there are no specific CPT codes for this procedure; however, should these procedures receive codes, it is likely that a combination of existing codes or the unlisted code for the anatomic area would be used.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Composite tissue allotransplantation is offered at specialized centers.

FDA REGULATORY STATUS

Hand and face allotransplantations are surgical procedures and, as such, are not subject to regulation by the U.S. Food and Drug Administration.

RATIONALE

Summary of Evidence

For individuals who have a severely disfigured face due to burns or trauma who receive composite tissue allotransplantation, the evidence includes a case series and several systematic reviews of case series. Relevant outcomes are functional outcomes, quality of life, resource utilization, and treatment-related mortality and morbidity. The available studies on composite tissue allotransplantation of the face have suggested that the surgery is technically feasible; however, to date, only a limited number of patients worldwide have undergone the procedure, and the data are not sufficiently robust to determine whether the potential benefits to patients outweigh the potential risks (eg, of surgical complications, immunosuppression, opportunistic infections). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have hand and upper-extremity amputation(s) who receive composite tissue allotransplantation, the evidence includes a case series, several systematic reviews of case series, and a nonrandomized comparative study. Relevant outcomes are functional outcomes, quality of life, resource utilization, and treatment-related mortality and morbidity. The available studies on composite tissue allotransplantation of the hand have suggested that the surgery is technically feasible. The only study comparing outcomes in patients who had hand transplants with those who received prostheses included 12 patients. It found no differences between groups in functional outcomes and little difference in the quality of life. Given the limited number of patients worldwide who have undergone the procedure and the limited amount of data comparing outcomes with the best available prosthetics, the evidence is not sufficiently robust to determine whether the potential benefits to patients outweigh the potential risks (eg, of surgical complications, immunosuppression, opportunistic infections). The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Institute for Health and Care Excellence

In 2011, the National Institute for Health and Care Excellence published guidance on hand allotransplantation.⁹ The guidance stated that the quantity of current evidence on the efficacy and safety of hand allotransplantation was inadequate.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

1. Milek D, Reed LT, Echternacht SR, et al. A Systematic Review of the Reported Complications Related to Facial and Upper Extremity Vascularized Composite Allotransplantation. *J Surg Res.* Jan 2023; 281: 164-175. PMID 36162189
2. Infante-Cossio P, Barrera-Pulido F, Gomez-Cia T, et al. Facial transplantation: a concise update. *Med Oral Patol Oral Cir Bucal.* Mar 01 2013; 18(2): e263-71. PMID 23229268
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4. Smeets R, Rendenbach C, Birkelbach M, et al. Face transplantation: on the verge of becoming clinical routine?. *Biomed Res Int.* 2014; 2014: 907272. PMID 25009821

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6. Shores JT, Brandacher G, Lee WPA. Hand and upper extremity transplantation: an update of outcomes in the worldwide experience. *Plast Reconstr Surg*. Feb 2015; 135(2): 351e-360e. PMID 25401735
7. Petruzzo P, Dubernard JM. The International Registry on Hand and Composite Tissue allotransplantation. *Clin Transpl*. 2011: 247-53. PMID 22755418
8. Salminger S, Sturma A, Roche AD, et al. Functional and Psychosocial Outcomes of Hand Transplantation Compared with Prosthetic Fitting in Below-Elbow Amputees: A Multicenter Cohort Study. *PLoS One*. 2016; 11(9): e0162507. PMID 27589057
9. National Institute for Health and Care Excellence (NICE). Hand allotransplantation [IPG383]. 2011; <https://www.nice.org.uk/guidance/ipg383>. Accessed June 12, 2023.

POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

| Date | Action | Description |
|---------------|----------------|--|
| June 2013 | New policy | |
| June 2014 | Replace policy | Policy updated with literature review. References 2, 7, and 8 added. No change to policy statements. |
| June 2015 | Replace policy | Policy updated with literature review. References 2, 4-5, and 12 added. Policy statement unchanged. |
| June 2016 | Replace policy | Policy updated with literature review through December 14, 2015; reference 2 added. Policy statement unchanged. |
| December 2017 | Replace policy | Policy updated with literature review through June 22, 2017; references 2 and 7 added. Policy statement unchanged. |
| December 2018 | Replace policy | Policy updated with literature review through June 7, 2018; no references added. Policy statement unchanged. |
| December 2019 | Replace policy | Policy updated with literature review through June 10, 2019; no references added. Policy statement unchanged. |
| December 2020 | Replace policy | Policy updated with literature review through May 22, 2020; no references added. Policy statement unchanged. |
| December 2021 | Replace policy | Policy updated with literature review through May 17, 2021; no references added. Policy statement unchanged. |
| December 2022 | Replace policy | Policy updated with literature review through May 16, 2022; no references added. Policy statement unchanged. |
| December 2023 | Replace policy | Policy updated with literature review through June 12, 2023; references added. Policy statement unchanged. |

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