

Face Transplant Patient Guide

Why are facial transplantations being done?

You may have heard in the news lately about a new surgical procedure called facial transplant or partial face transplant. Only a small number (less than 10) of these surgeries have been performed so far around the world. The first and most well-known case was in France, where a woman received a transplant of the central part of the face.

The procedure of facial transplantation is a promising new method to restore the faces of patients with the most severe of facial injuries. However, this procedure is new and not without significant risks. Therefore, facial transplantations have to, and should, be performed as part of a research study. The facial transplant team at Brigham and Women's Hospital has received major funding from the Department of Defense to set up a study for facial transplantation.

The purpose of the study is to find out more about outcomes of facial transplantation. We are studying people who have suffered a serious injury to their faces, or who must have surgery (cancer surgery, for example) to remove part of their faces. Injury or surgery has left our patients with a facial deformity (serious damage). We hope to learn more in this research study about how to do a partial facial transplant in the best possible way and how to stop the body from rejecting the transplant.

In this study, our patients will have already lost at least $\frac{1}{4}$ of the entire face, or perhaps an important part of the face. For example, some patients will have lost the whole nose, the entire upper lip or the entire lower lip.

Most patients in our study have already had reconstructive facial surgery to repair the damage, but the results have not been satisfactory. Some facial deformities are simply impossible to fix. Any serious damage to the soft tissues of the face is very difficult to repair completely.

Skin and tissue grafts (also called transplants) taken from another part of the patient's own body usually leave serious scars and require many operations. A transplant of facial tissue from another person is a new research approach for patients with damaged faces. A lot is unknown about the outcomes of this procedure. Studies show that facial appearance of the patient will change and to a various degree may not resemble the appearance before injury. At the same time, the partially new face does not reveal the donor. We also don't know how easy it will be to find tissue donors for this purpose. As there are so many different colors and textures of skin, it might be hard to find an acceptable match.

Normally, the body's immune (protective) system treats any new organ or tissue as an invader, like a germ, and tries to destroy it. Transplant drugs, however, partially shut down the immune system so that the body can accept the new organ or tissue. Patients have to take strong drugs for the rest of their lives to prevent rejection of the transplant.

This is a pilot study. The purpose of a pilot study is to see if something is possible and to learn more about how best to do it. We are doing a pilot study on a small group of patients to learn more about the partial face transplant procedure.

Screening

Each patient that is considered for a facial transplant has to undergo a screening period that may require several visits. During this time, the patient will meet with the various specialists on the facial transplant team. The purpose of the screening is to find out whether the patients are suitable candidates for facial transplantation. The facial injury, as well as the patients overall physical and mental health, will be thoroughly evaluated. More specifically, the evaluation includes various blood tests, imaging tests and appointments with physicians and nurses from many different medical disciplines.

The minimum age requirement for participation in the study is 18 years. Moreover, pregnant women cannot take part, as the transplant drugs may harm a fetus or embryo (a developing baby still inside the mother's body).

The research study

Patients enrolled in the study will have several different examinations before and after the procedure. These examinations are important to plan and prepare for the procedure, monitor for complications and evaluate the results. We also want to make sure that all patients accepted for the procedure have the necessary social/family support and overall capability to cope with the different psychological and practical aspects of this procedure.

There will be imaging before and after the transplant surgery. These tests are non-invasive pictures (like x-rays) to look at internal tissues, nerves and blood vessels. The imaging tests are called CT (CAT-scan) and magnetic resonance imaging (MRI).

We also have included a test called functional MRI (fMRI). Functional MRI shows brain areas that are active when the patient moves, sees, hears, speaks, reads or remembers. Since the muscles and tissues of the face are involved in many critical activities, such as speaking, eating and facial expression, we are interested in how the brain adapts to facial injury and to the repair through transplantation. Using this test, we may be able to detect changes in these brain areas that result from the gradual return of sensation and motor activity to the patient's face.

Quality of life surveys will be used to assess perception of health and well-being. The surveys will be given at the time of listing on the transplant list, approximately every 6 months while the patient is on the list, and periodically (1, 3, 6, 9 and 12 months) after transplantation.

The partial facial transplant procedure

We are working with the New England Organ Bank (NEOB) team to find donors for partial facial transplantation. This search may take days or weeks, but, more commonly, months. If we have not located a suitable donor within one year, then we will talk with the patients and make sure they still want to take part in this study.

When a donor is found, then we will contact the patient with instructions about when to come to BWH for the operation. This timing is very important. It is imperative that the BWH staff can reach the patient at all times, and that the total travel time for the patient to reach our hospital does not exceed 12 hours.

Facial transplantation includes the transfer of soft tissues, with or without facial bone, from the donor to the recipient. The survival of the transferred tissues depends on the re-establishment of blood circulation. This is accomplished by connecting blood vessels of the facial transplant to vessels on the recipient. Nerves are also connected to allow for the return of sensation and motility to the face. Connection (anastomosis) of vessels and nerves is made by the use of a microscope.

In order to check on the health of the transplanted facial tissue without leaving scars, another small operation will be performed at the same time as facial transplantation. We will take a skin sample (graft) from the arm of the facial donor and attach the sample to the chest of the patient. The graft will behave like the facial transplant tissue, allowing us to take tiny samples (biopsies) of the new tissue to look for signs of rejection. This way, we will not have to frequently disturb or mark the new tissue on the face after surgery.

The hospital stay

After the surgery, the patient will first go to the Intensive Care Unit (ICU) for close observation and then move to a private transplant room on a patient floor. All aspects of the patient's gradual recovery will be closely followed by the different specialists on the team. A physical therapist will help the patient regain as much movement as possible in the face, and a psychiatrist will help with any psychological concerns. The hospital stay will last about 7 to 14 days.

Follow-up

After discharge from the hospital, patients will need to come to BWH for routine visits. Close observation and rigorous testing serves to monitor for any complications and to evaluate the results of the procedure. It is also very important that we give patients all the help and support needed to cope with the psychological and social aspects of this procedure.

These follow-up visits will include checking transplant drug levels through regular blood draws; taking small tissue samples from the graft on the chest to look for any signs of rejection; monitoring the transplanted face for the return of sensation and motility; imaging tests; and quality-of-life surveys. In order to make the intense follow-up practical, we highly recommend that our patients reside in the Boston area for at least 3 months after the procedure. When the facial transplant has fully stabilized, patients will continue to make regular visits to BWH for progress checks. After that, the planned visits will be less frequent and some check-ups could be done through video conferences with collaborating medical centers closer to the patient's home. Just as in any organ transplantation, facial transplant patients will have to reside near a major medical center for the rest of their lives.

Medications

Facial transplant patients need to take several different medications on a daily basis. The most important ones are the different types of medications that suppress the immune system. The level of these transplant drugs in the blood will be monitored by regular blood draws. Any signs of side effects will be closely checked. It is imperative that all transplant patients, for any organ or tissue, closely follow the prescriptions of these medications and keep their follow-up appointments. Drug doses that are too high may cause serious side effects and drug doses that are too low may cause rejection of the transplant. The risks and side effects of these medications are described below.

If the facial transplant is completely rejected by the patient's immune system, the transplanted tissues will, unfortunately, have to be removed. This has not happened yet, but may in the future. In that case, different treatment options will have to be discussed with our surgical team. Options include conventional reconstructive facial surgery according to an already prepared plan or another facial transplant at a later time.

Publicity/Privacy

Because this type of transplant is so new, it is likely that the news media will be very interested in both the donors and the people who receive the transplants. We will make every effort to protect the privacy of our patients, but it is not possible to guarantee complete confidentiality. The press may find out the names of both the donor and recipient. This may cause problems, including the stress and anxiety that come with such a loss of privacy.

Risks and discomforts

There are psychological risks and discomforts associated with participation in this study, as well as the physical risks of the experimental facial transplant procedure itself.

General transplant risks

All transplant patients face the following challenges:

- Difficulty following the strict medication dosing after the operation.
- Understanding the complicated side effects and risks of taking drugs that stop your immune system from working normally.
- Swings in emotions following transplant surgery.
- Stress related to study procedures, and other new feelings and thoughts.

Facial transplant risks

We will provide psychiatric support to all patients before and after partial facial transplantation. This support will help the patients to cope with this event and learn to live with the changes, both positive and negative, that it brings.

Risks of taking transplant drugs for a lifetime

The medications suppressing the immune response, and thus preventing rejection of the transplanted tissue, have multiple side effects:

Infections:

It is important that patients receive certain vaccinations prior to transplant (pneumococcal vaccine, flu vaccine, etc).

Medications that prevent the occurrence of infections will be given at the time of the procedure and for some time afterwards.

Diabetes:

Some of the transplant drugs may give rise to diabetes. The blood sugar levels will therefore be monitored and, if needed, anti-diabetes medication will be given.

Cancer:

Certain cancers are more common in people who have undergone transplantation. This is probably because the immune system after the transplant is not as effective at eliminating very early cancer cells. It is important to note that most transplant patients DO NOT develop serious cancers. Some cancers that are more common after transplant are those of the:

- skin (especially in white people)
- lymph glands
- cervix (of the uterus) in women

To minimize the chances of having cancer before a transplant, we ensure that all patients are screened before transplantation as follows:

- Patients over 50 years have a colonoscopy (screening test for bowel cancer).
- All men over 50 years have a PSA (screening test for prostate cancer). Because prostate cancer is more common in African-Americans, they should have a PSA if aged over 40 years.
- All women over 40 years have a mammogram.
- All women have a Pap smear.

The chances of developing skin cancer are best minimized by thorough protection from the sun.

We can also detect other types of cancer early by following guidelines for the general population.

Kidney failure:

Immunosuppressive medications have a negative impact on kidney function. A small number of transplant patients end up requiring dialysis because of kidney failure caused by these medications. It is therefore very important to test kidney function during the regular visits and change medications as needed to prevent kidney failure from happening. The lifetime risk of losing kidney function is unknown, but we believe that it should not exceed 10%.

The benefits of facial transplantation

We do not know if facial transplants will have more long-term success than standard reconstructive surgery for the face. We hope so, but there is no guarantee. Although the early experience of the French face transplant patient has been good, she is only one case. Her success does not guarantee any other transplant patient's success.

There may be less pain and discomfort after surgery (as compared to conventional reconstructive surgery). There are two reasons for this:

There will be no other surgical sites on the body where the patient's own skin was removed for use on the face.

There will be only one large surgical procedure, instead of many smaller ones. The standard way of rebuilding a damaged face involves many surgeries, with time for healing in between. A partial facial transplant, still in the experimental stage, happens all at one time.

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