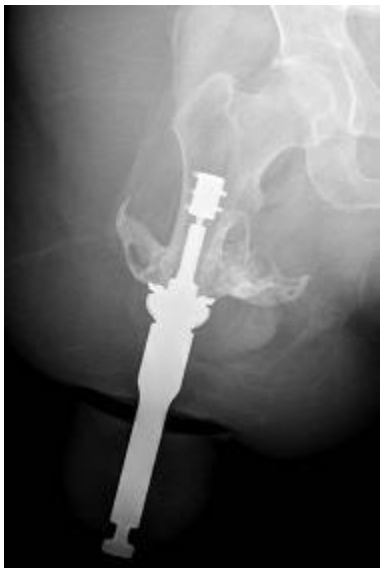
OSSEOINTEGRATION FOR DIRECT SKELETAL ATTACHMENT OF PROSTHETIC LIMBS IN BENEFICIARIES WITH AMPUTATIONS

This Fact Sheet provides information on osseointegration (OI) and the use of this procedure for the direct skeletal attachment of prosthetic limbs in Military Health System (MHS) beneficiaries with amputations. This is a rapidly evolving field with significant potential benefits for MHS beneficiaries, especially beneficiaries with major limb amputation who have difficulty with traditional prosthetic socket use. As of 2021, there is one OI implant with Food and Drug Administration (FDA) approval that is in use at Walter Reed National Military Medical Center (WRNMMC). Additionally, the U.S. Army Medical Research and Development Command supports research with other implants for OI interventions in upper and lower limb amputation. There are active OI studies at WRNMMC, in partnership with the Uniformed Services University of the Health Sciences (USU), the Extremity Trauma and Amputation Center of Excellence (EACE) and other federal and non-federal agencies.



Percutaneous osseointegrated implants have been developed and used to achieve direct skeletal attachment of a prosthetic limb to the residual limb of a person with an amputation. Compared to traditional prostheses that utilize a socket, direct skeletal attachment of a prosthesis offers potential advantages. These advantages include: 1) ease and speed of donning and doffing the prosthesis; 2) improved comfort and fit; 3) reduced skin irritation caused by traditional sockets; 4) improved joint range-of-motion and likely improved biomechanics; 5) opportunity for prosthetic use by individuals who cannot wear/tolerate a traditional prosthesis; and, 6) increased "osseoperception" sensory input (e.g., sense of limb position and interaction with environment). While these advantages offer notable potential benefits, significant risks are still associated with this procedure, including the risks associated with surgery, infection, possible bone-implant interface failure and risk of skeletal fracture. There are also additional rehabilitation requirements associated with OI as well as delayed weight bearing when compared to traditional prosthetic fitting.

FDA CLASSIFICATION

The FDA considers OI implants to be Class III (highest risk category) devices, requiring the highest degree of control to assure that the device is safe and effective.

The Integrum Osseointegrated Prosthesis for the Rehabilitation of Amputees (OPRA) Implant System received FDA premarket approval (PMA) in December 2020 for use in patients with above knee amputation. The Integrum is the only OI device to have FDA PMA as of March 2021.

Several other percutaneous OI implants are being used in the United States under Institutional Review Board approved research protocols or as custom implants. Custom implants are designed to be used in unique individual cases on a "one-time" basis when other options are not possible.

There are also OI implants in use outside of the United States such as the Orthodynamics Integral Leg Prosthesis and the Osseointegrated Prosthetic Limb, neither of which have been approved by the FDA for implantation within the United States.

Prosthetic limb components that are currently commercially available and fit externally to the residual limb of the person with an amputation are commonly classified by FDA as Class I devices (lowest risk

category requiring the lowest degree of control). There is no formal FDA guidance regarding the classification of externally located prosthetic limb components when these components are connected to a percutaneous osseointegrated implant. It is generally recommended that when fitting Class I externally located prosthetic limb components to an OI implant, the provider refers to the implant manufacturer's labeling to determine if certain externally located prosthetic limb components should or should not be used with the implant.

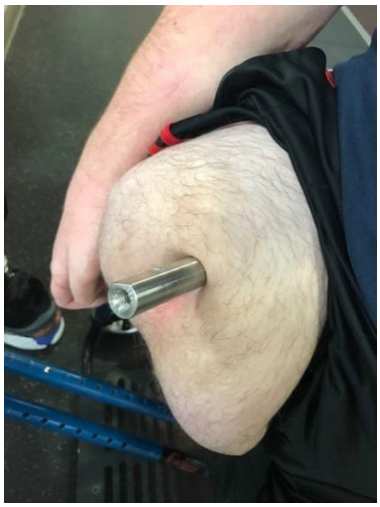
CURRENT RESEARCH

The MHS currently supports research outcomes studies for transfemoral and transhumeral OPRA devices at WRNMMC, Bethesda, Maryland, as well as patients who have received custom devices. Beneficiaries are also eligible to participate in research protocols being conducted outside of the MHS, although MHS provides no financial support for beneficiaries participating in such outside research.

BENEFICIARY ACCESS

A device with FDA PMA may be a TRICARE covered benefit in accordance with the TRICARE Policy Manual, Chapter 8, Section 5.1, states that

> Medical devices may be covered when medically necessary, appropriate, the standard of care, and not otherwise excluded. Medical devices must be FDA approved or of a type not requiring pre-market approval by the FDA. Coverage of any such device is subject to all other requirements of the law, rules, and policy governing TRICARE.



This policy covers all beneficiary categories.

Beneficiaries are encouraged to work closely with their primary care manager or specialty care provider and their regional Managed Care Support Contractor to ensure all applicable TRICARE policies and FDA requirements are met prior to undergoing treatment. This can prevent later reimbursement issues such as denials or delays in payment of submitted claims.

If a beneficiary receives a percutaneous OI implant, either through a MHS research protocol or outside of the MHS within a research protocol, the beneficiary may receive follow-on care and treatment at a MHS medical facility if eligible for MHS care.

PROSTHESIS FITTING

The scope of practice for certified prosthetists encompasses the fabrication and fitting of prosthetic limbs for persons with amputation. At the present time, there is no specific training or certification required for the fitting and alignment of external prosthetic components that are connected to a percutaneous OI implant.

Fitting and alignment of the externally located prosthetic limb components requires special considerations when there is direct skeletal attachment of these components through use of a

percutaneous OI implant. Such fitting and alignment is within the scope of practice for certified prosthetists working in the MHS. MHS clinicians are encouraged to work closely with research personnel when caring for a Veteran or Active Duty member who has undergone an OI implant procedure under a research protocol, either within or outside of the MHS.

- Clinicians should follow any prosthetic component fitting and alignment restrictions as recommended by the surgical care team regardless of whether the beneficiary has received the implant from within or outside of the United States. Any fitting and alignment recommendations that cannot be met should be discussed with the surgical care team.

- If a beneficiary has received an OI implant within a research protocol (either within or outside of the United States), MHS clinicians are encouraged to communicate and coordinate care with the research team prior to the initial prosthetic fitting or when component or alignment changes are required.

- Any concerns with the residual limb at the skin-implant interface should be directed to the appropriate treating surgeon or research team and, if appropriate, consultation with other medical professionals is recommended.

- In general, prosthetic knee and prosthetic foot/ankle components that are capable of generating internal power have not been tested or approved for use in conjunction with OI implants. As previously noted, MHS recommends that when fitting externally located prosthetic limb components to an OI implant, the provider refers to the implant manufacturers labeling to determine if certain externally located prosthetic limb components should or should not be used with the implant.

REHABILITATION SERVICES

Presently, there is no specific training or certification that is required for rehabilitation professionals who are providing care for beneficiaries following an OI procedure. Such rehabilitation providers should follow the same aforementioned guidance in directing any questions or concerns regarding treatment to the treating surgeon or research team. Rehabilitation professionals should adhere to any range-of-motion or weight-bearing restrictions, per instructions from the treating surgeon or research team. Rehabilitation professionals should otherwise provide treatment to beneficiaries with OI implants within their currently established scope of practice and obtain consultation from other medical or surgical professionals for issues outside of their scope of practice.

INQUIRIES

Information contained in the document will continue to be updated on a regular basis. Questions regarding the clinical aspects of osseointegration may be directed to Andrea Crunkhorn, DPT; Chief, Clinical Programs, Extremity Trauma and Amputation Center of Excellence (EACE), at 703-681-4262 or andrea.e.crunkhorn.civ@mail.mil.

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