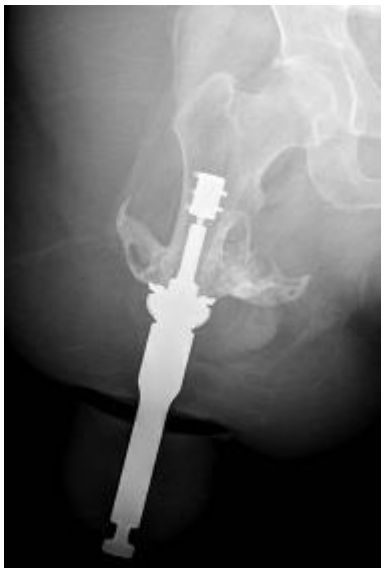
OSSEOINTEGRATION (OI) FOR DIRECT SKELETAL ATTACHMENT OF PROSTHETIC LIMBS IN BENEFICIARIES WITH AMPUTATIONS

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 Wounded Warriors with major limb amputation who have difficulty with traditional prosthetic socket use. The U.S. Army Medical Research and Material Command (MRMC) is currently supporting research efforts for OI interventions for individuals with upper and lower limb amputation. There is an active OI study at Walter Reed National Military Medical Center (WRNMMC), in partnership with the Uniformed Services University of the Health Sciences (USUHS), 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 "osseo-proprioception" 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

Several different types of percutaneous OI implants are currently being used for the direct skeletal attachment of prosthetic limbs in the United States, either under Institutional Review Board (IRB) approved research protocols through Food and Drug Administration (FDA) approved Humanitarian Device Exemptions, or as custom implants. There are also OI implants in use outside of the United States such as the Orthodynamics Integral Leg Prosthesis (ILP) and the Osseointegrated Prosthetic Limb (OPL), which have not been approved by the FDA for implantation within the United States. Custom implants are designed to be used in unique individual cases on a "one-time" basis when other options are not possible.

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 has received FDA approval through the Humanitarian

Device Exemptions pathway for use in a limited number of adults with transfemoral level amputations. Currently, no percutaneous OI implant has received full FDA premarket medical device approval and classification.

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

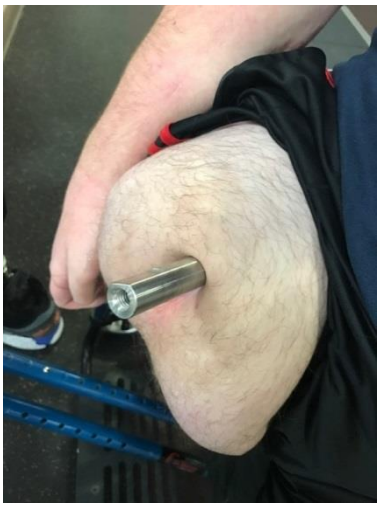
The MHS currently supports an IRB approved FDA early feasibility research study for upper limb (transhumeral) osseointegration that is being conducted at WRNMMC, Bethesda, Maryland. Beneficiaries who meet inclusion and exclusion criteria for this study, both Active Duty and Veterans, are eligible to enroll in this research protocol under standard research recruitment and participation regulations. 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.

HUMANITARIAN DEVICE EXEMPTIONS

The MHS currently supports Food and Drug Administration (FDA) approved Humanitarian Device Exemptions as well as custom implants for lower extremity amputation using the Integrum OPRA Implant System.

BENEFICIARY ACCESS

Presently, OI is not a generally accepted standard of medical practice within the United States where use of these implants for the direct skeletal attachment of prosthetic limbs is still considered experimental. Consequently, OI is not a covered TRICARE benefit. Coverage for the procedure is not included in the care and services provided within MHS outside of research being conducted at participating military treatment facilities, currently limited to WRNMMC. Although TRICARE does not reimburse for this procedure, active duty members may apply for a waiver under the Supplemental Health Care Program process.



If a beneficiary receives a percutaneous OI implant, either through a MHS research protocol or independently outside of the MHS (either within or outside of 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. M H S 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 research team. Any fitting and alignment recommendations that cannot be met should be discussed with the research team.

- If a beneficiary has received an OI implant outside of a research protocol (either within or outside of the United States), MHS clinicians are encouraged to communicate and coordinate care with the treating surgeon 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 research team or treating surgeon 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 research team or treating surgeon. Rehabilitation professionals should adhere to any range-of-motion or weight-bearing restrictions, per instructions from the research team or treating surgeon. 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 Chief, Clinical Programs, Extremity Trauma and Amputation Center of Excellence, at 703-681-4262 or usarmy.ncr.hqda-otsg.list.eace-clinical-affairs@mail.mil.

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ACKNOWLEDGEMENT

The MHS would like to give special thanks to the Veterans Administration for their generous sharing of their references and Fact Sheet for the development of the MHS OI Fact Sheet