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

This Veterans Health Administration (VHA) Fact Sheet provides information on osseointegration (OI) and the use of this procedure for the direct skeletal attachment of prosthetic limbs in Veterans with amputations. This is a rapidly evolving field and the Department of Veterans Affairs (VA) currently supports an approved, Food and Drug Administration (FDA) early feasibility research study that is currently being conducted at the George E. Wahlen VA Medical Center in Salt Lake City, Utah.

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 socket suspension techniques, direct skeletal attachment of a prosthetic limb through OI offers many potential advantages including improved mechanical transfer of motion, reduced skin irritation from a prosthetic socket, improved joint range-of-motion, heightened osseo-perception, and enhanced comfort. However, OI also presents the possibility of serious risks such as infection, failure at the bone-implant interface, or skeletal fracture, and requires a longer period of post-operative recovery and rehabilitation compared to traditional amputation rehabilitation.

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 Osseointegrated Prosthetic Limb (OPL) that 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). Since no OI implants have received fully approved medical device status by the FDA, 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. VHA recommends 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 VA currently supports an IRB approved, FDA early feasibility research study that is being conducted at the George E. Wahlen VA Medical Center in Salt Lake City, Utah. Veterans who meet inclusion and exclusion criteria for this study are eligible to enroll in this research protocol under standard research recruitment and participation regulations. Veterans are also eligible to participate in research protocols being conducted outside of VA, although the Department provides no financial support for Veterans participating in such outside research.

VETERAN 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, coverage for the procedure is not included in the care and services provided under the VA Medical Benefits Package (see Title 38 Code of Federal Regulations (CFR) 17.38).

If a Veteran receives a percutaneous OI implant, either through a VA research protocol or independently outside of the VA (either within or outside of a research protocol), the Veteran may receive follow-on care and treatment at a VA medical facility if eligible for VA care (see VHA Handbook 1601A.02, Eligibility Determination).

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, although this is still considered within the scope of practice for certified prosthetists working in the VA. VA clinicians are encouraged to work closely with research personnel when caring for a Veteran who has undergone an OI implant procedure under a research protocol, either within or outside of the VA.
• Clinicians should follow any prosthetic component fitting and alignment restrictions as recommended by the research team. Any fitting and alignment regulations that cannot be met should be discussed with the research team.

• If a Veteran has received an OI implant outside of a research protocol (either within or outside of the United States), VA 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, VHA 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 Veterans 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 as per instructions from the research team or treating surgeon. Rehabilitation professionals should otherwise provide treatment to Veterans 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 Joseph B. Webster, M.D.; National Medical Director for the VHA Amputation System of Care at 804-675-5648 or joseph.webster@va.gov.
Questions regarding eligibility, enrollment, and reimbursement for services may be referred to VHA Chief Business Office (10NB) at 202-461-1589.

REFERENCES


