Published in final edited form as:

Technol Innov. 2016 September ; 18(2-3): 211–216. doi:10.21300/18.2-3.2016.211.

RADIOGRAPHIC ASSESSMENT OF EXTREMITY OSSEOINTEGRATION FOR THE AMPUTEE

Munjed Al Muderis^{1,2,3}, Belinda A. Bosley³, Anthony V. Florschutz⁴, Paul A. Lunseth⁴, Tyler D. Klenow⁵, M. Jason Highsmith^{6,7,8}, and Jason T. Kahle^{9,10}

¹The Australian School of Advanced Medicine, Macquarie University, Macquarie, Australia

²School of Medicine, University of Notre Dame Australia, Auburn, Australia

³Norwest Private Hospital, Bella Vista, Australia

⁴BayCare Medical Group, Tampa, FL, USA

⁵Prosthetics and Sensory Aids Service, James A. Haley Veterans' Hospital, Tampa, FL, USA

⁶School of Physical Therapy & Rehabilitation Sciences, University of South Florida, Tampa, FL, USA

⁷Extremity Trauma & Amputation Center of Excellence (EACE), U.S. Department of Veterans Affairs, Tampa, FL, USA

⁸319th Minimal Care Detachment, U.S. Army Reserves, Pinellas Park, FL, USA

⁹OP Solutions, Tampa, FL, USA

¹⁰Prosthetic Design + Research, Tampa, FL, USA

Abstract

Osseointegration (OI) is a bone-anchoring procedure that allows the direct skeletal attachment of a prosthesis through the use of an implant. Transcutaneous OI implants are similar to subcutaneous intramedullary joint implants with some exceptions. Particularly, OI implants are inserted at the distal aspect of the femur, while intramedullary implants are inserted at the proximal aspect of the femur. In this report, an additional adaptation of the radiographic zonal analysis used for intramedullary implants, known as Gruen zones, is introduced to include OI implants of extremity prosthetics. Radiographic zonal analyses and interpretations are proposed. Gruen zones are used for intramedullary implants, which are generally inserted from the proximal aspect of the bone. OI extremity implants are inserted from the distal end of the bone. Therefore, the zonal analysis is inverted. A radiographic zonal analysis has been introduced by the Osseointegration Group of Australia (OGA). This analysis is needed specifically for the clinical evaluation of extremity OI, as significant changes to the bone and OI implant have been reported and need to be clinically described. A classification technique is necessary for establishing treatment guidelines for the

Address correspondence to: Jason T. Kahle, OP Solutions, 12206 Bruce B. Downs Blvd., Tampa, FL 33612, USA. Tel: +1 (813) 971-1100; Fax: +1 (813) 971-9300; Jason@opsolutions.us.

Authors declare no conflicts of interest.

extremity osseointegrated implant. The OGA Zonal analysis addresses this need by adapting a common reference standard to osseointegration of the extremity amputee.

Keywords

Amputation surgery; Implant; Interface; Socket; Prosthesis; Transfemoral amputation

INTRODUCTION

The current standard of care for a person living with limb loss who uses an artificial limb is a socket attached to the prosthetic limb components. Examples of prosthetic components for the lower extremity amputee would be the knee, foot, and pylon, and, for the upper extremity amputee, they would be the elbow and hand. The prosthetic socket interface is the aspect of the prosthesis that attaches the components to the residual limb, or the remaining part of the amputated arm or leg. The socket interface has two primary functions: 1) to suspend the prosthesis to the human body during periods of unweighting and 2) to support the body weight of user during periods of weight bearing (1). A socket interface is designed to support the weight through the sidewalls, as walking on the distal end would cause excessive pain and discomfort. To achieve this and give the user control, the socket interface must be tightly fit and must enclose the majority of the residual limb. This can be uncomfortable, evidenced by more than 30% of lower extremity users noting problems with their socket interfaces, including skin breakdown, excessive heat and subsequent perspiration, limited range of motion, interference with urogenital function, quality of life, and function (2,3). Socket interface problems lead to more than 30 percent of amputees reducing their prosthetic use and having diminished quality of life and some choosing not to wear a prosthesis at all (4,5).

Osseointegration (OI) is a bone-anchoring procedure that allows direct skeletal attachment of a prosthesis through the use of an implant (6–8). Increasing in popularity, OI is now used routinely in maxillofacial prosthetics and dentistry and, more recently, is gaining support for use in attaching lower and upper extremity prosthetics. In an extremity OI, the implant is an intramedullary attachment similar to a total hip arthroplasty (THA) or hip joint replacement. Extremity OI is transcutaneous, whereas other joint replacements are contained beneath the skin and underlying soft anatomy (subcutaneous) (6,7). Modern intramedullary joints report high rates of success (9); however, when first introduced, failure rates were near 20% (10,11). There are several techniques to subcutaneous intramedullary joint replacement, and all techniques do not perform equally. Additionally, there are several types of failures that can occur. Because of the popularity of joint replacement and the prevalence of failure at the time, Gruen et al. reported on the modes of failure and a technique to radiographically identify the area, or zone, of failure (10,12). The stability of the joint replacement is graded using this zonal analysis, or Gruen zones. Gruen zones and modes of failure are the standard for evaluating the condition of a subcutaneous intramedullary joint replacement (Figure 1).

OI for the extremity amputee is only offered in a limited number of countries. In those countries, however, OI is beginning to gain popularity similar to the way subcutaneous joint

replacement did nearly 50 years ago, and a protocol for zonal analysis must be similarly implemented. Recently, OI for the extremity amputee cleared Food and Drug Administration (FDA) approval with an Investigational Device Exemption for limited inclusion criteria in the U.S. Given the high incidence of amputees with socket interface problems, it is likely that OI for the extremity amputee will garner a significant patient population seeking solutions, similar to those with pain associated with joints over 50 years ago. As with joint replacement, there are many OI techniques. Different modes and types of failures associated with these techniques have been reported and can be anticipated as these techniques are studied over time. A system for radiographically analyzing transcutaneous extremity OI, similar to a traditional intramedullary implant, would be beneficial for future analysis of OI extremity implants. Therefore, the purpose of this report is to introduce a radiological zonal analysis for the use of the extremity OI transcutaneous implants.

METHODS

While Gruen et al. originally reported on using an analysis for intramedullary implants, there is precedence for modifying the protocol (10). In a later report, Gruen et al. changed the seven zones to include uncemented stems with porous coatings. Ten years after the original report, Johnston et al. described a more comprehensive approach to include extensive clinical parameters, such as demographics, pain levels, and activities of daily living. Additionally, they expanded the radiographic approach to include sagittal (M/L) zonal analysis, adding Zones 8 to 14. Further, an algorithmic scoring system was added to provide an overall rating (12). Amstutz et al. also added three zones to include the short metaphyseal stem of a metal hip joint (13). Ultimately, Santori and Santori modified this approach to five zones for the proximal-loading short femoral stem (14).

In this report, an additional adaptation of the Gruen zones technique is introduced to include OI implants of extremity prosthetics. Gruen zones are used for intramedullary implants, which are generally inserted from the proximal aspect of the bone. OI extremity implants are inserted from the distal end of the bone. Therefore, the zonal analysis is inverted. This extremity OI zonal analysis technique, first reported by the Osseointegration Group of Australia (OGA) as the OGA Zones, would simply invert the zones to properly correspond with the aspects to the uncemented portion of the implant (9,15). Adaptation is necessary to transpose the spatial terms because extremity OI terminates proximal into the bone, whereas the traditional implant terminates distal into the bone. Therefore, to stay consistent with using Zones 1 and 7 to describe the coated area, where the implant exits the bone, the zones must be inverted.

ZONES

Gruen originally divided the femur into seven zones using the coronal (A/P) radiograph view (Figure 2a). While Johnston et al. added the sagittal (ML) view zones, OGA Zones are divided into seven zones and radiographically measured on the coronal (A/P) view only. These include three equally divided zones on each side of the radiograph and a zone (Zone 4) at the proximal aspect of the implant (Figure 1). Zone 1 is the most distolateral aspect of the bone implant interface opposite to Zone 7, which is the most vital, on the medial aspect

on the radiograph. Zone 2 is mid-lateral portion opposite to zone 6 medially, and Zone 3 is at the lateral proximal aspect of the implant bone interface opposite to Zone 5 medially (Figure 2).

IMPLANT DESIGN CHANGES AND THE EFFECT ON BONE

The initial design of the Integral Leg Prosthesis (ILP; Orthodynamic GmbH, Lübeck, Germany) was made from a Chrome cobalt alloy with a surface coating having a spongy metal macroporous structure of 300 to 1500 μm in pore diameter with titanium coating (press fit cementless implant; Figure 3). The area of the implant that has this macroporous structure covers most of the implant with the exception of the distal 1.5 cm at Zones 1 and 7 and at the proximal portion of the implant at Zone 4, where the surface is smooth. The observation first reported by OGA was that the cortical bone remodels over time and follow-up radiographs demonstrate bone resorption at the area where the implant portion is smooth (Zones 1 and 7), with the resorption stopping at the beginning of the spongy metal structure (Figures 2a and 2b). Conversely, the area of Zones 3 and 5 shows significant cortical bone thickening. These observations led to fundamental changes in the implant design of the Osseointegrated Prosthetic Limb (OPL; Permedica s.p.a, Milan, Italy) (Figure 3). First, the material was changed to titanium, which has a modulus of elasticity closer to bone of 110 GPa (bone modulus of elasticity is 17 GPa), while chrome cobalt alloy modulus of elasticity is 190 GPa. Second, the implant shape was changed, making a proximal 80 mm smooth surface with multiple longitudinal sharp splines of 1 mm high to cut through the cortical bone during implantation to provide initial rotational stability. Third, the distal 80 mm of the implant is fully coated with microporous plasma spray particles to provide potential bony ingrowth and has a similar collar to the ILP to provide initial axial stability against subsidence. The design changes have led to recent observations of distal stress shielding and proximal cortical bone thickening over time (Figures 2c and 2d) (9,15).

DISCUSSION

Clinical trials of OI have not yet been extensively reported. OI for the extremity amputee is relatively early in the cycle of product, procedure, and technique development. Currently it is only offered in a few countries and has only recently been introduced in the U.S. There is an opportunity for amputees to potentially benefit from this technology. However, potential side effects must also be understood. As the health care community observes changes and results of OI use, the evolution of OI implant design and technique can progress. Bone resorption, growth, and problems may be associated with the extremity OI at different locations than traditional intramedullary implants. Muderis et al. first reported these changes using the OGA Zonal analysis and has noted changes particularly in the distal aspects of the implant, or Zones 1 and 7 (9,15). Implementation of the OGA Zones allows determination of location of radiographic changes, such as resorption, overgrowth, extremity OI implant changes, description, and consistency in clinical reporting. The OGA Zonal analysis will allow a practitioner to accurately track changes that occur over a timeframe to allow evidence-based decision making regarding OI extremity implants.

CONCLUSION

Radiographic zonal analysis is used in orthopedic intramedullary implant evaluation to clinically assess the location of changes as a result of the implant. OI using an intramedullary implant for the extremity amputee may yield similar changes. A classification technique is necessary for establishing treatment guidelines. The OGA Zonal analysis addresses this need by adapting a common reference standard to OI of the extremity amputee.

Acknowledgments

Contents of this manuscript represent the opinions of the authors and not necessarily those of the U.S. Department of Defense, U.S. Department of the Army, U.S. Department of Veterans Affairs, or any academic or health care institution. This project was partially supported by the National Institutes of Health Scholars in Patient Oriented Research (SPOR) grant (1K30RR22270).

REFERENCES

1. Smith, DG.; Bowker, J.; Michael, J., editors. Atlas of amputations and limb deficiencies: surgical, prosthetic and rehabilitation principles. 3rd. Rosemont (IL): American Academy of Orthopaedic Surgeons; 2004.
2. Kahle JT, Highsmith MJ. Transfemoral sockets with vacuum-assisted suspension comparison of hip kinematics, socket position, contact pressure, and preference: ischial containment versus brimless. *J Rehabil Res Dev*. 2013; 50:1241–1252. [PubMed: 24458964]
3. Kahle JT, Highsmith MJ. Transfemoral interfaces with vacuum assisted suspension comparison of gait, balance, and subjective analysis: ischial containment versus brimless. *Gait Posture*. 2014; 40:315–320. [PubMed: 24852508]
4. Dillingham TR, Pezzin LE, MacKenzie EJ, Burgess AR. Use and satisfaction with prosthetic devices among persons with trauma-related amputations: a long-term outcome study. *Am J Phys Med Rehabil*. 2001; 80:563–571.
5. Lyon CC, Kulkarni J, Zimerson E, Van Ross E, Beck MH. Skin disorders in amputees. *J Am Acad Dermatol*. 2000; 42:501–507. [PubMed: 10688725]
6. Branemark R, Berlin O, Hagberg K, Bergh P, Gunterberg B, Rydevik B. A novel osseointegrated percutaneous prosthetic system for the treatment of patients with transfemoral amputation: a prospective study of 51 patients. *Bone Joint J*. 2014; 96-B:106–113. [PubMed: 24395320]
7. Branemark R, Branemark PI, Rydevik B, Myers RR. Osseointegration in skeletal reconstruction and rehabilitation: a review. *J Rehabil Res Dev*. 2001; 38:175–181. [PubMed: 11392650]
8. Hagberg K, Branemark R. One hundred patients treated with osseointegrated transfemoral amputation prostheses--rehabilitation perspective. *J Rehabil Res Dev*. 2009; 46:331–344. [PubMed: 19675986]
9. Al Muderis, M.; Bosley, B.; Tungusova, A. Post limb reconstruction strategy for post traumatic amputees (OGAAP-2); Paper presented at: First World Congress on Innovations in Amputation Surgery and Prosthetic Technologies; 2016 May 12–13; Chicago, IL.
10. Gruen TA, McNeice GM, Amstutz HC. "Modes of failure" of cemented stem-type femoral components: a radiographic analysis of loosening. *Clin Orthop Relat Res*. 1979:17–27.
11. Banaszkiewicz, PA.; Kader, DF., editors. Classic papers in orthopaedics. London (UK): Springer-Verlag; 2014.
12. Johnston RC, Fitzgerald RH Jr, Harris WH, Poss R, Muller ME, Sledge CB. Clinical and radiographic evaluation of total hip replacement. A standard system of terminology for reporting results. *J Bone Joint Surg*. 1990; 72:161–168. [PubMed: 2303502]
13. Amstutz HC, Beaule PE, Dorey FJ, Le Duff MJ, Campbell PA, Gruen TA. Metal-on-metal hybrid surface arthroplasty: two to six-year follow-up study. *J Bone Joint Surg*. 2004; 86-A:28–39. [PubMed: 14711942]

14. Santori FS, Santori N. Mid-term results of a custom-made short proximal loading femoral component. *J Bone Joint Surg.* 2010; 92:1231–1237. [PubMed: 20439670]
15. Tetsworth, K.; Al Muderis, M.; Khemka, A.; Wilmot, S.; Bosley, B.; Lord, S.; Glatt, V. The Osseointegration Group of Australia Accelerated Protocol (OGAAP-1) for Two-stage osseointegrated reconstruction of amputees; Paper presented at: First World Congress on Innovations in Amputation Surgery and Prosthetic Technologies; 2016 May 12–13; Chicago, IL.

Figure 1.

Gruen zones compared to OGA Zones. The zones are simply inverted to properly place the exit of the OI extremity implant from the bone distal.

Figure 2.

Two separate subjects with an ILP OI implant with distal bone resorption of the femur in Zones 1 and 7 (a and b); Two separate subjects with an OPL OI implant with distal cortical bone thickening in Zones 1 and 7 (c and d).

Figure 3. Design changes in the OPL implant (bottom) compared to the IPL (top): 1) Titanium material, 2) proximal 80 mm smooth surface with multiple longitudinal sharp splines of 1 mm high to cut through the cortical bone, and 3) distal 80 mm of the implant is fully coated with microporous plasma spray particles.