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Design features of implants for direct skeletal attachment of limb prostheses

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Abstract

In direct skeletal attachment (DSA) of limb prostheses, a construct is implanted into an amputee's residuum bone and protrudes out of the residuum's skin. This technology represents an alternative to traditional suspension of prostheses via various socket systems, with clear indications when the sockets cannot be properly fitted. Contemporary DSA was invented in the 1990s, and several implant systems have been introduced since then. The current review is intended to compare the design features of implants for DSA whose use in humans or in animal studies has been reported in the literature.

Keywords

design features; implants; direct skeletal attachment; osseointegration; limb prostheses

INTRODUCTION

A method of direct skeletal attachment (DSA) of the limb prosthesis is a way of improving quality of life for amputees, who could not be treated adequately with the socket suspension of their prostheses.^{1–4} Short residuum, skin and soft tissue problems, phantom pain could result in rejecting the use of prosthesis and relying on aids (e.g., crutches and wheelchair).^{5–8}

The principles of direct and permanent attachment of artificial limbs were formulated in the 1970s, after which the topic became a subject of research and development^{4,9,10} (Fig. 1).

Fernie et al.¹¹ tested a percutaneous implant in 14 pigs. The intramedullary metal stem was porous-surface layered, and Dacron velour was used at the soft tissue interface. The authors reported that some adhesion of bone cells to the porous stem was achieved, but the velour was unable to maintain adequate epithelial adhesion to form an anatomical seal and a barrier to bacteria.

The first skeletal prosthesis attachment unit for application in humans was developed and tested in three patients—above-knee and above-elbow amputees—at Rancho Los Amigos Hospital (RLAH, Downey, CA).¹² The device had a stainless steel shaft for intramedullary implantation and a subcutaneous collar made of unpolished carbon [Fig. 2(A)]. The implant was cemented with methylmethacrylate to the intramedullary canal of the bone in the amputee's stump and then passed through the skin [Fig. 2(B)]. Suspension of the prosthesis

was made possible with a quick disconnect device that locks into the shaft of the implant. It was reported that all implants had to be removed within 6 months postimplantation due to chronic infection aggravated by mechanical irritation. A main catalyst of infection was assumed to be the relative motion between skin and the device.

The design features of the RLAH system are summarized in Table I. The most practical ones have been replicated in contemporary systems (see Table I). The RLAH system could not be successful because there was no bond between the stainless steel shaft and the bone. The required bond probably could have been achieved if the RLAH shaft had been made of titanium, whose “osseointegration” capacity was already reported by Dr. Per-Ingvar Branemark in 1959.¹³ He discovered that chambers made of titanium could be permanently incorporated (osseointegrated) into bone. Indeed, study¹⁴ found very close apposition of the bone to the titanium implant’s surface—50 Å—and tissue was found to respond to the tightly adherent titanium oxide layer on the surface of the implant similarly as to a ceramic material.

The first contemporary system for DSA, called Osseointegrated Prostheses for the Rehabilitation of Amputees (OPRA), was introduced by Dr. Branemark himself in the 1990s¹⁵ following his experience in using titanium in dental implants.^{16–19}

The success of the DSA technology generically rests on the long-lasting integrity of the interface of human tissues with a nonbiological implant.^{4,12,20,21} In contrast with freely suspended subcutaneous implants like pace makers, DSA implants must transmit high loads and moments to the bone^{22–24} and deal with infections at the skin-device barrier.^{25–28}

In addition to the challenges faced by DSA in skeletal fixation and transcutaneous interface, there are also issues of occasional infections²⁹ and breakage of fixation components.^{24,30} To protect the integrity of the hosting bone in case of falls, different clutching systems have been considered to disintegrate the prosthesis from the residuum when the loads and moments exceed the safety threshold.^{31–33} The skin seal issue is illustrated in Figure 3(A), showing a pus layer (c) around the abutment (a) penetrating the skin stoma (b) of the residuum.³⁴

The bone-device interface, even if there were no problems with infection, may be associated with the thinning of the cortical bone, as illustrated in Figure 3(B) from Ref. 35. The study found that 2 years after DSA procedure, 35% of patients experienced cortical thinning in the distal zones. That percentage increased to 55% by 5 years after the procedure.

Over 150 patients in Sweden, Germany, the Netherlands, and Australia have been operated on with DSA.^{36–39} Analysis of an in-depth interview with patients living with osseointegrated prostheses^{40–42} showed that participants described living with an osseointegrated prosthesis as a revolutionary change. The change went beyond the objectively confirmed functional improvements,^{43,44} but also impacted the broad concept of quality of life.^{43–48}

Among the advantages of the method of DSA is how easy it is to attach the prosthesis when compared to the frequent difficulties from donning and doffing the socket.⁴⁹ Since the prosthesis is not supported over the skin, all skin and soft tissue issues related to sockets are eliminated. Due to fusion of the prosthesis with the residual bone, the DSA allows also for more natural osseoperception, which is an important factor for functionality and safety^{35,41,50} for patients with upper-limb amputations as well.^{51,52}

Amputees who use conventional sockets are aware of both the advantages and disadvantages of DSA, and are influenced by them. In a survey,⁵³ 33% of respondents with above knee

amputation stated that they would consider undergoing the osseointegration procedure for prosthetic attachment. Forty-two percent of the participants responded that they would not consider having the procedure due to potential infection, implant failure, long rehabilitation course, and risk of a broken bone in the residual limb.

The DSA procedure is still not allowed by the Food and Drug Administration in the United States, even though there are a substantial number of amputees, including US Veterans, who would benefit and whose quality of life would improve from DSA. The agency requires a compelling response to the issues of skin seal and bone interface viability. After the first skeletal prosthesis attachment unit had been tested at Rancho Los Amigos¹² several implant systems have been introduced in attempts to address the challenges of DSA.

In this article, we will present the design features of the systems whose use in humans or in animal trials was reported in the literature known to the author.

METHODS

In selecting which DSA implantation systems to review, we restrict ourselves to those which have already demonstrated their practicality by their application in human subjects/ patients or in animal studies. References are made to the published reports and to the patent information related to the systems selected. Keywords associated with DSA of limb prostheses were used to search the literature available on PubMed, ScienceDirect, Web of Science, and Google Scholar databases.

Eight systems were selected for further analysis according to the selection criteria (see Table I). One of them [Skin and Bone Integrated Pylon (SBIP)] was developed by the author. For this reason, it was considered not to be ethical to range the systems in terms of their effectiveness. We also do not critically compare the systems' design features, because some of them, as with the RLAH system with the reported failure, were given a "second life," with new features, in the current designs. Thus, we leave to the reader to make his/her own judgement after reviewing the references and the features of the selected systems presented in this article.

Implant systems for DSA

We will consider the features of seven implant systems for DSA:

- RLAH system¹²;
- OPRA (Integrum AB, Sweden, <http://www.integrum.se>)⁵⁴;
- Endo-exo femoral prosthesis (EEFP), ESKA Orthodynamics GmbH (www.orthodynamics.de), formerly ESKA IMPLANTS AG, Lubeck, Germany³⁷;
- Intraosseous transcutaneous amputation prosthesis (ITAP), Stanmore group (University College, London, UK)⁵⁵;
- Percutaneous osseointegrated prostheses (POP), IMDS Co-Innovative, Logan, UT (<http://www.imds.net>)⁵⁶;
- SBIP, Poly-Orth International, Sharon, MA³⁴;
- The Alameda East Animal Hospital & BioMedtrix (AEAHBM) system, the Alameda East Animal Hospital, Denver, CO; the BioMedtrix, Boonton NJ; and the Colorado Limb Consultants, Denver Clinic for Extremities at Risk, Denver, CO.⁵⁷
- The University of Akron (UA) system, The University of Akron, Akron, OH.⁵⁸

Summarized in Table I is the following information about the selected systems: in human patients or in animals only; structure of the surgery: one-stage or two-stage, materials, and some other design features.

As is presented the Table I, only four systems: RLAH, OPRA, EEFP, and ITAP have been applied to human patients. The POP, SBIP, and UA systems are currently being used in the preclinical studies.

OPRA system

Schematics of the design used in OPRA technology is depicted in Figure 4. The *fixture* is a threaded cylinder which is screwed into the marrow canal of the residuum bone.⁵⁹ The *abutment* is a construct which is coupled with the fixture at the second stage of implantation 6 months after implanting the fixture (see Table I). The abutment penetrates the residuum skin, and its outer part, capped by the *abutment screw*, is used for attaching the leg prosthesis.³⁹ The threads on the fixture increase the mechanical stability of the bone-device bond, and also increase the implant surface; such a threaded implant was originally used in dental implantation.⁶⁰

The OPRA is a system with continuously developing components for better device-bone connection.^{19,61,62} The system have been applied to more than 100 patients in Sweden³⁹ and to 10 patients in Australia.³⁸

The functionality of the OPRA system was confirmed in follow up gait studies.^{41,63} However, the risk of skin infection and bone thinning remain unresolved issues for the OPRA system.^{35,64}

The OPRA approach influenced the development of bone-anchored hearing aids which implant a titanium threaded fixture into the skull.^{65,66}

EEFP system

Application of the EEFP system was reported in 54 patients in Germany³⁷ and 24 patients in the Netherlands.³⁶ Similar to OPRA, the EEFP system follows a two-stage approach^{46,67,68} (see Table I). The intramedullar component is press fit, rather than screwed into the bone canal as in the OPRA technology (Fig. 5). The EEFP is a cobalt–chrome alloy device covered with spongiosa metal which creates a deep porous surface and favorable modulus for bone formation. The polished coupler exits distally through the skin for attachment of limb prosthesis.

In the first operation, the femoral stem is implanted and the residuum is closed up again. In the following 4–6–8 weeks, a circular skin opening (stoma) is created. The dual cone adapter is connected to the internal femur stem through this exit hole (stoma). The silicone cover is used to protect the stoma.

The skin and soft tissues in the area where the coupler exits the stoma require constant careful care to deal with infection. Infection in the stoma region was observed in 14 of the 37 patients who underwent minor revisions because of problems around the stoma, with twelve of the 14 electing to exchange the coupler as a result of soft-tissue problems or irritation.⁴⁶ It has been reported that the initially high rate of stoma-associated infections of the soft tissue coat could be dramatically reduced through a change of design of the skin-penetrating parts, such as using smoothly polished couplers instead of rough textured couplers.⁴⁶

The special feature of the implant is the Spongiosa-Metal® II porous surface. Bone grows through this three-dimensional grid structure, providing secure fixation of the prosthesis.

ITAP system

The ITAP system: <http://www.itap-prosthetics.com/> was designed for a one-step implantation procedure (see Table I).^{69,70} It was reported to be applied to one transhumeral amputee,⁷¹ to the human thumb and index finger in one human patient and to four dogs⁷². The approach for the system design is rooted in analysis of special biological structures such as horns, hair, feathers, fingernails, hooves, teeth, and antlers as examples where nature has solved the problems of percutaneous devices.^{73,74} As a result, the ITAP system emulates antlers: a flange caps the residuum, and is perforated by twenty-four 0.7 mm holes are bored immediately below the epithelium to increase dermal attachment.⁵⁵

The ITAP flange (see Fig. 6) is the system's key feature. It serves as a mediator for the bone and skin to integrate, and creates a stable interface among the implant, the bone, and the soft tissues.⁷¹ Interestingly, the ITAP flange resembles the flange in the RLAH system, except the latter was made of carbon (see Fig. 1).

Studies were conducted that demonstrated improved fibroblast adhesion to the silanized fibronectin (SiFn) titanium alloy, and on fibronectin adsorbed onto hydroxyapatite (HAFn),⁷⁵ suggesting that SiFn and HAFn surfaces could be useful in optimizing the soft tissue seal around ITAP.

POP system

The POP system was developed for a one-stage implantation procedure (see Table I). The design features include a double tempered stem (Fig. 7), which supports at least 3-point fixation along the length of the implant, validating the surgical principle of 3-point fixation for implant survivorship. From the scanned images of the metatarsal II bones of 20 mature sheep carcasses, three implant sizes and surgical broaches, corresponding to the 25th, 50th, and 75th percentiles, were designed (Intelligent Implant Systems, LLC, Charlotte, NC) and fabricated (IMDS Co-Innovative) from medical grade Ti6Al4V titanium alloy.⁵⁶ In a study with 14 sheep, the majority of the implants ($n = 11$) were in contact with the bone walls on at least two sides, which ensured the load transmission from the implant to the bone at the distal surface of the residual bone end.⁵⁶ The device has a porous-coated subcutaneous collar (Fig. 4) intended to achieve skin-implant integration and to prevent periprosthetic infection. Clinical, microbiological, and histopathological data showed that the porous-coated Ti collar prevented superficial and deep tissue infections in all animals (14/14, 100%) at the 9-month endpoint, while animals with the smooth Ti implant construct had a 25% (2/8) infection rate.⁷⁶

SBIP system

The SBIP system was developed by Poly-Orth International in several modifications⁷⁷ both for one-step and two-stage implantation procedure (see Table I). A key feature of the system is the total permeability of the composite structure consisting of porous cladding and an enforcing frame with the holes in the web (Fig. 8). The frame maintains the F8 needed strength, and is selectively perforated to allow for complete ingrowth of bone and soft tissues.⁷⁸ Total porosity distinguishes the SBIP system from other systems, which use porous metal in a limited fashion as a relatively thin layer of coating.¹¹

The system has been applied to rats, rabbits, and cats.^{34,79–85}

A modification without the enforcing frame (SBIP-1) constitutes a totally porous cylinder of cone and was used only for *in vitro* studies^{34,86} due to its low strength.

The SBIP-2 modification is a composite of porous cladding and different enforcing frames like wires and bars with a cross-shaped cross-section (see Fig. 8).⁷⁸

Similar to SBIP-2, the SBIP-3 is also a composite, but includes side elements (fins) that are placed in the precut slots in the cortical bone walls.^{84,87,115}

A modification with a peripheral nerve interface (SBIP-PNI) is a wired device for transcutaneous transmission of electric signals from a residuum's muscle or nerve to an outside receiver for neurocontrol over a powered prosthesis.⁷⁹ The SBIP-PNI is depicted in Figure 9, with a silicon shield (1) for wire electrodes (2) passing through the tube (3) surrounded by porous cladding (4).

A two-stage procedure can be performed with the SBIP-F10 TS kits. As shown in Figure 10, a part to be implanted to the bone can be porous (A) or solid (B), similar to the OPRA system.

AEAHBM system

Two implants were designed, custom fabricated and applied to a dog with bilateral transtibial amputation.⁵⁷ They were composed of a tapered, threaded titanium stem with a preassembled porous tantalum outer 14-mm-diameter sleeve and a 35mm distal segment with a Morse taper fitting (Fig. 11). The tantalum pores were dodecahedral in shape F11 with an average diameter of 500 nm. The tantalum collar was 70–80% porous by volume.

In 14 months, the modified devices were reimplanted due to loosening. Positive outcomes were reported following 27 months after the first procedure.

UA system

The UA system for DSA was evaluated in one Yucatan micropig.⁵⁸ The key feature of the system is a carbon sleeve (ring) threaded over a titanium rod for the device-skin interface (see Table I; Fig. 12). Unlike the carbon flange in the RLAH system¹² (see Fig. 1), the device was incorporated with 99.9% pure silver to induce silver ion release into the amputation site, which is meant to increase the chance of successful, antibacterial interfacing.⁸⁸ Silver wire was wrapped around a vitreous carbon ring and soldered to a 1.5 V battery and a 10 MΩ resistor to release a constant ionic charge of 150 nA.

The authors report the trial's failure 10 weeks following implantation. However, they believe that the Ti6Al4V/ carbon/silver combination should be further investigated.

DISCUSSION

The safety of the skin-device interface constitutes the obvious challenge for a wider acceptance of the method of DSA.^{29,71,89–91} The longevity of the bone-device bond is also an important issue considering the relatively short hosting bone of the residuum and the high loads associated with operating limb prostheses.^{22,24,87,92} An additional concern for longevity of the bone-device bond is that after replacement surgery, the porosity of the cortical bone hosting the femur implant increases compared to the ipsilateral bone, potentially reducing cortical bone strength.^{93,94}

To meet the existing challenges faced by DSA, the development of new designs and methodologies for reducing the associated risks^{95,96} continues. New challenges may arise

with the promising use of the transcutaneous implants for neuromuscular control of the limb prostheses.^{79,97} These systems have an additional vulnerable interface between the tissues and the electrodes implanted to the muscles or nerves.^{98,99,116}

There are reports on positive effects of different chemical, mechanical and biological treatments of the implant surface.^{100–102}

Positive results were reported following treatment of the implant surface with fibronectin,¹⁰³ laminin,¹⁰⁴ and fibroblast growth factor FGF18.¹⁰⁵ Bone morphogenic protein 2 (BMP-2) was suggested to enhance peri-implant osteogenesis in patients whose bone-healing capacity is compromised. That was confirmed in an animal study in which implants had a coating-incorporated depot of BMP-2.¹⁰⁶

The osteoconductive properties of impacted titanium particles with a calcium–phosphate coating were found comparable to impacted allograft bone and impacted biphasic ceramics in a study analyzing the restoration of bone defects in hip arthroplasty.¹⁰⁷ Osseointegration of porous surfaced ceramic implants made of an alumina matrix composite (AMC) was assessed on maximum shear strength and histomorphometric bone ongrowth.¹⁰⁸ Despite the low percentage of bone ingrowth, the AMC test implants demonstrated good mechanical stability due to bone ingrowth into the pores with subsequent interlocking.

Bone tissue response to implantation was investigated in the whole cavity, close to the implant and in its vicinity. Porous titanium coatings, a thickened titanium dioxide layer, amorphous microporous silica and bioactive glass were implanted into the tibia of 20 rabbits.¹⁰⁹ A new finding was that bioactive glass was highly osteogenic, even at some distance from the implant.

It has been shown that the roughness of the metal surface increases cell apposition.¹¹⁰ Microroughened and nanosurface superimposed featured implants improved osteogenesis and the inflammatory/immune responses.^{111–114}

CONCLUSIONS

1. Various implantation systems for DSA of limb prostheses have been developed for clinical and for preclinical applications. These systems possess their specific features and are at different levels of development in terms of number of patients treated worldwide and evidence provided in literature.
2. The high risks associated with DSA could be reduced with specific design features, including means for safer interface of the implanted device with the hosting tissues.

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FIGURE 1.

(A) Apparatus for connecting a prosthesis to a bone—US Patent 3947897;¹⁰ (B) permanently attached artificial limb—US Patent 4143426.⁹

FIGURE 2.

(A) Intramedullary skeletal prosthesis attachment unit; stainless steel shaft with a carbon subcutaneous collar. (B) Skeletal prosthesis attachment unit (A) implanted in leg of amputee at Rancho Los Amigos Hospital (Modified from Ref. 12 with permission from Springer Science + Business Media).

FIGURE 3.

(A) Skin issues in DSA: (a) solid titanium abutment penetrating the residuum skin stoma. Adapted from Ref. 34. (B) Cortical thinning in the distal zones. Adapted from Ref. 35; copyright © 2012, Informa Healthcare. Reproduced with permission from Informa Healthcare. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

FIGURE 4.

Schematics of the design of the device for a two-stage technique of direct skeletal attachment. *Fixture* is a threaded cylinder which is screwed into the marrow canal of the residuum bone. *Abutment* is a construct which is coupled with the fixture at the second stage of implantation several months after implanting the fixture. The abutment penetrates the residuum skin, and its outer part, capped by the *abutment screw*, is used for attaching the leg prosthesis. Adapted from Ref. 39. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

FIGURE 5.

Endo-exo prosthetic system (EEFP). The device is a modular construct with a femoral stem with a porous surface, and a smoothly polished coupler exiting distally through the skin enabling for attachment of a limb prosthesis (Reproduced from Ref. 46 with kind permission from JBJS-A). [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

FIGURE 6.

ITAP system (Adapted from Ref. 71 with kind permission from Elsevier). [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

FIGURE 7.
POP system (Adapted from Ref. 56 with kind permission from Elsevier).

FIGURE 8. Cross section of the pylon with a solid cross-shape insert and the surrounding porous cladding. Dashed lines indicate projections of the holes in the web (Reproduced from Ref. 78 with kind permission from John Wiley and Sons).

FIGURE 9.

(A) SBIP-PNI: silicon shield (1) electrodes, (2) tube, and (3) porous cladding (4). (B) Bone of the residuum (5) with the hole (6) for releasing the electrodes for implanting to a muscle or nerve (Adapted from Ref. 79). [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

FIGURE 10. SBIP-TS kits. (A) A kit with porous in-bone implant; (B) with solid in-bone implant. Dashed line indicates the skin-device line of interface. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

FIGURE 11. AEAHBM system. Yellow lines represent the patient's tibial shaft. Upper arrow identifies the Morse taper fitting. Lower arrow identifies the base of the tantalum metal (Reproduced from Ref. 57 with kind permission from John Wiley and Sons). [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]

FIGURE 12.

The UA system for the skin-interfacing stage. The carbon ring (upper left) (Adapted from Ref. 58; copyright © 2012, Informa Healthcare, with permission from Informa Healthcare).

Implant Systems for Direct Skeletal Attachment and Their Design Features

TABLE I

Systems	Usage		Surgery		Material				Medullary Part				Percutaneous Part					Provision For Cable Passage	Coated
	In Humans	In Animals	One-Stage	Two-Stage	Stainless Steel	Carbon	Titanium Alloy Ti6Al4V	Cobalt-Chrome Alloy	Tantalum	Cylindrical	Conical	Double Tempered	Permeable	Elastic Sleeve	Polished	Porous Surface	Permeable		
RLAH	X		X		X	X					X							X	
OPRA	X	X		X			X			X					X				
EEFP	X	X		X				X		X					X				
ITAP	X	X		X			X			X						X		X	X
POP		X	X				X					X		X		X			
SBIP		X	X	X			X			X	X		X				X		X
AEAHBM		X	X						X		X								
UA				X		X	X												