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REVIEW ARTICLE

Osseointegrated Metallic Implants for Finger Amputees: A Review of the Literature

Chiara Bregoli, MSc¹, Carlo Alberto Biffi, PhD¹, Kavin Morellato, MSc², Emanuele Gruppioni, PhD², Matteo Primavera, MD³, Michele Rampoldi, MD³, Mario Lando, MD⁴, Roberto Adani, MD⁴, Ausonio Tuissi, MSc¹

¹Unit of Lecco, CNR ICMATE, National Research Council, Lecco, ²INAIL Centro Protesi, Bologna, ³Hand and Reconstructive Surgery Unit, Centro Traumatologico Ortopedico A. Alesini, Rome and ⁴Department of Hand surgery and Microsurgery, University Hospital of Modena, Modena, Italy

Abstract

Digital trauma amputations and digital agenesis strongly affect the functionality and aesthetic appearance of the hand. Autologous reconstruction is the gold standard of treatment. Unfortunately, microsurgical options and transplantation procedures are not possible for patients who present contraindications or refuse to undergo transplantation from the toe (e.g. toe-to-thumb transplantation). To address these issues, osseointegrated finger prostheses are a promising alternative. The functional assessments registered during follow-up confirmed the promising outcomes of osseointegrated prostheses in the treatment of hand finger amputees. This review outlines (a) a detailed analysis of osseointegrated finger metallic components of the implants, (b) the surgical procedures suggested in the literature, and (c) the functional assessments and promising outcomes that demonstrate the potential of these medical osseointegrated devices in the treatment of finger amputees.

Key words: bone screw; digital amputation; microsurgery; osseointegrated implant; prosthetic finger; thumb

Introduction

Digital and partial hand amputation is one of the most common injuries affecting the upper extremities.^{1,2} Digital amputations are consequent to traumatic injuries and elective surgery settings, such as in cases of cancer resection and chronic conditions.³

The Global Burden of Disease (GDB) reports the highest overall number of digit amputations in North America and western and eastern Europe and the highest incidence of thumb amputation in Australasia, central and eastern Europe.⁴ Regarding the trend of digits' amputations in Italy, a recent ministerial report⁵ stated that the number of long finger amputations had decreased. In 2018, there were 1039 fewer injuries than in 2008. Similarly, thumb amputations, which annually have an incidence lower than an order of magnitude than the amputations of long fingers, also showed a decreasing trend. In 2018, there were 135 fewer injuries than in 2008.⁵ Despite this decrease, finger amputations constitute about 90% of the total amputations affecting the upper limb,

demonstrating the relevance of research on the treatment of finger amputees. In the United States, from 1997 to 2016, the incidence of finger amputees has been 7.5/100,000 person per year. Children and older adults are at a greater risk of undergoing finger amputations⁶: these amputations cause an impairment that affects the performance of activities and the psychological well-being of people. For instance, the presence of the thumb is paramount for the fulfillment of active hand functions such as lateral pinching, kneading with three fingers, and grasping.^{7,8} Indeed, thumb amputation accounts for 50% of the entire hand function and is estimated to cover 80% of the activity required for holding, while long finger amputations accounts for about 10% of disability.8-10 Although thumb amputation impacts daily activities more negatively than long finger amputation, the current review will refer to all finger amputations.

For any type of injury or level of finger amputation, it is imperative to proceed with re-implantation.¹¹ Surgery aims to reconstruct the amputee finger to restore active

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Address for correspondence Ausonio Tuissi, MSc, CNR ICMATE, National Research Council, Unit of Lecco, Via Previati 1/e, 23900, Lecco, Italy. Email: ausonio.tuissi@cnr.it

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functionality and to preserve the aesthetic aspect of the hand, which has the same importance as its active function.^{7,12}

Autologous reconstruction is the gold standard for the reconstruction of digits. Microsurgery techniques, such as toe-to-thumb transplantation, phalangization of the thumb metacarpal, lengthening procedures, and index pollicization, allow great results with reconstruction and replantation. However, not all patients are eligible due to their clinical conditions, in which case, vacuum prostheses, naked prosthesis, and osseointegrated prostheses are valid alternatives.^{13–15}

Silicone vacuum prostheses are passive devices made of viscoelastic materials inserted on the stump³ and replicate the anatomical morphology of the hand, providing an excellent cosmesis for distal amputations and stump protection.^{2,16,17} Pilley et al.¹⁸ treated 15 patients with silicon digital prostheses, and Pereira et al.7 produced 136 digital prostheses for 90 patients, demonstrating that vacuum-retained prostheses are a cosmetic solution that is easy to use. However, they require a digital stump length greater than 1.5 cm,¹⁹ which may not always be available. Despite recent improvements, instability and low retention, lack of sensibility, excessive sweating, and irritation are frequent drawbacks.^{2,7,20,21} Longterm use of silicone vacuum prostheses has been reported to be between 64% and 97%, which means a non-constant use of external prostheses in a great number of patients.²² Naked prostheses are American commercialized medical devices supposed to restore the amputee's ability to perform daily task and support job retention.¹⁵ The device is an external customized prosthesis worn by the patient: despite the good outcomes reported by the industry, the medical device, being like a glove, may cause irritation, excessive sweating, and low retention.

Retention is a key factor for the success of a finger prosthesis, and it has been strongly improved by the use of osseointegrated prostheses. 16,23

The successful osseointegration principle was introduced by Branemark in the early 1960s.¹⁴ Branemark defined osseointegration as "a direct connection between living bone and a load-carrying endosseous implant at the light microscopic level"²⁴ to guarantee the structural and functional continuity between bone and implant.^{25,26} The first osseointegrated thumb prosthesis was inserted in 1990,²¹ but this procedure started to gain attention only in 1996 when Lundborg¹⁴ first reported a successful clinical study on three thumb-osseointegrated prostheses.

In addition to the improved stability provided by bone fixation, osseointegrated prostheses allow osseoperception,^{10,27} which describes the ability to identify tactile stimuli transmitted through the osseointegrated fixture inserted into the medullary bone canal, which increases the confidence of the patient during daily activities and allows a partial restoration of the finger functionality.

In addition to the aforementioned benefits, osseointegrated prostheses may present infection, implant mobilization, mechanical failure, and eventual osteolysis in the absence of osseointegration.²² To minimize the previous shortcomings, beside a proper design of the implant, a precise preoperative assessment should be performed since not all patients may be eligible for the osseointegrated prostheses due to diabetes, osteoporosis, osteomyelitis, and infections.

However, considering the overwhelming majority of osseointegrated prostheses' advantages and positive outcomes of the Branemark technique, recent studies have demonstrated great interest in this technique.

The present review provides a detailed overview of osseointegrated prostheses adopted specifically in the treatment of digital amputations. To date, no similar recent review has been conducted.

This review aimed to investigate the different osseointegrated prostheses adopted so far for the management of finger amputees, identify the key points in surgical procedures, detail the key aspects of the design process, and demonstrate the benefits of the Branemark technique, which may encourage the development of future patient-specific osseointegrated medical devices for finger amputees.

Cost-Analysis: The Italian Perspective

 \mathbf{B} eside all promising outcomes of the osseointegrated prosthesis, a cost analysis is necessary to highlight its effective benefits for the sanitary system.

"Diagnosis Related Groups" (Merrien-webster.com.2021. https://www.merriam-webster.com) (DRG) represent the system of remuneration of hospitals by the NHS (National Health Service) for the treatment activity: indeed, DRG are used as a reference for the purpose of remuneration for hospital activity, to specify the hospitalization services to which specific predetermined rates should be attributed to each country.

In the current case study, authors focused on Italian reimbursements. DRG 228²⁸ covers the cost of pollicization procedure: it refunds about 1800 euros for the first 4 days of hospitalization and then 250 euros for each additional day of hospitalization (after the first 4 days). DRG 229²⁸ corresponds both to the lengthening of the metacarpus and to the application of osseointegrated prosthesis: it covers a cost of approximately 1300 euros and it meets expenses for a hospitalization ranging from 1 to 4 days.

Lengthening of the thumb metacarpal surgical procedure and osseointegrated implant surgery require around 1 day of hospitalization, pollicization requires at least 7 days of hospital stay, with a consequent higher cost for the NHS.

Nevertheless, these cost are underestimated because they do not consider the instrumentation or all the materials adopted in the surgery room and therapies administrated after hospital discharge. External fixator for finger, for instance, costs about 600 euros, osseointegrated prostheses including the implant components and the digital external prosthesis cost about 4000 euros (Centro Protesi di Budrio, INAIL) while pollicization does not necessitate any implantable device: despite the higher cost of osseointegrated prostheses, the surgical room is occupied much less than during pollicization procedure. Indeed, osseointegrated technique requires 1 h of surgery, while the reconstruction by means of pollicization needs 6 h of surgery.

Moreover, the osseointegrated patient, in absence of complications, can immediately come back to work, while the patients treated with external fixator need a recovery time of at least 3 months^{9,29} with a consequent expense to be paid by health insurance fund. Finally, pollicization damages the donor site and may lead to vascular complications,³⁰ while osseointegrated prosthesis does not affect any other anatomical site. Figure 1 pictures the qualitative impact of four relevant variables in the cost assessment.

Thus, the cost-analysis, the related variables and the benefits provided by osseointegration, justify the growing interest in bone-anchored prostheses for the treatment of finger amputations.

Surgical Procedures

The majority of the operations related to osseointegrated implants adopted a two-stage procedure, which has been widely used in dental surgery and the implant of osseointegrated prostheses in the lower limbs,³¹ and is composed of a first stage (S1) and second stage (S2), which is executed after a few months.

S1 Procedure

The brachial plexus²³ is anesthetized, and an ischemic tourniquet is used: S1 is performed under local anesthesia and lasts approximately 40 min.^{23,32}

Preoperative radiological analysis of the anatomical site assesses the good quality of the bone, the length of the stump, and the consequent size of the implant that best fits the stump of the patient.^{16,33,34}

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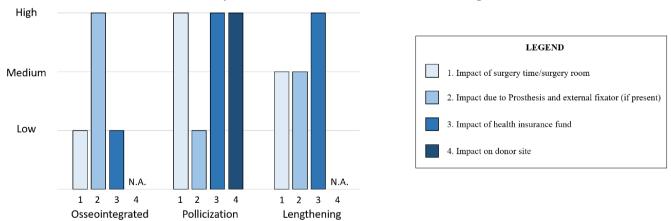
In the case of small proximal phalanges, surgeons usually prefer to remove them and insert the fixture directly into the metacarpal bone.²³

The skin incision was made at the implant side, and a skin flap was raised on the stump^{2,23,34} (Figure 2a). A pilot hole was drilled through a pilot drill whose diameter depended on the diameter of the fixture. The insertion of Kirschner wires (K-wires) or a drill was guided using fluoros-copy²² or radiovisiography (RVG).³⁴

The drill hole was enlarged with a lance drill,³⁵ and the implant was usually manually inserted using a hand wrench (Figure 2b). Lundborg *et al.*¹⁴ suggested the transplantation of cancellous bone from the iliac crest packed into the medullary cavity to improve bone integration. Li Yan *et al.*¹⁰ agreed on seeding bone marrow into the fixture before implant insertion to guarantee a sufficient presence of osteoprogenitors in the bone-implant interface.

The initial stability of the implant indicated as the implant stability quotient can be assessed using resonance frequency analysis (RFA).²³ RFA is a common technique used to quantify the stability of implants inserted into the bone and the consequent grade of osseointegration and can be applied immediately after placement and/or during the healing time. Satisfactory primary stability usually indicates promising future osseointegration.¹⁰

Finally, a cover screw was mounted into the fixture, and the skin flap was positioned to cover the site. Final radiography analysis was performed to determine the correct position of the implant.



Qualitative comparison of four variables evaluated for each surgical treatment

Fig. 1 graphical representation of the qualitative impact of four relevant variables on NSH. The four considered variables are: surgery room time, use of prosthesis or implantable devices (e.g. external fixators), impact of health insurance which has to pay during the absence from work, damage of the donor site. The three surgical procedures which are analyzed are: osseointegrated prosthesis, pollicization, and lengthening of the thumb metacarpal. For each of these treatments, all the four variables have been qualitatively evaluated as "low impact," "medium impact," and "high impact" in comparison among the other analyzed procedures. Osseointegrated procedure, despite the high impact due to the cost of implantable device, present the lowest impact for all the other three categories, such as low surgery time, low cost for the health insurance fund, no damage at donor site. N.A., not available, because no donor site is necessary during the surgical procedure.

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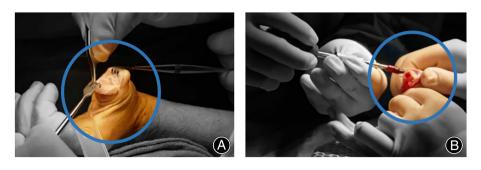


Fig. 2 Steps of S1: (A) opening of the skin to access the metacarpal bone. (B) After reaming and tapping the bone, the fixture is manually inserted into the metacarpal bone (images reproduced with modifications from study by Li et al.).¹⁰

After 10 days, the sutures were removed in cases where no complications or infections occurred.^{23,34}

S2 Procedure

Between S1 and S2, the implant is usually left unloaded to allow osseointegration. 36 S2 is usually performed 3 months after S1. 14,27

Before proceeding with S2, a radiography analysis is usually performed and necessary to ensure proper osseointegration, which is essential to proceed with the further steps.² Besides good osseointegration, the absence of infection and other complications must be confirmed. This second stage is performed under brachial plexus block, with regional anesthesia of 15 min.³² The skin was incised, and the cover screw was removed (Figure 3a,b). Depending on the type of implant, the abutment^{23,34} or healing $cups^{33}$ are placed over the implant using an abutment screw¹⁴ or directly screwed into the abutment.¹⁶ In S2, it is possible to insert the temporary abutment instead of the permanent abutment to create a well-epithelized canal.²² Subcutaneous fat is usually removed at least 1 cm to guarantee hair follicular-free around the abutment,¹⁰ and the skin around the abutment is trimmed to avoid future infections and minimize the mobility of the tissue around the abutment.^{14,36} To overcome the issue related to the mobility of the skin around the abutment, Manurangsee et al.¹⁹ suggested lining the central tract with a split skin graft.

The adopted surgical technique took strong inspiration from oral surgery: despite the advantages and successful results, the surgical technique should be studied for digit application to identify a standard surgical protocol.

One-Stage vs Two-Stage Procedure

The only study that compared the two-stage and one-stage techniques was reported by Amornvit *et al.*²³ Two amputees were treated with different procedures, and the pros and cons of both techniques were explored, in which the benefits related to the one-stage surgical procedure were highlighted.²³

The two-stage technique shows better management of the soft tissue, resulting in a lower risk of infection^{24,37} and it is suggested that implants present an initial stability insertion torque of less than 10 Ncm.

Thomas *et al.*³⁴ supported the two-stage procedure because it kept the stump safer, improving osseointegration in an undisturbed and unloaded environment. Nevertheless, two-stage surgery requires longer hospitalization time and more effort for patients who undergo two surgeries, and the surgeon has to complete two surgeries instead of one, lessening the trauma for the patient.³⁷

Considering the successful follow-up of the two patients treated with the one-stage and two-stage procedures, the authors²⁴ considered the one-stage procedure reliable, safe, and efficient.

The one-stage procedure would reduce hospital visits, hospital costs, and operating time, which would result in reduced operating time, hospital visits, and postoperative complications. At the same time, patients were more prone to undergo a single surgery instead of two.

This topic remains controversial due to the poor literature and lack of strong clinical evidence. However, the authors believe a specific surgical protocol for a specific digital amputation application is crucial to gain successful longterm outcomes and minimize the drawbacks related to implanted permanent osseointegrated medical devices.

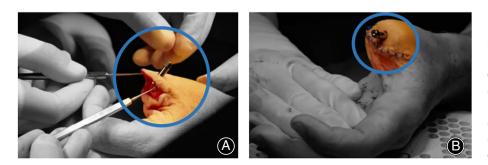


Fig. 3 Steps of S2: (A) removing of the cover screw and insertion of the abutment (in this case the abutment is inserted in the fixture and fixed by means of the abutment screw – Integrum AB system). (B) The skin is defatted and immobilized around the abutment. (images reproduced with modifications from Li et al.).¹⁰

Implant Components

The osseointegrated prosthesis design concept comes from dental implant technology, which demonstrates a positive outcome with osseointegrated screw fixation. In oral surgery, osseointegrated prostheses are composed of three main components: fixture, abutment, and abutment screw (Figure 4a). The first thumb implant proposed by Lundborg *et al.*¹⁴ was composed of the same three components, and it reached 3 years of successful follow-up.

One of the first osseointegrated thumb prostheses commercially available was introduced by Integrum AB, called the osseointegrated prostheses for the rehabilitation of amputees (OPRA) system. This system comprises the same three components³⁸ (Figure 4b). From 1990 to 2014, 13 patients were treated with thumb OPRA systems. From 1990 to 2005, customized implants modified from dental implants were used, and the success rate was 75%. After that, from 2005 to 2014, a standardized procedure based on the use of standard prostheses increased the success rate up to 100%.^{10,39}

A postoperative image highlights the great functional and aesthetic result obtained by means of osseointegrated digital prosthesis (Figure 4c,d).

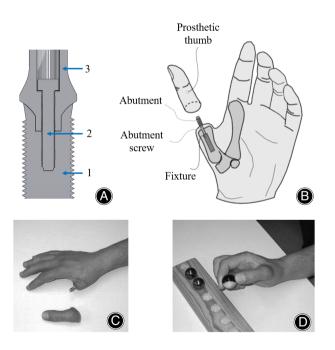


Fig. 4 (A) Schematic illustration created in SolidWorks of dental implant components: (1) fixture; (2) abutment screw; (3) abutment. (B) OPRA system commercialized by the Integrum AB (image reproduced with modification from https://integrum.se/what-we-do/our-products-futuresolutions/opra-implant-system/finger-thumb-amputations/).⁴⁰ (C) postoperative result obtained by means of osseointegrated implant. The thumb stump presents the distal part of the implant which is the abutment; the silicone finger reaches great esthetical appearance. (D) example of digital prosthesis use: the patient restores grasp and grip and the ability to perform daily activities (image reproduced from Li and Brånemark).³⁹

Moreover, Li *et al.*²⁷ compared the adoption of 11 OPRA systems screwed into the medullary canal of six patients, demonstrating that long-term osseointegration is a safe reconstructive option for appropriately selected patients. In addition to the standardized component offered by the OPRA system, research and literature have focused on different design solutions for the treatment of finger amputation.

The following paragraphs detail the development and solutions related to each specific component of the entire osseointegrated prosthesis: fixture, abutment, and external digital prosthesis.

Component in Contact with the Bone—the Fixture

The fixture is the component screwed or press-fitted into the medullary bone canal. It must be osseointegrated with the inner cortex surface to guarantee long-term stability. Fixture designs may have different lengths and diameters, according to bone stump: few surgeons require the longest fixture admissible,¹⁴ while others suggest short fixture to not stress the bone stump and preserve the proximal joint.^{1,37}

Regarding the length of the fixtures, Doppen *et al.*²² suggested adopting the longest possible fixture for the remaining bone, whose length had to be at least 5 mm, while Sierakowski *et al.*¹⁶ suggested having a minimum length of 10 mm of bone stock to fix the implant. Concerning the diameter of the fixture, in a study by Sierakowski *et al.*¹⁶ the minimum implant diameter was suggested as 3.25 mm to guarantee a circular bone crown with a thickness equal to 1.5 mm. Nevertheless, radiographic evaluation is always performed to assess the best fixture length for a specific patient.^{2,16} By means of specific medical software, a trained operator can reconstruct the contours of the anatomical region of interest to quantify all the anatomical measurements fundamental to select the best implant for the patient, which is already widespread in the orthopaedic field.⁴¹

The benefits of oral osseointegrated components inserted into the mandibular and maxilla led researchers and surgeons to use and implant dental fixtures into the phalanges bone and thumb metacarpal bone to treat finger amputees.^{2,19,23,31,33-38,42-44}

Manurangsee *et al.*¹⁹ reported for the first time the use of dental implants for extraoral application, obtaining positive results (Figure 6b). A threaded self-tapping titanium dental implant coated with hydroxyapatite was inserted into the medullary bone canal of the index, medium, and ring fingers. The diameter of the fixtures (3.25–3.8 mm) was selected by measuring the width of the inner cortex of the stumps, and the length of the implants (8–14 mm) was chosen by measuring the length of the bone to the subchondral area. Similarly, Infager *et al.*⁴³ decided to implant endomedullary osseointegrated dental titanium implants.

Aydin *et al.* reported three studies on the treatment of finger amputees treated with intraoral fixtures.^{33,35,36} The length of the fixtures was assessed by radiographic analysis.³⁶ Similarly, Goiato *et al.*^{43,45} and Benny *et al.*³⁴ supported the idea of using dental implants. Benny *et al.*³⁴ implanted a

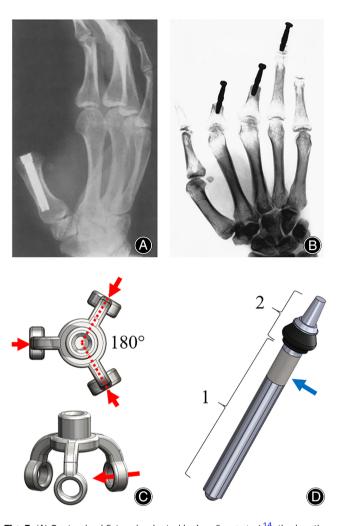


Fig. 5 (A) Customized fixture implanted by Lundborg et al.¹⁴: the length and the diameter of the fixture is personalized on the anatomical dimensions of the metacarpal bone (image reproduced with copyright permission from Lundborg *et al.*).¹⁴ (B) Three dental fixtures implanted into the phalanges bones to treat long fingers amputation¹⁹ (image reproduced with copyright permission from Manurangsee et al.)¹⁹. (C) Schematic representation of the tripod fixture developed by Manrique et al.¹ The three arches are equidistant and small screws (red arrows) are inserted to fix the device to the metacarpal bone. (image created in SolidWorks, based on the concept reported in Manrique et al.)¹. (D-1) Press-fit fixtures implanted by Vaux et al.⁴⁷The stem presents a porous area (blue arrow) which improves the bone tissue growth. (D-2) distal part of the implant that is called abutment. This section will be detailed in the following paragraph (image created in SolidWorks, based on the concept reported in Vaux et al.)47 (image reproduced in SolidWorks based on the concept reported in Vaux et al.).47

dental fixture of 3.5 mm in diameter and 11.5 mm in length using a hand wrench with 30 Ncm torque. Recently, Razak *et al.*³⁷ implanted a one-piece bicortical dental implant of 3.5×23 mm with a square post; the square part was successively modified to realize the abutment.

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Vinnakota *et al.*² inserted a single-stage overdenture implant in the phalanx into the medullary canal of the stump, even though the distal part of the dental implant was immediately exposed from the skin, 3 months before the application of the external prosthesis to allow osseointegration.

All these clinical experiences demonstrated the use of dental fixtures as a valid solution to treat the injury of finger amputees using an osseointegrated device. Most studies have focused on mimicking dental fixture design, in which knowledge about osseointegration is well-established and which research is going on developing specific dental fixture designed to fix the issue related to initial stability in sponge bone.³⁶ Despite the acceptable clinical outcomes obtained in using dental fixtures to treat finger amputees, such implants were not an optimal choice for extraoral applications because they had been designed and developed explicitly for oral applications and did not meet the requirements of a medical device intended for the finger amputees management.³⁴

Cervelli *et al.*³² treated a patient with congenital hypoplasia of the index using an extraoral titanium osseointegrated implant inserted in the medullary canal. Extraoral implants are osseointegrated implants based on the Branemark technique. In contrast to dental fixtures, extraoral implants are versatile devices with shorter lengths than intraoral dental implants and are commonly adopted for maxillofacial treatments.^{38,45-47} Aydin *et al.*³⁶ inserted an extraoral fixture whose length depends on the length of the bone to the subchondral area. The shorter length allowed protection of the interphalangeal joint.

Almost all previous cases have reported good results, but few cases have registered infection and component breaking/loosening.^{16,19,39} The negative outcomes observed in using intraoral and extraoral fixtures for the treatment of finger amputations is mainly due to the wrong intended purpose of the medical device and to the infection that frequently occurred at the implant-skin interface favoring bacterial adhesion.

The treatment of digit amputees using dental and maxillofacial implants remains controversial, and customized fixture design solutions have been proposed to develop medical devices specific to hand injuries.^{1,14,47}

Lundeborg *et al.*¹⁴ selected three patients with amputations at the metacarpophalangeal joint level and treated them with customized titanium fixtures designed so that the screw was in contact with the endosteal cortical bone at the midlevel of the first metacarpal (Figure 5a). The customization referred only to the length and diameters, and no novelties were introduced in the design fixture concept.

An innovative design concept was introduced by Manrique *et al.*¹ They suggested a different fixture design to reduce the bone canal. Indeed, the new fixture was not inserted in the medullary canal but presented a triple attachment on the distal part of the bone (Figure 5c). The implant was composed of a tripod titanium mini-plate secured in three axes with 1.5-mm mini-plates and screws. This tripod attachment to the bone prevented lateral torque movements

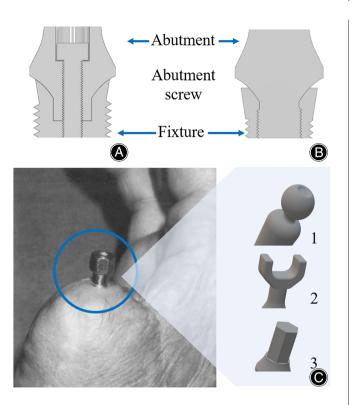


Fig. 6 (A) Schematic reproduction of the coupling between abutment and fixture reached by means of a third component, abutment screw (image designed in Solidworks). (B) Schematic reproduction of the coupling between abutment and fixture by means of the threaded abutment (image designed in Solidworks). (C) Focus on the percutaneous component: the distal external part of the abutment can present different shapes to reach stability by means of shape coupling (1—ball attachment, 2—customized shape, 3—hexagon shape). (Image reproduced with copyright permission¹⁴ and images designed in Solidworks based on concept in Ayden et *al.*³⁶ and Goiato et *al.*)⁴⁴

and loosening of the implants during insertion and removal of the external prostheses. Moreover, this technique did not stress either the stump or medullary canal, preventing fracture or weakening of the distal stump. The tissue covered all the tripod implants except for the magnetic tip on the top of the device. This solution had great functional outcomes: both the device and the surgical procedure have been reported to be less invasive. The main constraint is the length of the stump, which should be at least 1.5 cm to secure the tripod over the distal phalangeal stump.

While all previous dental fixtures and extraoral devices have been screwed inside the bone, Vaux *et al.* designed a press-fit implant⁴⁷ (Figure 5d). Indeed, the fixture, designed to fit the morphometric measurements, was composed of a porous stem pressed into the medullary canal, and recent findings have highlighted the use of porous structures to increase osseointegration and long-term stability.⁴⁷

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To date, different strategies have been developed to increase the osteogenic capacity of the surrounding bone tissue to guarantee stable osseointegration of the implant. The addition of bone grafting around the fixture has been demonstrated to enhance bone tissue growth.¹⁴ Surface treatments such as hydroxyapatite coating promote tissue generation and accelerate the osseointegration process.¹⁹ The porous surface increases the growth of tissue, as demonstrated in a study by Vaux *et al.*⁴⁷; porous surface enhances the proliferation of soft tissue as well, as established in a study by Chimutengwende-Gordon *et al.*⁴⁸. The better the osseointegration and soft tissue integration, the better the long-term stability and implant-skin interface sealing.

The presented design solutions represent the state-ofthe-art fixture implemented for the treatment of finger amputees, and the drawbacks and limitations of each specific design can be overcome by means of specific research, as has been performed for low limb amputations.⁴⁹

To summarize the most widespread fixture type implanted to treat finger amputations were dental, extraoral, overdenture, and customized fixtures (Table 1).

The mostly adopted kind of component was dental fixture (Figure 6b); this finding is due to the well-established knowledge related to osseointegrated dental implants which encouraged surgeons to use the same medical device. The first custom fixtures^{14,16} had a length and a diameter tailored to the patient's bone anatomy; beside the customized dimensions, the design of these custom fixtures were almost equal to the dental ones. The commercialized OPRA system^{10,27} (Figure 4) presents a design comparable to the well-known dental fixture one (Figure 6a). A major step forward in the customization of the bone anchored design were proposed in other studies.^{1,47} They implanted two diverse novel design solutions: a tripod short fixture and a porous long stem inserted into the medullary canal (Figure 5c,d). The first minimized the bone stress and improved the rotational stability of the fixture, while the latter enhanced the bone ingrowth and the long-term osseointegration.

As mentioned in the section 3 ("Surgical procedure"), the most recommend method of insertion consists in twostage surgery. The two-step surgery minimizes the risk of infection, avoids the mobilization of osseointegrated implant, and improves the management of soft tissue.³⁴

The longest follow-up was observed with the OPRA implant.^{10,27} The follow-up of the literature is still quite short; therefore, further studies should be performed to demonstrate the promising procedure of osseointegration for the treatment of finger amputations.

Once the fixture is inserted and before suturing the surgical site, surgeons usually insert cover screws into the fixture, which is intended to prevent infections and save the internal thread of the fixture, which is planned to host the abutment inserted in S2.

Percutaneous Component—the Abutment

The abutment is the percutaneous component of the implant and usually presents a standard range of length $(10-15 \text{ mm})^{14,19}$

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mplant type	Surgery stages	Finger	Follow-up	Re
Custom fixture	2	Thumb	3 years	14
		Thumb	2.5 years	
		Thumb	1.5 years	
	2	Index	13 years	16
	_	Middle finger	20 90010	
	1	Index	4 years	
	Ŧ	Middle finger	1 youro	
		Ring finger		
	1	Thumb at MCP level	3.5 years	
	2	Thumb (10 amputees)	1–15 years	21
ripod titanium mini-plate anchored and secured in 3 axes	2	Index	3.3 years	1
with 1.5mm mini plates and screw	2	Middle finger	5.5 years	-
		Ring finger		
		Ring finger	2.7 years	
		Index		
		Index	2 years	
		Index	1.8 years	
		Middle finger	1.7 years	
		8	1 5 10000	
		Ring finger	1.5 years	
	2	Index	1.2 years	
ress fit stem implant with porous section	2	—a	—a	47
ental fixture	2	Index	2 years	19
		Middle finger		
		Ring finger		
		Index	1.6 years	
		Middle finger		
		Index	1.3 years	
		Middle finger		
	2	Index	1.5 years	43
		Middle finger		
		Ring finger		
		Little finger		
		Little finger	1.8 years	
	2	Thumb	0.25 years	36
		Middle finger		
		Ring finger		
	2	Thumb	1.5 years	35
		Thumb	1.8 years	
	2	Thumb	0.5 years	42
	2	Index	2 years	22
		Ring finger	1.5 years	
		Index	0.25 years	
		Middle finger	-	
		Middle finger	N.A.	
	2	Thumb	0.5 years	33
		Index		
	2	Index	0.5 years	44
	2	Thumb	0.5 years	34
		Index		
	N.A.	Thumb	0.25 years	50
ixtureb	1	Index	0.5 years	23
	2	Thumb	0.4 years	
verdenture implant	1	Middle finger		2
ne-piece dental implant	N.A.	Thumb	0.5 years	37
PRA system	2	Thumb (13 amputees)	From 1990–2014	10
· · · · - <i>j</i> · · ·	2	Thumb	22.25 years	27
	~	Thumb	9.7 years	21
		Thumb	5.5 years	
		Index	19.5 years	
			19.0 years	
		Middle finger		
		Index	4.5 years	
		Middle finger		
		Ring finger		
		Index	6.2 years	
		Middle finger		

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mplant type	Surgery stages	Finger	Follow-up	Re
		Ring finger		
Extraoral fixture	2	Index	0.5 years	3
		Index	0.25 years	3

tions.; Abbreviation: N.A.: not available data.; ^a The design has been proposed but not implanted.; ^b The type of the fixture is not specified.

which can be screwed directly into the fixture²² or fixed into the fixture using the abutment $screw^{14,19}$ (Figure 6a,b).

The first article on osseointegrated finger prostheses¹⁴ reported the insertion of a 15-mm purpose-designed abutment that was attached to the fixture using an abutment screw (Figure 6b). The same surgical technique was adopted by Manurangsee *et al.*¹⁹ in which a 10-mm long dental abutment was fixed into the fixture through an abutment screw.

Similarly, Infager *et al.*⁴⁴ implanted endomedullary osseointegrated dental titanium implants, which resulted in good outcomes and restoration of perception. The titanium abutment contained a magnetic part to create a stable magnetic coupling between the fixture and external finger prosthesis.

Goiato *et al.*⁴⁴ explored the potential of dental ball attachments (Figure 6C-1), already implemented in overdenture treatment, demonstrating them as valid solutions for extraoral applications. Based on the ball attachment, a hexagon-shaped base was created to guarantee stability against rotation using frictional forces.

Axial stability can be achieved through ball attachments, while rotation must be guaranteed through shape coupling, which has been demonstrated as a valid solution to retentive abutment-external prosthesis attachment.

Focusing on shape coupling, Aydin et al.^{33,35,36} provided external custom-designed attachments (Figure 6C-2, Figure 6C-3), where the inner surface of the attachment is adapted to the abutment, while the external surface is designed with a specific shape to firmly grasp the external prosthesis. Goiato et al.42 stated that custom attachments could achieve stable retention of the external prostheses. An intraoral implant abutment and extraoral conical abutment were implanted into the fixture, and a UCLA retention system already adopted in the treatment of edentulous patients was screwed into the implant.⁵¹ The UCLA retentive system adopted in this study was made of a retentive two-bar system cast in a silver-palladium alloy. In addition to the retention issue, infections continue to remain the main challenge due to the transcutaneous nature of the implant and contact with the external environment.

Doppen *et al.*²² focused on abutment design to prevent this issue. The solution consisted of two different abutments: a temporary and permanent one. The former was used until the soft tissue healed, and it was designed to allow its free

rotation: in the 3 weeks following the first stage of surgery, the patient had to slightly rotate the healing abutment and guarantee regular stump cleaning to create a well-epithelized canal. After that, the temporary abutment was removed and substituted by the permanent abutment, on which the external silicon prosthesis was attached.

In 2017, a new custom-made abutment design was proposed.³⁴ In particular, during S2, a healing collar was inserted with an open tray impression material, employing a custom impression tray. The open tray impression is a technique implemented by a dentist to take the impression of the implant to replicate its position. The open tray transfer coping was then modified to realize the custom abutment, which was modified to create a ribbed form along the sides, so the abutment was retentive for the external silicone prosthesis.

Amorvit *et al.*⁵⁰ have been looking for better biomaterials that guarantee both osseointegration and tissue integration. They identified polyether ketone (PEEK) as a promising material for abutment-prosthesis attachment. PEEK exhibits good mechanical properties and decreases inflammation at the tissue-implant site. A length of 10 mm is reported to be sufficient to preserve the abutment, even in the case of skin growth, which may cover a few millimeters of the abutment. They were designed to be 15 mm in length, and a small ball is inserted on the tip to improve axial retention. The silicone finger prosthesis is connected to the PEEK abutment using polyvinyl siloxane that needs to be changed every 4 to 5 months.

The proposed abutments presented different design solution and different mechanical coupling with the fixture: abutment locking screw, abutment screwed directly into the fixture, abutment firmly fixed into the fixture with shape coupling and a small internal screw. Table 2 offers a correlation between the type of implanted fixture and the corresponding transcutaneous component fixed on it.

The transcutaneous component plays a crucial role in retaining the external prostheses and reducing infection at the skin-implant interface. Recent studies have focused on developing designs and surface treatments that mitigate infections at the skin-implant interface, which remains the main issue for all osseointegrated prostheses. The percutaneous component creates a skin opening, which is a favorable chronic colonization of external bacteria.³¹ Vaux *et al.*⁴⁷ tried to assure retention and non-infection through a porous

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surface titanium abutment to allow skin and subcutaneous ingrowth and create a dermal barrier against infection.³¹ In addition, porous PEEK has been demonstrated to enhance cellular osteogenic differentiation.⁵² Studies have demonstrated a strong relationship between biomaterials and the geometric surface, which is paramount to increase implant-tissue integration. A complete comparison among the alternatives to address cutaneous integration issues is specified in the chapter "Functional assessment."

As reported in the literature mentioned above, dental components have been good initial attempts to gain acceptable outcomes, but new technologies, such as additive manufacturing and new biomaterials, are gaining attention due to their capability to meet patient-specific requirements.

Table2 Correlationbecorrespondingpercutantabutment		the the
Implant type	Abutment	Ref
Custom fixture	Abutment locking screw	14
	Abutment screwed directly into the fixture	16
	Abutment locking screw	21
Tripod titanium mini-plate anchored and secured in 3 axes with 1.5 mm mini plates and screw	Abutment is an unique part with the fixture	1
Press fit stem implant with porous section	Abutment is an unique part with the fixture	47
Dental fixture	Abutment locking screw	19
	Skin-penetrating titan- magnetic abutment	43
	screwed directly into	
	the fixture	20
	Abutment fixed firmly into the fixture	36
	Abutment fixed firmly into	35
	the fixture Abutment (UCLA)	42
	screwed into the	
	Permanent abutment screwed directly into the fixture	22
	Abutment fixed firmly into the fixture	33
	Abutment fixed firmly into the fixture	44
	Custom abutment attached to the fixture	34
	N.A.	50
Fixture	Abutment locking screw	53
Overdenture implant	N.A.	2
One piece dental implant	N.A.	37
OPRA system	Abutment locking screw	10
	Abutment locking screw	27
Extraoral fixture	N.A.	32
	Abutment fixed firmly into the fixture	36

Abbreviation: N.A.: not available data.

External Digital Shape Prosthesis

An external silicone prosthesis must be stably fixed on the percutaneous component and removable to allow patients to clean the implant site daily and remove it whenever they desire.

The attachment between the silicon prosthesis and abutment can be obtained through: (i) a transversal screw^{14,27} (Figure 7a); (ii) a magnetic attachment^{1,19,43} (Figure 7b); (iii) ball attachments^{23,35,44}; and (iv) mechanical frictional forces obtained by different designs and interfaces^{33,35,36,42,50} (Figure 7c). The attachments have been analyzed and mapped in the dedicated table (Table 3).

Although osseoperception is mainly due to the metallic fixture inserted in the bone, a rigid external prosthesis may improve the stimuli perception of the patient.¹⁹ Silicone material allows grip and high-definition aesthetic appearance²¹ but it is not rigid. Therefore, the transmission of mechanical stimuli is weakened. To address this issue, a metal framework can be inserted into the silicone prosthesis to increase its rigidity with a consequent improvement in the transmission of mechanical stimuli.² Recent cutting-edge technologies, such as additive manufacturing, can allow the creation of complicated structures that can be embedded in external digital prostheses.

3D printing technology allows new freedom to design and develop rapid coupling and release systems for prosthetic devices which may be integrated with internal structures pre-positioned in their housing, otherwise impossible with normal silicone processing techniques.

Materials

Most authors who treated thumb amputees with osseointegration prostheses adopted pure titanium and Ti6Al4V for all components,⁵⁵ especially in abutment/ attachments design.

Titanium and its alloys are the gold standard materials for endosseous dental implants and are the most widely used materials in osseointegrated applications.^{56–58}

The success of osseointegration requires three synergistic systems: good quality of the host bone, biocompatible metallic material, an optimized skin-implant interface, and a bone-implant interface.⁵⁸ The quantity and quality of the bone available, with the surgical procedure and implant design, influences the success of osseointegrated devices.⁵⁹ Biocompatibility implies that the selected materials need to avoid undesirable systemic responses in the short and long term.⁵⁶ The skin-implant interface needs to close access to external bacteria, which may result in infection and complications causing implant failure.⁵⁸ Similarly, the bone-implant interface plays an essential role in the long-term success of the fixture⁶⁰: osseointegration can be enhanced by means of bioactive coating such as collagen or hydroxyapatite.⁶¹

Titanium and its alloys have high specific strength (per density) and high corrosion resistance due to the formation of a passive titanium oxide surface layer.⁵⁸ The titanium Young's modulus is 102 GPa, and it increases in titanium

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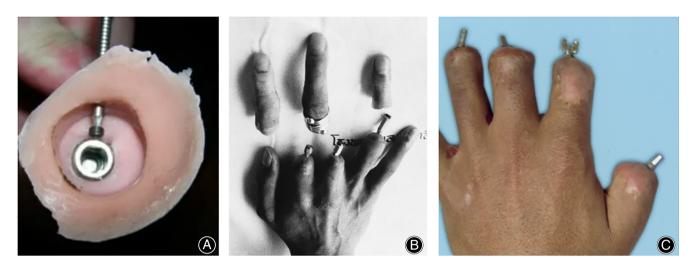


Fig. 7 (A) the silicon external prosthesis is attached by means of a transversal screw stabilized by means of a hex key. (B) Magnetic coupling between external prosthesis and distal part of the abutment. (C) Shape coupling: the external prosthesis fixation is reached by means of frictional forces (images with copyright permission from Manurangsee *et al.*¹⁹ and https://www.royalfreeprivatepatients.com/treatments/osseointegrated-bone-anchors-for-securing-a-prosthesis-in-the-hand/.⁵⁴ image reproduced from Aydin *et al.*)³⁶

alloys reaching the value of 113 GPa.⁶² Despite these values being inferior to those of other biomedical alloys, they are still greater than the bone elastic modulus, which is 4– 30 GPa for cortical bone and 0.2–2 GPa for trabecular bone.⁵⁵ Therefore, considering that a material elastic modulus close to the bone is desired, porous implants are receiving special attention because they help reduce Young's modulus and enhance bone ingrowth.⁵⁵ Indeed, better modulus matching results in a more favorable stress distribution at the bone-implant interface, thus avoiding stress shielding.

Among other fielded materials, PEEK has been reported to be used for the realization of the abutment in retained finger prostheses.⁵⁰ PEEK is a white semicrystalline synthetic polymeric material with good biocompatibility, fatigue resistance, and a low elastic modulus (3–4 GPa). The authors reported the absence of tissue reactions close to the PEEK abutment and the achievement of good final retention.

Functional Assessment

T o date, the largest studies on digital osseointegrated prostheses in terms of follow-up and number of patients have been reported.^{10,27}

The functional assessment was executed using quantitative and qualitative tests on the amputee patients: the range of motion (ROM) measurement, the Jamar test to measure the grip strength, the Semmes–Weinstein test to check the sensory assessment, the Jebsen–Taylor hand function test to verify the ability of key actions, the Sollerman test to assess the global function of the hand, and the quick disabilities of the arm, shoulder, and hand (Q-DASH) self-report questionnaire to evaluate the ability to complete daily activities. In addition to the reported tests, clinical images were obtained to correlate with the self-reported outcomes of the patient.²⁷ Overall, functional assessment has demonstrated promising outcomes. Although researchers have observed less ROM test and poorer sensitivity than in replantation,²⁷ the Jamar test has reported an improvement in the grip strength with the prosthesis.^{19,39,43} The Sollerman test registered an acceptable global function of the hand of 94%.⁴¹ The Q-DASH test has demonstrated excellent functional outcomes.¹

Patients have reported that osseointegrated prostheses provide much more confidence than vacuum silicon prostheses due to osseoperception. Osseoperception is a benefit that has been highlighted in every article previously cited and has been registered since the first article in 1996.¹⁴ Lundborg *et al.*⁶³ explored the mechanism of osseoperception using functional magnetic resonance in an amputee patient, demonstrating the capability of the brain to balance the deficit with stronger activation of a specific area that should not normally be activated using a compensatory mechanism. Although the benefits of osseoperception are still small compared with the role of sight,¹⁶ they are key factors for successful application.

Potential Complications Assessment

P otential risks related to finger osseointegrated prostheses are mechanical failure of specific components, loosening of the abutment, discoloration of silicon prostheses, infections, and granulation tissue formation around the transcutaneous component.^{19,32,39,58,64} In one study,¹⁰ few patients reported mechanical failure, which required the change of components, superficial infections solved with oral antibiotics. In two other studies^{1,35} loosening of the abutment screw was solved with accurate tightening of the component. The low number of complications strictly correlated to the use of osseointegrated implants for the treatment of finger

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Table 3 Continued		
Abutment	Attachment	Ref
	Mechanical frictional forces obtained by means of custom designed shape attachment for retention	36

amputees encourage its use: nevertheless, it is worth noting the poor literature currently available on this specific topic and the high number of case studies reporting failure and infections of osseointegrated prostheses in oral field; these findings explain how research is relevant to solve the potential risks above mentioned.

These risks can also occur in the implantation of percutaneous prostheses at the level of the lower limbs.³¹ Due to the general relevance of these issues, researchers are seeking to solve them, and innovative solutions are expected.

Despite few complications, the functional assessment of osseointegrated digital prostheses has demonstrated numerous advantages.²⁷

Implant-Skin Interface

The implant-skin interface must be sealed well to prevent infection in osseointegrated digit prostheses. A possible procedure to address cutaneous integration is to line the tract created at S2 with a split graft¹⁹ or trim the skin around the implant to the thickness of the split skin graft and directly attach to the cortical bone to reduce skin mobility.¹⁴ Daily home care of the implant site is crucial to prevent infections that may lead to long-term complications.⁴² The optimization of implant-skin sealing is guaranteed whether epithelial cells and fibroblast adhere and proliferate⁶⁴ and infections do not occur: indeed, the paradigm described by Gristina et al.⁶⁵ known as the "race to the surface" well describes the competition between tissue integration and bacterial adhesion.⁶⁶ Various strategies based on physical, chemical, and biological modifications have been utilized to enhance soft tissue integration around the titanium implants and encourage the use of osseointegrated prostheses. For instance, surface physical modifications include porosity, groove shaping, micro and nanoscale roughness: grooves have been demonstrated to increase the adhesion, proliferation, and spreading of epithelial cells and fibroblast,⁶⁶ while a mutual agreement on optimal surface roughness values is still controversial. Simultaneously, surgeons aim to minimize the bacterial adhesion on the implant: therefore, growing interest is focused on developing surface coating to prevent bacterial adhesion and the consequent infections which may lead to the implant failure.

To date, no definitive surface modifications or optimal antibacterial coatings have been commonly accepted making

Table 3 Correlation between the abutment and the attachmentadopted to provide the retention of the digital externalprosthesis

prosthesis		
Abutment	Attachment	Ref
Abutment locking screw	Transversal screw	14
-	Transversal screw	27
	Hexagonal locking	21
	mechanism screwed	
	with Allen key	
	Hexagonal magnetic	19
	suprastructure system	
	Transversal screw	10
	N.A.	53
Abutment screwed	Mechanical frictional forces	16
directly into the fixture	obtained by means of a	
	titanium rod covered by acrylic	
	resin mechanism which is	
	screwed into the abutment: on	
	the blade of acrylic resin the	
	silicone prosthesis itself is located	
	N.A.	22
	Magnetic attachment	43
Abutment (UCLA)	Custom designed shape-	42
screwed into the	attachment with antirational	12
implant	system (Mechanical frictional	
mplane	forces obtained by means of	
	two-bar system that is cast in	
	metallic silver palladium)	
Abutment is an unique	Magnetic attachment	1
part with the fixture	Tapered attachment	47
Abutment fixed firmly into	Mechanical frictional forces	36
the fixture	obtained by means of custom	
	designed shape attachment	
	for retention	
	Ball attachment	33
	Mechanical frictional	35
	forces obtained by	
	means of custom	
	designed shape	
	attachment for	
	retention Mechanical frictional	34
	forces obtained by	34
	means of custom	
	designed shape	
	attachment for	
	retention	
	Hexagon-shaped base	44
	and metallic ball	
	attachment	
	Ball attachment and	50
	mechanical frictional	
	forces obtained by	
	means of custom	
	designed shape	
	attachment for	
	retention	
	Ball attachment	2
	Ball attachment	37
	Mechanical frictional	32
	forces obtained by	
	means of custom	
	designed shape	
	attachment for retention	
	recention	

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the "race to the surface" one of the most important future challenges.

Mechanical Failure

The loosening of the abutment is a minor issue.^{19,35} The abutment can be substituted without affecting the fixture implanted into the bone.

Implant mechanical failure in osseointegrated finger prosthesis rarely occurs because the weight bearing to the thumb does not overcome the strength of the dental and maxillofacial implants inserted so far.³³ Nevertheless, the authors believe that mechanical studies should be implemented to develop a specific design for the treatment of finger amputees. The only detailed mechanical study on osseointegrated finger prostheses is reported by Amornvit et al.^{53,67}: they studied the stress distribution in implantretained finger prosthesis composed of abutment, fixture, and abutment screw. When a loading force has been applied along the axis of the implant, the maximum Von Mises stress has been located around the neck of the fixture. Cortical bone received more stress than the trabecular bone, while the minimum stress has been located in the apical third of the implant fixture. This finite element analysis (FEA), despite assuming certain simplifications that should be improved, as reported by the authors themselves, provides a first general understanding of the stress supported by the implant and suggests a possible workflow to validate the prostheses design. Indeed, the design of abutments and attachments must be designed to respond to load conditions specific for the anatomical site of interest. The FEA is crucial to base the design choices to optimize the bone contact and the consequent osseointegration and reduce local stresses which may lead to implant failure.

The loosening of the abutment is a minor issue. The abutment can be substituted without affecting the fixture implanted into the bone. It is necessary to take this into account to minimize patient discomfort.

Future Perspective of Finger Osseointegrated Prostheses

O sseointegrated prostheses proved to be excellent solutions. They provide stability and retention thanks to their design and restore osseoperception, increasing the percentage of prosthesis use.

Additive manufacturing technology has been demonstrated to have strengths in the orthopaedic field due to its capability to realize prostheses that match each patient's specific anatomy.⁶⁸ Future research related to osseointegrated finger prostheses could lead to the design and printing of customized finger prostheses that meet the specific requirements of both the surgeon and patient and that presents lower cost.

Additive manufacturing techniques could be key to the acceptance and use of digital prostheses in terms of osseoperception and aesthetic and functional perception. Moreover, 3D printing techniques open the way for

developing digital prostheses capable of incorporating electrical components for specific needs, such as restoring sensorial feedback. Currently, none of the presented studies can restore sensorial feedback in addition to osseoperception. A concrete future development related to osseointegrated prosthesis is supported in one study,⁶⁹ whose authors developed a cosmetic finger capable of reading force information to convert them in a vibrotactile stimulation on the stump. The lack of this aspect in osseointegrated implants for fingers is clear. Different experiments have been conducted to restore tactile feedback⁷⁰⁻⁷⁴ and slippage information⁷⁵ through intraneural and cuff electrodes. In some of these scenarios, the amputee had an osseointegrated implant modified to provide bidirectional communication to implanted electrodes in nerves and muscles using a series of feedthrough mechanisms (e-OPRA).^{72,75} Based on these studies, an investigation into the possibility of restoring tactile feedback to a single finger could be performed to improve the grasping and acceptability of amputees.

Conclusions

 $F_{appearance}^{inger}$ amputation affects the functionality and aesthetic appearance of the hand.

Microsurgery treatments are valid solutions for treating patients who suffer from finger amputations. Nevertheless, due to the stump length or patient conditions, microsurgery is not always the best option. In the past, silicon vacuum prostheses have been valid alternatives to surgical treatment, but they had reduced retention and stability, which are key factors for external prostheses.

The functional assessment revealed good outcomes for osseointegrated finger prostheses. Thus, researchers should be encouraged to study and improve their drawbacks. Moreover, the need to reduce the cost of external digital prostheses could lead to additive or subtractive technologies.

Surgical techniques often present two stages, but the benefits of a one-stage procedure are becoming increasingly evident. Further studies could statistically demonstrate the advantages of a one-stage procedure over a two-stage procedure.

So far, the studies on this topic have had short followup periods and small sample sizes. Further studies with a longer follow-up period are required to improve the knowledge and confidence.

Fingers are fundamental daily life. Osseointegrated finger prostheses allow patients to return to their activities of daily living, reducing the trauma from digital amputation, enhancing self-confidence, and improving the functionality of the hand.

Conflicts of Interest

The authors declare no conflict of interest.

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Authorship Declaration

ll authors listed meet the authorship criteria according A to the latest guidelines of the International Committee of Medical Journal Editors, and all authors are in agreement with the manuscript.

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