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Investigating the Future of Prosthetics Using Osseointegration Technology- Review

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Abstract

Additionally, it has been demonstrated that osseointegrated implantation offers superior proprioception and control over the prosthesis, enabling more natural movement and improved functional results. Additionally, it lowers the chance of falling and increases energy transfer efficiency, making it simpler for amputees to engage in physical activity. Furthermore, as compared to conventional socket prosthesis attachment, osseointegrated implantation has been linked to higher patient satisfaction and quality of life.

It is crucial to remember that osseointegration is a surgical operation with risks including infection and implant failure. Additionally, for effective implantation, it needs a specific amount and quality of bone, which may restrict its usage in some individuals. Furthermore, osseointegrated implantation could be more expensive than conventional socket prosthetics.

Understanding the efficacy and safety of this method requires research on complication rates and outcome metrics in patients having osseointegrated prosthesis implantation. You may acquire information on things like infection rates, implant failure, patient satisfaction, and functional results by studying original research papers. Clinical decision-making can then be improved with the use of this information.

In transfemoral amputees, osseointegration has showed promise as a powerful substitute for socket prostheses. A growing corpus of research has shown that osseointegrated implantation provides advantages in terms of increasing mobility, decreasing discomfort, and improving general quality of life. The efficiency of osseointegration for transtibial and upper extremity implants has received little attention.

Minor soft tissue infections are the most frequent consequences, although they are manageable with the right treatment and monitoring. To further reduce the risk of problems and improve the overall success of osseointegrated implantation, research and development are ongoingly focused on enhancing surgical methods and implant design.

Although osseointegration has a lot of potential, not all amputees may be good candidates for it. Considerations for osseointegrated implantation must take into consideration elements including the degree and nature of the amputation, the quality and density of the bone, and the desires of the patient.

Keywords: Osseointegration, Lower Limb Amputation, Implant System, Prosthetics.

مراجعة لاستكشاف مستقبل الأطراف الصناعية باستخدام تقنية الاندماج العظمي

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الخلاصة:

بالإضافة إلى ذلك ، فقد ثبت أن الزرع العظمي يوفر تحسسًا فائقًا وتحكمًا في الطرف الاصطناعي ، مما يتيح

مزيدًا من الحركة الطبيعية والنتائج الوظيفية المحسنة. بالإضافة إلى ذلك ، فإنه يقلل من فرصة السقوط ويزيد من كفاءة نقل الطاقة ، مما يجعل من السهل على مبتوري الأطراف الانخراط في النشاط البدني. علاوة على ذلك ، وبالمقارنة مع ملحق البدلة التقليدية ، فقد تم ربط الزرع العظمي بزيادة رضا المريض ونوعية الحياة.

من المهم أن نتذكر أن الاندماج العظمي عملية جراحية تنطوي على مخاطر تشمل العدوى وفشل الزرع. بالإضافة إلى ذلك ، من أجل الزرع الفعال ، فإنه يحتاج إلى كمية ونوعية محددة من العظام ، مما قد يقيد استخدامه لدى بعض الأفراد. علاوة على ذلك ، يمكن أن يكون الزرع العظمي أكثر تكلفة من الأطراف الصناعية التقليدية.

يتطلب فهم فعالية وسلامة هذه الطريقة إجراء بحث حول معدلات المضاعفات ومقاييس النتائج في المرضى الذين خضعوا لزراعة الأطراف الاصطناعية العظمي. يمكنك الحصول على معلومات حول أشياء مثل معدلات العدوى وفشل الزرع ورضا المريض والنتائج الوظيفية من خلال دراسة الأوراق البحثية الأصلية. يمكن بعد ذلك تحسين عملية اتخاذ القرار السريري باستخدام هذه المعلومات.

أظهر الاندماج العظمي الوعد لدى مبتوري الأطراف عن طريق الفم كبديل قوي للأطراف الاصطناعية ذات التجويفات. أظهرت مجموعة متزايدة من الأبحاث أن الانغراس العظمي يوفر مزايا من حيث زيادة الحركة ، وتقليل الانزعاج ، وتحسين نوعية الحياة العامة. لم تحظ كفاءة الاندماج العظمي في عمليات زرع الأطراف العلوية والطرف العلوي إلا بالقليل من الاهتمام.

تعد التهابات الأنسجة الرخوة الطفيفة هي العواقب الأكثر شيوعًا ، على الرغم من أنه يمكن التحكم فيها من خلال العلاج والمراقبة المناسبين. لتقليل مخاطر المشاكل وتحسين النجاح العام للزرع العظمي ، يركز البحث والتطوير باستمرار على تحسين الأساليب الجراحية وتصميم الزرع.

على الرغم من أن الاندماج العظمي لديه الكثير من الإمكانات ، إلا أنه ليس كل مبتوري الأطراف قد يكونون مرشحين جيدين لذلك. يجب أن تأخذ الاعتبارات الخاصة بالزرع العظمي في الاعتبار العناصر بما في ذلك درجة وطبيعة البتر ، ونوعية وكثافة العظام ، ورغبات المريض..

1. Introduction

A lower extremity amputation can significantly affect a person's level of functionality and general quality of life. Reduced mobility, limited independence, and a variety of physical and mental difficulties can all be brought on by the loss of a limb. Following an amputation, people may have trouble doing basic everyday tasks including walking, using stairs, and even standing for long amounts of time. Losing freedom as a result and maybe affecting one's capacity to work or engage in leisure activities. [1,2]

Traditional suspended socket prostheses often require a lengthy period of rehabilitation before being fitted. This is due to the fact that the socket needs to be constructed specifically to suit the residual limb, and alterations may need to be made over time to guarantee a correct fit and alignment.

The fitting procedure might be more difficult the greater the level of amputation, as there may be less residual limb available to support the prosthesis. Additionally, amputees with more severe amputations could need more sophisticated prosthetic devices, including knee or hip units, complicating the fitting procedure. [3]

Physical therapy to increase strength and range of motion may be used during rehabilitation for classic socket prostheses, in addition to instruction in how to operate the prosthesis itself. In order to make sure that the prosthesis is cozy, practical, and matches the amputee's specific demands, it is crucial for healthcare professionals to work closely with them.

Although the procedure of fitting a typical socket prosthesis can be drawn-out and difficult, it is a crucial step in the rehabilitation of amputees. Amputees can acquire a comfortable and functioning prosthesis that improves their mobility and quality of life by collaborating closely with their healthcare team and investing the required time and effort in the fitting procedure. [4,5]

For amputees, especially those with transfemoral amputations, chronic skin issues related to socket prostheses can be a serious concern. Up to one-third of transfemoral amputees wearing socket prosthesis have been documented to have chronic skin issues such pressure sores, itching, and rashes.

Poor socket fit, undue pressure on certain regions of the residual limb, and insufficient ventilation within the socket are only a few of the causes of these skin issues. Chronic skin conditions can restrict an amputee's mobility and quality of life in addition to being uneasy and perhaps painful.

The reduced risk of persistent skin issues is one of the possible benefits of osseointegrated implantation as an alternative to socket prosthesis. An osseointegrated implant eliminates the need for a socket by anchoring the prosthesis directly to the bone. This can get rid of a lot of the pain, friction, and pressure points that come with socket prostheses [6].

Osseointegration has been suggested as a viable replacement for conventional socket prosthesis for some amputees, despite the fact that it has significant drawbacks of its own, including a lower chance of persistent skin issues. [5-8]

Despite advances in prosthetic technology, amputees still frequently have skin issues including pressure sores and discomfort, especially in places that bear weight. A metal post is implanted into the bone using the osseointegration (OI) procedure to act as an anchor for the prosthetic limb. OI lowers pressure and friction on the skin by doing away with the necessity for a socket, potentially lowering the occurrence of skin issues. Although OI has showed promise in enhancing the function and quality of life for amputees, there are certain risks and problems that should be carefully evaluated before performing the treatment. Fig.1. [9].

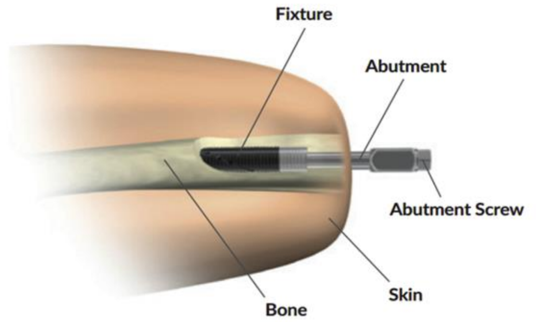

Figure (1): The Osseointegrated Prostheses for the Rehabilitation of Amputees (OPRA) Implant System.

Though osseointegration is a relatively new method in the arena of extremities amputation, it has been utilized effectively in dentistry for many years. Osseointegration was used for the first time in a clinical setting for amputees of the lower limb in the 1990s, and since then, the method has undergone more development and improvement. OI still requires specific knowledge and training and is currently seen as a rather experimental treatment. However, osseointegration is gaining attention and investigation as a viable treatment for amputees' skin issues and enhancing prosthesis effectiveness [10–13].

Amputees may benefit from osseointegration in a number of ways, including:

1. Direct prosthesis control: Osseointegration enables for more direct control of the limb and improved proprioception since the prosthetic limb is attached directly to the bone.
2. Increased stability: By doing away with the socket, osseointegration creates a stronger bond between the natural limb and the prosthetic limb, which can enhance balance and stability while walking and doing other tasks.
3. A higher capacity to walk: Osseointegration may enable a more natural gait pattern and longer walking distances since it lowers the possibility of skin issues and pain brought on by conventional socket prosthesis.
4. Increased functional capacity: Amputees may be able to carry out more difficult and complicated tasks with their prosthetic limbs if they have better control and stability.
5. Better quality of life: Osteointegration may enhance amputees' overall quality of life by enhancing function and lowering their chance of developing skin issues.

It is crucial to remember that the advantages of osseointegration might vary based on the patient and the particulars of the amputation, and that there are also possible hazards and side effects. [14, 15]

The goal of a review of osseointegration in upper and lower limb amputation is to look at the procedure's benefits as well as any possible drawbacks. Analyzing data on elements like functional results, prosthesis usage, quality of life, and complication rates would include looking at research and clinical reports of individuals who have had osseointegration. The review would seek to identify any areas that need more study or development and to offer an unbiased assessment of the advantages and hazards of osseointegration.

2. Transcutaneous osseointegrated Prostheses

Over 2 million persons in the United States are now living with limb loss, and there are roughly 185,000 amputations performed each year, according to the Amputee Coalition. Along with vascular disease and cancer, trauma is one of the main causes of limb loss. A growing older population, the prevalence of diabetes and other chronic illnesses, and other variables all point to a rise in the number of amputations in the future years. This emphasizes how crucial it is to keep researching and developing innovative medical procedures and technology in order to enhance amputees' quality of life and ability to operate. [16,17]

The most typical prosthetic limb used for lower limb amputees is a socket prosthesis, although these devices can cause a number of issues, such as pressure sores, skin irritation, and pain. These issues may restrict how well the amputee can utilize their prosthesis and lower their overall quality of life. Additionally, because it can be challenging to establish a tight and comfortable fit, socket prostheses may not be appropriate for many patients, particularly those who have multiple limb loss or short residual limbs.

Alternative strategies, such osseointegration, have been created as a consequence to overcome these drawbacks and provide amputees a more practical option. To be sure, before choosing a course of treatment, it is crucial to carefully consider the possible advantages and hazards of osseointegration because it is still a relatively new and experimental technology. The amputee's unique demands and circumstances will ultimately determine which prosthesis is best for them, thus this decision should be made in cooperation with a trained healthcare professional. [18,19]

Military troops who have had their lower limbs amputated due to trauma frequently exhibit blast-related heterotopic ossification (HO), especially those who have been hurt by explosive devices. HO is the abnormal growth of bone in soft tissues, which might affect how well a socket prosthesis fits and works. The amputee may find it difficult or impossible to use the prosthesis comfortably or securely as a result.

Osseointegration, which does away with the requirement for a socket and creates a more direct link between the residual limb and the prosthetic limb, has been suggested as a viable treatment option for amputees with HO. Infection and implant failure are two possible hazards related to osseointegration in this group, though. The choice to pursue osseointegration should be founded on a rigorous analysis of the risks and benefits, as with any medical procedure, and should involve a group of skilled healthcare professionals. [20]

The last 20 years have seen the development of percutaneous implants as an alternative to conventional socket prosthesis. With these implants, a metal fixture is surgically inserted into the bone and connected to the prosthetic limb directly, doing away with the requirement for a socket interface.

The decision to use osseointegrated prostheses will be based on the specific needs and circumstances of the amputee, as with any medical procedure, and should be decided in conjunction with a licensed healthcare professional. Osseointegration can be quite beneficial for certain patients, but it is crucial to carefully weigh the dangers and side effects, as well as the long-term effects of the treatment. [21]

Before choosing this course of therapy, it is important to carefully assess the restrictions and clinical difficulties that come with osseointegrated prostheses. Among these restrictions and difficulties are:

1. Infection risk: Osseointegrated prostheses can increase the risk of infection at the implant site since they are inserted directly into the bone. This danger can be decreased with precise surgical technique and continuous observation, but it is still something to be aware of.
2. Implant failure: Even though osseointegrated prostheses are intended to provide a solid and long-lasting bond between the bone and the artificial limb, implant failure can still happen for a number of reasons, including implant loosening or fracture.
3. Limited bone stock: Patients who have experienced significant bone loss or who have health issues that impact bone density may find it difficult to meet the requirements for osseointegrated prosthesis since they need a particular quantity of bone to be present in the residual limb.
4. Surgical complications: Implanting an osseointegrated prosthesis is a difficult surgical process that calls for specific knowledge and skill. Nerve injury, hemorrhage, and subpar wound healing are possible complications.
5. High price: Osseointegrated prostheses can be costly, and insurance may not always cover them. The cost of the treatment, continuing maintenance, and component replacement must all be taken into account.

Despite these drawbacks and difficulties, some patients with limb loss may benefit from osseointegrated prosthesis, especially those who have had trouble using socket prostheses. The choice to pursue osseointegration should be decided in consultation with a licensed healthcare professional, based on an individual evaluation of the patient's needs and circumstances, as is the case with any medical therapy. [22]

For patients receiving the implantation of an osseointegrated prosthesis, rehabilitation is a critical component of the therapeutic process. Patients often have a period of immobility following surgery before starting a formal rehabilitation program. The objectives of rehabilitation include teaching the patient how to use and operate the prosthetic limb as well as increasing the strength and range of motion of the residual limb.

Patients may need to work with a team of healthcare professionals, including physical therapists, occupational therapists, and prosthetists, since rehabilitation may be a time-consuming and difficult procedure. A number of variables, including as the patient's general health and level of mobility before to surgery, the precise type of osseointegrated implant utilized, and the patient's unique objectives and demands, will affect the length and severity of rehabilitation.

For certain patients with limb loss, the osseointegrated prosthetic implantation can be a very effective therapeutic option; nevertheless, it is vital to understand that the procedure is complicated and necessitates a large time and financial commitment. For the treatment and rehabilitation process to be successful, there must be close communication between the patient and their healthcare professionals. [23-27]

As germs can enter the limb through the prosthesis and cause skin breakdown, tissue damage, and possibly even prosthesis failure, infection is a major worry for patients having osseointegrated prosthetics implanted. Maintaining the integrity of the skin-implant contact, which is crucial, requires careful consideration.

In order to lower the risk of infection, it is crucial to regularly clean the region where the implant leaves the body and to take antibiotics to treat infections when they arise. To further lower the risk of infection, antimicrobial coatings may also be added to the implant.

The possibility for bone remodeling to happen during osseointegrated prosthesis implantation presents another difficulty. The process through which bone thickness varies over time in response to stress and strain is known as bone remodeling. It is crucial to make sure the implant is placed so it does not obstruct the natural processes of bone remodeling and that it is sufficiently maintained to prevent loosening or migration.

Overall, osseointegrated prosthetic implantation provides patients with limb loss a number of possible benefits, but it is crucial to carefully monitor the risks and potential side effects connected with this therapeutic strategy. To get the greatest results, close communication between the patient and their healthcare team is essential. [28]

In 2015, the FDA did permit the use of osseointegration prosthesis for above-the-knee amputees; however, this approval did not apply primarily to humanitarian purposes. The approval was for commercial use in persons with above-the-knee amputations who had previously tried but failed to utilize prosthetics. However, it's feasible that some humanitarian projects or efforts give individuals who might not fit the commercial criteria access to osseointegration prosthesis. [29]

The screw-type fixation, sometimes called the Brnemark implant since it was created by Professor Per-Ingvar Brnemark, was the first osseointegrated implant system. It was first created for dental implantology and then modified for use in amputees of the limbs. The screw-type device has a roughened surface to encourage bone ingrowth and is constructed of commercially pure titanium. The skin is sutured over it as it heals after being inserted directly into the bone Fig.2.

The first part of the Integrum OPRA system's two-stage surgical process is inserting a threaded titanium implant into the femur's medullary canal, which is followed by a six-month osseointegration phase. The osseointegrated fixture is connected to a titanium abutment in the second stage, which is subsequently utilized to connect the prosthetic parts. In order to encourage and facilitate the process of osseointegration, the rehabilitation program comprises gradually loading the bone-implant contact over a period of six months. [30,31]

There are two main types of osseointegrated prostheses: the Integral Leg Prosthesis (ILP) and the Osseointegrated Prosthetic Limb (OPL). The ILP is a joint arthroplasty-like procedure that was created in Germany and uses a porous-coated alloy device that is press-fit into the medullary canal. The OPL, in contrast, was unveiled by Dr. Munjed Al Muderis in 2011 and has a highly polished, smooth transcutaneous twin cone adapter coated with titanium oxide to reduce friction with the surrounding soft tissue. Both approaches are meant to promote osseointegration and offer a secure bond between the prosthesis and the bone. 2 [31]

Figure (2): OPL implant system commercialized. [31].

A distal flare is present inside the intramedullary section of the OPL (Osseointegrated Prosthetic Limb) to aid in bone anchoring. The goal of this design element is to improve implant stability and osseointegration. [32]

Two procedures, often separated by four to eight weeks, are normally needed for the OPL (Osseointegrated Prostheses for the Lower Limb) system. The soft tissues are prepped, extra subcutaneous fat is eliminated, and any neuromas are removed during the initial operation. The intramedullary component of the prosthesis is put into the medullary canal of the bone after the bone has been prepared to receive the implant. The intramedullary component is often created such that it may fit snugly and securely into the patient's unique bone architecture.

The soft tissues are closed after the intramedullary component is implanted and are left to recover for a few weeks. During this period, the implant and bone interface start to integrate and osseointegrate, creating a solid link that serves as the prosthetic limb's sturdy basis. The transcutaneous dual-cone adapter is attached to the implant's intramedullary component during the second procedure by being introduced through the skin. A safe and reliable connection between the implant and the external prosthetic limb is made possible by the dual-cone adapter.

A torque control safety device is frequently utilized during the second operation to make sure the adapter is fastened firmly to the implant without harming the bone or soft tissues. With the use of the torque control tool, the implant may be set in place with a regulated amount of force, protecting the surrounding tissues from undue strain or harm.

The OPL system's two-stage surgical method enables thorough planning and preparation for the implantation process while also guaranteeing that the implant and bone interface have enough time to osseointegrate before the external prosthetic limb is placed.

This might lessen the chance of issues like infection or implant failure while also enhancing the implant's long-term success and functionality. [33-37]

It is significant to emphasize that the single-stage OPL process is currently regarded as experimental and has not yet gained widespread acceptance. The most popular technique for implanting osseointegrated prosthesis is still the traditional two-stage surgery. The OPL single-stage treatment features a distinct rehabilitation strategy that places more of a focus on early weight-bearing and quicker recovery.

However, further research is required to evaluate the single-stage operation's long-term effectiveness and safety to those of the two-stage surgery. The OGAAP-2 protocol is a one-stage process that entails fitting a prosthetic limb right away after the osseointegrated implant is placed. This greatly shortens the total amount of time needed for the rehabilitation and final osseointegrated reconstruction to only 3 to 6 weeks. This is in contrast to the conventional two-stage treatment, which requires a six-month delay between implant surgery and prosthetic limb fitting. To reduce the risk of problems, the OGAAP-2 procedure necessitates careful patient selection and surgical planning, and it is not appropriate for all patients. [38]

Rehabilitation might be sped up and results could be improved by keeping track of the prosthesis' stability in the host bone and measuring the level of osseointegration and bone remodeling. Regular follow-up visits and imaging tests, including X-rays, CT scans, or MRI scans, might help with this. In order to test the stability of the prosthesis and evaluate bone remodeling, methods like radiostereometric analysis (RSA) and quantitative computed tomography (qCT) have been developed. These methods enable the early identification of any possible problems and can direct the right course of action for maintaining or enhancing implant stability. [34,39]

The risk of bone fracture and implant loosening might be decreased with the use of noninvasive assessment techniques. Regularly checking the prosthesis's stability in the host bone with noninvasive methods like radiography, ultrasound, or magnetic resonance imaging (MRI) could help spot any early indications of implant loosening or bone fracture, allowing for prompt intervention and averting further complications. The degree of osseointegration and bone remodeling may also be evaluated using these noninvasive techniques, which might be helpful in refining the rehabilitation plan and assuring the long-term effectiveness of the osseointegrated prosthesis.

3. Methods

The most popular non-invasive method for assessing an implant's health, including osseointegrated implants, is X-ray technology. Although the interpretation of the photographs is typically subjective and based on the healthcare provider's expertise, the analysis of the photos is typically qualitative. It can be challenging to determine the exact level of osseointegration or bone remodeling surrounding the implant because the titanium components of the implant might distort images [36]. The limitations of X-rays stem from the requirement for specialized tools, such an X-ray machine, as well as the requirement for skilled individuals to operate the device and analyze the pictures. Furthermore, X-rays subject the patient to ionizing radiation, which can be dangerous if the patient is exposed to it excessively. This is crucial for patients who could require regular imaging, such as those with osseointegrated prostheses who would require ongoing implant monitoring [19,37].

The structure of the skeletal residuum is often assessed using pre-operative radiological techniques, including as X-rays and CT scans, to assist choose the right implant type and size for each patient. The design of external prosthetic parts that suit the patient's remaining limb and interact with the implanted prosthesis also uses this information. [38]

The work by Xu and Robinson shows the possibility of integrating FEM and X-ray images to more fully comprehend the process of bone remodeling in patients with implanted fixtures. They were able to offer a biomechanical explanation for the observed bone remodeling by looking at the distribution of stress and strain in the femur. The cortical bone development surrounding the implant's proximal end and the femur's distal end were both evident in the radiography pictures, demonstrating the impact of stress and strain transfer across the fixture-bone interface on bone remodeling. [41]

The study showed that a male amputee with an OPRA implant experienced considerable bone remodeling, which caused strain to be redistributed along the longitudinal axis of the femur. As a result, it may be desirable to use implants made of functionally graded materials since they may have more constant mechanical characteristics and disperse stress more evenly at the bone-implant contact.

The study did, however, have certain shortcomings. For instance, the study's model neglected to take changes in cortical bone density into account, which may have an effect on strain distribution and bone remodeling. The results may not be as accurate since the change in bone thickness was approximated rather than directly assessed by X-ray.

The degree and type of bone remodeling around the implant might potentially be influenced by the loading rate and the number of cycles per day, which were not taken into consideration. It is feasible that under various loading circumstances or with a different number of loading cycles each day, the reported bone remodeling and strain redistribution might vary.

Although the work sheds light on the mechanical behavior of bone around implants, more investigation is necessary to completely comprehend the intricate biomechanics involved in bone-implant integration and to improve implant design for long-term stability and functionality. [42]

That is a legitimate strategy for doing a literature review since it assures that the review is more focused and pertinent by only include research that evaluate stresses and strains using both FEM and non-invasive techniques. This makes it more likely that the reviews' research will be of high caliber and offer insightful information about the use of FEM to the design and assessment of orthopedic implants. It's true that Resonance Frequency Analysis (RFA) has also been utilized to assess trans-femoral implants. By examining an implant's vibrational properties in response to a magnetic impulse, RFA measures the implant stability quotient (ISQ). The degree of osseointegration between an implant and the surrounding bone can be determined by measuring ISQ.

RFA was utilized in one research to evaluate the stability of 10 patients' trans-femoral implants. The findings revealed that as osseointegration progressed, the mean ISQ values rose. According to the study's findings by Dillingham TR, Pezzin LE and MacKenzie EJ, RFA can be a helpful technique for evaluating the stability of trans-femoral implants and keeping track of the osseointegration process.[33,44,45]

In a research published by Ortiz-Catalan, M., E. Mastinu, R. Bra˚ nemark, and B. Ha˚ kansson.[33,44], the use of resonant frequency analysis (RFA) to assess trans-femoral implants was investigated. The study included implants with dimensions of 17 and 18 mm that were implanted into an above-the-knee amputee as well as a synthetic femur model constructed of Sawbones. Excitations were triggered by a tiny pendulum, and the signals they produced were monitored by an accelerometer connected to the implant's tip. The fundamental natural frequency of the implant was subsequently determined using Fast Fourier Transform software, and it was discovered to be inversely correlated with the elastic modulus of the material utilized as the interface between the implant and the Sawbones.

The study also carried out in vivo trials in addition to in vitro experiments utilizing various silicone rubbers to imitate various interface circumstances. These studies shown that the natural frequency of the implant reduced during the initial weight-bearing activity, then rose to become constant 38 days later after returning to the pre-loading level around day 24[46]. These findings imply that the mechanical characteristics of the bone-implant interface vary over time as the bone remodels and acclimates to the implant, and that a valuable method for evaluating the stability and integration of the implant over time is to monitor the natural frequency of the implant.[47]

The method measures the surface strain of the skin covering the implant using digital speckle pattern interferometry. This method offers a high spatial resolution and accuracy full-field assessment of the surface strain distribution. This method was utilized by the researchers to track the distribution of strain on the skin's surface eight months after implantation in a goat model. The findings demonstrated that as osseointegration advanced, the strain distribution underwent a substantial shift over time. According to the researchers, this method may be valuable for tracking osseointegration in people as well. [48,49]

When osseointegrated prostheses are used, the covered implant acts as a dielectric and adjusts its electrical permittivity in response to axial stresses. The researchers can calculate the stresses encountered by the implant and the surrounding bone by measuring the changes in capacitance as a result of this utilizing ECT. This data may be used to assess how osseointegration is going and to spot any possible problems early on.

The technique's noncontact aspect is especially beneficial because it does not need intrusive procedures like implant removal or disassembly. The thin film covering is also biocompatible and simple to remove if required. The researchers are presently working on improving the imaging equipment and confirming the procedure in vivo after demonstrating the technique's viability using phantom models [50].

The findings demonstrated that the prosthetic phantom's strain distribution under various loading circumstances could be precisely captured and visualized using the ECT approach.

Additionally, the approach was shown to be sensitive enough to pick up minute variations in strain distribution brought on by alterations in prosthetic design or component characteristics. But before it can be utilized as a trustworthy tool for tracking osseointegration in people, more validation and clinical testing of the technique is required. ECT and strain-sensitive nanocomposites have been used in research to track osseointegrated prostheses, and the results have shown significant potential for the creation of a noncontact strain monitoring system. Such a device may be implemented into wearable prostheses in the future to offer real-time feedback on the degree of osseointegration and implant stability.

However, to confirm the efficiency and security of such a system in a human population, clinical studies would be required. [51]

An elastic wave that travels over a structure's surface or through its thickness is called a guided ultrasonic wave (GUW). They are frequently utilized for structural health monitoring and nondestructive testing of a variety of engineering structures, such as mechanical, civil, and aeronautical systems.

In the idea put out by Lynch and his team, GUWs are employed to observe an implant's osseointegration from the outside. A few piezoelectric transducers are positioned on the skin's surface close to the implant as part of the procedure to create GUWs that go through bone and soft tissue. The waves that are reflected and transmitted are then captured and analyzed to learn more about the implant.

This approach has the benefits of being noninvasive, not requiring the insertion of sensors, and being able to offer information about the whole interface region. However, the presence of soft tissue and the intricate geometry of the implant-bone contact may have an impact on the method's accuracy. The approach has to be improved, and more study is required to confirm its clinical viability. [52]

GUWs are beneficial in SHM applications in a number of ways. With just one probe, they may be utilized for ongoing surveillance over huge regions. Additionally, GUWs have low attenuation over extended distances and may take use of a number of acoustic energy transmission, reflection, scattering, mode-conversion, and absorption processes. Due to these characteristics, GUWs are a viable choice for non-invasive implanted device monitoring. Fig.3. [53].

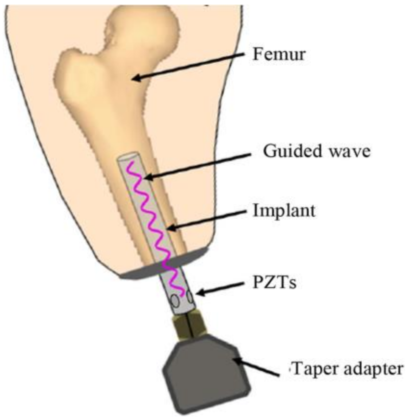

Figure (3): Schematic of the guided ultrasonic wave. [16]

4. Conclusions

The analysis also covered how these techniques can provide a noninvasive, in-the-moment evaluation of implant stability, which might enhance patient outcomes and lessen the demand for revision surgery. The review did, however, also draw attention to some of these treatments' drawbacks, such as the requirement for specialized tools and knowledge, as well as the possibility of outcomes variability due to variations in implant design and patient characteristics. Overall, the study indicates various areas for further research and development and offers insightful information on the state of the art in noninvasive evaluation of trans-femoral implant stability. Due to the limited clinical experience, it is uncertain how well the implant will function over the long term because the skin and soft tissues around the implant site are vulnerable to infections and need strict maintenance and care. In order to enhance the overall performance and lifetime of transcutaneous implants, implant design and material selection still need to be optimized. Additionally, the long-term consequences of bone resorption and remodeling in the region of the implant are still poorly known. [21]

To ensure the long-term success of osseointegrated prostheses, it is essential to develop efficient monitoring and detection techniques. Imaging tools like computed tomography (CT) and X-rays can also be used to evaluate the osseointegration process and identify any issues like infections or bone fractures, in addition to the bio-chemical and mechanical approaches already discussed. Additionally, improvements in manufacturing methods like additive manufacturing and materials science can make it possible to design patient-specific implant geometries with unique surface textures that are best for bone ongrowth and ingrowth. These initiatives can improve the results of osseointegrated prosthesis and raise the standard of living for those who have lost their lower limbs.

Big data and data mining approaches can be useful for foretelling orthopedic implant failure. Algorithms may be created to find trends and risk factors related to implant failure by evaluating huge volumes of data from many sources, such as electronic health records and implant registries. This can assist patients and surgeons make decisions and raise the overall success rate of orthopedic operations. Prior to being utilized in clinical practice, it is crucial to make sure that the algorithms created have undergone thorough validation and that the data used is accurate, complete, and ethically collected. [39,51]

Through assessments of the patients and implants, the study seeks to pinpoint the risk variables connected to both early and late implant loss. The study can offer a thorough knowledge of the factors that lead to implant failure by looking at both patient and implant characteristics. The development of solutions to lower the risk of implant loss and enhance the results of orthopedic surgeries may be done using this knowledge. [52]

It is possible to improve the precision and dependability of osseointegration diagnosis by integrating several sensing techniques. For instance, combining ultrasonic detection with acoustic emission may result in a more thorough knowledge of the osseointegration process. Additionally, the use of engineering techniques like finite element analysis (FEA) might make it easier to forecast how osseointegrated implants would behave under various loading scenarios and speed up the process of design optimization. Additionally, data gathered from various sensing techniques may be analyzed and understood using machine learning and artificial intelligence algorithms, which can also be used to improve the diagnostic and monitoring processes. These advancements may result in more rapid and accurate osseointegrated implant diagnosis, monitoring, and therapy.

5. References

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