THE IMPORTANCE OF ANATOMY IN PROTHESES FIXATION BY OSSEOINTEGRATION FOR AMPUTATION OF THE UPPER LIMBS: METHODS, PROSTHETICS AND REHABILITATION

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THE IMPORTANCE OF ANATOMY IN PROTHESES FIXATION BY OSSEOINTEGRATION FOR AMPUTATION OF THE UPPER LIMBS: METHODS, PROSTHETICS AND REHABILITATION (abstract): Aim: The program of osseointegration for amputations of the upper extremity began in the year 1990 in Sweden, when into a thumb, for the first time, a titanium fixture was implanted. Since then this method has been used for amputations of the humerus and below-elbow. Two surgical procedures are needed to do the treatment. Surgically attaching a titanium fixture to the skeleton is the first procedure, followed by insertion of an abutment that penetrates the skin, six month later, which is the second procedure, ended by the attachment of the prosthesis to it. Objectives: Surgical method, prosthetics and rehabilitation description for the osseointegration procedure. Methods: Selection of patients with prior difficulties with prosthetic fitting and short stumps. Thirty seven amputation cases of the upper limb were treated and fitted with prosthesis, from 1990 to April 2010, of which: 10 thumbs, 1 partial hand, 10 transradial and 16 transhumeral amputations. Currently, only seven patients from those treated are not using a prosthesis. Results: Since osseointegration, improvement of quality of life and function has been reported by the patients treated. Conclusion: The technology of present and future prosthetics has an important basis that is osseointegration. Because of the freedom of motion, functionality and stable fixation, the prosthetic situation is improved. Key words: OSSEOINTEGRATION, SKELETAL ANCHORING, UPPER LIMB PROSTHETICS, UPPER LIMB AMPUTATION, PROSTHETIC REHABILITATION.

Upper limb amputees that use prostheses have difficulties with ordinary prostheses. The range of motion is often limited by the socket and the demands that should be achieved, such as stability, functionality and comfort, by the prostheses are not every time met (1-7). There have been reported matters concerning irritation and excessive sweating due to the socket or harness (2, 6, 8-12). Socket suspension, the capacity to count on the prosthesis being well secured and range of movement of the hand/arm (7) are areas that require improvement. After amputation at the TH (Transhumeral) point this is especially obvious, where most often a harness is required, or at the thumb level, where prosthetic suspension has to be ensured by covering part of the hand. Both functional and cosmetic demands are failed by conventional suspension technology and prosthetic sockets, thus having the potential to severely affect the quality of life. Using direct bone anchorage, a socket is no longer needed and the prosthesis is appended to the residual limb. At the base of this method lays the principle of osseointegration that has been used clinically since 1965 for tooth and maxillofacial replacements (13-15).

A major challenge in Sweden was the start of the osseointegration program for extremity amputees. In 1990 was treated the first patient, a women with a bilateral transfemoral amputation, followed by a thumb ampute and a number of amputations at the radial level. By surgically implanting into the bone a threaded titanium...
implant (fixture), a direct attachment for the prosthesis is created, and a secondary titanium implant (abutment) penetrates the skin and is connected to the fixture. Direct contact between bone tissue and the fixture is the principle of osseointegration, thus securing a stable attachment (15). No methods or components were available for this kind of prostheses or rehabilitation. Designing components and methods was the aim that would allow various amputation levels and residual limb variants to be equipped with different types of prostheses without using a socket. The main difference between bone anchored prostheses and conventional socket prostheses is the absence of a socket. The titanium implant and the prosthetic attachment device hold firmly in place the bone-anchored prosthesis which always fits and is correctly attached. Adverse events, such as heat, chafing, sweating and discomfort, caused by a socket use are eliminated this way. Upper limb amputations at the thumb, transhumeral (TH) and transradial (TR) levels are competent for the use of osseointegration, which has also been used for the treatment of a large number of transfemoral amputates (12, 16-20).

METHODS

a) Requirements and assessment for treatment

A team consisting of a prosthetist, an occupational therapist (OT), orthopaedic surgeons and a coordinator assessed patients referred to the Centre of Orthopaedic Osseointegration (COO). Detailed notions about the treatment plan are given to the patients by the OT and prosthetist, before the team assessment. They can meet a patient with the same level of amputation that has a bone-anchored prosthesis attached, and can ask whatever question they want.

Bone-anchored upper extremity prostheses have the following criteria:

- Difficult to fit with a conventional prosthesis, or previous experience with a socket prosthesis with highly documented wear and, socket- or harness-related problems
- Adequate X-ray assessed bone quality
- No contraindicated illnesses or disabilities, such as ongoing chemotherapy or corticosteroid treatment
- Highly motivated patient who can conform to the treatment plan

Prior to the decision of treatment all other prosthetic solutions/options demand to be taken account of.

The assessment results and information is analyzed by the team. The assessment done by the team is reevaluated by the patient who has different options: osseointegration, recommendation to change the existing socket prosthesis or no further steps at this time.

If osseointegration is the best choice for the patient then the entire process of planning and coordination starts to takes place.

b) Surgery and implant system

The implant system consists of three main components: a threaded titanium implant (the fixture), a skin-penetrating cylindrical implant (the abutment), and a titanium screw (the abutment screw) which holds the system together. Two stages (S1 and S2) sum up the surgical procedure. The bone is surgically assessed in S1. The threaded titanium implant is introduced intramedullary with the help of fluoroscopy, closing the wound afterwards. Based on clinical experience of osseointegration in the dental field, we estimated the healing period to about six months (13). Until the bone grows into the threads, the implant is not loaded. High external forces are to be eluded by the patient at the distal end of the residual limb. The abutment is attached to the fixture at S2 by re-exposing the implanted fixture. At the end the abutment penetrates the skin, with the wound closed (15, 16, 21-23). The soft tissue and skin around the abutment is stabilized and trimmed carefully, having the purpose of covering the end of the distal bone with skin. A rigorous prosthetic and rehabilitation protocol follows after the surgery, for the patient.

c) General prosthetic procedures and construction

The first osseointegration procedure (S1) for a thumb amputee was performed in 1990, for a transradial amputee in 1992 and for a transhumeral amputee in 1994. The patient can utilize the socket prosthesis he was using, with some restrictions, during the period between S1 and S2 (6 months). The distal part of the stumps’ bone must not be loaded, so the prosthesis endures some changes. Depending on the level of amputation, the prosthetic procedure following S2 surgery varies, keeping the purpose of increasing gradually over time the load on the implant.

Reliable, stable fixation of the prosthesis to the abutment is assured with the help of particularly developed attachment devices for osseointegration, that includes the puck system.
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Fig. 1. Implant system

<table>
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<th>TABLE 1: Technical terms/components and their characteristics</th>
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<tr>
<td><strong>Abutment</strong>: Skin penetrating part of the implant, which represents the fixation seat for the prosthesis. Applied during S2 surgery.</td>
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<td><strong>Abutment screw</strong>: Part of the implant system that locks the abutment to the fixture.</td>
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<td><strong>Alignment component</strong>: It is most used in TH applications and located on the proximal part of the prosthesis for easy adjustment of prosthetic alignment.</td>
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<td><strong>Attachment device</strong>: This component is built into the prosthesis, and achieves quick connection of the prosthesis and a high degree of fixation to the implant. It facilitates easy donning and doffing of the prosthesis by means of a small locking lever or a hexagon tool. It comes in standard sizes, is highly durable and right/left side convertible.</td>
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<td><strong>Distal cap</strong>: Cover to use on the abutment when not wearing the prosthesis.</td>
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<td><strong>Electrode holder</strong>: A construction of flexible bars/uprights mounted distal to the attachment device to keep the myoelectrodes in position with even force resistance to the stump tissue.</td>
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<td><strong>Fixture</strong>: Titanium implant component applied at stage 1 surgery.</td>
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<tr>
<td><strong>Myoelectrically prepared prosthesis</strong>: A prosthetic construction and application, initially used with a low weight hand without grip function and no batteries mounted. Can easily be converted/upgraded to complete myoelectric/hybrid/multifunctional prosthesis.</td>
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<td><strong>Puck</strong>: A separate component of the attachment system. It forms the interface between the abutment and the attachment device and handles all individual geometrics abutment situations in transradial applications. It is round, easy to keep clean, highly durable and provides the abutment with a gentle surface. It is made of low thermal conduction material and used in all applications except thumb level.</td>
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<td><strong>Rotation safety device</strong>: This is mounted to the proximal section of the prosthesis above the elbow in TH applications to avoid transfer of high torsion moments to the implant. Adjustable to selected maximum torsion moment, and can also be used for manual pre-positioning of the forearm.</td>
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<td><strong>Shock absorber</strong>: This component is built into special working prostheses to absorb unwanted shock peaks and forces.</td>
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<tr>
<td><strong>Soft tissue support (STS)</strong>: Silicone construction that lifts and keeps distal soft tissue in a stable position. Very few users need this arrangement on the upper limb.</td>
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<tr>
<td><strong>Temperature insulator</strong>: A built-in construction to prevent thermal conduction through the implant. Titanium has low thermal conduction (19 W/m+K).</td>
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<td><strong>Training prosthesis</strong>: A short-frame prosthesis model used in the initial stage of transhumeral treatment to control the generated loading to the implant before supplying a full-length prosthesis. Different weights can be added, to gradually increase total load over time.</td>
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Two standard sizes of the attachment are available for transradial and transhumeral levels, which have low weight, are easy to be kept clean and have a quick-locking mechanism. Only one size of the attachment is available for thumb levels amputations, which is secured with an Allen key to the abutment. Components for implant protection at some amputation levels are needed for overload in rotation/torsion. If it is necessary, a temperature insulator and a shock absorber can be built-in to shun unwelcomed peaks or forces (table 1). Flexible bars are utilized to keep in place the electrodes in cases of myoelectric control. Ventilation is a must for the constructions that leave a hollow space and a closed chamber in the penetration area. The risk of infection is increased by moisture, which can also cause unwanted skin events. When the prosthesis is not worn, a distal cap over the exposed abutment can be placed for its protection.

**TRANSHUMERAL LEVEL PROSTHETHICS**

For the transhumeral amputee, a reliable, stable socket suspension in most cases leads to a harness-and-socket design that has the effect of limiting, in the shoulder joint, the range of motion. It is a problematic thing to obtain humerus rotation and socket stability by using a socket. The SISA concept, or even angulation osteotomy represent viable suspension alternatives to elude those matters (24-26). In both cases surgery and the use of a socket for suspension is needed.

Three weeks after S2 intervention is the beginning of the prosthetic procedure at the transhumeral level. A training prosthesis is attached to the patient who has the possibility to increase the load from a set at the moment the patient gains more strength. The patient should use the training prosthesis only temporarily until he is able to bare the weight of the final full-length prosthesis. A standard attachment device is used to connect the final prosthesis to the abutment. Alignment components, spacers, and rotation safety devices represent special elements that are fabricated for amputations at transhumeral level. A trustworthy rotation/torsion function is already integrated in some elbow joints that are on the market now. Electrode holders are placed in case of myoelectric control. Normally, a cosmetic or a myoelectrically prepared variant is used as a first full-length prosthesis. Electrodes are mounted at first but no batteries are used along with a lightweight hand that lacks the grip function, with the purpose of keeping a low weight. After that, a more functional type of prosthesis can be used. Myoelectric hybrid, multifunctional, cosmetic and body powered prosthesis have been used for amputations at TH level. At the end of the osseointegration process, all patients face the choice of upgrading to a more functional prosthetic type or continuing wearing the initial prostheses they were fitted with.

**TRANSHUMERAL LEVEL PROSTHETIC REHABILITATION**

Before surgery, to profit from the superior motion produced by osseointegration, a maximal range of motion and a good muscle strength is a must have for the patient. By using a bone-anchored prosthesis, the patient experiences a situation in which the joint closest to the prosthesis is loaded almost in a normal way that has been missing since he became an amputee. A limited range of motion is executed by the patient at the shoulder level, without pain, after S1 surgery. The patient can start to exercise, after 3 weeks from surgery, external/internal rotation of the shoulder having the purpose of avoiding the rotational forces of the distal soft tissues. Full range of motion reached in six weeks after the surgery is the goal intended. Chest, back, arms and shoulder muscle strengthening exercises can be initiated. The same exercises are performed by the patient after S2. The bone must be loaded attentively in order to provide a solid binding between the bone and the titanium fixture. Using a short training prosthesis three weeks after S2 surgery assures this is done in a controlled way. Initially, low weights (50-100g) are attached to the training prostheses, being grown (50-100g) each week until the weight of the final prosthesis is reached by the patient. Bone quality and pain dictate the loading of the implant system. Axial weight loading is carried out twice a day by the patient, in accordance to a special treatment plan, by pressing the short training prosthesis against a bathroom scale. The interface between the bone and fixture gains controlled loading by using this procedure over time. By using the visual analogue score we admit that pain above level 4 is not permitted (27). A full-length prosthesis
without grip function is attached to the patient at about 12 weeks after surgery. The patient executes light exercises, which grow in intensity over time, with the prosthesis. Bilateral easy activities can be done. When the time is right and the surgeon gives his acceptance, a heavier functional prosthesis can be attached to the patient. Bilateral activities involving functional prosthetic grip training can be initiated.

**Transradial level prosthetics**

Although the socket sometimes causes discomfort, abrasion, reduced range of motion and tissue problems in the elbow joint, ordinary socket suspension techniques usually work satisfactorily for this level. These complications are usually associated with the length of the residual limb. A long residual limb exhibits more tissue to the socket interface, whereas a short residual limb has the inconvenience to be subjected to an increased tissue load.

Stable, reliable fixation is obtained with osseointegration by inserting implants in both the ulna and the radius. Following the bone anatomy, we use two abutments that pierce the skin to form a particular personalized geometrical configuration. That’s why a personal impression is needed, that can usually be made 3 weeks after S2 surgery, by using a particular impression jig in which the abutment status is apprehended in a most favorable position. The prosthetic alignment is optimized and the prosthetic length is verified by the prosthettist with the help of the impression jig. In case of myoelectrical control, the jig is used as a reference for electrode positioning. We copy into a plastic puck the geometrical situation of the abutment. After that, without any other checkpoints or control, the prosthesis can be fabricated ready for shipment. The load on the ulnar implant is increased if active supination or pronation is built in, thus not being normally used. Electrode holders are installed if myoelectrical
electrodes are utilized. Myoelectric, cosmetic, body-powered, and passive-hook/working prostheses have been mounted for the TR amputation level. At the end of the osseointegration process, all patients face the choice of upgrading to a more functional prosthetic type or continuing wearing the initial prostheses they were fitted with, as in TH level amputation.

TRANSRADIAL LEVEL PROSTHETIC REHABILITATION

With the difference of not using short training prostheses, we can admit that rehabilitation has a similar program as for the Transhumeral level. The patient can begin to utilize the prosthesis as a help in daily activities, having the possibility of wearing a lightweight myoelectrically prepared or a cosmetic prosthesis. Assessing pain and bone quality (X-ray) permits the use of heavier prosthesis followed by a general rehabilitation regime.

THUMB LEVEL PROSTHETICS

The most visual obvious parts of the body are the hands and the face. Major cosmetic effects and severe deterioration of hand function can be inflicted by finger loss and especially thumb loss (28). Pollicization, toe-to-finger transfer or a prosthesis can be used as treatments for this type of amputation (29-31). A large area of the remaining hand is covered by a conventional prosthesis for a thumb amputee with the purpose of accomplishing suspension, which affects function and appearance of the hand. An excellent platform for prosthetic fixation is created by a fixture that is inserted into the metacarpal bone and a skin-piercing abutment. The start of the prosthetic procedure is given by an impression that captures the form of the residual limb in relation to the position of the abutment. With the use of silicone impression compounds we can do this procedure if no edema is present. This impression procedure is not required by all silicone prosthesis fabrication methods. The best prosthetic fingertip position can be found with the use of special test prosthesis. Around an attachment device, that has a hexagonal locking mechanism, the final prosthesis is built. The prosthesis stability is given by a prosthetic inner frame which is linked to the attachment device. Silicone is normally used to produce the outer part of the prosthesis, which also leaves the impression of a high-definition aesthetic appearance of the prosthesis. The patient has exceedingly high functionality owing to a full freedom of movement in the proximal thumb joint, which includes positioning from a key grip to all fingertips. The patient’s hand function is enhanced by an osseointegrated thumb prosthesis which drastically improves the grip. The silicone prosthesis is worn out fast by high-frequency active use. That’s the reason why in some cases patients are supplied with both a special type of high-durability working prosthesis and HD silicone.

THUMB LEVEL PROSTHETIC REHABILITATION

At thumb level, between the first and second intervention, the healing time is decreased to about a four-month period. Postoperatively the patient has to exercise the range of motion and decrease the edema. When the edema has been minimized, than the patient can be equipped with a prosthesis. It is advised that the thumb prosthesis is only used for easy activities of day to day living during the first 3 months after the operation. The load should be increased in time and initially the patient should avoid key grip/heavy pinch. On the visual analogue scale pain should not be higher than 4.0 (27).

RESULTS

A total of 37 cases were treated with osseointegrated implants on the upper extremities between 1990 and April 2010. The mean number of years since primary amputation was 12.9 (range 0–25 years) and the mean age at SI surgery was 40.9 years (range 18–64 years). The demographic data include 16 TH, 10 TR, 10 thumbs and 1 partial hand. One patient was treated bilaterally at TR level and is presented as two cases. The cause of amputation was trauma in 32 patients, congenital deformity in 3 and tumour in 2 cases; 24 were amputated on the right side and 13 on the left. There were 6 females and 31 males. Prosthetic constructions have made it possible to provide patients with long or short residual limbs at TH and TR level. The patients have been fitted with prostheses of various types. The average prosthetic usage time for TH is 5.6 years (range 0.3–15 years), TR 13.9 years (range 5–17.6 years), partial hand 10 years (range 10 years) and thumbs 8.1 years (range 0–20 years). Seven patients are non-users today. Their limited usage time is...
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included in the results above. One patient with a thumb amputation, treated in 2001, developed an infection and the fixture was removed five months after S2. Two patients with thumb amputations experienced loosening of fixtures because of incomplete integration shortly after prosthetic fitting. Another patient with a congenital deformity at TR level was a successful user but had an overload accident that caused a fracture in the implant. Two transhumeral patients are non-users; one had a severe arthrosis of the shoulder joint. An arthrodesis improved the situation, but after a trauma, the arthrodesis became mobile and painful and the patient was unable to use the implant for suspension, so the abutment was removed and the patient now has a ‘sleeping’ implant. This was not an osseointegration-related problem. The third TH case failed because of incomplete integration after two surgical trials. In one partial congenital hand amputee, the implant was removed. The patient experienced improved suspension and stability from the osseointegration, but the improvement did not override the long-term disadvantages. The main problem was related to the lack of protection of the distally placed abutment, which caused substantial problems for the patient when the prosthesis was not being used.

DISCUSSION

Most candidates for the osseointegration procedure had a history of problems with their previous socket prostheses. The majority suffered from skin/tissue problems, had problems with sweating, or had extremely short residual limbs, which in some cases caused low prosthetic use or nonuse. Many of these problems have been resolved using the osseointegration technique, which eliminates the need for a socket. Full perception of touch at the residual limb surface is achieved with osseointegration due to full skin exposure.

No negative effects of osseointegration have been reported in the working situation and patients have a wide spectrum of jobs, ranging from office work to heavy-duty farming. Concerning patients’ family life, a small number of patients mention that the protruding abutment can be disturbing in specific situations when they are not using their prosthesis, for example, when performing baby care. A special baby-care prosthesis was made for one TH with good results. Patients can be provided with a ‘distal cap’ for protection, which can be used when not wearing the prosthesis.

Without any residual limb volume to consider, direct bone-anchored prostheses always fit and have long durability. The need for prosthetic replacement is not frequent, and worn-out sockets are no longer an issue. This reduces the prosthetic cost over a long time period.

CONCLUSION

The rehabilitation strategy can be changed by osseointegration for selected upper extremity amputees and new prosthetic technology can be introduced on this platform, because of stable fixation. The clinical relevance of this new system of treatment will be increased by further studies on complications and outcome data and assessment of quality of life.

REFERENCES


17. Hagberg K. Transfemoral amputation, quality of life and prosthetic function: studies focusing on individuals with amputation due to reasons other than peripheral vascular disease, with socket and osseointegrated prostheses (dissertation). Goteborg: Goteborg University; 2006.


