NEW TECHNOLOGY FOR THE SUSPENSION OF TRANS-HUMERAL PROSTHESES – SISA (SUBFASCIAL IMPLANT SUPPORTED ATTACHMENT)

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INTRODUCTION

Trans-humeral amputees have for a long time had suspension methods that limit the functionality and use of the prosthesis. Due to the cone shape of the amputated stump, suspension of the prosthesis has mainly been done with harness securing the prosthesis to the body. The harness crosses the back and goes around the axilla of the contralateral shoulder. This may cause back and neck problems together with pain in the contralateral axilla.

The range of movement for positioning the prosthesis is also limited with the harnessed prosthesis. For the trans-humeral amputee, positioning the artificial arm is crucial to obtain the benefits the prosthesis can give. Since the elbow joint is absent, the only way of positioning the prosthesis is by using the shoulder movements. If the prosthesis and its suspension limit the effective range of movement, the functionality of the prosthesis will be reduced. The prosthesis will in most cases hardly respond to internal or external rotation of humerus due to the circular shape of the stump and no condyles at the distal end to effectuate the movement.

By trying to recreate the lost condyles of the amputated humerus, we aimed to overcome the suspension problems, including improving the range of movement and control of the prosthesis.

The aim of this study was to create artificial humeral condyles, which would allow the CPO to fit a prosthesis that did not interfere with the shoulder movement on the amputated side. This should increase the functionality of the prosthesis due to increased positioning possibilities, while the pain and problems of the back and neck would be reduced.

Initially, three patients took part in this pilot study, where a titanium implant shaped like a T was surgically cemented into the humerus. At present time, a total of six patients have had their humerus modified in this way.

METHOD

All three patients in the pilot study used harness suspended prostheses, controlled their prostheses myoelectrically, two of them with an electric elbow joint. In common, they all had problems with pain from the neck and discomfort in the axilla of the contralateral shoulder.

Patient 1
Male, age 67 years. Amputated right arm at the distal half of the humerus due to trauma 15 years prior to the study. This patient had earlier tried a prosthesis with a silicon liner without success. Just before the surgery, he was using a hybrid prosthesis with a mechanical elbow joint and a myoelectrically controlled hand.
The titanium implant this patient received had an intercondylar diameter of 55 mm and his amputation stump was elongated by 5 mm.

**Patient 2**
Male, age 58 years. Amputated left arm proximal to the condyles due to a trauma 33 years prior to the study. The prosthesis this patient used was a myoelectrically controlled prosthesis with a Utah elbow. It was harness suspended and pulled on by a stockinette. This allowed, together with the length of the stump, a fairly good range of motion with the prosthesis on.

This patient’s stump was shortened by 40 mm and had an intercondylar width of 60 mm.

**Patient 3**
Male, age 22 years. Left arm amputated through the proximal half of the humerus due to a trauma 3 years prior to the study. He used a prosthesis where the hand- and the elbow functions were controlled myoelectrically. By using a push button on the outside of the prosthesis, pro- and supination was also controlled with the electrodes.

Due to the short length of patient 3’s stump, this was elongated by 12.5 mm. The intercondylar diameter of the titanium implant was 65 mm.

After a presurgical examination with a CT scan of the patient’s amputated stump, a titanium implant was made with an intercondylar diameter fitting the patient’s humerus. The diameter of the stem was also decided by the diameter of the medullar cavity of the humerus. This diameter should allow a cement mantle of no less than 3 mm on each side. The titanium implant was cemented into the medullar cavity of the humerus. The skin surrounded the titanium implant and created a closed environment for the new condyles.

Early prosthetic fitting was made after 3-4 weeks, and different types of sockets were made. Though the oedema was still present, different casting techniques were tried out to control the new "condyles" within the socket. The socket shape should also not interfere with the shoulder movement, and no harness should be needed. It was important that the socket fit would withstand torsional forces without the condyles "slipping" out of their position. The weight of the prosthesis acting as a tractional force should also be acceptable to the patient without creating pain or discomfort.

**RESULTS**

The check sockets were initially made as a laminated socket in Siegelhartz; where we made a posterior lid to allow for donning and doffing. A cast was taken where the CPO used the first and second finger to maintain a superior pressure on the condyles, similar to casting techniques used in trans-radial prostheses.

The patient put the check socket on by first extending the shoulder and putting the stump into the socket. Then by flexion of the shoulder, the new condyles were placed into the anterior part of the socket. The lid was closed thereafter by using Velcro and the socket was supposed to stay firmly on the patient’s stump. A second Velcro secured the check socket at the proximal end, close to the axilla. After testing the socket fit by pulling and twisting the socket on to the patient’s stump, we soon realised that this technique did not give sufficient control and support needed for a good prosthetic fit. At
high torsional force, the stump had a tendency of slipping out of its position on the lateral condyle, which caused pain and discomfort.

We thereafter discussed how to control the condyles more efficiently, and came up with a solution where ”doughnuts” were made in hard polyurethane to fit around the condyles. These “doughnuts” were mounted in a jig to maintain the control of the condyles throughout the casting session. The jig stayed on the patient during casting, and was only removed from the plaster negative after it was filled with plaster of paris.

The check socket was laminated in Siegelhartz and for donning and doffing purposes the lid was now moved to the lateral condyle, where it was slid on without any hinges. It was again secured with a Velcro strap over the lid.

This procedure seemed to work better when the check socket was tried on the patient. Positioning the condyles correctly into the socket was easier, and they maintained their position. Displacement of the condyles within the prosthesis was initially not present. After attaching the hand, forearm and elbow to the socket, the patient was able to position the prosthesis in a far better way than he could with his old prosthesis prior to the surgery. (See table 1)

<table>
<thead>
<tr>
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<th>Patient 1</th>
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<th>Patient 2</th>
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<th>Patient 3</th>
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<tbody>
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<td>Preop</td>
<td>1 year po</td>
<td>Preop</td>
<td>1 year po</td>
<td>Preop</td>
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<td>15°</td>
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<td>45°</td>
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<td>135°</td>
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<td>80°</td>
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<td>4,8</td>
<td>4,8</td>
<td>0,2</td>
<td>0,2</td>
</tr>
<tr>
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<td>1,0</td>
<td>8,8</td>
<td>0,2</td>
<td>8,6</td>
<td>1,0</td>
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Table 1: VAS (Visual Analogue Scale): Worst imaginable: 10; Best imaginable: 0

However, after wearing the prosthesis for a few hours, the shape of the stump changed due to compression of the soft tissue. We therefore had to make adjustment possibilities in the M-L direction, so the pressure could be adjusted to maintain a good fit.

The socket was made like a framework of metal and the customized ”doughnuts” were mounted into the metal frame, where the lateral lid was made adjustable. This allowed the patient to adjust the M-L pressure according to the stump condition and a snug fit around the condyles was maintained to secure the control of the prosthesis.

To minimise skin pressure further development of the socket was done to increase the surface of contact. Shape and material of the pads that encompass the implant changed from doughnut-like pads made of Pedilin to tear drop shaped pads out of silicone.

After using the new SISA prosthesis, all three patients reported disappearance of neck and shoulder pain.
DISCUSSION

The basic idea of this project was to create an amputation stump similar to that in elbow disarticulation amputees, where the humeral condyles allow a secure fit of the arm prosthesis, without any harness.

All patients still use their SISA-system and there was no loosening of an implant until now. The first three patients had been fitted with different intercondylar widths of the implants and this showed to affect the fitting capability of the prosthetic socket. Patient 1 had an intercondylar width of 55 mm, and due to the shape of the humerus, the lateral condyle became small.

This gave us a very small weight bearing area on the lateral side, and the prosthetic socket had a tendency to slip over the condyle when torsional forces were added.

On patient 2 and 3, the width was increased and control of the prosthetic socket was made easier. However, there is still a high load that should be carried on the condyles and this could easily cause skin damage and pressure sores. The width and size of the artificial condyles are of great importance to the quality of the prosthetic fit. The soft tissue coverage over the condyles also affects the control of the socket. Patient 2 had a very bony stump with little soft tissue coverage. Here it was very easy to control the stump in the socket, but due to shortness of soft tissue coverage, the pressure area became intolerable, and had to be increased to the maximum.

When the patients put their stump into the socket, it is crucial to have the correct position within the socket. Pressure marks and discomfort will arrive if this is not done correctly. Due to the continuous pressure on the skin around the condyles, it is important to have sufficient space on the tip of the condyle. This will allow the skin be more free and prevent excessive stretching of the skin.
A second generation of the titanium implant has been made, where the shape has been altered. Three patients have been fitted with this new implant, and rehabilitation time for prosthetic fitting has decreased compared to the patients with the first generation of the implant. The weight bearing area has been increased and the angulation of the condyles has also been altered. This made it easier for the CPO to make a prosthetic socket that was more comfortable for the patient.

CONCLUSION

This study demonstrates that by means of non-percutaneous implants the function and control of the exoprosthesis can be significantly improved. In total, we managed to make an amputation stump that could support the weight of the trans-humeral prosthesis without any harness. Pain in the neck and contralateral shoulder area was eliminated and this was of great importance to the patients. When socket shape and fit were optimized, the patients had an increased control of the prostheses and positioning for function became easy.

The shape and width of the artificial titanium implant is of great importance to maintain a good prosthetic fit. The second generation of the implant, proved easier fitting of the prosthetic socket. Minimization of the stress of the skin in the area of the implants is of great importance to the quality of the fitting. Further development of this system will be done in collaboration with Otto Bock Healthcare focusing on an improvement of the implant to reduce the skin pressure by increasing the stressed area and decreasing the required pretension. The fixation of the implant shall be as well non-cemented so that younger patients can also benefit from this new technology. A modular design and a two stage surgery will make the procedure easier to handle. To increase the wearing comfort of the system the load transmission of the prosthetic socket will be optimized. All this development will be scientifically proven by means of FEM-calculation, extensive measurements and a clinical trial.