UTILIZATION OF NEGATIVE PRESSURE FOR SOCKET SUSPENSION IN UPPER EXTREMITY PROSTHETICS

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ABSTRACT
Negative pressure, or vacuum, has been utilized for suspension in lower extremity prosthetics with impressive results. The authors describe a technique to enable the application of vacuum in the suspension of a transradial prosthesis. A discussion of the merits and challenges of such a system follows with emphasis on troubleshooting and common causes of failure. Examples of this technique in various applications will be presented. Future innovations and potential for further development of this technique for other levels of upper extremity amputation will also be offered.

INTRODUCTION
The negative impact of poor suspension is a primary concern for many prosthesis users. Improving suspension can lead to enhanced function, increased comfort, decreased perceived weight of the prosthesis, and potentially decreased skin trauma. The advantages of elevated vacuum socket design for suspension are well documented in the area of lower extremity prosthetics. Numerous systems are currently commercially available. Our clinical group is exploring these concepts for application to upper extremity socket design at all amputation levels up to and including transhumeral.

This paper presents a technique for elevated socket fabrication for the transradial level. Eight patients fit with the elevated vacuum socket design for a task specific application. These eight transradial fittings serve as a “proof of concept” that vacuum sockets are effective in suspension of prostheses typically requiring considerable resistance to forces of distraction. While these early fittings have not yet incorporated electric components or control strategies of electric prostheses it is clearly a next step in the developmental process that requires attention.

SELF-SUSPENDING TRANSRADIAL SOCKET DESIGNS

Many transradial self-suspending sockets designs have been developed and used in an effort to eliminate the need for a harness for suspension. Variations of self-suspending designs are widely used in upper extremity prosthetics today, especially in myoelectric devices. Examples of self suspension utilizing the elbow bony anatomy are the Muenster technique, the Northwestern University socket, and the Trans Radial Anatomically Contoured (TRAC) socket. Other socket designs have utilized elastic materials such as silicone to create suction between the socket and residuum. Examples of this type of suspension are roll-on liners with locking mechanisms or lanyards, and custom silicone sockets.

Elevated vacuum systems for suspension are an evolution of suction systems. The larger the air volume remaining in the sealed socket the larger potential for motion is present. By removing this air and creating a vacuum internally, motion between socket and residuum is virtually eliminated.
PATIENT SELECTION CRITERIA AND TYPICAL CURRENT APPLICATIONS

Eight patients were fit with an elevated vacuum socket for use with a transradial activity specific prosthesis. Each of the patients was previously successfully using a self-suspending socket design for a myoelectric prosthesis and a roll on liner with pin lock with auxiliary suspension harness for a body-powered prosthesis. Each patient requested a task specific prosthesis that would reduce pressures on the bony anatomy of the elbow or eliminate the confining harness during specific activities. All agreed to be fit with an elevated vacuum system.

The general indications for fitting were: a well healed mature residuum that had already successfully tolerated the suspension of both a self-suspending socket design and a roll on sleeve with pin-lock design. The length and shape of the residual limbs were not used as selection criteria. Caution was exercised for limbs with deep invaginations as the effect on the skin folds under vacuum were unclear.

FABRICATION AND FITTING

Casting and Model Rectification

The patient is fit with a silicone roll-on liner with no internal matrix or distal pin. Both custom and off the shelf liners were used in our cases depending on the uniformity of the residuum shape. The off the shelf liner used was the ESP Streamline. The residuum is positioned with the muscle tissue relaxed, the elbow joint in slight flexion, but at rest, and the patient standing with the shoulder joint relaxed. A container of alginate is prepared that is tall enough to cover the residuum to a point two inches proximal to the elbow. The limb is positioned in the alginate and the alginate is allowed to set with the limb relaxed. The resulting negative mold is filled with plaster. The model is gently smoothed with no build-ups or reductions in the rectification process. There is no attempt to create a volume change of any kind during this rectification. It is our intention with this technique to have the tissue of the residuum come into full and firm contact with the hard socket prior to the introduction of vacuum. It is important that when vacuum is applied, that the soft tissue is not distended, distracted or otherwise stressed in the socket.

Test Socket Fabrication and Fitting

A test socket is blister formed from a clear plastic such as DurrPlex. The socket should be thick enough to ensure rigidity at the proximal brim. The socket is removed from the model and the trimlines established. The trimlines for the finished socket are distal to the olecranon process, the medial and lateral epicondyles, and the cubital fold. A vacuum tubing barb (Otto Bock 4Y300) is installed into the distal aspect of the plastic by drilling and tapping the plastic. The threads are sealed with a quickset two part epoxy during installation. A one way auto expulsion valve (Otto Bock 4Y311) is then installed using vacuum tubing to connect it with the barb on the socket.

The patient dons the same silicone liner used during casting. An interface to wick out trapped air such as a nylon sock must be used between the liner and the plastic test socket. This also allows the residuum to slide into the test socket without excessive friction. If a custom liner is being used, this interface can be integrated into the outer surface of the liner. The most important aspect of this test is to ensure total contact of the liner and residuum to the test socket without the introduction of vacuum. This point cannot be stressed enough and the success of the system depends upon this total contact. Total contact must be achieved with a minimum of force. No gapping proximally or voids distally can be present. After this is verified, a sealing
sleeve (Streifeneder 3s10/s) is applied higher than most proximal portion of the nylon wick. A hand vacuum pump (Actron CP7830) is used to produce the internal vacuum. Vacuum of up to -25inLb can be applied. The comfort of the socket can now be evaluated by pulling distally, pushing proximally, medially, and laterally. Rotational stability should also be confirmed.

Fabrication

1. Obtain a positive model by pouring the test socket with plaster and blister form an 1/8” layer of DurrPlex over the model
2. Abrade the surface of the plastic prior to an initial carbon lamination. This lamination is meant to be thin and light. One layer of braded carbon is sufficient
3. Created the outer frame shape out of plaster. Include a recess on the medial or anterior aspect deep enough to set the valve barb below the surface of the frame. Install a lamination dummy the appropriate size for the wrist to be installed later
4. Apply a PVA bag over the shaped plaster and inner socket. Laminate an outer frame using a preferred material lay-up. 3 layers braded carbon and nylon separators were used for our cases
5. Trim frame proximal to trimline and remove inner socket and plaster
6. Drill and tap inner socket for barb application
7. Screw in barb and seal with quick set two part epoxy and install tubing on barb
8. Drill hole in frame large enough to accommodate valve centered in the recess
9. Seal inner socket to frame by painting abraded inner socket with Orthocryl and inserting socket into frame. Finish sealing by drizzling Orthocryl into wrist opening
10. Feed tubing through valve hole and connect to valve
11. Seat valve into hole with quick-set two part epoxy
12. Seal in wrist unit of choice with Orthocryl

Application

The same liner used during casting is donned over the user’s residuum. Again care must be taken to ensure no air gaps or voids are present between the liner and residuum. An air wick is applied over liner if one is not present in the liner. The socket is donned over residuum. The sealing sleeve previously applied to the prosthesis frame is rolled up to its full extent. The user
then applies distally directed force into the prosthesis. This will seat the residuum into the socket prior to applying vacuum. Vacuum is now created in the prosthesis using the hand pump.

Check-Out
Once the prosthesis has been donned and vacuum has been established the fit of the finished prosthesis is examined. A typical critique of the prosthesis fit and function should be made but the prosthetist should take special note of three areas.

Range of Motion: There will be some restriction to flexion due to the material from the liner and sealing sleeve in the anticubital fossa. Flexion should be no more than 10 degrees less than active flexion without prosthesis on. This would be an indication of an anterior trimline that is too high.

Comfort in distal distraction: When the prosthesis is pulled distally there should be no discomfort at the user’s distal residuum. This will sometimes be described as “pulling” or “sucking”. This is an indication of lack of contact between the residuum and socket prior to vacuum application, or a residuum that deforms significantly during flexion.

Reliability of vacuum over time: The vacuum should be tested at the time of initial application with the pressure gauge attached to the hand pump. The vacuum level should also be confirmed after 10 min. There should be no perceptible loss of vacuum during this time. Loss of vacuum indicates an air leak within the system.

Trouble Shooting Loss of Suction
The most common cause of air infiltration is the sealing sleeve. This is the least durable aspect of the system. Any small hole in the sleeve can allow air in and a reduction in vacuum over time. An incorrectly or incompletely sealed inner socket and frame can also allow air to leak between the layers of laminate. These leaks most often happen slowly and the suspension is still adequate enough to hold the prosthesis on but the many advantages of the vacuum are lost. In rare cases the valve itself can be faulty but this will result in the inability to achieve vacuum.

RESULTS
All eight patients were successfully fit with an elevated vacuum task specific prosthesis. All prostheses fit were examined and consistent vacuum levels were confirmed. None of the patients experienced any discomfort or skin trauma secondary to prosthesis wear. Exceptional suspension was noted in all cases. One patient discontinued use of prosthesis due to poor biceps musculature and a resulting range of motion limitation greater than 10 degrees. One patient required assistance in donning as the strength and dexterity of his contra-lateral hand was not sufficient for the donning process and manipulation of the hand pump used to initiate vacuum.

Each prosthesis was designed for a specific activity or activities which determined the patient’s use of the prosthesis. Figure 4 shows a patient with a prosthesis created for sports such as baseball and golf. The patient was able to comfortably perform these activities with less restriction to motion. He noted improved control and performance. Figure 5 shows a patient with a prosthesis created for rock-climbing. The patient was able to suspend his entire body weight from the prosthesis without discomfort. Weightlifting, biking, and swimming specific devices were also fabricated with similar improvements in suspension and performance.
FUTURE DEVELOPMENTAL FOCUS AND APPLICATIONS

The technique described in this paper explores the use of elevated vacuum for task specific prostheses only. The application of this technique to myoelectrically controlled prostheses is being examined. The hurdle of passing myoelectric signals through the silicone interface without sacrificing the elevated vacuum must be solved. As new materials and techniques are developed, many of which are currently being researched, it will be possible to apply elevated vacuum to a much larger range of prosthetic devices.

CONCLUSION

The eight patients fit with the elevated vacuum system have demonstrated a proof-of-concept for the application of elevated vacuum in transradial activity specific devices. This procedure can be used as a springboard for future applications which will expand its clinical relevance.

REFERENCES

5) Hepp, O., Kuhn, G.G., "Upper extremity prostheses”, Proceedings of the Second International Prosthetics Course, Copenhagen, Denmark July 30-August 8, 1959