A Custom-Made Interface for Stoma Care Products for Total Laryngectomees.
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Materials & Methods:
An impression was taken of the stoma site using a standard silicone laryngectomy tube (Provox® LaryTube™, Atos Medical, Sweden) to allow for an unobstructed airway. Nasal packing gauze thoroughly saturated with lubricating solution was used to block any gaps between the laryngectomy tube and stoma. Next, an impression was taken using vinyl polysiloxane impression material (VPS mix, Patterson Dental, St. Paul, MN) further reinforced using tongue depressor blades. The impression allowed for a 1.5" minimum width for fixation to the patient's skin. A stone model of the site (Resin Die Stone, Patterson Dental, St. Paul, MN) was then created using the impression.

Above the patient model, the proposed prosthesis was sculpted using baseplate wax (Neowax®, Dentsply, York, PA). To allow for the insertion of a standard Provox® Heat and Moisture Exchange (HME) cartridge (Atos Medical, Sweden), an opening equal to that of the adhesive base plate was achieved by incorporating the rim of the plate into the wax sculpture. During the subsequent patient visit, the proposed shape and edge margins for the prosthesis were verified. Then the patient model was adjusted by grinding down the edge perimeter. Silicone was intrinsically color matched to the patient (Platsil Gel-10 silicone, Polytek Development Corp., Easton PA and Human Coloration Kit, Siliclonne Studios, Valley Forge, PA).

The wax form was adapted onto the patient model and moldmaking proceeded by back pouring resin die stone up to the top of the lip of the incorporated adhesive base plate. After boxing the model, additional stone was poured above to create the top half of the mold. Because we observed that the Provox® cartridges would easily disengage from a retention ring cast using the same soft durometer silicone used for the rest of the prosthesis (Shore A 10), we chose to precast the retention ring portion using a harder durometer silicone (Shore A 40). Additionally, its diameter was reduced to more firmly grasp the cartridge in place. This was accomplished by pouring silicone duplicating material (Platsil® 71-10, Polytek Development Corp) above a Provox® HME cartridge. It was then cast in stone and carved to reduce the outside diameter. A shore 40 durometer silicone (Shin-Etsu KE1310ST, Medford Silicones, Medford, NJ) was then poured around the model to create a pre-cast HME cartridge retention ring.

Because of the high degree of flexibility at the retention site, due to constant neck movement, silicone adhesive was to be used (Blom-Singer® Silicone Adhesive, InHealth Technologies, Carpinteria, CA). To protect the silicone prosthesis from the rigors of daily cleaning, a polyurethane sheeting was bonded to the back of the prosthesis. The sheeting was vacuformed onto the bottom portion of the mold, and silicone bonding primer was applied (330Gold, Factor II, Lakeside Arizona) prior to packing the mold. Previously colored silicone was catalyzed and packed into the top and bottom portions of the mold. The pre-cast housing ring was placed into the bottom mold, the mold was closed, and allowed to cure.

The patient returned for a final fitting and colorization session. The prosthesis was further colorized using pigments suspended in extrinsic coloring fluid (Extrinsic Fluid, Factor II) and sealed using a silicone sealant system (564 system, Factor II). Instructions in care and maintenance were reviewed, and the patient left with the prosthetic device in place.

Results:
The final silicone prosthesis is meant to be worn on a daily basis. Silicone adhesive (Blom Singer® Silicone Adhesive) is applied on the back side of the prosthesis and allowed to dry. A non-alcohol barrier film (Cavilon™ No Sting Barrier Film, 3M™, St. Paul, MN) is applied onto the skin. The prosthesis is adhered to the site and a HME cartridge or hands-free valve can be incorporated into the base plate. The prosthesis is removed using a silicone adhesive solvent (ReliaMed® Adhesive Remover Wipes, Reliamed, Ft. Worth, TX).
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