

## The Custom Silicone Interface: Clinical Applications and Observations Robert Dodson, C.P.O., Bridget Jowid, O.T.R.

### *Abstract*

Silicone interfaces have been utilized in the field of prosthetics in a multitude of applications over the last three decades. From suspension techniques to the enhancement of comfort and protection of atypical or diseased residual limbs, silicone has become an integral part of the prosthetic system. Beyond the field of prosthetics, the use of silicone has become a mainstay in wound management, scar maturation, and in the overall promotion of healing in the world of occupational and physical therapy. Extreme cases such as severe burns and or extensive skin grafts have forced many practitioners to consider utilizing silicone interfaces to protect fragile skin.

Clinically, as we incorporate custom silicone into the mainstream design of the "standard" upper extremity prosthesis, we are beginning to see unexpected benefits with the usage of this material on otherwise healthy skin. All of the therapeutic benefits of silicone are now being combined with normal prosthetic usage including limb healing and scar tissue maturation and management. This presentation will provide a historical look at the applications of silicone in the fields of prosthetics and occupational / physical therapy as well as consider unique applications in upper extremity prosthetics.

### *Introduction and History*

Silicone, a synthetic polymer made of repeating silicon to oxygen bonds to form polymeric chains, has become a mainstay in medicine and is commonly utilized in a variety of medical applications. In 1824, Jons Jacob Berzelius discovered silicon from the reduction of silicon tetrafluoride with potassium. (Colas, Curtis, 2004). He unknowingly purified a substance that would change the world and unleashed one of the most widely used elements on the periodic table. Silicon is the second most abundant element on earth, eclipsed only by oxygen, and makes up 25.7% of the earth's crust although is not found free in nature and must be prepared for use in the industrial world (Lide, 2004). Frederick Kipping is credited as "the father of silicone chemistry" by developing a method for studying organo-silicon compounds. He published 54 papers on the subject between 1899 and 1937, but failed to see the potential commercial value of these new silicone compounds. In 1943, a new company by the name of Dow-Corning Corporation found an industrial use for silicone and began the manufacture of silicone polymers (Plastics Historical Society, 1986).

Silicone polymers have been used in many industries because of their exceptional physical properties ranging from liquids to hard solids (Colas, Curtis, 2004). Because of its unique biocompatibility and biodurability, silicone has found a permanent place in medicine through a wide variety of applications. Hydrophobicity, low surface tension, along with chemical and thermal stability are all properties that prompted silicone's initial introduction into the medical field. By the end of the 1960's, silicone materials were being employed in orthopedic applications, catheters, drains / shunts, kidney dialysis, heart bypass machines, and aesthetic implants (Colas, Curtis, 2004). Further development of silicone technology over the last four decades have branched into the rehabilitation arena in the form of scar management, wound care, burn care, and prosthetic interface materials.

### *Therapeutic Uses of Silicone*

The use of silicone products in the therapeutic realm are largely related to the treatment and prevention of hypertrophic and keloid scar formation. These abnormal types of scarring can cause significant issues with range of motion, can be painful and may have psychological implications as a constant reminder of the trauma endured by the patient (Berman, 2007). In the late 1980's, various types of silicone elastomer sheeting began to be used on patients with these types of scar formations. Although the precise mechanism of action of silicone elastomer sheeting has not been clearly defined, there is evidence that consistent use of this product can help minimize scar formation and increase scar elasticity and has become widely accepted by occupational therapists in clinical practice (Berman, 2007).

Wound care and burn management have also seen the introduction of silicone materials into clinical practice. Burn management is mostly concerned with hypertrophic and keloid scar formation and the loss of range due to these changes in skin composition. There is some evidence that silicone gel sheets are more effective with the concomitant use of pressure dressings and that better results are found when worn under a pressure garment (deLinde, 1992). This fact is supported by a study recently finished at the University of Taiwan in which the effects of pressure on the growth of human scar fibroblasts showed that with pressure application, fibroblast cell growth rate was slower than that of normal cells (Cheng, 2008). Whether or not this is a positive or a negative result needs further investigation.

Wound care is a therapeutic area that is beginning to see the introduction of silicone products into the mainstream of clinical treatment. Products such as Biobrane dressing act as a semi-permeable "pseudoeepithelium" which allows gas exchange at the wound surface. Evaporative water loss from the wound is decreased 90% and because of the adherence of the Biobrane to the wound surface, pain is reduced and bacteria proliferation is minimized (Smith, Price, 2002). The use of these materials requires that the wound itself be healthy. An infected or necrotic wound is not recommended for the application of silicone therapies (Hunter, 2002).

### *Prosthetic Uses of Silicone*

The use of silicone in the discipline of prosthetics first began with the advent of the aesthetic hand prosthesis in the mid 1950s. The passive devices were used to restore near-normal appearance and improve a patient's overall function (Pillet, 2002). In 1986, Ossur Kristinsson introduced the first "silicone liner socket" in the form of the Icelandic Roll-On Silicone Socket. Over the past two decades, this concept and this technology has revolutionized the fitting of lower extremity prosthetic devices. Suspension and comfort were the main objectives of this type of silicone application and great success has been achieved by both clinicians and patients alike (Baars, Geertzen 2005). Through the use of silicone liner technology, new ideas are emerging with the application of vacuum assistance which eliminates much of the pistoning of the socket during swing phase by creating a negative pressure environment against the residual limb. Sealing type socket designs, first described by Haberman in 1995, utilize the flexible properties of silicone with the addition of a one-way valve to provide another option in the fitting of prosthetic devices (Haberman, 1995).

The recent emergence of the upper extremity specialist in prosthetics has led to a new focus on clinical applications of silicone materials and their benefit to the design of upper extremity prostheses. Dillingham showed that the average upper extremity amputation occurs in a traumatic scenario thus increasing the chance that these patients will have severe scarring on various areas of their residual limb (Dillingham, 2002). Working in conjunction with occupational therapists uniquely interested in upper extremity prosthetics, the advantages of applying silicone in scar, burn and wound management are now being correlated with benefits seen when silicone is introduced into prosthetic design. Uellendahl, et al. described the use of custom silicone sockets for myoelectric prostheses in 2006. This research concluded that custom silicone socket design enhanced three of the primary goals in fitting upper limb prostheses including comfort, function, and appearance (Uellendahl, 2006). Along with these enhancements, custom silicone sockets are now being seen as a way to promote skin health, provide a proper wound healing environment, and possibly reduce the negative effects of hypertrophic and keloid scar formation seen in patients with skin grafts and burns. Clinical observations are the first step in the research process and can begin the quest to answer basic questions of efficacy and necessity. Therapeutic benefits of silicone in the form of wound care and scar management can be seen in a recent case seen in our clinic.

### *Silicone Case Study*

Mr. W. is a 43 year old white male that suffered third degree electrical burns to over 85% of his TBSA. This traumatic, on the job, injury in 1999 resulted in bilateral transradial amputations. He has severe scarring to his face, neck, chest, back, arms and legs. He fights MRSA infections on a regular basis which are primarily restricted to his facial region. He takes vitamins regularly and he eats two home cooked meals daily. "I am a healthy eater." Over the past nine years, Mr. W. has worked with three different prosthetic companies and multiple occupational therapists. His initial prostheses were fabricated using inner flexible liners made of Proflex™ with silicone. This first set of bilateral prostheses could only be worn two to three hours per day and only when absolutely necessary. This was due in large part to the sensitivity and integrity of his skin when wearing the prostheses. A chronic wound developed on his left elbow and over the course of the last four years, many medical interventions including wound care and surgical debridement have been used in an attempt to heal this wound. Even with multiple courses of exhaustive methods using traditional wound healing therapies, the wound never fully healed. Mr. W. reports, "Whenever my left side would get pressure and moisture, a sore would develop." "My wounds would bleed daily. I had to change my sheets on a daily basis."

In June of 2007, Mr. W's current prosthetist re-fabricated the inner flexible liner using a 10 shore silicone material. Within a month of using this new liner on a daily basis, Mr. W's wound began to heal. He reports that the prosthesis was comfortable and that he was able to tolerate his prosthesis for 14-16 hours per day. Mr. W's wound healing progress was followed over a four month period. By the end of the four month period his red weeping wound was healed with dry epithelial tissue. To this day, no further wounds have developed and Mr. W is wearing his prostheses daily for 14-16 hours per day.

This case study demonstrates the need for further case studies and research in on the implication and potential benefit of the use of silicone with persons with amputations, burns, and specifically for those persons with open wounds and/or scarring. These clinical observations raise the question how and why did a chronic wound heal inside a prosthesis, especially after traditional methods of wound healing were employed and failed. The opportunity for further research on this subject is great and should be considered.

### References

1. Colas, A., Curtis, J. Silicone biomaterials: History and chemistry & medical applications of silicones. *Biomaterials Science, Second Edition: An Introduction to Materials in Medicine*. 2004
2. Wikipedia, <http://www.en.wikipedia.org/wiki/Silicone>. Silicone, 2008
3. Plastics Historical Society. <http://www.plastiquarian.com/kiping.htm#top>
4. Lide, D. CRC Handbook of Chemistry & Physics (85th Ed.) 1992.
5. Zang, M. (1999) In vivo friction properties of human skin. O & P virtual Library.
6. Berman, B., M.D., P.H.D., Perez, O. M.D., Konda, Sailesh, BS, Kohut., B. E., D.M.D., Viera, M. H., M.D., Delgado, S., B.S., Zell, D., M.D., and Li Q., M.D., P.H.D. A review of the biologic effects, clinical efficacy, and safety of silicone elastomer sheeting for hypertrophic and keloid scar treatment and management. *Dermatologic surgery* 2007; 33:1291-1303.
7. Baars, ECT, Geertzen, JHB. (2005). Literature review of the possible advantages of silicon liner socket use in trans-tibial prostheses. *Prosthetics and Orthotics International*, Vol. 29, Issue 1, pp. 27-37.
8. O'Donovan, D.A., Mehdi, S.Y., and Eadie, P.A. (1999) The role of mepitel silicone net dressings in the management of fingertip injuries in children. *Journal of Hand Surgery* (British and European Volume, 1999) 24B: 6: 727-730.
9. Chavez, B. (2004) Addressing the pain: Making the case for using a silicone dressing in burn wound management. *Ostomy/Wound Management*, Volume 50, Issue 6, June 2004, pp. 11-12.
10. Gleaves, J. R., M.D., FACS, and Eldridge, K., R.N., CNOR, RNFA. Addressing the Pain: Silicone sheeting as an alternative to elastic bandages in dressing lower extremity amputations. *Ostomy/Wound Management*, Volume 50, Issue 9, September 2004, pp. 8-10.
11. Evens, R. B., McAuliffe, J. A.: Wound classification and management. In Hunter, J.M. M.D., Mackin, E. J., L.P.T., Callahan, A.D.M.S., O.T.R./L., C.H.T., Skirven, T.M., O.T.R./L., C.H.T., Schneider, L.H., M.D., Osterman, A.L. M.D., editors: *Rehabilitation of the hand and upper extremity*, St. Louis, 2
12. deLinde, L., Knothe B. Therapist's management of the burned hand. In Hunter, J.M. M.D., Mackin, E. J., L.P.T., Callahan, A.D.M.S., O.T.R./L., C.H.T., Skirven, T.M., O.T.R./L., C.H.T., Schneider, L.H., M.D., Osterman, A.L. M.D., editors: *Rehabilitation of the hand and upper extremity*, St. Louis, 2
13. Cheng, L., Deng, W., Yeong, E., Wu, C., Yeh, S. Pressure effects on the growth of human scar fibroblasts. *Journal of Burn Care and Research*. Future publication, 2008.
14. Haberman, L. Silicone-only suspension (SOS) with socket-loc and the ring for the lower limb. *Journal of Prosthetics and Orthotics*, 1995; Vol 7, Num 1, p. 2
15. Dillingham, et al: Limb Deficiency and Amputation – Epidemiology and Recent Trends in the US. *Southern Medical Journal*, 2002;95:875-83.