Survey of Currently Used Materials for Fabrication of Extraoral Maxillofacial Prostheses in North America, Europe, Asia, and Australia

Patricia C. Montgomery[1]* & Sudarat Kiat-Amnuay, DDS, MS[2]

[1] Department of Head and Neck Surgery, Section of Oncologic Dentistry and Maxillofacial Prosthodontics, University of Texas M.D. Anderson Cancer Center, Houston, TX
[2] Department of Restorative Dentistry and Biomaterials, University of Texas M.D. Anderson Cancer Center, Houston, TX

Keywords
Facial prosthetics; prosthetic elastomer; silicone elastomer.

Correspondence
Sudarat Kiat-Amnuay, University of Texas at Houston Dental Branch – Restorative Dentistry and Biomaterials, 6516 M.D. Anderson Blvd., Suite #493 Houston, TX 77030. E-mail: Sudarat.Kiat-amnuay@uth.tmc.edu

*Attended 2-year certificate program in graphic design and illustration from the Texas Academy of Art, Houston, TX, in the year 1976. Patricia C. Montgomery is working as Anaplastologist since 2003 for on-site training in the art and science of anaplastology at M.D. Anderson Cancer Center.

Accepted February 11, 2009

doi: 10.1111/j.1532-849X.2009.00538.x

Abstract

Purpose: The purpose of this survey was to review the extraoral maxillofacial materials currently used as well as the advantages and disadvantages of the materials in the fabrication of facial prostheses. Results of this survey will enhance scientific knowledge, generate research study ideas, and possibly lead to production of alternative or new maxillofacial materials.
Material and Methods: A 47-question survey was delivered via e-mail to all members (combined total of 260 members) of the American Anaplastology Association (AAA) and American Academy of Maxillofacial Prosthetics (AAMP) for evaluation of personal preference involving maxillofacial prosthetic materials (intrinsic/extrinsic silicone elastomers and pigments/colorants used, polymerization/curing process, advantages and disadvantages of the most often used materials, most important characteristic of material/technique used).
Results: The views of 43 (16%) respondents indicated that the majority surveyed were using room temperature-vulcanized (RTV) silicone products. Silicone pigments for intrinsic and silicone pastes for extrinsic coloring were favored over artist's oil colors and dry earth pigments. The polymerization process and/or curing times and temperatures for the same silicone material varied between users. The top five advantages of most often used materials were good esthetics, ease of coloring, easy manipulation, thin margins possible, and adhesive compatibility. The top five disadvantages were discoloration over time, technique-sensitivity, lack of repairability, extrinsic colors peel/fade, and lack of longevity. Nontoxic/nonallergenic materials with high edge strength and color stability were the most important features when choosing a maxillofacial prosthetic material/technique.
Conclusions: The responses to this survey indicate that the majority of AAA and AAMP members are using or have used a variety of RTV silicones, pigments, and colorants in the quest to provide the best possible facial prosthetic service. Further research is needed to further refine and improve extraoral maxillofacial materials/techniques based on the results of this study.

Elastomers have been used for almost 50 years to fabricate facial prostheses for individuals missing facial anatomy due to resection, trauma, or congenital anomalies. The prostheses are colored to approximate human skin shade with various pigments often suspended in various solutions. The success of any facial prosthesis depends on the physical and mechanical properties of the materials comprising the prosthesis.[1]

In 1992, Dr. Carl Andres of Indiana University, Indianapolis conducted a survey to determine the most frequently used materials in the fabrication of facial and somato prostheses among members of the American Academy of Maxillofacial Prosthetics (AAMP), the American College of Prosthodontists (ACP), and the American Anaplastology Association (AAA).[2] Three hundred forty surveys were mailed with a total of 88 returned for a response rate of 26%.

The silicone materials used by the majority of respondents in 1992 were two Dow-Corning (Midland, MI) room-temperature vulcanizing (RTV) silicone products. The top preferred

silicone material was MDX4-4210, followed by Medical Adhesive Type A (A-891). Several respondents were using a combination of the two materials, and others were using the urethane bonding technique,[3] incorporating a combination of these two materials. MDX4-4210, a clear-to-translucent two-part (10:1, base:catalyst) silicone was introduced to the maxillofacial prosthetics field in the 1970s. The physical and mechanical properties of this silicone elastomer were the subject of many research studies.[4-8] The top three advantages of this RTV silicone material were the use of stone molds, ease of manipulation, and ease of coloring. The top three disadvantages were poor edge strength, discoloration with time, and technique-sensitivity.

The materials and methods used to provide skin coloration by respondents were divided into intrinsic and extrinsic methods of coloring. Most practitioners reported using dry earth pigments, rayon flocking fibers, artist's oil pigments, or a combination of these materials for intrinsic tinting. Kaolin material was commonly used as an opacifier. The most-used extrinsic coloring method was Medical Adhesive Type A mixed with xylene as a retardant/thinner tinted with dry earth pigments or artist's oil pigments applied to the surface of the prosthesis in a thin layer.

A-2186 was included in the 1992 survey but not chosen as a preferred silicone material. Introduced in 1986 by Factor II (Lakeside, AZ), the sole maxillofacial prosthetic material company providing technical expertise and customer support, A-2186 was the first commercial platinum-catalyzed silicone elastomer. It is a clear-to-translucent two-part (10:1 base:catalyst) pourable silicone. A fast polymerization rate version of A-2186 with higher platinum content, "A-2186F," became commercially available in 1987.

Continuing the advancement of silicone technology, in 2000, Factor II introduced A-2000 as the first generation of a 1:1 mixture platinum silicone followed by A-2006 in 2006. Several other commercially available silicone products have been introduced since 1992, including Cosmesil, Realastic, VerSil-Tal (VST), and Liquid Silicone Rubber (LSR) Systems to name a few. The introduction of silicone colorant technology began in 1992 with Factor II's silicone intrinsic colorants. In 1999, the silicone colorants were further refined using a crosslinking fluid to maintain viscosity to allow drop-by-drop dispensing. Silicone extrinsic paste pigments (Factor II) with additional pigment to the crosslinking fluid were introduced shortly after.

Among the conclusions from Dr. Andres' 1992 study was the statement that research in maxillofacial materials has been poorly funded and of little interest to manufacturers because of limited markets. He further stated that the demand for extraoral prosthetic services will increase with an aging population, thereby supporting the need for extensive research and development of materials that fulfill the needs of the patients and of the profession.

A Cancer Trends Progress Report in 2002 estimated that each year approximately $3.2 billion[9] is spent on treatment of head and neck cancers in the United States alone. Further supporting the growing diagnosis of head and neck cancers, the National Cancer Institute's investment[10] in research on head and neck cancers has increased from $58.9 million in fiscal year 2002 to an estimated $71.3 million in fiscal year 2006.

In the interest of continuing to advance the knowledge in the science of extraoral maxillofacial materials, the authors conducted a survey of current and past extraoral maxillofacial materials used in the fabrication of extraoral maxillofacial prostheses. Although not a novel proposition, a new maxillofacial materials survey is relevant in light of the growing diagnosis of head and neck cancers, the development of new materials since the 1992 survey, and the continued need to increase the interest in developing new materials and techniques for extraoral maxillofacial prosthetic rehabilitation. The purpose of this article is to review professional responses to this survey on materials and their satisfaction with those materials used to fabricate facial prostheses.

Materials and methods

A request to participate in an online survey (www.zoomerang.com) was delivered via e-mail beginning June 27, 2008 and lasting through October 7, 2008, to 79 AAA members and 181 AAMP members, for a total of 260 possible respondents. The survey request was e-mailed twice as a reminder for participation. Respondents were asked to evaluate their choices involving extraoral maxillofacial materials. A 47-question survey targeted facial prosthetic-producing professionals including anaplastologists, maxillofacial prosthodontists, and dental technicians. Several parameters were identified, including primary materials and other materials used, advantages and disadvantages of materials used, and importance in choosing a maxillofacial material.

Specifically, the professionals were queried regarding materials used in facial prosthetic fabrication, such as silicone elastomer materials for intrinsic or base color packing, type of pigments for colorization for intrinsic or base color packing, pigments for intrinsic or extrinsic opacifying, silicone for extrinsic colorization, pigments for extrinsic colorization, and extrinsic coating of the final facial prosthetic. Other questions related to the advantages of the material most often used, the possible disadvantages, and what is most important in choosing a maxillofacial prosthetic material. In addition, demographic information such as recipient primary title, primary workplace, fabrication done, and years of experience were surveyed. Finally, an opportunity was given to explain their choice(s), indicate brand name(s), and if needed, briefly explain their method, if modifying the manufacturer's instructions.

In the interest of showing variations in the materials written in by the respondents, the responses to other, as shown in the tables of this article, are recorded as received from the respondents and were not verified for accuracy or spelling by the authors.

Results

A total of 43 (16%) respondents completed and submitted the survey (Table 1). The gender of those respondents was 29 men, 13 women, and one unidentified participant. Responses to this survey were not broken down by organization, as some individuals are members of both the AAA and AAMP. The survey site received 124 visits. There was one survey completed and submitted with no name or primary title. Twenty-seven surveys

Table 1 Response rate by organization and country

Organization	AAA	AAMP	Total
Emailed	79	181	260
Completed/submitted			43
Total response rate			16%
Country**			
United States	37 (86%)		
Canada	1 (2%)		
Asia	1 (2%)		
Europe	1 (2%)		
Australia	2 (5%)		
Unidentified	1 (2%)		

AAA = American Anaplastology Association; AAMP = American Academy of Maxillofacial Prosthetics.

**Country only without organization specified.

were partially completed and are not included in this report. The overall response rate by primary title and demographic information consisting of primary workplace, facial prosthetic fabrication most often done, and number of years fabricating is shown in Table 2.

The first questions on the survey related to: "Which Silicone – Intrinsic or Base Color Packing do you currently use, most often use and tried in the past for fabrication of facial prostheses in your primary workplace?" Table 3 combines the results of these

Table 2 Response rate by primary title and demographic information

Primary title	
Anaplastologist	15 (38%)
Maxillofacial prosthodontist	20 (51%)
Dental technician	2 (5%)
Other: please specify*	5 (13%)
No name specified	1 (2%)
Total response	43 (16%)
*Other: ocularist, clinical associate professor, prosthodontist, prosthetist/anaplastologist, maxillofacial technician	
Primary workplace	
Private practice	15
Institution/hospital	26
Company	0
Other: please specify	0
Facial prosthetic fabrication most often done by	
Supervise only, all fabrication done by someone else	2
Fabricate prostheses myself	23
Supervise others and fabricate prostheses myself	12
Other: please specify*	3
*Other: practice in conjunction with maxillofacial prosthodontist, work under supervision of maxillofacial prosthodontist, refer to Mayo Clinic	
Number of years fabricating facial prostheses	
1 to 5	7
6 to 10	1
11 to 15	9
16 to 20	7
21 or more	19

The greatest number of years fabricating by an individual was 36 years.

Table 3 Silicone used for intrinsic or base color packing for fabrication of facial prostheses in primary workplace

	Currently used	Most often used	Tried in past
MDX4-4210 w/catalyst A-103	8	6	15
MDX4-4210 w/Medical Adhesive Type A	7	7	16
A-2186	14	8	21
A-2186-F	9	6	12
A-2000	9	6	17
A-2006	5	4	9
Cosmesil	1	0	7
Other: indicate name and manufacturer*	14 responses	12 responses	10 responses

*Other currently used: MED-4095 from Nusil; Med Adhesive Type A Dow Coming; Poly Tek Platsil 10 and ShinEtsu 1310 ST; Episil Dreve; VerSil-Tal Silicone Elastomer – Accelerated Cure 50F by Factor II; VST 50F; Dow Corning Q7–4720; Shin-Etsu 1310ST (for finger and toe restorations); VST-50, A-223–30, A-223–40, A-223–65, A-223–05; Factor 2 A584-V-12, A564, LSR-05; Polytek (Plastsil Gel 10, 71–40); Nusil (Med 4011); Smooth-On (00–30, Psycho-paint); Gel 10 by Platsil as interface with MDX4-4210 when making polyurethane backed devices; Techsil 25, Technovent, UK, Cosmesil M511, Technovent, Multsil Epithetik, Bredent, VST50, Factor 2; A-588, Factor II.

*Other most often used: ShinEtsu 1310 ST; Episil Dreve; Factor II Functional Intrinsic skin colors; Customized Earth pigments from Factor II; Functional Intrinsic II – Silicone Coloring System – Individual Bottles by Factor II; VST 50F; Q7–4720 Dow Corning; A-223–30, A-223–40, A-223–65, A-223–05; A-2186-F base with A-564 crosslinker; Techsil 25, Technovent; A-588, Factor II.

*Other tried in past: Sorta Clear by Smooth-On Inc; Episil Dreve; 4-4210 with silicone solvent to decrease viscosity; Shinitsu silicones; Shin-Etsu 1310St, Smooth-On Dragon Skin (for large below the neck restorations); Gel-10 by Smooth-On, Platsil 71-40 by Polytek and KE1310 by ShinEtsu; Polyteck products, Guy Louis's silicone system, Platsil products; Prestige Dental (UK) silicone.

*Responses to other are written as received from respondents and were not verified for accuracy or spelling by the author.

questions. The majority of respondents are currently using RTV platinum-catalyzed silicone elastomers developed by Factor II, Lakeside, AZ. These Factor II silicones (A-2186, A-2186F, A-2000) were listed as the top three, followed by Dow Corning MDX4-4210 with catalyst A-103 and MDX4-4210 with Silastic Medical Adhesive Silicone Type A (Dow Corning Corp.).

Table 4 summarizes extrinsic coloring silicone material(s) currently used, most often used, and tried in the past. The majority of respondents indicated Silastic Medical Adhesive Type A for current, most often, and tried in the past.

To achieve the final appearance of a lifelike facial prosthesis, pigments are used as opacifiers and colorants for both intrinsic and extrinsic coloring. There were two questions pertaining to pigments as intrinsic (Table 5) and extrinsic (Table 6) opacifiers currently used and tried in past. Most respondents chose silicone intrinsic pigment white (Factor II), followed by dry earth pigments and oil pigments, respectively, for intrinsic opacifiers. Most of the survey respondents do not currently use an extrinsic opacifier.

Table 4 Silicone used for extrinsic coloring of facial prostheses

	Currently used	Most often used	Tried in past
MDX4-4210 w/catalyst A-103	3	2	7
Medical Adhesive Type A	16	13	17
A-2186	6	5	7
A-2186-F	3	1	7
A-2000	3	3	5
A-2006	3	2	3
Cosmesil	0	0	1
None	1	1	1
Other: indicate name and manufacturer*	17 responses	12 responses	6 responses

*Other currently used: Factor 2 technique of painting and covering; A-564 from Factor 2; ShinEtsu 1310 ST; Episil Dreve; Factor II Extrinsic Coloration Kit: A-564, MD-564, TS-564; Customized Earth Pigments from Factor II; Extrinsic Coloration System by Factor II; A564-TS564-MD564 used to seal final extrinsic color on VST 50 or 2186 prosthesis. All have been intrinsically colored first; Fe-100–1 extrinsic solvent – Factor II, TS-564 silicone dispersion – Factor II, MD-564–1 matting dispersion – Factor II, A-564 acetoxy silicone – Factor II; Human Silicone Coloration System by Robert Erb; also use 564 acetoxy from Factor 2; A-564; A-564, Psycho-paint; mix of 564 silicone from Factor II with Medical adhesive A. Basically this is the Factor II 564 method of extrinsic coloring using 564, T564, M564; Multisil Sealing agent (Silicone Dispersion), Bredent; A-588, Factor II.

*Other most often used: ShinEtsu 1310 ST; Episil Dreve; Factor II Extrinsic coloration kit, A-564, MD-564, TS-564; Customized Earth Pigments from Factor II; A-564, MD-564, TS-564 system by Factor II; Human Silicone Coloration System by Robert Erb; A-564; A-588, Factor II.

*Other tried in past: ShinEtsu 1310 ST; Episil Dreve; A-564; Tattooing of pigments into the silicone in past per technique described by De. Norm Schaaf; Techsil25, Technovent, Prestige Platinum silicone.

*Responses to other are written as received from respondents and were not verified for accuracy or spelling by the author.

Tables 7 and 8 show the preference of intrinsic pigments, extrinsic pigments, and other colorants. The top three choices for intrinsic and extrinsic were silicone intrinsic pigment or silicone extrinsic paste (Factor II), rayon flocking fibers, and dry earth pigments.

The next series of questions pertained to polymerization of the silicone during intrinsic packing and extrinsic coloring of the prosthesis. Tables 9 and 10 list the five most currently used intrinsic silicones and extrinsic silicones, respectively. Both tables list the varying curing temperature and curing time as reported by the currently used respondents. Four of the top five silicones in both tables were Factor II platinum silicones.

Next, respondents were asked if they follow or modify manufacturer's instructions for the intrinsic packing and extrinsic coloring of the silicone (Table 11). A disparity is noted between the majority following manufacturer's instructions for the intrinsic packing and the extrinsic coloring and the inconsistency in curing temperatures and times reported by those respondents.

Upon finalization of the extrinsic coloring, a coating or a matte coating may be applied to seal the pigments and colorants (Table 12). Respondents were evenly divided on using some type of final coating or not.

Table 5 Pigments used as intrinsic opacifiers in the fabrication of facial prostheses in primary workplace

Opacifiers	Intrinsic currently used	Intrinsic tried in past
Silicone intrinsic pigment	22	18
Oil pigments	6	7
Dry earth pigments	11	14
None	0	0
Other	7	8
Indicate brand name*	19 responses	16 responses

*Other/brand name currently use: Georgia Kaolin; Oil Stains Factor II; Perma Color and Kremer pigments; Episil Dreve; Ferro pigments; Standard Art Supply; Factor II; Ferro pigments in DC silicone fluid medium; Winsor & Newton and Grumbacher oil paints, Kaolin from Factor II; Grumbacher oil colors; Silicone intrinsic functional pigments from Factor II; Human Silicone Coloration System by Robert Erb; Factor II dry earth pigments; Factor II; Silicone system (Robert & Doretta Erb's); From a variety of sources, Mainly art stores; Ferro pigments or kaolin; Silicone pigments (Robert & Doretta Erb).

*Other/brand name tried in past: Kaolin; Kremer Pigments; Episil Dreve; Dr. Erb's paint system; White Ferro paste suspended in DC silicone fluid; Georgia Kaolin; Kaolin from Factor II; Silicone paste pigments Factor II; Factor II; Flocking, Robert & Doretta Erb's Silicone colorant; Cosmesil intrinsic pigments-base colors and master colors; Bought in art store.

*Responses to other are written as received from respondents and were not verified for accuracy or spelling by the author.

One question referred to the current and past use of a urethane-to-silicone bonding technique as proposed by Udagama.[3] Table 13 shows the majority of responders had used or are using 0.005 polyurethane sheeting (Factor II) along with 1205 primer (Dow Corning). Respondents were not asked to explain their reason for no longer using urethane backing materials.

The next series of questions provided an in-depth look at specific characteristics of the most often used maxillofacial

Table 6 Pigments used as extrinsic opacifiers in the fabrication of facial prostheses in primary workplace

Opacifiers	Extrinsic currently used	Extrinsic tried in past
Silicone extrinsic paste	9	6
Oil pigments	3	8
Dry earth pigments	9	11
None	16	9
Other	4	4
Indicate brand name*	12 responses	10 responses

* Other/brand name currently used: Perma Color and Kremer pigments; Episil Dreve; Kaolin from Factor II;Kaolin-Georgia; Silicone Extrinsic Functional Pigments-Factor II; Hock; Cabosil or M564 mixed with Ad-A or 564; Silskin dry earth pigments.

*Other/brand name tried in past: Kremer Pigments, Winsor & Newton and Grumbacher oil paints, Kaolin from Factor II; Grumbacher oil colors and rayon fibers from Factor II; Silicone paste pigments Factor II; Factor II Kaolin; Siliskin dry earth powders; Bought in art store.

*Responses to other are written as received from respondents and were not verified for accuracy or spelling by the author.

Table 7 Pigments/other colorants used in the intrinsic coloring of facial prostheses

	Intrinsic currently used	Intrinsic tried in past
Silicone intrinsic pigment	23	18
Oil pigments	5	12
Dry earth pigments	12	14
Rayon flocking fibers	25	23
Other	5	6
Indicate brand name*	19 responses	19 responses

*Other/brand name currently used: Flocking from Factor 2; Perma Color and Kremer Pigments; Episil Dreve; Ferro pigments; Standard Art; Ferro pigments suspended in DC silicone fluid medium; Winsor & Newton and Grumbacher oil paints, Factor II rayon fibers; Grumbacher oil colors and rayon fibers from Factor II; Silicone intrinsic functional pigments – Factor II, Rayon flocking fibers – Factor II and Cosmesil, Wool fibers from knitting yarn; Factor II Rayon Fibers (red and plum only); Factor II; Silicone system (Robert & Doretta Erb); Also use flock; Ferro pigments, Claremont flocking.

*Other/brand name tried in past: Elizabeth Arden cosmetic pigments; Kremer Pigments; Episil Dreve; Ferro Pigments; Ferro paste; Makeup; Winsor & Newton and Grumbacher oil paints, Factor II rayon fibers; Grumbacher oil colors and rayon fibers from Factor II, Silicone paste pigments Factor II, Rayon flock from Factor II and Cosmesil; Factor II; Flocking from DorJer and pigments from the Bob Erg coloration system; R&D Erb Silicone pigments; artists oils, Dep and flocking from Factor II; Silskin Rayon fibers, Cosmesil rayon fibers; Bought from art store, Factor II and art needlepoint supplier.

*Responses to other are written as received from respondents and were not verified for accuracy or spelling by the author.

Table 8 Pigments/other colorants used in the extrinsic coloring of facial prostheses

	Extrinsic currently used	Extrinsic tried in past
Silicone extrinsic pigment	20	16
Oil pigments	4	9
Dry earth pigments	13	11
Rayon flocking fibers	19	17
None	1	3
Other	5	3
Indicate brand name*	20 responses	13 responses

*Other/brand name currently used: Factor II flocking; Perma Color and Kremer Pigments; Episil Dreve; Ferro pigments; tattoo with oil paints; Factor II; Ferro paste; Winsor & Newton and Grumbacher oil paints, Factor II rayon fibers; Supplied by Factor II; Grumbacher oil colors and rayon fibers from Factor II; Silicone extrinsic functional pigments-Factor II, Rayon Flock-Factor II and Cosmesil; Human Silicone Coloration System by Robert Erb; Unknown.

*Other/brand name tried in past: Kremer Pigments; Episil Dreve; Ferro Paste; Do not remember; Winsor & Newton and Grumbacher oil paints, Factor II rayon fibers; Grumbacher oil colors and rayon fibers from Factor II; Silicone paste pigments Factor II, Rayon flock from Factor II and Cosmesil; Flocking from DorJer and pigments from the Bob Erb coloration system; None; Silicone Pigments; Silskin dry earth powders, Factor II silicone extrinsic colors, Cosmesil Rayon Fibers.

*Responses to other are written as received from respondents and were not verified for accuracy or spelling by the author.

materials. "What do you consider the advantages and disadvantages of the material you most often use over others currently commercially available?" Respondents were asked to check all that apply from a list of 20 and 24 possible material advantages (Table 14) and disadvantages (Table 15), respectively. Good esthetics was chosen as the number one advantage, followed by ease of coloring, easy manipulation, thin margins possible, adhesive compatibility, repeatable results, and nonallergenic/nontoxic. The use of stone (gypsum) molds was written in as an advantage. The top five disadvantages were discoloration over time, technique-sensitivity, lack of repairability, extrinsic colors peel/fade, and lack of longevity. Poor edge strength and growth of microorganisms followed closely as disadvantages.

The last question asked on the survey was, "What do you consider to be the most important when choosing a maxillofacial prosthetic material or technique?" From a list of nine characteristics the respondents were asked to rank the importance of each item using the scale from 1 (least important) to 9 (most important). Each number could only be used once. The results are shown in Table 16. Nontoxic, nonallergic to both clinician and patient was cited as most important, followed by margin integrity, high edge strength, and durable. Short fabrication time was shown to be least important.

Discussion

It is important to note that the majority of respondents to this survey are located in North America, Europe, Asia, and Australia. Responses to this survey of anaplastologists and maxillofacial prosthodontists from other areas of the world may result in different materials/techniques than presented in this survey.

The majority of anaplastologists, maxillofacial prosthodontists, and dental technicians who fabricate extraoral facial prostheses are still using RTV silicone elastomer products. MDX4-4210 silicone was the most commonly used elastomer from the 1992 survey by Andres. Currently, A-2186 silicone for intrinsic or base color packing is the most commonly used product. One reason that MDX4-4210 popularity has declined could be due to the cost (the cost of purchasing A-2186 is about half of MDX4-4210).[11] Shortly after A-2186 was introduced, a comparison study of the physical properties in their base form (without thinner or color) of A-2186 compared to MDX4-4210 was published.[12] The findings of that study reported that A-2186 had greater tensile strength and tear strength and a softer, more skin-like surface feeling;[12] however, the results from another research study published the same year by a different group of researchers evaluating six maxillofacial elastomers found that the physical and mechanical properties of A-2186 may degrade after being subjected to seven environmental variables: natural weathering, normal aging, two types of adhesives, two types of cleaning agents, and cosmetics.[13]

Most survey respondents selected silicone intrinsic pigments and silicone extrinsic paste developed by Factor II for intrinsic and extrinsic color matching of the skin. As stated on the Factor II website, the intrinsic and extrinsic coloration system are a blend of FD&C cosmetic pigments ground into a silicone crosslinking fluid to create a viscous liquid silicone pigment for intrinsic and a thixotropic pigment paste for extrinsic that

Table 9 Polymerization/curing process currently followed when packing or base color packing intrinsic silicone (top five currently used silicones with curing temperature and time as reported by the currently used respondents)

	Number of respondents currently using			Curing temperature by respondent	Average curing time by respondent
A-2186	6	*Respondent*	*1*	80°C	1 hour or bench cure overnight
			2	Boiling water	1 hour
			3	Room temp	24 hours
			4	90°C	1–2 hours
			5	80°C	60 minutes
			6	150°F	Overnight
MDX4-4210	5	*Respondent*	*1*	80°C	3.5 hours
			2	Room temp	12 hours
			3	Bench cure	12 hours
			4	Boiling water	40 minutes
			5	160°F	1 hour or bench cure overnight
A-2000	4	*Respondent*	*1*	100°C	3 hours
			2	180°F	2 hours
			3	100°C	Overnight
			4	185°F	1 hour
A-2006	3	*Respondent*	*1*	100°C	1 hour
			2	95°C	90 minutes
			3	80°C	1 hour
A-2186-F	3	*Respondent*	*1*	80°C	1 hour or bench cure overnight
			2	40°C	12 hours/overnight
			3	Room temp or elevated for faster cure	25 minutes in boiling water or bench set overnight

Other currently used*: MED 4905 from Nusil; Heat pressure; Perma Color and Kremer Pigments; Epsil; VerSilTal Silicone Elastomer – Accelerated Cure 5; Q7–4720; 71–40 by Polytec; A-223–30; Techsil 25; A-588.

*Responses to other are written as received from respondents and were not verified for accuracy or spelling by the author.

Table 10 Silicone: extrinsic coloring of a prosthesis (top five currently used silicones with curing temperature and time as reported by the currently used respondents)

	Number of respondents currently using			Curing temperature by respondent	Average curing time by respondent
Medical Adhesive Type A	7	*Respondent*	*1*	150°F	1 hour
			2	80°C	10 minutes
			3	100°C	30 minutes
			4	87.5°C	15 minutes
			5	80°C	15 to 20 minutes
			6	Room temp	12 hours or oven to fast set
			7	None/hot water	Unspecified
A-564	5	*Respondent*	*1*	60–80°C	20 minutes or more per layer
			2	Unspecified	Unspecified
			3	100°C	30 minutes convection oven
			4	Case sensitive	Case sensitive
			5	Bench set	15–20 minutes
A-2000	2	*Respondent*	*1*	212°F	10 minutes
			2	200°F	30 minutes
A-2006	2	*Respondent*	*1*	95°C	90 minutes
			2	80°C	1 hour
A-2186	2	*Respondent*	*1*	Unspecified	Unspecified
			2	150°C	Overnight

Other currently used*: PolyTek Plasti 10 and ShinEtsu 1310 ST; Episil; Tattoo; FE-100; Acetoxy 564; A-2186F; Bredent Multisil; Dilute A-564 with F-100.

*Responses to other are written as received from respondents and were not verified for accuracy or spelling by the author.

Table 11 Follow manufacturer's instructions for intrinsic silicone packing and extrinsic silicone coloring

Intrinsic silicone packing	
I follow the manufacturer's instructions exactly	26
I modify the manufacturer's instructions	8
If modified, please explain*	9 responses

*If modified: Workable set-up time is quicker than stated; Layering of glazes of silicones into the mold; Use Med Type A as catalyst to MDX4-4210; 10% catalyst in some areas, 5% in others; I have created my own formula using spectrometry; I interchange crosslinkers with bases; Depends on the case; Slightly shorter cure

Extrinsic silicone coloring	
I follow the manufacturer's instructions exactly	24
I modify the manufacturer's instructions	7
If modified, please explain*	11 responses

*If modified: Curing time and application; Workable set-up time is quicker than stated; Length of cure times sometimes vary; I combine Med A with extrinsic trifluid; Use technique developed by Dr. Udagama; I will sometimes use fibers to get the color; I don't know the manufacturer's instructions; Mix 564 with Ad-A to increase set time; Depends on the case; No instructions provided; I do what I was taught.

is compatible with all addition-cured (platinum) silicones. The intrinsic coloration system is designed to chemically bind internally to the silicone device, and the extrinsic system is designed to both mechanically and chemically bond to the surface of a silicone device. Factor II asserts best results will be achieved if mixed with FE-100 solvent, which is a silicone fluid used to dilute the extrinsic colors. These coloring systems are also used to opacify the silicone elastomer.

In most instances, extrinsic color was obtained by mixing Silastic Medical Adhesive Type A (Dow Corning) or A-564 (Factor II) with one or more of the preferred colorants. A research study investigated the interactions of oil pigments and five opacifiers at different concentrations on the color stability of MDX4-4210/Type A silicone elastomer when subjected to artificial aging. This study showed that the addition of oil pigments helped protect the silicone from color degradation over time.[14] Another study by the same group determined the effect of dry earth opacifiers used at different concentrations on the color stability of cosmetic pigmented A-2186 silicone subjected to artificial aging. This study showed

Table 12 Coating applied after extrinsic coloring of facial prostheses

	Coating
No coating used	13
Trichloroethane	7
Other coating	9
Specify ratio*	13 responses

*Ratios: A-564 coating applied; 564 series instructions followed exactly; A-564, MD-564, TS-564; One thin layer of Med Type A; TS-564 2 coats, 0 min to dry after each coat; TS-564, A-564, sodium bicarbonate; Type A silicone adhesive Dow Corning straight; Silicone/trichlor = 1:5; Medical Adhesive A diluted with trichloroethane; Don't understand the question; 100% Mutisil sealing agent, Bredent; 1:10 trichlor to A-2000; TS-564–1 x3 coats

	Matte Coating
No matte coat used	10
MD564 in trichloroethane & silicone	16
Other matte coat	7
Specify ratio*	14 responses

*Ratios: Bicarbonate; 3 step 564 series followed exactly; 1 part MD-564 to 5 parts TS-564; MD5641 part, A564 5 parts or white flock v light; Sodium bicarbonate until partial cure of A-564; Cabosil rub with toothbrush; Confectioners sugar; Rub dried Adhesive A with kaolin or talc; 10/2; 1–10 trichlor to A-2000 10% MD564; MD-564-l(10):A-564(2)

*Responses to ratios are written as received from respondents and were not verified for accuracy or spelling by the author

Table 13 Technique of using urethane-backing material

Never used	11
Yes, but no longer use	18
Yes, please indicate name of urethane material and primer used*	9

*Material/Primer: 1205 and 2260 with polyurethane; .005 polyurethane sheeting from Factor II with primer Dow Corning 1205; Polyurethane .005 mil; Polyurethane with 1205 primer; Polyurethane film with sofreliner primer; Polysheeting .005; .005 sheeting from Factor 2 primed with A-330-G and with a Gel-10 interface between poly and the silicone; Factor II urethane; .05 mm from Factor II, Gold Primer Factor II, Sofreliner; Fine mosquito netting used once, primer A-330.

*Responses to material/primer are written as received from respondents and were not verified for accuracy or spelling by the author.

Table 14 Advantages of most often used materials (select all that apply)

Ease of coloring	27
Can layer intrinsic color	21
Good esthetics	29
Color stable	23
Durable	23
Easy manipulation	27
Easily cleaned	21
Thin margins possible	26
High edge strength	18
Soft tissue-like consistency	22
Lightweight	16
Adhesive compatible	25
Nonallergenic, nontoxic	24
Short polymerization	17
Long working time	20
Repeatable results	24
Variable consistency	10
Availability	22
Cost	15
Translucency	22
Others, please specify*	2 responses

*Other stone molds, depends on material used for each prosthesis.

Table 15 Possible disadvantages of most often used materials (select all that apply)

Difficult to color	3
Could not layer intrinsic color	5
Discoloration with time	17
Extrinsic colors peel/fade	11
Lack of longevity	11
Technique-sensitive	12
Short working time	1
Air entrapment in mixing	8
Poor adhesive compatible	4
Difficult adhesive removal	6
Thick margins	3
Poor edge strength	8
Hardness, insufficient elasticity	5
Weight of large prosthesis	8
Toxic components/byproducts	3
Odor when processing	3
Long polymerization time	2
Short working time	1
Lack of adjustability	8
Growth of microorganisms	8
Lack of repairability	12
Availability	1
Cost	4
Too translucent	0
Others, please specify*	2 responses

* Other: yellows with time because of catalyst, technique sensitive.

contrasting results, concluding that the mixing of different concentrations of dry earth opacifiers with cosmetic pigmented A-2186 did not protect the silicone from color degradation over time, especially in the case of cosmetic pigment red.[15] Dry earth pigments and oil pigments chosen in the 1992 survey[2] for intrinsic and extrinsic coloration are now less popular due to the silicone intrinsic and extrinsic systems developed by Factor II, despite good results when using oil pigments with MDX4-4210/ Type A silicone elastomer.

Discrepancies in polymerization curing temperatures and times suggest that silicone polymerization can be technique-sensitive and user-influenced. Some respondents to this survey stated that they did not know the manufacturer's instructions or instructions for the material were not provided. Manufacturer's instructions can be interpreted differently among users. These major variations could lead to different physical and mechanical properties, thus compromising the result of the final prostheses. In the interest of providing the best possible material for the fabrication of facial prostheses, maxillofacial material companies/suppliers should provide clear and precise step-by-step instructions based on valid scientific support to help clinicians fabricate the best possible prosthesis for their patients.

It is interesting to note that, similar to the 1992 survey, nearly all advantages or desirable characteristics listed by the respondents have been previously listed by other investigators.[13–19] The top five disadvantages from this survey were discoloration with time, technique-sensitivity, lack of repairability, extrinsic colors peel/fade, and lack of longevity. Advances have been made in silicone materials over the years, yet the top six silicones most often used in this survey have been cited to still have the same disadvantages. Continued development of extraoral maxillofacial materials is necessary to fulfill the needs of the professionals who design and fabricate prosthetics. Future research studies comparing the physical and mechanical properties, toxicity, color stability, and longevity of all materials as they enter the market are needed.

In addition, nontoxic/nonallergenic materials with high edge strength and color stability were the most important features when choosing a maxillofacial prosthetic material/technique as shown in this survey. Toxicity of materials is important due to the constant day-to-day handling of these materials by the clinicians and day-to-day skin contact with the patients who wear prostheses. It is important to note that 1,1,1-trichloroethane, referred to as "trichloroethane" in the manuscript, is being phased out for most uses because of its ozone depletion potential in the upper atmosphere. Under the Montreal Protocol, production for emissive uses was phased out toward the end of 1995 in Europe and in the United States, Japan, and other industrialized countries in 1996; however, it is permitted for "essential uses," such as certain laboratory, analytical, and pharmaceutical applications.[20] Another material used in the fabrication of a facial prosthesis is Silastic Medical Adhesive Silicone Type A (Dow Corning Corp.), which releases acetic acid vapor as a byproduct during the curing process. Oil-based and dry pigments used in the intrinsic and extrinsic coloring of a prosthesis may contain heavy metals such as cadmium, chromium, and lead. Only a miniscule amount of these pigments are needed to color the silicone – not enough to cause a health hazard to patients and

Table 16 What do you consider to be the most important when choosing a maxillofacial prosthetic material/technique? Please rank the importance of each item using the scale from 1 (least important) to 9 (most important). Each number may be used only once.

Ranking	Least important 1	2	3	4	5	*6*	7	8	Most important 9
Color stability	0	2	2	0	2	4	4	7	6
Margin integrity, high edge strength, durable	1	1	1	0	0	1	5	6	9
Softness close to skin	2	4	1	3	4	6	5	1	0
Light weight	2	1	3	4	5	6	3	0	0
Ease of use	0	1	1	2	6	7	4	3	2
Easy to adjust or add without remake	2	4	7	5	3	2	1	5	1
Cost	3	7	5	3	1	3	2	1	1
Nontoxic/nonallergenic to both clinician and patient	2	2	1	5	3	0	4	2	12
Short fabrication time	9	3	3	5	4	0	3	4	3

technicians. It is very important to emphasize that clinicians be aware of the health and environmental effects when using these materials by reading the manufacturers' material safety data sheets (MSDS) associated with these materials. Taking the proper precautions when using these materials is important for reducing health problems. The use of appropriate protection such as gloves, masks, goggles, and a high-volume suction system are essential to prevent toxicity to patients and technicians.

Finally, research in maxillofacial materials over the past 10 years is developing or advancing gradually based on limited funding in the field of maxillofacial prosthetics. With the growing number of head and neck cancers diagnosed each year, the demand for both intraoral and extraoral prosthetic rehabilitation continues to rise. Although prosthetic rehabilitation is not always considered a necessary course of treatment, it should be noted that prosthetic rehabilitation is not a vanity issue; rather, it is a psychological issue that impacts more and more people throughout the world each year. More extensive research and development of materials to fulfill the needs of these patients and the professionals who design and fabricate prostheses are necessary. Collaboration between manufacturers and researchers are needed to search for the best possible outcome. Continued and increasing support from public and private agencies is extremely essential in this field.

Conclusion

1. The responses to this survey indicate that the majority of clinicians are using or have used a variety of RTV silicones in their quest to provide the best possible prosthetic service. The most popular material in this survey was A-2186.
2. The majority of survey respondents attempted to achieve the final appearance of a lifelike prosthesis using silicone intrinsic and extrinsic pigments along with rayon flocking.
3. Silastic Medical Adhesive Type A is still the most commonly used silicone for extrinsic coloring of prostheses.
4. The polymerization process used for both intrinsic and extrinsic silicone varied among clinicians. The overall properties of silicones may therefore be affected.
5. Despite the development of silicones in the past four decades, the top six silicones most often used in this survey have been cited to still have the same disadvantages. Continued and increasing support from public and private agencies in the development of new or alternative maxillofacial prosthetic elastomers is essential to improve the quality of prostheses and the quality of patients' lives.

Acknowledgments

The authors wish to acknowledge Dr. Carl J. Andres, Dr. Rhonda F. Jacob, Stephanie Aramwattananont, and Peggy J. Wesley for their support and assistance.

References

1. McKinstry RE: Fundamentals of Facial Prosthetics: Facial Materials. Clearwater, FL, ABI Professional Publications, 1995, pp. 79-97
2. Andres CJ, Haug SP, Brown DT: Effects of environmental factors on maxillofacial elastomers: Part II – report of survey. J Prosthet Dent 1992;68:519-522
3. Udagama A: Urethane lined silicone facial prostheses. J Prosthet Dent 1987;58:351-354
4. Bulbulian AH: Facial Prosthetics. Springfield, IL, Charles C. Thomas, 1973, pp. 364-377
5. Craig RG, Koran A, Yu R, et al: Color stability of elastomers for maxillofacial appliances. J Dent Res 1978;57:866-871
6. Koran A, Powers JM, Lepeak PJ, et al: Stain resistance of maxillofacial materials. J Dent Res 1979;58:1455-1460
7. Raptis CN, Yu R, Knapp JG: Properties of silicone maxillofacial elastomer processed in stone and metal. J Prosthet Dent 1980;44:447-450
8. Yu R, Koran A 3rd, Craig RG: Physical properties of maxillofacial elastomers under conditions of accelerated aging. J Dent Res 1980;59:1041-1047
9. Cancer Trends Progress Report. Available at http://progressreport.cancer.gov, in 2004 dollars, based on methods described in Medical Care 2002 Aug, 40 (8 Suppl), pp. IV-104-117 (accessed on August 25, 2009)
10. http://www.nih.gov/about/ under estimated NCI investment (accessed August 25, 2009)
11. Cost comparison from http://www.factor2.com (accessed August 25, 2009)
12. Sanchez RA, Moore DJ, Cruz DL, et al: Comparison of the physical properties of two types of polydimethylsiloxane for fabrication of facial prostheses. J Prosthet Dent 1992;67:679-682
13. Haug SP, Andres CJ, Munoz CA, et al: Effects of environmental factors on maxillofacial elastomers: Part IV: optical properties. J Prosthet Dent 1992;68:820-823
14. Kiat-amnuay S, Mekayarajjananonth T, Powers JM, et al: Interactions of pigments and opacifiers on color stability of MDX4-4210/type A maxillofacial elastomers subjected to artificial aging. J Prosthet Dent 2006;95:249-257
15. Kiat-amnuay S, Lemon JC, Powers JM: Effect of opacifiers on color stability of pigmented maxillofacial silicone A-2186 subjected to artificial aging. J Prosthodont 2002;11:109-116
16. Phillips RW, Margetis PM, Urban JJ, et al: Materials for the fabrication of maxillofacial prosthesis. In Chalian VA, Drane JB, Standish SM (eds): Maxillofacial Prosthetics: Multidisciplinary Practice. Baltimore, Williams & Wilkins, 1971, pp. 89-107
17. Clarke CD: Facial and Body Prosthesis. St. Louis, Mosby, 1945, pp. 13-31
18. Barnhart GW: A new material and technic in the art of somato-prosthesis. J Dent Res 1960;39:836-844
19. Bulbulian AH: Problems of facial prosthesis. Surg Clin North Am 1946;26:846-858
20. De Rooij C, Defourny C, Thompson RS, et al: 1,1,1-trichloroethane marine risk assessment with special reference to the OSPARCOM region: North Sea. Environ Monit Assess 2004;97:39-56