Evaluation of Effect of Intrinsic Pigment on Tensile Strength, Tear Strength and Percentage of Elongation in Two Commercially Available Room Temperature Vulcanizing Maxillofacial Silicone Elastomers - An Invitro Study

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Abstract: ***Background**: Silicone elastomers are indispensable materials in maxillofacial prosthetics owing to their flexibility, biocompatibility, and ability to replicate natural tissue appearance. Although intrinsic pigmentation enhances esthetics, it may influence the mechanical integrity of the material, thereby affecting the long-term performance and durability of prostheses. Achieving an optimal balance between color enhancement and mechanical strength remains a key challenge. **Aim**: To evaluate the effect of intrinsic pigmentation on the tensile strength, tear strength, and percentage of elongation of two commercially available room temperature vulcanizing (RTV) maxillofacial silicone elastomers. **Materials and methods**: Two RTV silicones-A-2186 (Factor II, USA) and Biomed Silicone (MP Sai Pvt. Ltd., India)-were tested with and without 0.2 wt% intrinsic pigment (P107 Sienna, Technovent). Standardized dumbbell-shaped and trouser-shaped specimens were fabricated according to ASTM D412 and ASTM D624 specifications, respectively. Mechanical testing was conducted using an Instron Universal Testing Machine. The independent t-test was used to compare quantitative parameters between groups, with statistical significance set at $p < 0.05$. Analyses were performed using SPSS software, version 20.0. **Results**: A-2186 exhibited superior mechanical properties compared to Biomed Silicone. Pigment incorporation significantly improved the tensile, tear, and elongation properties of A-2186 ($p < 0.01$), whereas Biomed Silicone showed reduced tensile strength and elongation but enhanced tear strength. **Conclusion**: A-2186 demonstrated greater resilience and flexibility, making it a more suitable choice for maxillofacial prostheses. Controlled pigment addition is essential to preserve mechanical integrity and achieve long-term esthetic and functional success.*

Keywords: A-2186, Biomed Silicone, RTV silicone, Tensile strength, Tear strength, Elongation

1. Introduction

Facial defects resulting from congenital anomalies, trauma, or surgical resection of tumors can significantly impact a patient's appearance, function, and psychological well-being. In situations where surgical reconstruction is not viable or insufficient, maxillofacial prostheses serve as an effective alternative to restore facial form, enhance function, and improve the patient's overall quality of life. Silicone elastomers, especially room temperature vulcanizing (RTV) silicones, are commonly used in these prostheses due to their superior biocompatibility, flexibility, and skin-like appearance[1]. However, despite these advantages, silicone prostheses are prone to mechanical and esthetic degradation over time, with an average clinical lifespan of 1.5 to 2 years. Factors such as ultraviolet (UV) exposure, repeated handling, and interaction with adhesives can lead to marginal tearing, discoloration, and reduced durability.[2]

Intrinsic pigmentation, which involves incorporating pigments directly into the silicone matrix during processing, is widely preferred for its improved color stability and natural appearance[3]. However, the addition of pigments may influence the mechanical behavior of the material, affecting key properties like tensile strength, tear resistance, and elasticity[4]. Although previous studies have explored the effects of pigmentation on certain commercial silicones, there is limited evidence regarding newer materials such as A-2186 and Biomed Silicone, which are gaining popularity in clinical practice due to their handling properties and availability. This study aims to assess the impact of cosmetic-grade intrinsic pigmentation (Sienna, Technovent Color System Ltd., UK) on the tensile strength, tear strength, and percentage elongation of A-2186 and Biomed silicone elastomers, thereby evaluating their mechanical performance and suitability for long-term use in maxillofacial prosthetic rehabilitation.

2. Materials and Methods

Study Design

This in vitro study was conducted to evaluate the effect of intrinsic pigments on the mechanical properties, tensile strength, tear strength, and percentage elongation of two commercially available room-temperature vulcanizing (RTV) maxillofacial silicone elastomers. A total of 80 specimens were fabricated and equally divided into two main groups of 40 specimens each. Group A was used for the evaluation of tensile strength and percentage elongation, and Group B for the evaluation of tear strength. Each main group was further subdivided into four subgroups (n = 10) based on the type of silicone material (A-2186 or Biomed) and the presence or absence of intrinsic pigment.

Materials Used

Two RTV maxillofacial silicone elastomers-A-2186 (Factor II Inc., USA) and Biomed silicone (MP SAI Enterprises Pvt. Ltd., India)-and an intr/insic pigment, P142 Sienna (Technovent Color System Ltd., UK), were used in this study (Fig. 1).

Figure 1: Silicones and Pigment Used For the study

Specimen Fabrication

Specimens were fabricated using metal molds conforming to ASTM D412 standards for tensile and elongation testing, producing dumbbell-shaped samples measuring 115 mm × 25 mm × 2 mm with a uniform thickness of 1.8 mm. For tear strength evaluation, trouser-shaped specimens with a 90° angle and dimensions of 102 mm × 19 mm × 3 mm, also with a uniform thickness of 1.8 mm, were prepared according to a modified ASTM D624 standard.

The molds used for silicone packing were fabricated using Type III dental stone. The metal template was invested in dental stone within a metal flask to form the first half of the mold. After setting, the second half was poured to complete the assembly. Once the stone had fully set, the metal template was removed, leaving a mold cavity suitable for specimen fabrication.

Silicone manipulation and intrinsic pigmentation

For the A-2186 silicone elastomer (Factor II Inc.), Parts A and B (base and crosslinker) were mixed in a 10:1 weight ratio. A total of 100 g of base and 10 g of crosslinker were weighed using a digital precision balance and manually mixed until a homogeneous consistency was achieved. For the pigmented subgroups, 0.2% by weight of a cosmetic-grade intrinsic pigment (Sienna P107) was incorporated into the silicone using a ceramic slab and spatula. Mixing was continued until a uniform, bubble-free blend was obtained (figure 2.).

Biomed silicone (MP SAI Enterprises Pvt. Ltd.), a one-part RTV silicone, was dispensed and weighed (100 g), and the same pigment concentration (0.2% by weight) was incorporated using identical mixing techniques.

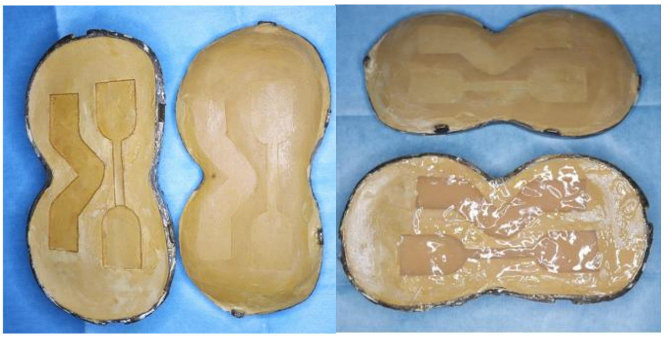

Figure. 2. Silicone material being packed into the mold.

Curing Procedure

Prior to packing, the stone molds were coated with a cold mold sealant and allowed to dry completely. The prepared silicone material was then packed into the molds and compressed using a hydraulic press to ensure uniform adaptation and minimize air entrapment. The A-2186 specimens were cured at room temperature for 48 hours, and the Biomed specimens for 24 hours, following the manufacturers' recommendations. A total of 80 specimens were fabricated for the study.

Mechanical Testing

Tensile Strength and Percentage Elongation:

Dumbbell-shaped specimens (Group A) were tested using an Instron universal testing machine at a crosshead speed of 500 mm/min (Fig. 2). The machine was fitted with a 100 kg load cell and an extensometer, and the grips were positioned 50 mm apart. Upon specimen failure, the fracture location and failure mode were examined to identify any material defects.

Tensile stress was calculated using the formula:

$$\text{Stress (N/mm2)} = \frac{\text{Load}}{\text{Initial cross-sectional area}}$$

$$\text{Percentage Strain (\%)} = \frac{\text{Extension} \quad \text{X 100}}{\text{Original Length}}$$

Tensile strength was recorded in pounds per square inch (psi), and elongation was expressed as a percentage.

Tear strength:

Tear strength testing (Group B) was performed on trouser-shaped specimens with a 90° angle using the same Instron universal testing machine at a crosshead speed of 500 mm/min. The fracture pattern and tear propagation were analyzed to assess material integrity. The maximum force required to tear each specimen was recorded in Newtons (N), and tear strength was calculated using the formula:

Tear strength (T): F/D

Where *F* represents the maximum force and *D* the specimen thickness. All tear strength specimens were prepared without notches and maintained at a consistent thickness of 1.8 mm, following modified ASTM D624 specifications.

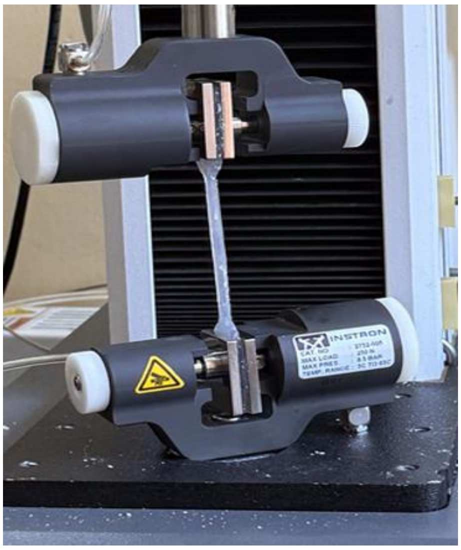

Figure 3: Test specimen in the Instron Universal testing machine

Statistical Analysis

All data were tabulated and analyzed to determine the influence of intrinsic pigment incorporation on the mechanical properties of the two silicone elastomers. Descriptive statistics, including mean ± SD, median with interquartile range, and minimum and maximum values, were used to describe quantitative variables. A box plot was employed for the graphical representation of descriptive summary statistics, such as the minimum, first quartile, median, third quartile, and maximum. The independent t-test was used to compare quantitative parameters between categories. For all statistical interpretations, a p-value of <0.05 was considered the threshold for statistical significance. Statistical analyses were performed using SPSS software, version 20.0.

3. Results

The descriptive and comparative statistics for tensile strength are summarized in Table 1. In A-2186 silicone without pigment (A1), the mean tensile strength was 4.1 ± 0.2 MPa, which increased significantly to 4.7 ± 0.3 MPa following pigment incorporation (A2; $p < 0.01$). By comparison, Biomed silicone without pigment (A3) exhibited a mean tensile strength of 3.2 ± 0.5 MPa, decreasing to 2.6 ± 0.6 MPa after pigmentation (A4; $p = 0.05$). Overall, A-2186 demonstrated significantly higher tensile strength than Biomed silicone both before and after pigment.

The tear strength results are presented in Table 3. Pigment addition enhanced tear strength in A-2186 silicone from 20.2 ± 3.1 MPa (B1) to 24.8 ± 2.4 MPa (B2; $p = 0.002$). Biomed silicone also showed an increase in tear strength, from 10.4 ± 2.2 MPa (B3) to 13.8 ± 1.6 MPa (B4; $p < 0.01$), although the values remained lower than those of A-2186 under all conditions ($p < 0.01$).

Analysis of percentage of elongation (Table 2) revealed a similar trend. Incorporation of pigment in A-2186 silicone resulted in a significant increase in elongation from 544.9 ± 28.5% (A1) to 588.1 ± 43.8% (A2; $p = 0.018$). In contrast, Biomed silicone showed a marked reduction in elongation, decreasing from 370.6 ± 49.3% (A3) to 271.1 ± 49.3% (A4; $p < 0.01$). Comparative analysis confirmed that A-2186 maintained higher elongation than Biomed silicone, both prior to and following pigmentation ($p < 0.01$). addition ($p < 0.01$).

Overall, the incorporation of intrinsic pigment improved all mechanical properties in A-2186 silicone, while Biomed silicone exhibited a mixed response, showing improved tear strength but reduced tensile strength and elongation. All observed differences were statistically significant ($p < 0.05$).

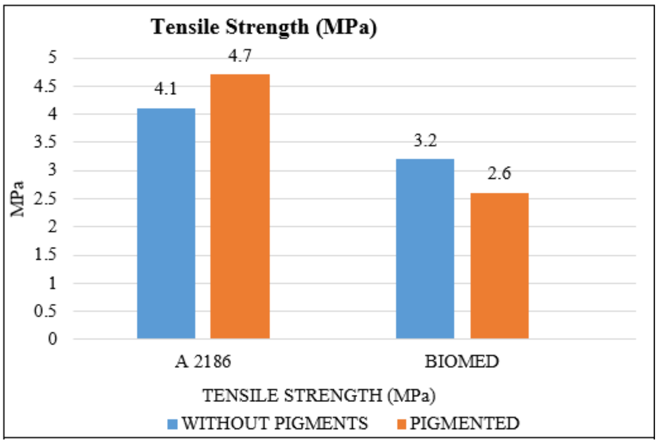

Figure 4: Comparison of tensile strength between A-2186 and Biomed silicones, with and without pigmentation

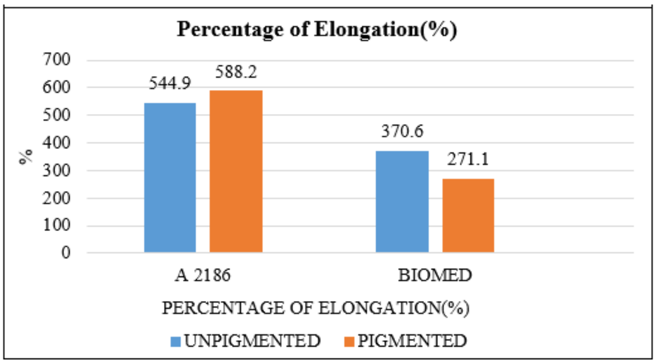

Figure 5: Comparison of Percentage of elongation between A-2186 and Biomed silicones, with and without pigmentation

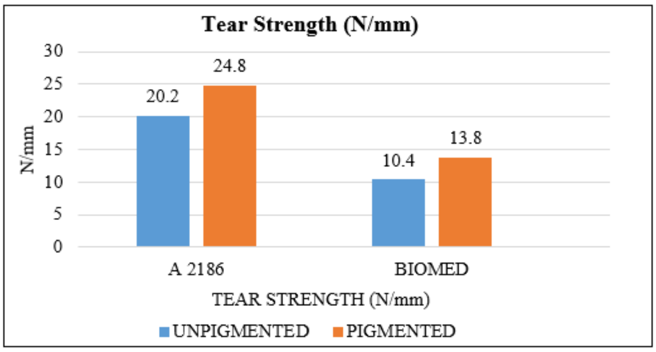

Figure 7: Comparison of Tear Strength between A-2186 and Biomed silicones, with and without pigmentation

Table 1: Descriptive and comparative statistics for tensile strength

Group	Material	Intrinsic Pigmentation	Mean ± SD (MPa)	Range	p-value	Significance
A1 A2	A2186	With Pigment Without Pigment	4.1 ± 0.2 4.7 ± 0.3	3.9–4.5 4.2–5.1	- <0.01	- ↑ Significant
A3 A4	BIOMED	With Pigment Without Pigment	3.2 ± 0.5 2.6 ± 0.6	2.5–3.9 2.1–3.6	- 0.05	- ↓ Significant
A1 vs A3	A-2186 vs Biomed	Without Pigment	-	-	<0.01	A-2186 > Biomed
A2 vs A4	A-2186 vs Biomed	With Pigment	-	-	<0.01	A-2186 > Biomed

Table 2: Descriptive and comparative statistics for Percentage of elongation

Group	Material	Intrinsic Pigmentation	Mean ± SD (MPa)	Range	p-value	Significance
A1 A2	A2186	With Pigment Without Pigment	544.9 ± 28.5 588.1 ± 43.8	505.2 - 585.2 530.1 - 666.5	- <0.01	- ↑ Significant
A3 A4	BIOMED	With Pigment Without Pigment	370.6 ± 49.3 271.1 ± 49.3	299.7–442.0 201.6–325.0	- 0.018	- ↓ Significant
A1 vs A3	A-2186 vs Biomed	Without Pigment	-	-	<0.01	A-2186 > Biomed
A2 vs A4	A-2186 vs Biomed	With Pigment	-	-	<0.01	A-2186 > Biomed

Table 3: Descriptive and comparative statistics for tensile strength

Group	Material	Intrinsic Pigmentation	Mean ± SD (MPa)	Range	p-value	Significance
B1 B2	A2186	With Pigment Without Pigment	20.2 ± 3.1 24.8 ± 2.4	15.7–24.8 22.0–29.0	- 0.02	- ↑ Significant
B3 B4	BIOMED	With Pigment Without Pigment	10.4 ± 2.2 13.8 ± 1.6	6.8–13.5 11.9–16.9	- <0.01	- ↑ Significant
B1 vs B3	A-2186 vs Biomed	Without Pigment	-	-	<0.01	A-2186 > Biomed
B2 vs B4	A-2186 vs Biomed	With Pigment	-	-	<0.01	A-2186 > Biomed

4.Discussion

This in vitro study evaluated the effect of intrinsic pigmentation on the mechanical properties of two commercially available room-temperature vulcanizing (RTV) maxillofacial silicone elastomers-A-2186 (Factor II) and Biomed (MP SAI Enterprises Pvt. Ltd). The mechanical properties assessed were tensile strength, percentage of elongation, and tear strength. Pigmentation was achieved by incorporating 0.2 wt% of a cosmetic-grade sienna pigment (P107). The findings demonstrated a material-dependent response to pigmentation.

The A-2186 silicone elastomer exhibited significantly higher tensile strength, percentage of elongation, and tear strength compared to Biomed, both in pigmented and unpigmented forms. These results align with previous studies which have consistently reported superior mechanical properties of A-2186 due to its optimized crosslinking density, filler dispersion, and polymer formulation (Kiat-Amnuay et al., 2008[5]; Zayed et al., 2014[6]). Notably, the incorporation of intrinsic pigment further enhanced the performance of A-2186 across all tested parameters. This improvement may be attributed to the pigment acting as a reinforcing agent, filling interstitial spaces in the polymer matrix and improving stress distribution, as proposed by Han et al. (2008)[7] and Vojdani et al. (2015)[8].

In contrast, Biomed silicone showed a reduction in tensile strength and percentage of elongation upon pigmentation, although a modest increase in tear strength was observed. This may suggest incompatibility between the pigment and the silicone base or inadequate pigment dispersion, which can lead to microstructural flaws and stress concentration sites. Similar reductions in mechanical performance following pigmentation have been reported in certain RTV silicones with less optimized filler-matrix interactions (Goiato et al., 2012[9]; Hatamleh & Watts, 2010[10]). Despite this, all tested Biomed samples still met minimum ISO 37:2017 requirements for maxillofacial silicone materials[11].

The divergent response to pigmentation observed between the two silicones highlights the importance of evaluating pigment compatibility with specific material formulations. While pigmentation is essential for esthetic integration of facial prostheses, it should not compromise mechanical properties critical to clinical performance, especially in high-mobility regions such as the lips, nose, or periorbital area[12].

The results emphasize that A-2186 silicone is more suitable for clinical use when intrinsic coloration is required. Its superior tensile and tear resistance and high elasticity indicate better durability and resilience to mechanical stresses during function and hygiene procedures. In contrast, the mechanical limitations observed in pigmented Biomed silicone may restrict its use to low-stress prosthetic applications unless further material modifications are introduced.

Limitations of this study include the evaluation of only one pigment type and concentration, and the absence of artificial aging or environmental exposure simulation. Future research should incorporate long-term aging protocols, evaluate multiple pigment types and concentrations, and explore nanoparticle-modified pigments or additives that may enhance pigment dispersion and mechanical reinforcement

4. Conclusion

Within the limitations of this in vitro study, incorporation of 0.2% intrinsic pigment showed material-dependent effects on RTV maxillofacial silicones. A-2186 exhibited superior mechanical properties, further enhanced with pigmentation, while Biomed silicone showed reduced tensile strength and elongation but slight improvement in tear strength. These findings highlight the importance of material, pigment compatibility, with A-2186 emerging as the more reliable option for intrinsic coloration in maxillofacial prostheses. Further research with varied pigments, concentrations, and aging conditions is recommended to optimize long-term clinical performance.

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