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# Estimation of the Aging of Breast Prosthesis Materials by Accelerated Tests

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## ABSTRACT

Breast prostheses are extensively employed for either aesthetic augmentation or medical aims. Clinical or subjective reasons may sometimes induce early removal; however, it is not uncommon for them to remain implanted for extended periods, often exceeding 20 years. Understanding the expected materials changes over time is crucial for deciding on their potential removal or replacement. This study examines the aging of silicone prosthesis materials, measuring the changes in the mechanical properties of the elastomeric shell and the viscosity of the inner gel after accelerated aging tests at various temperatures over a period exceeding two years. Predictive models based on the time-temperature superposition principle enable the estimation of mechanical performance over extended timeframes, providing valuable insights into the expected durability and lifespan of implants.

## 1 | Introduction

Silicone breast prostheses have been commonly implanted in plastic surgery for decades. Their diffusion for both aesthetic and post-surgery breast augmentation procedures is steadily growing; in the meantime, the average age of the patients is reducing. At present, the expected duration of implants is estimated in about 10–15 years, but if no adverse effects induce removal, prostheses remaining implanted for 20 years and even more are not uncommon [1, 2]. It is apparent that the growing diffusion of augmentation procedures, particularly among young people, demands a continuous increase in their safety and durability.

Modern prostheses are usually made of a thin PDMS-based silicone elastomeric shell, less than one mm in thickness, filled with a viscous silicone fluid gel. The external shell surface may be coated with a layer of dense polyurethane foam for better integration with body tissues. Substantial changes in elasticity, deformability, strength, and softness of the outer shell or of filling gel occurring with time may potentially affect the comfort, the figure, and the mechanical response of the implant. The knowledge of possible long-term aging effects is therefore relevant for both plastic surgeons and patients in making decisions about the opportunity of prostheses implantation and/or removal procedures.

For any application requiring the use of rubber material, which is highly deformable and able to maintain its properties for long times even in harsh conditions, silicone-based materials are generally considered as primary choice. Moreover, a number of silicone compounds satisfy the requirements of biocompatibility. Indications of the good response of silicone rubbers, both of general-purpose grade and of medical grade, in short-term aging tests have been reported in literature [3–6]. On the other hand, the actual changes in material properties expected after very long implantation times in the human body still necessitate full clarification.

The estimation of long-term aging of polymeric materials has been the subject of many studies. Significant changes in chemical, as well as physical, molecular structure affect macroscopic behavior; these changes usually take place with time, to an extent which depends on the thermal, mechanical, environmental, etc. history experienced [6]. In case of silicone rubbers and gels, increases in stiffness or viscosity and reduction of deformability with aging deriving from possible increased crosslinking are expected [5, 6]. Models to estimate the variation of viscoelastic properties of amorphous polymers with time have been studied for many decades. Provided the aging conditions are reasonably known and/or controlled, time-temperature superposition procedures demonstrated to produce reliable estimates of aging effects [3, 7–10]. According to the time-temperature superposition principle, an increase in temperature enhances the aging rate. If no additional mechanisms intervene in the observation temperature range, a correspondence between time effects and material temperature can be stated. A simple, semi-empirical approximation, which has been recognized as reliable for some polymers of biomedical interest, indicates that an increase of temperature of 10°C doubles the aging rate [3, 9]. Considering that PDMS-based rubbers display very good chemical stability even at considerably high temperatures and that prostheses stay in a sensibly constant environment during their lifetime, with practically no exposure to UV radiations (which often promote chemical reactions in polymers), the adoption of accelerated testing procedures in a controlled environment is likely to produce reliable predictions.

The outcomes of tests on rubber shell specimens taken from commercial prostheses after aging at four temperatures (37, 60, 75, 90°C) and 6 months of aging time were previously reported [11]. In this research, the mechanical properties of the shell, in particular deformability, and viscosity changes of the inner gel after more than two years of aging are explored. Based on the approach, indicating that the aging rate approximately increases by a factor of $2^{\Delta T/10}$ with an increase of temperature $\Delta T$, the expected changes in mechanical performances of breast prostheses on a human life-time scale are predicted.

## 2 | Results and Discussion

Tensile tests performed on specimens aged at different temperatures and times confirmed that the deformability of the silicone shell presents a decreasing trend with aging. However, only a quite limited increase in stiffness and no substantial variation in strength were observed. Figure 1 shows the mechanical response after two years of aging. Specimens in accordance with ASTM D1708 standard, with 0.5 mm thickness, were die-cut from commercial prostheses and used in the tests.

Assuming, as an approximation, that the aging rate doubles with a 10°C increase in temperature [3, 9], it is possible to estimate the changes in deformability over long periods at human body temperature.

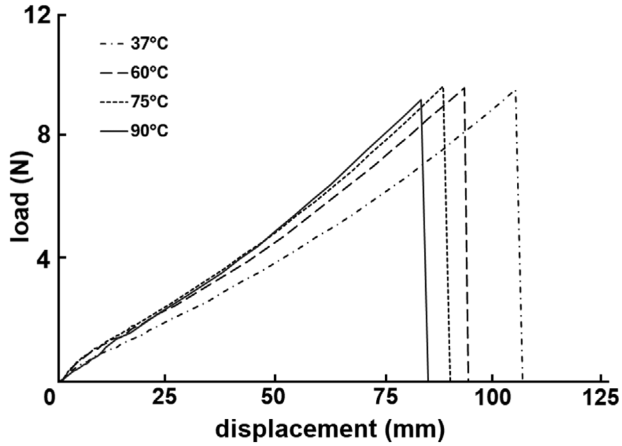


**FIGURE 1** | Mechanical response of silicone shell material after two years of aging.

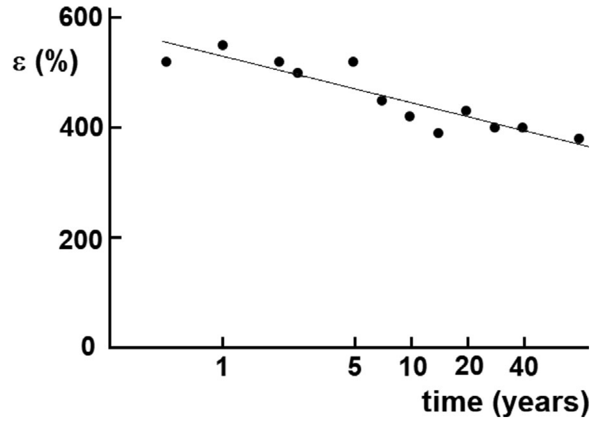


**FIGURE 2** | Estimation of decay of silicone shell deformability after aging at 37°C.

Based on this assumption, Figure 2 shows the expected change in deformability of the prosthesis shell at body temperature. It can be observed that very long times, well exceeding the range of interest, are covered by the applied prediction model. An appreciable reduction in shell deformability is estimated, approximately 30% of the original value, after 40 years of aging. Nevertheless, the overall elastomeric, highly deformable nature of the material is substantially maintained, with no significant loss of strength. Similarly, viscosity measurements of the inner gel, aged under the same conditions, showed no evident variations.

These results support the long-term durability of modern breast prostheses. However, these outcomes should be taken into consideration in case of accidental impacts or overstresses, supporting the recommendation for proper medical check-ups in such events.

## 3 | Conclusions

Mechanical tests of breast prosthesis materials, conducted after long-term aging, confirm the overall high durability and safety of these implants. However, a significant reduction in the silicone shell's deformability over time is confirmed and predicted on an approximation basis. Considering also the natural, human aging of patients carrying implants for a long time, this change in mechanical response is not expected to significantly affect comfort. Regular medical monitoring is, however, recommended, particularly in case of accidental events.


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### Conflicts of Interest

The authors declare no conflict of interest.

### Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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