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Long-Term Aging Effects of Breast Implant Materials

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Abstract

Breast prostheses are widely used for both aesthetic and medical purposes. Unless clinical or subjective factors impose early removal, these implants can remain in place for extended periods of time, often exceeding 20 years. Understanding the expected changes in their performance over time, in addition to medical issues, is crucial for decisions regarding potential removal or replacement. This study investigates the long-term aging effects on silicone breast implants by evaluating changes in the mechanical properties of the elastomeric shell and the viscoelastic behavior of the inner gel. Accelerated aging tests were conducted at different temperatures, and the data were analyzed using established predictive models to estimate mechanical performance over extended periods. These results provide valuable insights into the expected durability and lifespan of breast implants, supporting improved predictions of long-term safety.

Keywords: breast implants; silicone prosthesis; long-term aging; mechanical behavior; gel viscoelasticity; durability

1. Introduction

Silicone breast prostheses have been widely used for over 60 years, both in post-cancer reconstructive surgery and for aesthetic purposes. Their global use continues to rise steadily, and at the same time, the average implantation age of patients becomes lower. According to the International Society of Aesthetic Plastic Surgery (ISAPS), based on data from its members, more than 1.6 million breast augmentation procedures were performed worldwide in 2024. More than half of these procedures involved patients under the age of 34 [1]. Considering unreported data, it is likely that the actual number of procedures is probably consistently higher. Although some implants require early removal or replacement after a relatively short period, most are designed to remain implanted for many years. The average lifespan of breast implants is estimated to be around 10 to 15 years [2], but with regular monitoring and no signs of complications, implants can remain in place for up to 20 years or more [3].

There are various reasons for recommending the removal of implants before reaching the end of their expected lifespan, ranging from unsatisfactory aesthetic outcomes or clinical complications to damage caused by accidental impacts or excessive stress during their lifetime [4,5]. As the use of breast prostheses continues to rise, especially among younger patients, the demand for improvements in their safety and durability also grows.

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Breast prostheses typically consist of an outer elastomeric shell, made from multiple layers of silicone rubber, and are filled with a viscous silicone gel or, less commonly in modern systems, saline solution. In some cases, the outer shell is coated with a porous polyurethane layer to enhance tissue adhesion [6]. The functionality, appearance, and comfort of the implant depend significantly on the elasticity, strength, deformability, and softness of both the shell and the inner filling. Any significant changes in these properties over time could lead to disfigurement, patient discomfort, or reduced mechanical integrity. These aspects highlight the importance of understanding how silicone-based materials evolve mechanically over time in physiological conditions.

Mechanical damage to the prosthesis, as a result of impacts or loss of deformability in the shell, can cause its rupture and perfusion of the internal gel, often without immediate detection. If not identified promptly, such damage may lead to adverse effects on the surrounding body tissues. Although modern cohesive fillers are designed to minimize gel loss in the event of shell damage, regular instrumental checks are recommended for detecting potential issues [2,7–9].

Silicone-based materials are generally regarded as durable and are used in long-lasting, high-demand applications in industries like electronics, aerospace, mechanics, and biomedicine [10]. Previous studies have shown limited effects on the thermal and viscoelastic behavior of medical-grade silicone rubbers after short-term aging [11,12]. However, the long-term durability required for breast implants calls for a deeper understanding of the aging effects that silicone materials may undergo over extended periods.

Predicting long-term aging effects is a complex task, as material changes may result from both chemical and physical processes, depending on factors such as thermal, mechanical, and environmental exposure over time [13]. Phillips et al. [14] investigated the strength of breast prostheses explanted after many years, observing a decreasing trend in strength over time, although uncertainties related to control data, different manufacturers, different specimen locations, and possible pre-existing damages limited the analysis of strength loss mechanisms. The same authors point out that distensibility data may be relevant in the study of long-term durability. Jung et al. [15] measured the mechanical response of the shell of non-implanted silicone breast implants aged at room temperature for up to 5 years. While significant differences in strength and deformability were observed, no clear trend was evidenced by the authors. Shadrin et al. [16,17] studied the mechanical behavior of breast implants after five years of implantation by performing cyclic tests at various levels of deformation. The study also compared implants that had been in use for 2 to 8 years, observing a progressive softening of the shell. The results showed that, compared to tensile tests, cyclic tests led to earlier rupture due to the formation of microcracks during repeated elongation cycles. A subsequent study, involving prostheses explanted after a few days or after many years, suggested that the surgical procedure of implantation already affects the mechanical response of the prostheses. These studies found that the deformability of implant shells decreases by approximately one-third after 13 years in the body.

Under controlled conditions, prediction models for mechanical and viscoelastic behavior, based on the time–temperature superposition principle, have proven useful for amorphous polymers such as silicone rubbers [18–20]. These models form the basis for international standards, such as ISO 11346, which aim to predict the lifetime of polymeric materials exposed to long-term aging at different temperatures [21]. According to the time–temperature superposition principle, aging effects accelerate with increasing temperature. A correspondence between temperature increase and time effects can be defined, provided no additional aging mechanisms are activated at high temperatures, typically coming from possible chemical reactions. In the case of breast implants, however, a stable temperature during implantation and minimal exposure to UV radiation—a common cause of chemical degradation—suggest that aging effects can be predicted more reliably compared to other materials subjected to more variable conditions. For several polymers of biomedical interest, which have been previously characterized, a simplified approximation assumes that the rate of aging is doubled with every 10 °C increase in temperature [12,20,22]. The availability of results from experimental tests over a wide time–temperature range is essential for the definition of more reliable predictions.

The aging of crosslinked elastomers, such as PDMS-based silicone rubbers or gels, generally involves molecular-level changes, resulting in increased crosslink density over time [23,24]. These molecular changes can lead to significant alterations in stiffness, viscosity (in the case of low-crosslink-density fluid gels), and deformability. While strength variations are typically smaller, they may still be observed [13].

In previous studies, we reported results from aging tests conducted over a period of up to 10 months [5]. In the research presented here, we investigated the long-term aging effects on the mechanical and viscous behavior of the elastomeric shell and inner gel of commercial breast prostheses. We present and discuss the results of accelerated aging tests conducted at different temperatures over a span of more than two years. Using existing protocols, i.e., the ISO 11346 standard, the "10 °C rule" [20,22], and the procedure proposed by Gillen et al. [25], we estimate the expected mechanical property changes in prostheses' shell material over prolonged implantation times. Additionally, we provide comparative data on the mechanical response of the entire prosthesis under compression after aging.

2. Materials and Methods

Aging tests were conducted on the silicone elastomeric shell and the high-viscosity inner gel extracted from new breast implants, produced by Mentor™—Johnson & Johnson—Pratica di Mare, Rome, Italy. For the tests on shell and gel materials, CPG™ Gel—Cohesive III™—breast implants were used, which consisted of a medical-grade silicone rubber shell, approximately 0.5 mm thick, filled with a cohesive, high-viscosity medical-grade silicone gel. Regarding the unaged shell material, the manufacturer provided an estimated crosslink density of 1.3×10^{-4} mol/cm^3 and a network chain molecular weight of 8.6×10^3 g/mol. The inner gel used for viscoelastic measurements was also extracted from the same implants.

To investigate the effects of aging on the shell material properties, three new implants of the same type were opened, and the internal gel was completely removed. The implants were cleaned with paper towels after the gel removal. Subsequently, micro-tensile specimens were extracted from the upper portion of the shell using a die cutter with a dumbbell shape and dimensions conforming to ASTM D1708 Standard [26]. Specimens were not obtained from the lower flat portion of the implants, as the thickness in that region was consistently greater than that of the upper portion. Shell thickness measurements were carried out at various positions on each specimen using a micrometer, yielding an average thickness of 0.52 mm $\pm$ 0.02 mm.

Several sets of samples, each comprising 15 specimens, were maintained for aging in a physiological solution (0.9% NaCl) at four different temperatures: 37 °C, 60 °C, 75 °C, and 90 °C. The temperatures were selected over a wide range, while avoiding possible chemical degradation and in accordance with ISO 11346 Standard [11,23]. These specimens were periodically tested for tensile properties after aging periods of 6 months, 12 months, and 26 months at each temperature. Five specimens were tested at each aging time/temperature condition. An additional set of five unaged specimens was tested as an initial reference.

Specimens subjected to various aging conditions (time and temperature) were tensile tested at an extension rate of 50 mm/min until failure, using an INSTRON 4302 testing machine equipped with a 1000 N load cell (INSTRON—Norwood, MA, USA). Stress–

deformation curves were generated, and the material strength, ultimate deformation, and stiffness were compared. Stress data were evaluated as F/A_0, where F is the applied force and A_0 is the cross-section of the unloaded specimen. Deformation was estimated as $(L - L_0)/L_0$, where Lo is the gauge length of the unloaded specimen and L is the loaded specimen length. Given the small dimensions of specimens, approximate stiffness was estimated as the ratio between stress and deformation in the initial portion of the stress–deformation curve.

The inner gel extracted from the same implants was maintained in a sealed container and subjected to the same time–temperature aging conditions, not in contact with a physiological solution. The complex viscosity of the gel was measured via dynamic mechanical tests using a TA2000 torsional rheometer (Waters/TA Instruments—New Castle, DE, USA). The gel, after various aging periods under different time–temperature conditions, was tested at 25 °C in a frequency range of 1–50 Hz with a strain of 1%.

According to a previously described procedure [5,27], two new, identical, round implants (MemoryGel^{TM}) with a volume of 275 cm^3 (Figure 1) were compression tested between flat plates at a crosshead speed of 5 mm/min using an MTS858 Mini Bionix II dynamometer with a 15 kN load cell (MTS Systems Corporation—Eden Prairie, MN, USA). Video recordings were made throughout the tests. First, a new and unaged implant was compressed up to failure, and the compression load vs. displacement was recorded. The second implant was periodically tested at 70% of the initial failure load after aging in a 0.9% NaCl physiological solution at 37 °C, until failure occurred.

Figure 1. Compression-tested prostheses (initial volume: 275 cm^3, diameter: 11.7 cm, height projection: 3.7 cm).

The crosslink density of shell material aged for 26 months at different temperatures was estimated according to evaluated swelling measurements in toluene [28,29]. Specimens of about 2.5 g weight and 0.5 mm thickness were immersed in toluene at 25 °C. Their weight was periodically measured up to saturation and the polymer volume fraction ϕ was calculated accordingly. The cross-link density ν was calculated as:

$$\nu = -[ln\ (1 - \phi) + \phi + \chi\phi^2]/[V_l\ (\phi^{1/3} - \phi/2]$$

where V_l = 106.8 is the molar volume of toluene. A silicone–toluene interaction parameter χ = 0.62 was considered in the calculations [28].

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3. Results and Discussion

3.1. Mechanical Properties of Shell Material After Aging

All tests indicate a significant influence of long-term aging on the mechanical properties of the prosthetic shell. Tensile tests performed on specimens aged at different temperatures, between 37 °C and 90 °C, and for various durations, up to 26 months, show that the deformability of the silicone shell progressively decreases with increasing aging time (Table 1).

Table 1. Tensile test results of prosthetic shell specimens aged for 6, 12, and 26 months at four different temperatures: 37 °C, 60 °C, 75 °C, and 90 °C.

	Displacement (mm)	Load (N)	Stress (MPa)	Stiffness (MPa)	Deformation at Break (%)
Unaged	**121.7** ± 6.5	**9.99** ± 1.22	**4.75** ± 0.59	**0.79** ± 0.05	**560** ± 30
37 °C—6 months	**118.7** ± 10.0	**10.68** ± 1.88	**4.85** ± 0.66	**0.84** ± 0.09	**544** ± 45
60 °C—6 months	**111.0** ± 4.7	**9.95** ± 1.04	**4.69** ± 0.37	**0.87** ± 0.03	**514** ± 26
75 °C—6 months	**96.1** ± 3.4	**8.23** ± 0.78	**3.89** ± 0.26	**0.86** ± 0.03	**442** ± 19
90 °C—6 months	**91.0** ± 4.8	**8.48** ± 0.92	**3.91** ± 0.45	**0.90** ± 0.06	**420** ± 25
37 °C—12 months	**120.9** ± 9.3	**9.19** ± 3.36	**3.97** ± 1.36	**0.81** ± 0.08	**547** ± 28
60 °C—12 months	**116.5** ± 6.7	**11.28** ± 2.21	**4.46** ± 0.73	**0.76** ± 0.08	**530** ± 31
75 °C—12 months	**85.0** ± 2.6	**7.82** ± 0.54	**3.30** ± 0.16	**0.84** ± 0.02	**386** ± 12
90 °C—12 months	**91.5** ± 7.2	**8.87** ± 2.03	**3.59** ± 0.62	**0.84** ± 0.06	**416** ± 33
37 °C—26 months	**115.8** ± 6.7	**11.03** ± 2.75	**4.75** ± 1.08	**0.81** ± 0.04	**526** ± 76
60 °C—26 months	**97.1** ± 9.3	**8.85** ± 2.74	**3.66** ± 1.11	**0.86** ± 0.12	**441** ± 42
75 °C—26 months	**84.3** ± 3.8	**8.60** ± 1.67	**3.53** ± 0.53	**0.93** ± 0.08	**383** ± 18
90 °C—26 months	**83.6** ± 6.7	**8.83** ± 1.10	**3.53** ± 0.40	**0.90** ± 0.12	**380** ± 30

Figure 2 illustrates the mechanical response up to failure of specimens extracted from commercial implants, aged for 26 months at different temperatures; these data substantially extend over longer aging times than the results previously obtained with the same materials [5,27]. In the same figure, the response of unaged material extracted from the same implants is shown for comparison. It can be observed that the unaged shell displays a deformation at break well above 450%, exceeding the ISO 14607 requirement for new implants [30]. Referring to aged material, although a significant reduction in deformability and an appreciable increase in stiffness were recorded, the material retains a pronounced elastomeric character with relevant mechanical properties, a fundamental characteristic for these prosthetic devices.

3.2. Prediction of the Long-Term Mechanical Response of Shell Material

While the results of materials aged at 37 °C can give a direct view of the expected aging in a relatively short time period, accelerated aging at increasing temperatures represents the basis for any procedure to estimate the expected response in a long time period.

In line with previous studies, it was assumed that the aging rate of the material doubles with every 10 °C increase in temperature. This model is based on the application of the so-called "10 °C rule", which describes an exponential relationship between temperature and the aging rate of polymers [12]. This approach allowed for the estimation of long-term variations in material deformability, assuming a constant aging temperature of 37 °C, equivalent to human body temperature. As a result, the aging prediction was extended beyond the two-year experimental period, enabling a more comprehensive assessment of the evolution of mechanical extensibility over time.

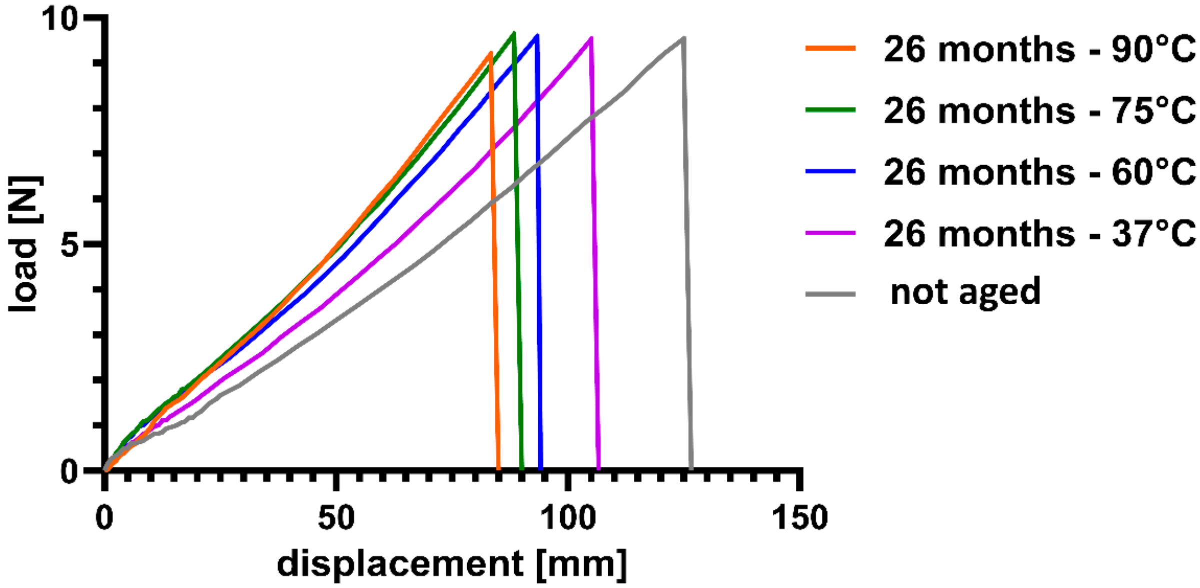

Figure 2. Tensile load–displacement curves of shell materials aged for 26 months at various temperatures.

Figure 3 illustrates the predicted variation in the ultimate extension of the prosthetic shell at body temperature, based on the predictive model derived from the hypothesis that the aging rate doubles for every 10 °C increase. The obtained relationship between time and deformability highlights the decreasing trend over time. According to the simulation results, after approximately 40 years of aging, the extensibility of the prosthetic shell is expected to decrease by about 30% compared to its initial value.

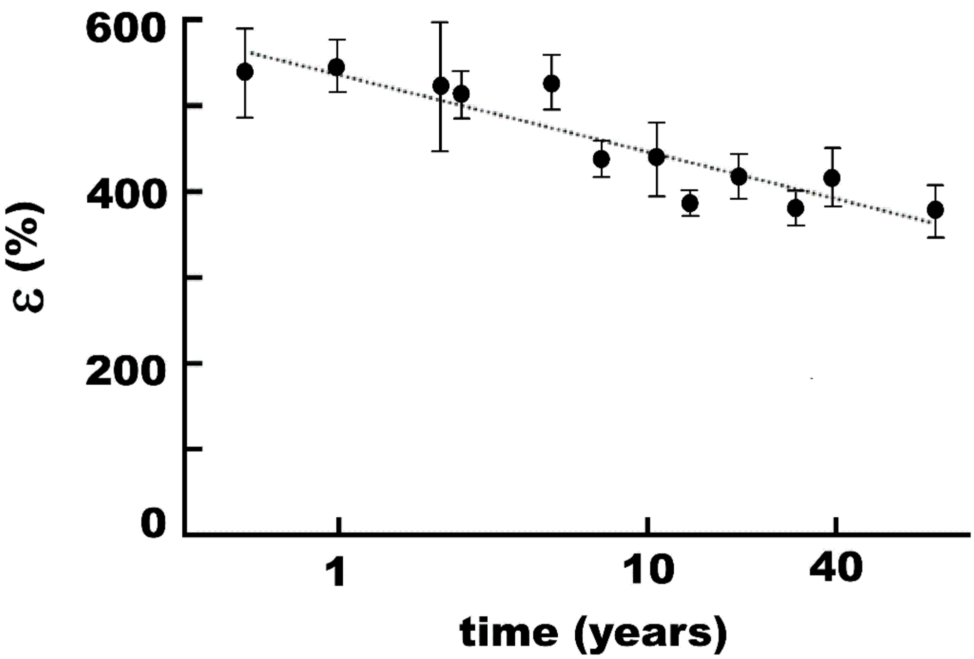

Figure 3. Estimated extensibility over time (in logarithmic scale) at 37 °C, according to the "10 °C rule".

The obtained relationship between elastic response and time, which highlights the decreasing trend in deformability with aging, is expressed as:

$$\varepsilon = 540 - 91 \times \mathrm{LOG}(t)$$

where t is the aging time in years, and ε is the deformation at break, in %.

These estimations are consistent with observations in prostheses aged for long times in the implanted conditions [16].

Despite this reduction, the mechanical properties of the material, particularly its ability to extensively deform before rupture, are expected to remain consistent with its highly elastomeric character, suggesting that degradation in mechanical strength is not critical enough to significantly affect the long-term safety and reliability of prosthetic devices.

As a comparison, the Arrhenius method for the estimation of thermal aging was applied to the same experimental results, in accordance with ISO 11346. The test results were processed by plotting the reduction in deformability as a function of the logarithm of time for each exposure temperature (Figure 4). By fitting data with a logarithmic function, the time to reach a preselected threshold was estimated. It is apparent that a reliable application of this method would require denser data, particularly in the high temperature/short time range and, possibly, additional results in the low temperature/long time range. A 10% deformability reduction threshold was, however, selected as a reference, and the reaction rate—i.e., the inverse of time to reach the selected threshold—was estimated. The logarithm of the reaction rate was plotted as a function of the inverse of the absolute temperature; the best-fit line through the points was estimated (Figure 5). The application of the Arrhenius/ISO 11346 methodology allowed the derivation of a relationship between time to reach the selected threshold and temperature, expressed by the following equation:

$$\mathrm{LOG}(1/t) = 23 - 7630\left(\frac{1}{T}\right)$$

where t is the time, in years, to reach the selected threshold, and T is the absolute temperature, in Kelvin. This relationship usually provides a useful tool for predicting the degradation of mechanical properties of polymers over time in response to temperature variations. In the case of prosthetic devices, body temperature (37 °C) serves as the reference condition, but a large part of the considered data at the highest temperatures is outside a useful range for prediction purposes. Given these limitations, however, according to this methodology, the threshold of the 10% deformability reduction is predicted to be reached after about 40 years of implantation time (represented by the red asterisk in Figure 4).

In a different procedure reported by Gillen et al. [19,25], the lowest experimental temperature (37 °C) is again selected as the reference temperature. Subsequently, each dataset of ultimate deformation at higher temperatures is shifted along the logarithmic scale of aging times to achieve the best possible overlap with data at the reference temperature. This time–temperature superposition procedure is analogous to that used to analyze the viscoelastic response of amorphous polymers [18]. Shift factors aT are thus evaluated as functions of temperature (aT = 1 at the reference temperature). Figure 6 reports the estimated "Master Curve" resulting from the overlap of relative deformability data at the selected reference temperature of 37 °C.

The obtained shift factors are consistent with the Arrhenius relationship, which implies a linear trend for the plot of ln (aT) versus $1/T$ (Figure 7), suggesting a reliable approximation of the extrapolated estimates.

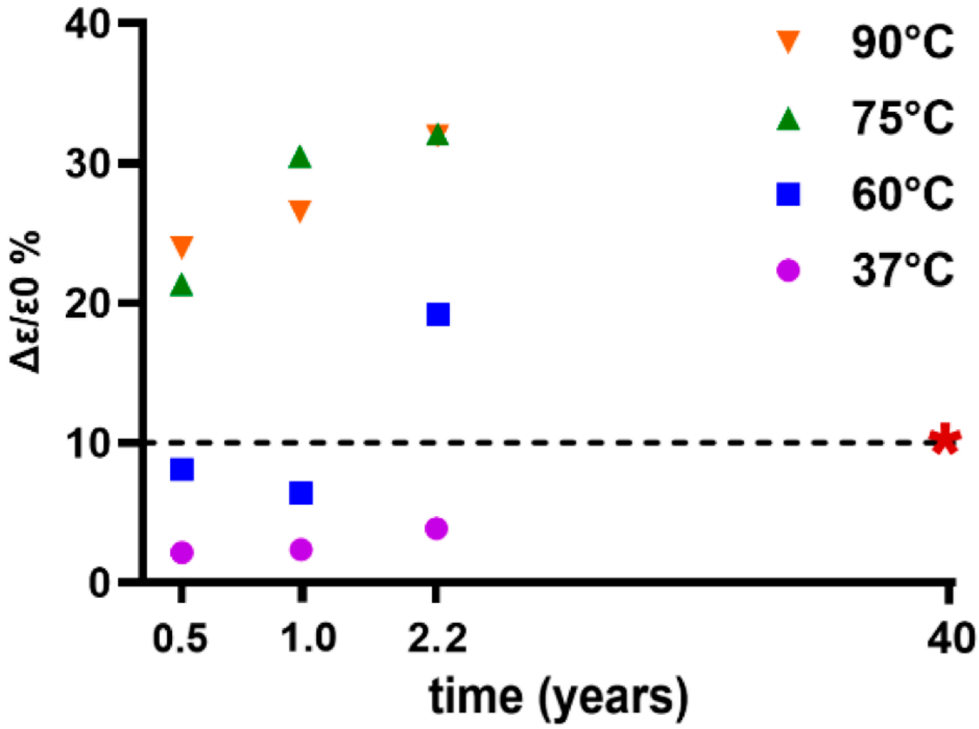

Figure 4. Reduction of extensibility as a function of aging time (in logarithmic scale) at different aging temperatures. Extensibility reduction of 10% is predicted to be reached after about 40 years aging (red asterisk).

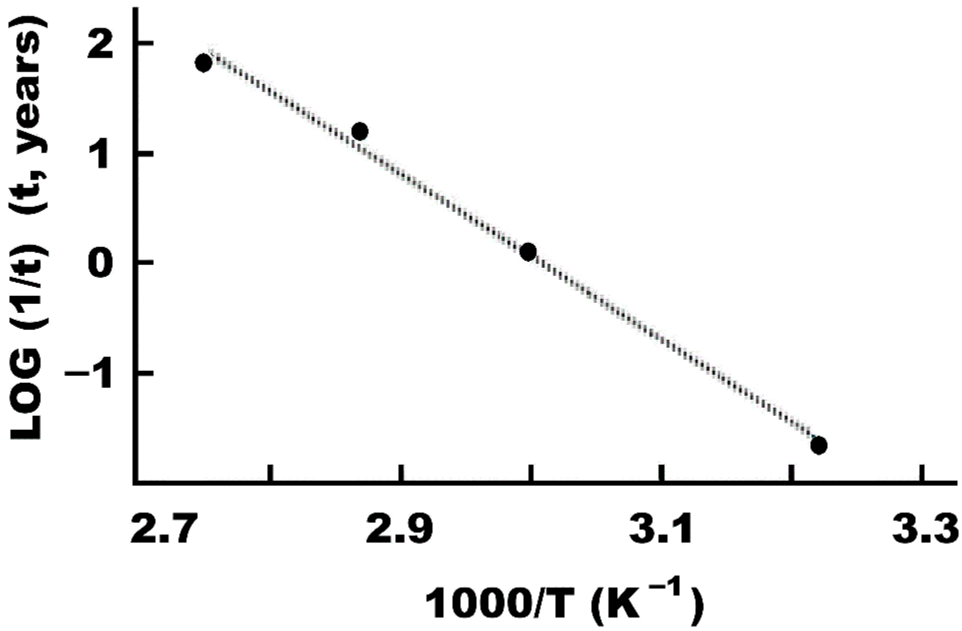

Figure 5. Relationship between time to threshold and temperature; Arrhenius plot according to ISO 11346.

The function approximating the relationship between time and extensibility at 37 °C is:

$$\varepsilon/\varepsilon_0 = 0.97 - 0.169 \text{ LOG } (t)$$

where t is the aging time, in years, and $\varepsilon/\varepsilon_0$ is the relative deformability (ε_0 = deformability of unaged material).

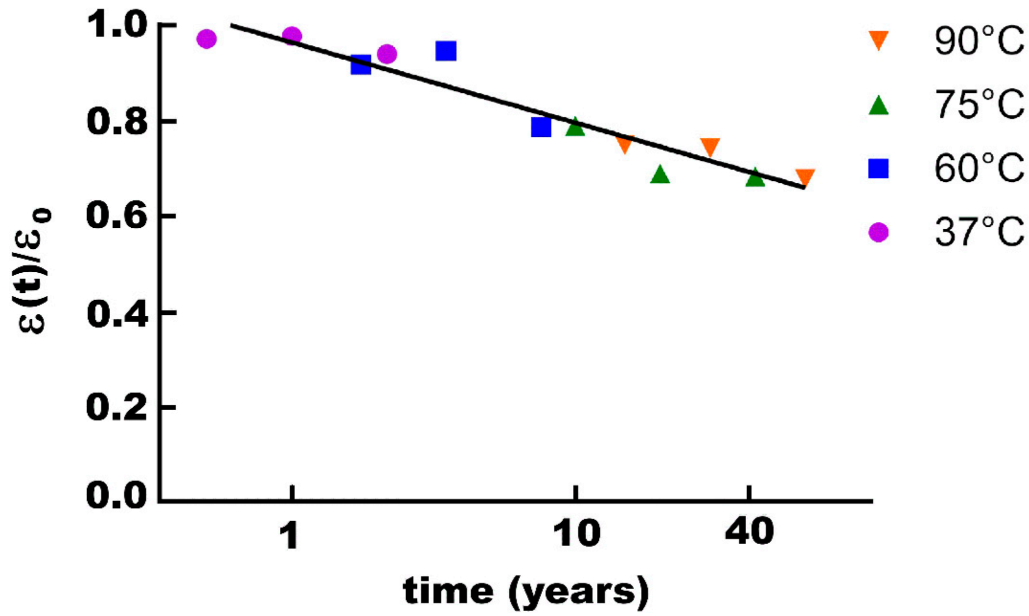

Figure 6. Estimated deformability over time (in logarithmic scale) at 37 °C, from superposition of data [19,25].

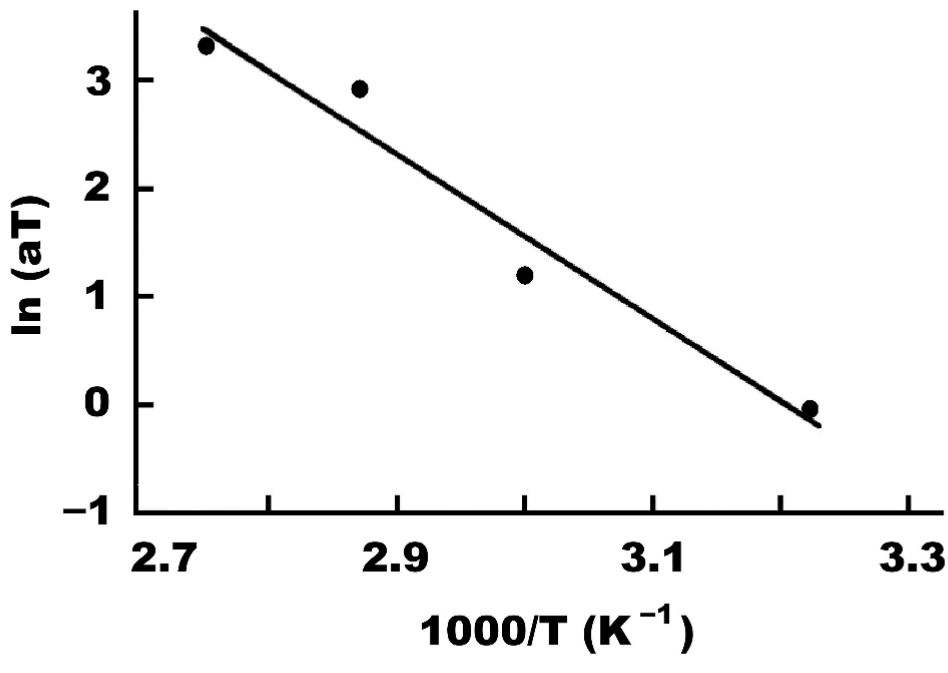

Figure 7. Arrhenius plot of shift factors obtained from reference time–temperature superposition.

It can be observed that the resulting prediction is quite close to that obtained by the "10 °C rule", although somewhat more conservative. By adopting this methodology, a prediction of the variation in deformability was obtained, indicating an approximate 30% reduction after 38–39 years. It is interesting to notice that both of these methods indicate that a mechanical extensibility of about 450%, the value required by ISO 14607 for new implants, is maintained in the first ten years, while progressive reduction below such a value is to be expected in the following years.

To summarize, different extrapolating models predict a reduction in prostheses shell deformability in the range between 10 and 30% over about 40 years, as a consequence of the material's natural aging.

3.3. Cross-Link Density of Shell Material and Viscosity Measurements of Gel After Aging

The aging of rubber materials, usually leading to an increase in stiffness, is often a result of additional crosslinking occurring with time within the molecular structure [23,24]. As a matter of fact, the estimation of crosslink density assessed in material aged for 26 months at different temperatures seems to confirm such a hypothesis. Based on swelling measurements in toluene, a crosslink density in the range of 2.3–4.4 $\times$ 10^{-4} mol/cm^3 was estimated, which is consistently higher than the original indicated value of 1.3 $\times$ 10^{-4} mol/cm^3.

The results on the mechanical response of the silicone shell over time were further complemented by the rheological analysis of the inner gel. Measurements of gel viscosity, aged at different temperatures (37 °C, 60 °C, 75 °C, and 90 °C) and for various durations (5, 8, 12, and 26 months), showed appreciable but quite limited variations over time (Figure 8). These results suggest that the gel maintains substantial stability in its viscoelastic properties also in the long-term period.

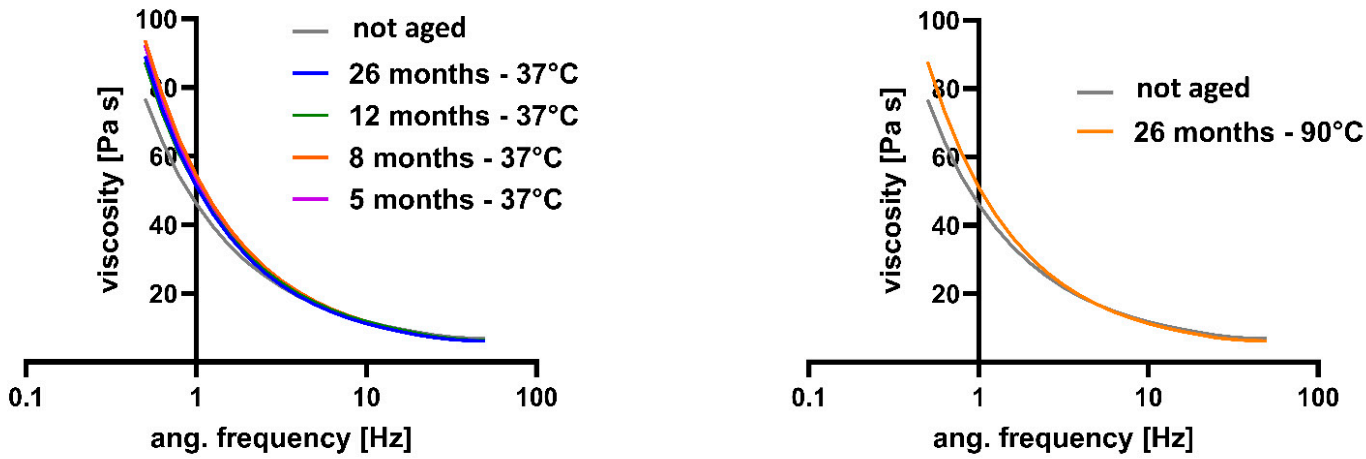

Figure 8. Change in complex viscosity of the internal silicone gel after more than 2 years of aging at 37 °C and 90 °C.

3.4. Compression Results of Aged Implants

Based on previous studies [5,27], static compression tests were conducted on two identical, unused, round breast implants (275 cc, 11.7 cm in diameter, 3.7 cm in height projection) to investigate their overall mechanical response up to failure. One implant was compressed until failure to evaluate the initial rupture force, while the other was subjected to a load corresponding to 70% of the rupture force after defined aging periods.

Figure 9 shows the load–displacement curves obtained from tests performed on the new implant compressed to failure, and on the aged implant that had been stored in saline solution at 37 °C for three, six, ten, and twelve months. These tests aimed to assess the possible influence of aging on the overall mechanical behavior of the entire implants, particularly regarding the rupture resistance of the shell and its deformation capacity. After each test, the aged implant was returned to the thermostatic bath to continue the aging process.

For the new implant, the measured rupture load was 7650 N. Compression tests conducted after 3, 6, and 10 months of aging, limited to a maximum load corresponding to 70% of the initial rupture load (5360 N), did not cause rupture or visible damage. After 12 months of aging, the implant failed at a load of 4990 N, i.e., before reaching the pre-selected limit.

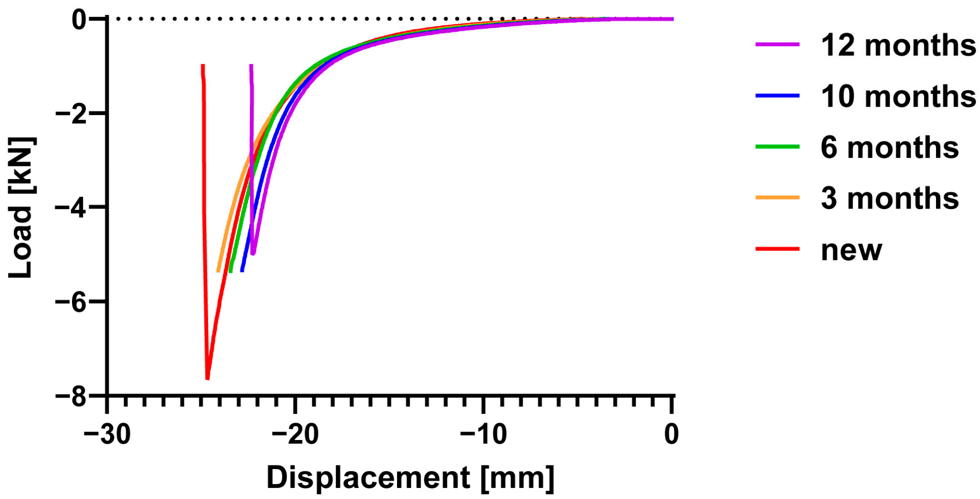

Figure 9. Uniaxial compression load–displacement curves for new (up to failure) and aged prostheses; the prosthesis aged for 12 months failed during the test.

Analysis of the load–displacement curves showed a limited increase in the load–deformation ratio with longer aging durations; this is consistent with the observed stiffening of the prosthesis shell and the limited but non-negligible increase in gel viscosity. It is important to emphasize that the same aged implant was used for all repeated compression tests. As also discussed by Shadrin et al. [16,17], compression cycles up to relevant deformation may promote micro damage accumulation, remarkably affecting the mechanical strength of the silicone shell, which otherwise would remain preserved. Considering that the implant was tested in compression only four times before failure, the effect of micro damage accumulation should be limited, although it cannot be ruled out.

The substantial stability of the gel, combined with the wide deformability of the silicone shell even in the aged state, suggests that, from a mechanical point of view, the implants can maintain their functional performance even after prolonged implantation periods. However, a periodical medical investigation of possible prosthesis damage remains highly advised, particularly for older patients or after accidental overstress.

4. Conclusions

The analysis of the tensile test results after two years of aging, conducted through three different computation models, allowed for the prediction of a variation in the deformability of the prosthetic shell ranging from 10% to 30% after 40 years of aging at 37 °C. However, the material's overall mechanical properties, particularly its elastomeric character, remain largely preserved. This indicates that, despite an appreciable reduction in deformability, the material's overall mechanical behavior is affected by degradation to a relatively limited extent, which is crucial for ensuring the long-term safety and reliability of the prostheses.

Existing models to predict the long-term aging response, in particular the "10 °C rule" and the time–temperature superposition method proposed by Gillen et al. [19,25], produce quite similar expectations, suggesting a fair mechanical stability over time. However, it is important to note that these findings refer to model calculations and to controlled aging conditions, which may be significantly different from the actual in-body situation; for instance, they do not account for actual body fluid contact, pathological issues, or external over-stresses. For instance, the non-negligible variation with aging of mechanical response may result in more critical situations in the case of accidental impacts or excessive stress, potentially compromising the safety and functionality of the implant. As also evidenced by Phillips et al. [14], considering the large variability of marketed implants over the years, the often-unknown history of the patient, the chance of damage during the surgical procedure, and the correlation between predictions of aging models and actual results obtained from tests on materials explanted after known implantation times remains a complex task. Therefore, it is recommended that individuals undergo regular medical check-ups, particularly in situations where they are exposed to unexpected mechanical stress or accidents, to ensure the safety and long-term functionality of the implants.

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