Research Square

Preprints are preliminary reports that have not undergone peer review.
They should not be considered conclusive, used to inform clinical practice,
or referenced by the media as validated information.

Effect of Clinical History and Irradiation on the Compressive Stiffness of Microtextured Silicone Breast Implants: An Exploratory Uniaxial Compression Study

FEDERICA GIUZIO

federica.giuzio@gmail.com

Ospedale di Stato della Repubblica di San Marino

Maria Assunta Acquavia
University of Basilicata

José Alejandro Heredia-Guerrero
University of Malaga

José Jesús Benítez
University of Seville

Carmela Saturnino
University of Basilicata

Domenico Nicola Massariello
Ospedale San Carlo

Antonio Toesca
Candiolo Cancer Institute

Fabiano Svolacchia
Sapienza University of Rome

Michele Di Marino
Ospedale San Carlo

Giuliana Bianco
University of Basilicata

Research Article

Keywords: Silicone Breast Implants, Compressive Stiffness, Uniaxial Compression Testing, Radiotherapy, Explanted Implants, Mechanical Properties, Clinical History

Posted Date: June 11th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-9802176/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License.
Read Full License

Additional Declarations: No competing interests reported.

Abstract

Background

Mechanical behavior of silicone breast implants is central to long-term clinical outcomes, patient comfort, and aesthetic performance. Although radiotherapy is frequently used after mastectomy and is associated with reconstructive complications, its direct effect on implant mechanical properties remains incompletely defined.

Objectives

To determine whether in vivo implantation and post-mastectomy radiotherapy are associated with measurable changes in compressive stiffness of silicone breast implants.

Methods

Three implants were evaluated: (A) a new commercially available microtextured silicone implant, (B) an explanted microtextured implant from a non-irradiated patient after one year, and (C) an explanted microtextured implant from an irradiated patient after one year. Uniaxial compression testing was performed under displacement control using a universal testing machine. Compressive stiffness was quantified as the compression constant (K, N/mm), calculated from the linear region of the force–deformation curve. Each test was repeated three times.

Results

No statistically significant difference in compressive stiffness was observed between the new implant and the non-irradiated explant, suggesting that implantation alone did not materially alter compressive behavior under the tested conditions. In contrast, the irradiated explant demonstrated a markedly higher K value, indicating increased stiffness and reduced compliance.

Conclusions

Radiotherapy, rather than implantation alone, was associated with increased compressive stiffness of silicone breast implants. Radiotherapy-related mechanical alterations should be considered in reconstructive decision-making and may inform future implant design.

Introduction

Silicone gel-filled devices are one of the most popular types of breast implants that are used in reconstructive and aesthetic surgery because of their positive tactile qualities, durability and a good clinical outcome (4). Mechanical behavior of these implants is a very crucial factor in their success, comfortability to the patient and long run results. Compressive stiffness is one of the other mechanical properties of significance as it directly affects the response of an implant to the physiological forces applied to it by neighboring tissues, gravitational and external forces during the normal day to day activities. Any change in rigidity can have an impact on the perceived softness of the implant as well as its compliance with host tissues and deformational resistance or failure with time (17).

In contemporary silicone breast implants, the shells and gels of the implants are complex multilayer elastomers with differing degrees of cohesiveness in order to strike a balance between the form stability and natural feel. Although implants have been carefully designed and manufactured, they could experience modifications in their mechanical properties after being implanted in the human body (5). Biological interactions, deterioration of materials, mechanical fatigue and exposure to therapeutic procedures like radiotherapy can be the cause of these changes. Radiotherapy is commonly used in the treatment of cancer in the context of reconstructive breast surgery, and their interactions with both the biological tissues and biomaterials used in implantation are of great clinical concern (9). Radiation can also cause chemical and structural change in polymeric materials, and this change can alter the mechanical behavior of polymeric material, and thereby jeopardize the performance of the implants.

The implantation of the breast gives a distinct chance of researching the effect of in vivo conditions on mechanical properties in comparison to unused reference implants. The comparison of the new implants to the ones taken out of the patients may shed light on the material stability and the performance over the long term. Moreover, the specific evaluation of radiation effects can be done by the comparison of the explants of patients that have experienced the irradiation process, and those that did not (10). The knowledge of these differences is critical to the Surgeon when he or she gives implants to patients who might be in need of radiation therapy and to the manufacturers of the implants who need to enhance the design and the life of the implant.

The uniaxial compression testing is an established experimental method of assessing the stiffness and elastic behavior of soft polymeric materials. The relationship between compression constant and deformation with respect to applied force can be quantified by measuring the relationship between applied force and deformation and thus provides a measurement of compression constant which gives an indication of how an implant withstands mechanical loading (27). This measure is direct and interpretable and allows an objective comparison of the different types of implants and clinical conditions based on this parameter. With the latter, experimental results obtained under controlled conditions and repeated to ascertain reproducibility can provide strong evidence of mechanical differences that can have clinical consequences.

The current paper aims at a comparative analysis of three microtextured silicone breast implants into a new commercially available implant, an explanted implant of a non-irradiated patient after one year, and

an explanted implant of an irradiated patient after one year. This study will seek to answer the question by performing an orderly examination of the compressive stiffness of the implants through uniaxial compression testing to determine whether the clinical history and radiotherapy exposure are correlated with the observable alterations in the implant rigidity. This kind of knowledge is crucial in enhancing clinical decision-making, optimum patient outcome, and also informing future studies that may focus on how medical devices relate to therapeutic interventions.

The implantation of silicone breast is essential to cosmetic augmentation as well as post-mastectomy breast reconstruction, due to its good mechanical properties, biocompatibility, and durability. The materials used in these implants are silicone elastomer shells which have a cohesive gel to ensure that they feel and perform like the natural breast tissue (20). Their application has increased over the last few decades and there is increased concern about the effect of internal and external factors on the integrity of implants and their mechanical behavior during clinical implant use.

Mechanical performance, such as compressive stiffness, is one of the decisive factors of implant behavior to physiological loads, movements of the patient, and manipulation of the surgeon. Stiffness is a measure of the ability of an implant to withstand deformation and has an impact on aesthetic performance and reliability over time (24). Mechanical characteristics have been postulated to be affected by factors including insertion during surgery, time in vivo and contact with surrounding tissues, but literature on these factors is sparse and contradictory. An example is a study on the strength of shells after implantation implying that tensile strength and modulus decrease individually as a result of surgery and microdamage, but the magnitude of the decline is modest (26).

The importance of adjuvant radiotherapy (that is typically administered following mastectomy to lower cancer recurrence) on the mechanics of implants is a controversial issue. It has been reported in clinical literature that irradiation raises the risk of complications such as capsular contracture and reconstructive failure, although its direct effect on the mechanical characteristics of the implant itself has not been so well understood. In vivo study on ready-to-use implants that are irradiated with single doses of radiation has not detected any significant alteration in tensile or rheological properties of the implants after irradiation. However, similar studies with clinical radiotherapy regimens have indicated minor variations in elongation and micromechanical performance that might not be detected with conventional assessments, which indicates a requirement of more detailed examination (19).

Knowledge about the influence of clinical history (aging in vivo, irradiation exposure, etc.) on compressive stiffness underlies the attempts to enhance the design of implants, choose the patients wisely, and predict the long-term outcomes. The paper fills these gaps by performing an experimental experiment on the measurement of compressive stiffness changes linked to implantation history and irradiation.

Research Questions

1. 1. Does exposure to in vivo conditions have significant effects on compressive stiffness of silicone breast implants compared to the unused reference implants?
2. 2. Is compressive stiffness increased in silicone breast implants explanted from irradiated patients compared with implants explanted from non-irradiated patients?

Literature Review

It is not new that mechanical performance of silicone breast implants is considered one of the determinants of their clinical success. Initial designs of implants were commonly linked to failure due to rupture, leakage of gel, and poor tactile properties and this encouraged much research on the composition of materials and structural design. The scientific breakthroughs in the field of polymer created cohesive silicone gels as well as multilayer shells of elastomers that contributed greatly to the reliability and aesthetic results of implants (23). Since then, mechanical testing has become a crucial part of the implant testing, both in the development of the products, and in the post-market monitoring.

Elastic Behavior of Soft Biomaterials

The elastic behavior of soft biomaterials such as silicone medical devices has been well studied using compression testing. With the help of uniaxial compression experiments, one can obtain parameters, which are related to stiffness, and characterize the way a material responds to load. Such parameters are especially important in the case of breast implants because they are associated with the perception of firmness and the possibility of the implant to retain its shape in the breast pocket (11). Research has shown that more stiffness value makes implants more form-stable and that less stiffness value may give the implants a softer and more natural feel. The possibility to attain the best balance between these properties is a key issue of implant design.

A number of studies have contrasted mechanical qualities across various generations and brands of breast implants and have indicated the role played by gel cohesiveness, shell thickness, and manufacturing methods. Newer implants are typically less irregular in their mechanical behavior, as they are actually of superior quality and are tested more uniformly. These implants however are subjected to a complex biological environment once implanted which could change their properties as time goes by (28). Temperature, enzymatic activity, oxidative, and repeated mechanical loading may cause aging and alterations in elasticity of materials.

Explanted breast implants have been studied and useful information about material behavior in the long term is obtained. Explant analysis has shown that shell integrity, gel consistency and mechanical response vary on comparison with unused implants. Such changes do not necessarily manifest themselves in a clinical setting but can be identified by laboratory examination. Notably, the extent of alteration on all explanted implants is not equal and this indicates that patient-specific factors and clinical interventions have a great influence on the outcome of implants.

Radiotherapy and its external threats

Radiotherapy is one of the most important external impacts which can affect mechanical properties of the implanted devices. The chemical changes in polymeric materials have been found to be caused by ionizing radiation and include chain scission and cross-linking that may cause polymer to become denser or brittle (14). Radiotherapy has also been linked to increased complication rates in the case of breast reconstruction like capsular contracture and discomfort of the implant. Although it has been reported that most of these complications are related to the alteration of the tissues around the implant, there is increased interest to know whether radiation has any effect on the implant material itself.

It has been shown through experimental research that even clinically relevant doses are able to modify mechanical properties of radiation exposed polymers. Radiation can also cause cross-link density to increase in silicon elastomers resulting in more rigid material that is less compliant (1). Nevertheless, there are few information that directly focuses on breast implants that undergo radiotherapy. The bulk of available data is based on secondary observations or mini-studies, which is why there is a strong necessity to perform systematic mechanical assessment of the irradiated explants (12).

The comparative studies involving new implants, non-irradiated, and irradiated explants would be especially useful, as they would enable isolating the radiation effects on the general in vivo aging. Through standardized experimental procedures and quantitative stiffness measurements, those studies can be objective in showing changes in materials that may not be noticeable by visual examination alone. There is growing literature that shows the combination of mechanical testing and clinical data to gain a better insight into how implants perform and inform surgical planning.

Breast Implant and its tissues

Breast implants are developed to emulate the mechanical behavior of natural breast tissue as well as achieving structural integrity with time. The silicone rubber shell and bonding gel core are created with the aim to achieve equilibrium between elasticity and strength, although physiological conditions can trigger the change in the properties of the materials (11). Research on explanted silicone implants indicates that materials change with time of implantation. In fact, a recent study of explanted shells of several different manufacturers showed that mechanical strength and deformation capacities diminished with time, which was ascribed to the increasing presence of microdamage in the elastomer network with time under long-term physiological loading (25). The strength of investigated implants dropped by 50% and rupture strain dropped by a third in vivo after around 13 years of loading and is an indication of how mechanical behavior may degrade with prolonged clinical loading.

The mechanical changes are also caused by surgical procedures in themselves and it has been experimentally demonstrated with cadaver implantation that the tensile strength and modulus of silicone elastomer shell can be marginally decreased by the act of insertion, presumably through handling stresses and focal deformation during implantation (7). Even though they were statistically significant,

the changes in strength properties were small, which implies that standard surgical methods do not significantly impair implant mechanics in the short term.

Another factor that may have some impact on the performance of the implants is radiotherapy. An important percentage of patients undergoing post-mastectomy care in the clinical site uses implants in situ with adjuvant radiotherapy. It has been known that radiotherapy causes fibrosis and increases the effect of the capsular contracture which is the excessive fibrotic tissue surrounding the implant, so it casts doubts on the direct influence on the implant material (6). In an ex vivo experiment that irradiated silicone implants with a single dose (60 Gy), there were no significant effects of irradiation on tensile strength, mechanical hysteresis or rheological properties relative to non-irradiated control groups, indicating that mechanical properties were not significantly affected by simplified irradiation conditions.

Clinical Dose and Radiotherapy

Nonetheless, clinical-dose radiotherapy given in a fractionated dose could have other effects. Treatment protocol doses investigated revealed a decrease in maximum elongation and evidence of micromechanical changes in silicone shell samples although bulk measures such as Young's modulus and tensile strength did not change (2). The results obtained herein emphasize the fact that conventional tensile and bulk mechanical measures may not be able to detect subtle material changes as a result of clinically relevant irradiation, and reinstate the importance of multiscale and multimode of mechanical measurements.

Other characterization of materials other than the conventional mechanical tests has given additional information. Finite element modeling analysis has described the effects of compressive and dynamic loads in forming high-stress regions in the implant shells, which are associated with rupture sites in the clinical context, and have focused on the fact that the mechanical performance of implants in the real world is nonuniform and not homogeneous under simple loading. In addition, studies that used ultrasonic elastography on explanted implants have demonstrated that stiffness may increase with the duration of implantation and that possible physicochemical interactions between silicone gel and host metabolites may explain such effects, implying that the effect of in vivo ageing processes on mechanical properties could be missed by conventional material tests (22).

There is also a problem of biocompatibility and surface interactions making the clinical picture more complex. Mechanical factors such as stiffness and surface topology, which depend on surface modifications to enhance tissue integration or decrease bacterial adhesion are also affected by mechanical factors (3). The overall perception of the effects of clinical history on the implant mechanics should thus go beyond the knowledge of the intrinsic material characteristics of materials and include interactions with biological conditions, surgical handling, and therapeutic exposures.

On the whole, the current literature shows the significance of mechanical characterization in evaluating the implant behavior of the breast implants, and also demonstrates the knowledge gaps when

discussing the impact of irradiation. These gaps are important to overcome in an attempt at enhancing the outcomes related to reconstruction and in creating implants that retain desirable mechanical characteristics even in demanding clinical settings.

Materials and Methods

Mechanical Testing equipment.

A uniaxial test set-up was used to determine the mechanical behavior of the implants under compressive loading. Compression tests were done on an MTS Criterion 42 universal testing machine (MTS Systems Corporation, Eden Prairie, MN, USA) with a load cell of 250 N. The choice of this load cell was due to the fact that it has sufficient sensitivity and accuracy at the anticipated force range produced during implant compression. Before testing, the machine was calibrated as per the requirements of the manufacturer to ensure the accurate measurements of the force and displacement during the process of the experiment.

The as received samples of the implants were tested without further surface modification or preconditioning. All samples were thoroughly checked to make sure that there were no visible defects that may affect mechanical response. To test, the implants were fitted in the middle between two rigid, circular plates of aluminum that were circular in nature so that the load can be distributed evenly. The bottom platen was kept still where the top platen was used as a texture analysis probe. The diameter of the upper platen was 83.4 mm, as this was large enough to reduce the effects of edges and allow it to fully cover during compression. Caution was exercised during centering of the sample concentrically with the platens so as to prevent off-axis loading and uneven distributions of stress. All mechanical tests were performed at room temperature (approximately 22–24°C).

Compression Testing Procedure.

Uniaxial compression tests were performed under displacement control. No mechanical preconditioning cycles were applied prior to testing. This choice was made to preserve the native mechanical response of the explanted implants, although it may influence viscoelastic effects. The upper platen was forced down with a steady crosshead speed of 5 mm/min until a desired range of deformation was obtained. This loading rate was selected to embody quasi-static conditions and to reduce possible viscoelastic or rate dependent effects on the measured mechanical response. The testing system was set to continuously record compressive force and displacement data during the test.

Deformation and Contact Conditions Definition.

Deformation was determined as the distance between the two platens in reference to an initial location of complete contact between the implant and the platens. The point at which a measurable increase in force was first observed was found to be full contact and this was the point at which both platens uniformly engaged the implant. Measuring all the subsequent displacement data relative to this contact

position was used to make certain that all values of deformation were due to actual compression of the implant material, and not to initial seating or alignment effects.

Stress-deformation Data Processing.

Analysis of the stress-deformation curves was done by conversion of raw force-displacement data produced in the testing process to the stress-deformation curve. Compressive stress was also determined by dividing the obtained force with the area of upper platen of aluminum. This method gave a perceived compressive stress that could be compared among samples that were under the same set of conditions. The values were a report of the deformation in millimeters and were equal to the deformation in the displacement of the crosshead with reference to the specified full-contact position. Each sample was subjected to compressive loading to obtain stress verses deformation curves to describe their mechanical behavior.

Stiffness (K Value) Determination.

The rigidity of all implants was measured by determining the value of K, which is a measure of the resistance of a material to deformation under the load acting on it. K value was calculated as the applied compressive force/applied force (in Newtons, N)/the deformation (in millimeters, mm). The change in the force per unit deformation is expressed as a ratio, and it gives a direct measure of the implant rigidity in compression. K values were determined on the linear section of the force deformation curve when the force deformation curve is on a proportional basis, which means that the relationship between the force and the deformation is proportional and that a comparison in the K values is consistent and meaningful across samples.

Data Analysis and Reporting.

The entire data in mechanical testing were analyzed and processed in a standard spreadsheet and data analysis software. Descriptively, the stress-deformation curves together with the values of K were compared to evaluate the compressive behavior of the implants. The reported results take the form of stress versus deformation to give the overall description of the mechanical performance of the implants under uniaxial compression conditions. Due to the exploratory nature of the study and the limited number of independent samples (one implant per condition), statistical analysis was performed for descriptive comparison purposes only. For each implant, three technical repetitions were conducted, and results are reported as mean ± standard deviation. Pairwise comparisons were assessed using a two-tailed Student’s t-test, with a significance threshold of $\alpha = 0.05$. No assumptions of population-level inference were made.

Results

The mechanical stiffness of three various breast implants with different clinical histories and material conditions was measured and compared using uniaxial compression testing. The test samples were: (i)

Implant A a new Contour Profile breast implant with low gel oozing, a silicone gel filler with level III cohesiveness, and exterior shell of multiple successively applied layers of superimposed reticular layers of silicone elastomer that were developed to provide elasticity and strength; (ii) Implant B, a breast implant that had been taken out of a patient who had not received radiotherapy; and (iii) Implant C, a breast implant that had been taken out of a patient who had received radiotherapy.

To allow the direct comparison of the mechanical behavior of the three implants, the stiffness was measured in terms of the compression constant (K value), which is N/mm. The K value is also used in relation to the phenomenon of uniaxial compression when the compressive force acting on the structure is compared with the corresponding deformation of this structure or the implant. The parameter gives an estimate of the ability of the material or structure to resist compressive loading. The higher the K values, the harder and more rigid the material is and thus does not deform as much with the applied force, while the lower the K values are the stretcher the material is and tends to deform more with compression. The K value is thus a convenient parameter used to describe the mechanical behavior of implants.

Every experiment of compression was repeated three times in case of every type of implants to achieve reproducibility and to consider the variation in the experiment. The K values obtained are indicated with the average and its corresponding standard deviation. This method enabled a sound statistical comparison of the implant stiffness of the three groups. The comparative K values obtained from uniaxial compression testing are summarized in Fig. 1, which illustrates the statistically significant differences among the three implant groups. The results of the analysis showed that Implant A (new, non-implanted control) and Implant B (explanted of a non-irradiated patient) had similar mechanical behavior under compressive loading. In particular, there were no statistically important differences in K values of these two implants, which means that the explanted, non-irradiated implant has the same stiffness as the unused commercial implant. This result implies that in the conditions studied, only implantation without irradiation did not significantly affect compressive stiffness of silicone-based implant material. Below we have reported the graphic representation (Fig. 1) in which are clearly visible K values obtained by uniaxial compression tests for implants A, B and C.

Figure 1. K values obtained by uniaxial compression tests for implants A, B and C. Values marked by the same letter are not significantly different ($p < 0.05$).

In contrast, Implant C (explanted from an irradiated patient) demonstrated a markedly different mechanical response. The K values obtained for Implant C were significantly higher than those measured for both Implant A and Implant B, indicating a pronounced increase in stiffness. This result reflects a greater resistance to deformation under compressive loading, consistent with a more rigid material or structural configuration. The observed increase in stiffness in Implant C suggests that exposure to irradiation may induce material or structural changes in the implant, leading to reduced compliance when subjected to mechanical stress.

Overall, these findings highlight a clear distinction between irradiated and non-irradiated implants in terms of compressive stiffness. While new implants and those explanted from non-irradiated patients

displayed similar elastic behavior, irradiation was associated with a significant increase in rigidity.

Discussion

The current experiment examined the impact of clinical history and irradiation on compressive stiffness of silicone breast implants on the basis of uniaxial compression testing. The comparison of an implant with explanted implants in irradiated and non-irradiated patients gives insights on how in vivo conditions (and radiotherapy in particular) can affect the mechanical behavior of the implant (18). These results show that, although implantation itself did not have a significant effect on compressive stiffness, irradiation had a significant effect on the increase in the rigidity of implants.

The fact that the new implant (Implant A) and the non-irradiated explant (Implant B) have a similar stiffness indicates that exposure to the physiological environment, without the assistance of radiotherapy, does not result in a significant mechanical degradation or stiffening of silicone breast implants within the duration of the study. This observation has a clinical implication, because it can be considered to support the argument that the current silicone-based implants have adequate material stability to withstand the mechanical effect of implantation (8). New developments in the design of implants, including cohesive gels and multilayer shells of elastomers, can help to resist mechanical fatigue, thermal environments and biochemical interactions found in vivo.

Conversely, the much greater compressive stiffness of the irradiated explant (Implant C) suggests radiotherapy can be very important in changing the mechanics of implants. Ionizing radiations are known to cause chemical transformations in polymeric materials such as cross-linking and chain scission (15). High cross-link density in silicone elastomers may cause a decrease in molecular mobility, an effect that causes the material to become more rigid and less compliant. Higher K values obtained with Implant C are in consistent agreement with this mechanism and indicate that radiation exposure can have a direct influence on the implant shell, gel filler or the interface.

These results are consistent with previous experimental research on radiation-exposed polymers that have indicated an increase in the stiffness and brittle nature on the irradiated polymers. Though most clinical complications that are experienced in breast reconstruction that is irradiated like capsular contracture, pain, and aesthetic deformity, are usually not due to tissue changes in the surroundings, the current findings show that the implant material can also be subjected to mechanical modification (21). The increase in the stiffness of the implants would lead to more discomfort of the patient and a decrease in the natural feel of the re-created breast, which would contribute to a suboptimal clinical outcome.

Uniaxial compression testing and calculation of K values were easy and reproducible techniques of studying implant stiffness. The analysis obtained a significant depiction of elastic behavior in quasi-static loading conditions because of concentrating on the linear portion of the force deformation on curve (16). This method made it possible to compare objectively across implants with various clinical histories and reduce confounding factors associated with the testing variability.

One should take into account that the fact of the greater stiffness of the irradiated implant can be attributed to the complex of the factors. Radiation might have a direct effect on silicone material, have an indirect effect on the behavior of implants by affecting the fibrotic capsules, or speed up aging in the implant (13). Although these mechanisms cannot be separated in this study, the definite difference in the irradiated and non-irradiated explants highlights the importance of considering radiotherapy in assessing implant performance.

The findings are useful in answering the two research questions in this study. Compressive stiffness was not affected significantly, but there was a significant increase in rigidity with irradiation only. Such results add to the evidence on the value of mechanical assessment of breast implants during clinically significant situations. The therapeutic intervention effects that in turn affect the implant behavior would be important in enhancing the reconstructive strategies and future implant design decisions.

Conclusion

This exploratory study suggests that clinical history and radiotherapy may offer different influences on the compressive stiffness of silicone breast implants. Uniaxial compression test showed that, while implantation alone did not result in measurable changes in stiffness, the irradiated explant exhibited increased rigidity compared to non-irradiated conditions.. These results suggest the significance of radiotherapy as one of the factors affecting implant structural integrity and the importance of mechanical testing in the assessment of implant performance and durability. Due to the limited sample size, these findings should be interpreted cautiously and considered hypothesis-generating rather than conclusive. Further studies involving larger cohorts and complementary mechanical and material analyses are required to clarify the mechanisms underlying radiation-associated mechanical changes.

Limitations

Various drawbacks need to be mentioned. First, the research analyzed a small number of implants, and this can limit the extrapolation of the results. Second, compression testing was only done, and in the implants in vivo multidirectional loads, which are more complex, are applied. Third, implantation period and radiation dose were not the control variables and could have affected the results. Also, the research only evaluated mechanical stiffness, and did not evaluate chemical and microstructural modifications in the implant material. The future studies should concern such aspects and offer a more holistic picture.

Recommendations

According to the results, the surgeons are advised to take into account the mechanical impact of radiotherapy when choosing the implants that are going to be used in the process of breast reconstruction. The manufactures are urged to make further refinements to the implant materials to make them more resistant to changes caused by radiations. The clinicians could also be updated of more postoperative monitoring of the irradiated implants due to increased rigidity or pain to the patients. The use of standardized mechanical tests in implants that have been tested in vitro should be part of the

post-market surveillance programs. These might enhance the choice of the implants, patient education, and the creation of more robust designs of implants.

Future Implications

Future studies ought to build up this study through conducting of more implant groups (microtextured, smooth, macrotextured) and adding more mechanical experiments, including cyclic loading and shear experiments to enhance physiological conditions. More complex methods of characterizing material such as spectroscopy and microscopy may also serve to clarify the mechanisms that cause stiffening caused by radiations. Mechanical changes would be better understood by studies that compare mechanical changes to clinical outcomes. Finally, the combination of mechanical data with clinical decision-making can result in individualized strategies of choosing an implant and create the next-generation breast implants, which are more suitable to be used in irradiated conditions.

Declarations

Conflict of interest

The authors declare that they have no conflicts of interest to disclose.

Ethical Approval

This material is the authors' own original work, which has not been previously published elsewhere. This study was performed in accordance with research ethical guidelines. There are no human subjects in this article and informed consent is not applicable. All authors have contributed to the paper and have given permission for their names to be included as co-authors. This manuscript is not submitted to or is currently under review at any other journal.

Clinical study reference number

not applicable

Funding

No funding was received for this article.

Author Contribution

F.G and M.A.A. writing and editing, J.H.G. and J.J.B. data analysesC.S. and D.N.M. supervisionA.T and F.S. MethodsM.D.M and G.B. conceptualization

References

1. Ahmed MS, Islam M, Hasan MK, Nam KW (2024) A Comprehensive review of radiation-induced hydrogels: Synthesis, properties, and multidimensional applications. Gels 10(6):381
2. Baiocco D, Zhang Z, He Y, Zhang Z (2023) Relationship between the Young's moduli of whole microcapsules and their shell material established by micromanipulation measurements based on diametric compression between two parallel surfaces and numerical modelling. Micromachines 14(1):123
3. bin Fadzil A, Pramanik AF, Basak A, Prakash AK, C., Shankar S (2022) Role of surface quality on biocompatibility of implants-A review. *Annals of 3D Printed Medicine*, *8*, 100082
4. Brown T, Harvie F, Kluess D (2024) Testing mechanical properties of silicone gel-filled breast implants and their degradation. Aesthetic Plast Surg 48(17):3362–3369
5. Busato F, Khouzai BE, Mognato M (2022) Biological mechanisms to reduce radioresistance and increase the efficacy of radiotherapy: state of the art. Int J Mol Sci 23(18):10211
6. DeLyzer T (2022) *Development of a Novel Rodent Model of Radiation-Induced Implant Capsular Contracture* (Master's thesis, The University of Western Ontario (Canada))
7. Dzobo K, Khumalo N, Mora VZ, Zoncsich A, de Mezerville R, Bayat A (2025) Advances in Silicone Implants Characterization: A Comprehensive Overview of Chemical, Physical and Biological Methods for Biocompatibility Assessment. Bioengineering 12(12):1307
8. Foroushani FT, Dzobo K, Khumalo NP, Mora VZ, de Mezerville R, Bayat A (2022) Advances in surface modifications of the silicone breast implant and impact on its biocompatibility and biointegration. Biomaterials Res 26(1):80
9. Hennequin C, Belkacémi Y, Bourgier C, Cowen D, Cutuli B, Fourquet A, Rivera S (2022) Radiotherapy of breast cancer. Cancer/Radiotherapie 26(1–2):221–230
10. Hippchen Y, Tewary G, Jung D, Schmal Z, Meessen S, Palm J, Rübe CE (2022) Cultured human foreskin as a model system for evaluating ionizing radiation-induced skin injury. Int J Mol Sci 23(17):9830
11. Janzekovic J, Hunt J, Peltz T, Wagels M, Brown T, Hutmacher DW (2022) Biomechanical principles of breast implants and current state of research in soft tissue engineering for cosmetic breast augmentation. Aesthetic Plast Surg 46(1):1–10
12. Jiang R, Fang Q, Liu W, Chen L, Yang H (2025) Recent Progress in Radiosensitive Nanomaterials for Radiotherapy-Triggered Drug Release. ACS Appl Mater Interfaces 17(10):14801–14821
13. Lee JS, Lee JH, Ryu JY, Park SH, Park JY, Han MH, Yang JD (2022) Influence of irradiation on capsules of silicone implants covered with acellular dermal matrix in mice. Aesthetic Plast Surg 46(2):937–946
14. Liang Y, Xu H, Tang W, Du X (2024) The impact of metal implants on the dose and clinical outcome of radiotherapy. Mol Clin Oncol 21(4):66

15. Mhaske ST, Mestry SU, Patil DA (2022) Cross-linking of polymers by various radiations: Mechanisms and parameters. Radiation Technologies and Applications in Materials Science. CRC, pp 1–28
16. Mirulla AI, Muccioli GMM, Fratini S, Zaffagnini S, Ingrassia T, Bragonzoni L, Innocenti B (2022) Analysis of different geometrical features to achieve close-to-bone stiffness material properties in medical device: A feasibility numerical study. Comput Methods Programs Biomed 221:106875
17. Mitevová D, Chotárová M, Čaniga F, Boháč M (2025) Breast Implants Throughout Time. When Breast Implants Become Safer. Bratislava Med J, 1–11
18. Padala SR (2023) Irradiation-induced bone changes in the mandible: a microstructural and biochemical study
19. Pereira S, Orlandi E, Deneuve S, Barcellini A, Chalaszczyk A, Behm-Ansmant I, Thariat J (2022) The normal, the radiosensitive, and the ataxic in the era of precision radiotherapy: A narrative review. Cancers 14(24):6252
20. Perrotta RE, Ronsivalle V, Minervini G, Cicciù M (2025) Incidence of Long-Term Complications in Breast Implant Prosthesis. Syst Rev Prosthesis 7(2):38
21. Rosa S (2025) Nanofat augmented fat grafting: a combined protocol for treatment of capsular contracture and actinic damage in patients undergoing implant-based breast reconstruction
22. Ruffenach L, Heintz D, Villette C, Cosentino C, Funfschilling D, Bodin F, Chatelin S (2024) Ultrasonic elastography for the prevention of breast implant rupture: Detection of an increase with stiffness over implantation time. J Biomech 163:111955
23. Sahu BB, Moharana S, Behera PK (2024) Elastomeric-based composite materials for engineering applications. Polymer Composites: Fundamentals and Applications. Springer Nature Singapore, Singapore, pp 329–355
24. Soliman MM, Islam MT, Chowdhury ME, Alqahtani A, Musharavati F, Alam T, Khandakar A (2023) Advancement in total hip implant: a comprehensive review of mechanics and performance parameters across diverse novelties. J Mater Chem B 11(44):10507–10537
25. Stoian A, Duru Ç, Chogan F, Biniazan F, Temple B, Karoubi G, Haykal S (2025) Breast tissue reconstruction strategies: a tissue engineering approach. Tissue Eng Part B: Reviews
26. Wurmshuber M, Wilmers J, Peng XL, Kim JK, Liu Y, Gao H, Kiener D (2024) Micromechanical assessment of the limpet tooth: Unraveling the secrets behind Nature's strongest material. In *# PLACEHOLDER_PARENT_METADATA_VALUE#*
27. Zhang Z, Zhu J, Deng J (2023) A comparative study for determining rock joint normal stiffness with destructive uniaxial compression and nondestructive ultrasonic wave testing. J Rock Mech Geotech Eng 15(7):1700–1712
28. Zwawi M (2022) Recent advances in bio-medical implants; mechanical properties, surface modifications and applications. Eng Res Express 4(3):032003

Figures

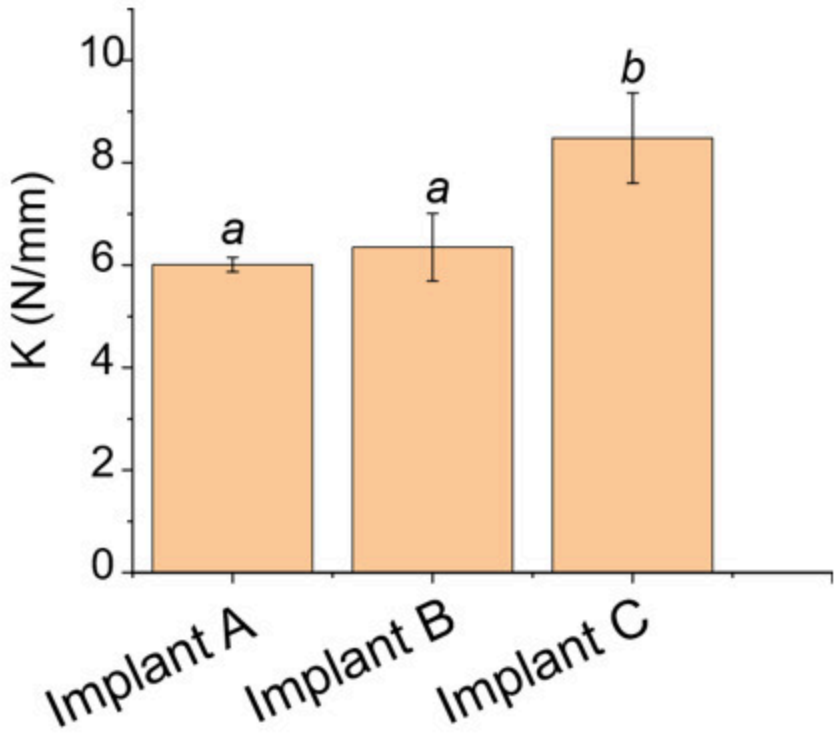


Figure 1

K values obtained by uniaxial compression tests for implants A, B and C. Values marked by the same letter are not significantly different ($p < 0.05$).