Is Banning Texturized Implants to Prevent Breast Implant-Associated Anaplastic Large Cell Lymphoma a Rational Decision? A Meta-Analysis and Cost-Effectiveness Study

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Abstract

Background: Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is an emergent disease that threatens patients with texturized breast implants. Major concerns about the safety of these implants are leading to global changes to restrict the utilization of this product. The principal alternative is to perform breast augmentation utilizing smooth implants, given the lack of association with BIA-ALCL. The implications and costs of this intervention are unknown.

Objectives: The authors of this study determined the cost-effectiveness of smooth implants compared with texturized implants for breast augmentation surgery.

Methods: A tree decision model was utilized to analyze the cost-effectiveness. Model input parameters were derived from published sources. The capsular contracture (CC) rate was calculated from a meta-analysis. Effectiveness measures were life years, avoided BIA-ALCL, avoided deaths, and avoided reoperations. A sensitivity analysis was performed to test the robustness of the model.

Results: For avoided BIA-ALCL, the incremental cost was $18,562,003 for smooth implants over texturized implants. The incremental cost-effectiveness ratio was negative for life years, and avoided death and avoided reoperations were negative. The sensitivity analysis revealed that to avoid 1 case of BIA-ALCL, the utilization of smooth implants would be cost-effective for a risk of developing BIA-ALCL equal to or greater than 1:196, and there is a probability of CC with smooth implants equal to or less than 0.096.

Conclusions: The utilization of smooth implants to prevent BIA-ALCL is not cost-effective. Banning texturized implants to prevent BIA-ALCL may involve additional consequences, which should be considered in light of higher CC rates and more reoperations associated with smooth implants than with texturized implants.

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Breast augmentation is the most common cosmetic surgery performed worldwide.[1-4] In 2018, a total of 329,914 breast augmentation procedures were performed in the United States.[1] After the lift of the moratorium in 2006 for silicone implants, efforts were focused on demonstrating the safety profile of these medical devices. In 1997, Keech and Creech[5] reported an unpublished lymphoma case related to breast implants. Subsequently, the entity was defined by the World Health Organization in 2016 as breast implant-associated anaplastic large cell lymphoma (BIA-ALCL), a rare type of lymphoma arising from the capsules of breast implants different from the other categories of ALCL.[6]

To date, 573 cases of BIA-ALCL have been reported, with 33 deaths.[7] Although BIA-ALCL is a rare event with incidence rates ranging from 1:3817 to 1:30,000 patients,[8] the widespread utilization of breast implants poses the threat of becoming a massive public health problem concerning several countries' health departments around the globe.[4] Silicone breast implants are composed of a silicone shell filled with silicone cohesive gel. The shell can have 1 of 2 types of surfaces: smooth or texturized. Texturization was added to improve the adherence of the implants to tissues and to decrease the rates of capsular contracture (CC).[9] Current research has demonstrated a strong association between texturized implants and BIA-ALCL.[10] To date, there have been no reports of BIA-ALCL associated with primary smooth implants.[4,11-13] Despite crescent evidence in patients, the pathophysiology mechanisms have yet to be fully elucidated.

Controversy exists about the restriction of texturized implants. Several plastic surgeons are shifting away from utilizing texturized implants and moving toward the exclusive utilization of smooth implants to avoid any risk of BIA-ALCL.[14,15] Some countries have completely banned texturized implants, whereas other board-certified societies still allow the commercialization of texturized breast implants. Moreover, one of the largest companies of breast implant manufacturers recently recalled their texturized implants from the market worldwide.[7] On the contrary, smooth implants were relegated as a second choice in many countries of the world[14] for a long time due to the higher rates of CC[16-18] that lead to disfigurement, pain, and increased rates of reoperation.

The shift toward smooth implants can potentially decrease the rates of BIA-ALCL but may cause a higher incidence of CC.[19-21] The aim of this study was to evaluate the cost-effectiveness of utilizing smooth implants compared with texturized implants for breast augmentation surgery. Our secondary endpoints were to provide a reliable answer to the following questions: (1) How many reoperations must be conducted to prevent 1 case of BIA-ALCL? (2) Will banning texturized implants prevent deaths or actually cause more deaths due to reoperations? and (3) How much money will it cost to prevent 1 case of BIA-ALCL?

METHODS

Study Design

A systematic review (SR) and meta-analysis were performed to obtain the best evidence to compare the outcomes from both types of implants. An economic evaluation was also performed utilizing a cost-effectiveness analysis, and different clinical scenarios were simulated through a sensitivity analysis.

Probability of Events

Capsular Contracture Probability

To calculate the CC rate in smooth and texturized implants, an SR of the literature was conducted in July 2019 on MEDLINE utilizing the keywords "breast implants," "breast augmentation," and "capsular contracture" as free and Medical Subject Headings terms. Studies were limited to randomized controlled trials (RCTs) and SRs of RCTs comparing smooth and texturized implants between patients and reporting CC as outcomes. In addition, SRs of RCTs were included in our literature search. Furthermore, the references of the retrieved articles were manually searched (Appendix A). A risk of bias assessment of the included studies was performed utilizing the Cochrane risk of bias assessment tool. The risk of bias was independently assessed by 2 authors (S.D. and R.J.), who resolved disagreements through discussion and consultation with a third author (C.A.).

Meta-analysis was performed with Cochrane's Review Manager v5.3 (Cochrane Library Software, Oxford, UK). For further statistical analysis, STATA 12.0 (StataCorp LP, College Station, TX) was utilized.

BIA-ALCL Estimated Risk

Based on the literature review, the current risk of BIA-ALCL is estimated to be 1:3817 to 1:30,000 women with texturized implants.[8,15] For the basal model, a probability of 1:16,909 was utilized as the basal risk.

BIA-ALCL Mortality Risk

The probability of death due to BIA-ALCL was estimated from the mortality rate reported in the updated US Food and Drug Administration statistics. The last reports included 33 deaths in 573 unique cases of BIA-ALCL.[7] The probability of the possible treatments for BIA-ALCL (eg, chemotherapy and/or radiotherapy and/or surgery) is related to the stage of the disease and was retrieved from clinical case series.[22-24]

Probability of Dying Due to Surgery

The mortality risk related to plastic surgery procedures was estimated to be 1:50,000.[25,26]

Probability of Reoperation Due to Capsular Contracture

Core studies by Allergan, Mentor, and Sientra (AMS) were analyzed to retrieve the number of patients with CC Baker grade III-IV who underwent reoperation or explantation due to CC.[27-30] The probability of reoperation for CC Baker III-IV was calculated utilizing Bayesian analysis.[31] Core studies did not break down the reoperation rate by implant type (smooth or texturized); therefore, for this model, it was assumed that the probability of reoperation due to CC Baker grade III-IV was the same among smooth and texturized implants.

Costs

The average total cost of primary breast augmentation was calculated for an individual. The cost-effectiveness model was performed to reflect the societal point of view; thus, health-related, loss of productivity, and death costs were considered. The direct and indirect costs of breast augmentation per patient included facility, anesthesia, and implant costs; surgeon fees; pain medication costs; and lost wages.[32] For CC, the average cost of reoperation was estimated from the cost of major complications and the cost of a surgical biopsy.[32,33]

The costs associated with BIA-ALCL include those of surgical treatment with en bloc explantation, radiotherapy, chemotherapy, and a combination of all treatments.[32,34-37] The costs associated with the long-term complications related to implants (CC and BIA-ALCL) were discounted at a rate of 3% per annum.

Legal services and loss of productivity caused by early death were included as the direct and indirect costs of death. The indirect costs related to loss of productivity due to mortality were calculated by adding the discounted value of the expected yearly income corresponding to the patient's years of life that were lost. For the yearly income, the US 2018 per capita gross domestic product was utilized.[38] The years of life that were lost correspond to the difference between a life expectancy of 82 years[39] and the estimated year of death during breast augmentation surgery, death during CC surgery, or death related to BIA-ALCL. The time of CC after breast augmentation surgery was calculated as the weighted mean follow-up of the AMS core studies (9.47 years), and the mean time to BIA-ALCL onset after breast augmentation surgery was 10.7 years[40]; to apply the discount, the number of years was rounded up to 10 and 11 years, respectively. Therefore, the estimated year of death during CC reoperation was 44 years, and the estimated year of death by BIA-ALCL in a breast augmentation patient was 45 years. Direct and indirect medical costs were included because the social perspective was adopted for this analysis.[41-43]

Cost-Effectiveness Model

For each intervention, there were 3 possible health statuses after surgery: successful surgery, complication (CC), and death (general risk of death from a general anesthesia procedure). For the texturized implant branch, a fourth health status was added: BIA-ALCL. CC Baker grade I-II was considered "successful surgery" because reoperation is not typically required. For CC grade III-IV, 3 possible outcomes were considered: reoperation with successful surgery, no surgery, and death due to reoperation. For BIA-ALCL, treatment alternatives were included as clinical events. Other general complications, such as hematoma and infection, were not included because there was no difference according to the implant type. The decision tree is shown on Figure 1.

Effectiveness

The measures of effectiveness were life years, avoided deaths, avoided BIA-ALCL cases, and avoided reoperations. Effectiveness measures were calculated for 100,000 hypothetical patients sharing the same baseline characteristics.

Cost-Effectiveness Analysis

The expected cost and effectiveness of each health status was multiplied by its relative probability of obtaining the incremental cost-effectiveness ratio (ICER). The ICER can be interpreted as the additional cost for obtaining a life year, avoided death, avoided BIA-ALCL case, and avoided reoperation when a breast augmentation surgery is performed with smooth instead of texturized implants. A willingness to pay (WTP) of $100,000 per life year gained was utilized for the sensitivity analysis.[43] The WTP for an avoided BIA-ALCL case was estimated as the expected cost of having BIA-ALCL.

Sensitivity Analysis

We performed a 1-way sensitivity analysis for CC and BIA-ALCL utilizing life years gained, avoiding BIA-ALCL cases as effectiveness measures. Additionally, a 1-way sensitivity analysis was conducted to determine thresholds in which the rate of smooth CC and the risk of developing BIA-ALCL would be cost-effective to ban texturized implants in order to gain 1 life year and to avoid 1 case of BIA-ALCL.

To illustrate a borderline scenario, a multivariate sensitivity analysis was performed by stressing the probabilities in favor of smooth implants: ALCL theoretical maximum risk (1:3817), a lower 95% confidence interval (95% CI) for CC from smooth implants (34.30%), a higher 95% CI for CC from texturized implants (13.55%), and the lowest 95% CI for the reoperation rate from CC of Baker III-IV (68.07%).

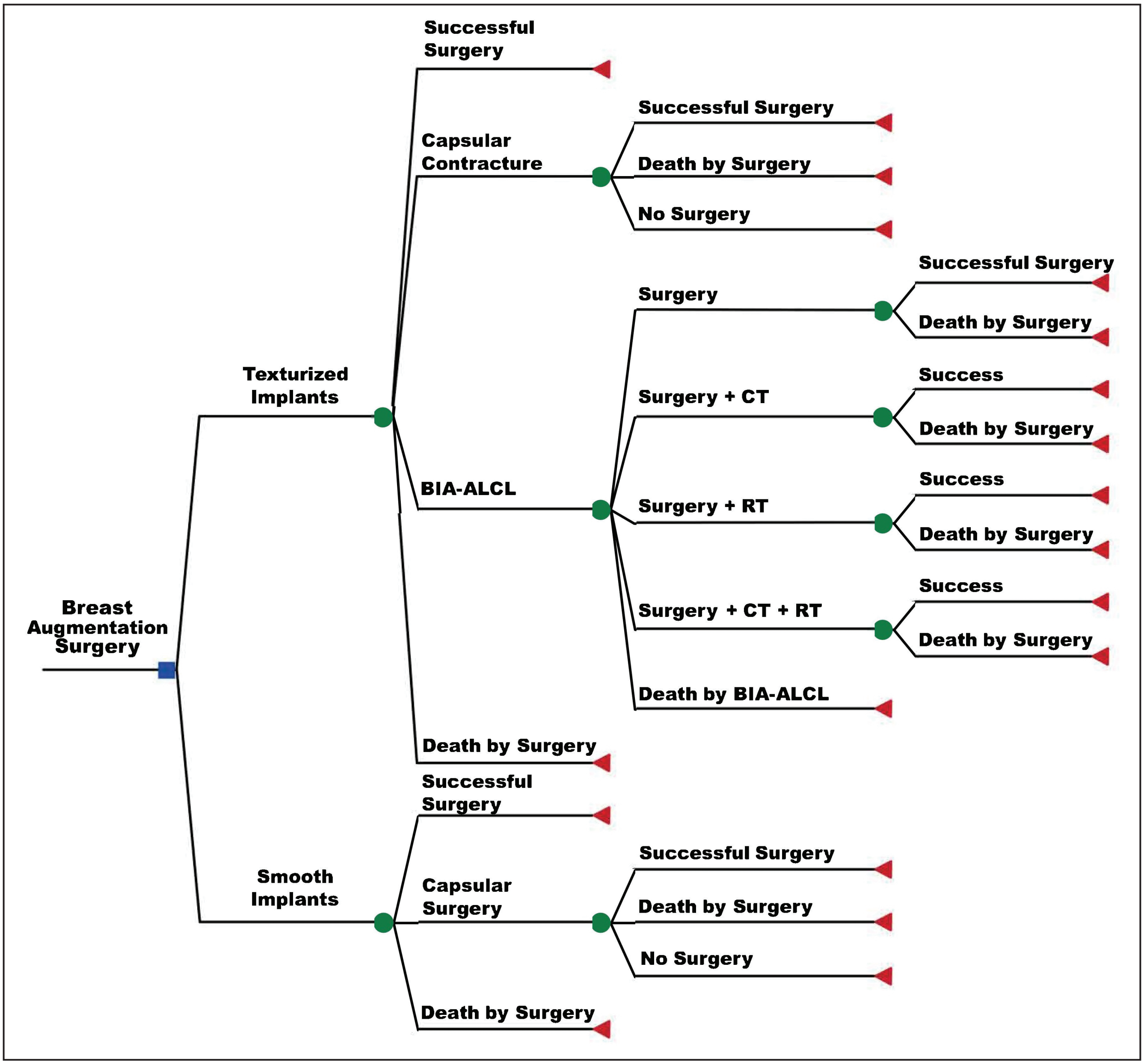

Figure 1. Decision tree for breast augmentation surgery. Squares represent the treatment decision node (smooth and texturized implants). Circles represent the chance node representing the probability of an event occurrence. Triangles represent the terminal nodes, representing the point at which no subsequent events are assumed to occur. BIA-ALCL, breast implant-associated anaplastic large cell lymphoma; QT, chemotherapy; RT, radiotherapy.

RESULTS

Probability of Events

Capsular Contracture Probability

From the literature search, 9 RCTs and 1 SR were analyzed,[21,44-52] of which 7 RCTs[44-50] were included in the meta-analysis. All of them reported rates of CC for implants in the subglandular pocket. One study[50] was excluded because the implants were inserted in a submuscular pocket and introduced heterogeneity to the model.

Pooled analysis showed a CC rate of 94/231 (40.56%, 95% CI = 34.30% to 47.33%) for smooth implants and 22/240 (9.07%, 95% CI = 5.83% to 13.55%) for texturized implants. The pooled relative risk (RR) of CC was 4.19 (95% CI = 1.87 to 9.39) in favor of smooth implants (Figure 2).

Probability of Reoperation Due to Capsular Contracture

The selected RCTs did not report the long-term rate of reoperations due to CC; therefore, we utilized the reported rate in the core studies of AMS. The weighted

Study or Subgroup	Smooth Implants Events	Smooth Implants Total	Texturized Implants Events	Texturized Implants Total	Weight	Risk Ratio M - H, Random, 95% CI
Burkhardt 1994	18	45	1	45	10.0%	18.00 [2.51, 129.18]
Burkhardt 1995	12	52	7	52	19.6%	1.71 [0.73, 4.01]
Coleman 1991	28	48	4	52	18.4%	7.58 [2.87, 20.03]
Fagrell 2001	4	18	1	18	9.3%	4.00 [0.49, 32.39]
Hakelius 1992	11	25	0	25	6.3%	23.00 [1.43, 370.27]
Malata 1997	13	22	3	27	16.9%	5.32 [1.73, 16.33]
Tarpila 1997	8	21	6	21	19.4%	1.33 [0.56, 3.18]
Total (95% CI)		231		240	100.0%	4.19 [1.87, 9.39]
Total events	94		22			

Heterogeneity $Tau^2 = 0.67$, $Chi^2 = 16.64$, df = 6 (P = 0.01); $I^2 = 64\%$
Test for overall effect: Z = 3.49 (p = 0.0005)

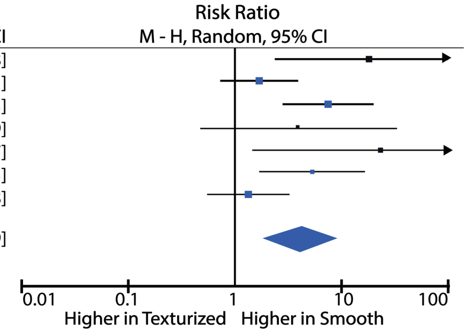

Figure 2. Forest plot of meta-analysis of randomized controlled trials. CI, confidence interval; M–H, Mantel–Haenszel.

mean follow-up for the 3 studies involving 2123 patients who underwent surgery for primary cosmetic breast augmentation was 9.5 years. The pooled risk of undergoing reoperation due to CC was 73.46% (95% CI = 68.08% to 78.52%). Other probabilities of the events utilized in the decision tree are described in Table 1.

Costs

The total expected social cost of breast augmentation surgery with texturized implants was $6805.25 per patient and was $8274.25 per patient for smooth implants. Compared with the cost of breast augmentation with texturized implants, the incremental cost of breast augmentation with smooth implants was $1469.00 per patient. Table 1 displays the resulting costs of the 2 possible options.

Effectiveness

According to our analysis, for every 100,000 patients with smooth implants, 7.9 cases of BIA-ALCL were prevented. No life years, avoided deaths, or avoided reoperations were gained. Moreover, utilizing smooth implants for breast augmentation surgery caused 23,153 additional reoperations, 0.12 additional deaths, and 2.3 fewer life years for every 100,000 patients over the alternative of utilizing texturized implants (Table 2).

To prevent 1 case of BIA-ALCL, 2925.65 additional reoperations had to be performed and 0.02 additional deaths had to occur, meaning that there was 1 extra death for every 50 cases of BIA-ALCL prevented.

Cost-Effectiveness Analysis

A tree decision model (TreeAge SoftWare, Williamstown, MA) was utilized in a hypothetical cohort of breast augmentation patients aged a median of 34 years (range, 22-75 years).[53] For avoided BIA-ALCL cases, the ICER was $18,562,003.01 for smooth implants over texturized implants, meaning that the additional cost of preventing 1 case of BIA-ALCL was $18.5 million. For life years, avoided deaths, and avoided reoperations, the ICER was negative, which implies that smooth compared with texturized implants were more expensive and less effective (Table 2).

Sensitivity Analysis

The sensitivity analysis of life years related to the probability of CC due to smooth implants revealed that when the probability of CC was lower than 0.31 in smooth implants over a 10-year period, the number of life years was higher for smooth implants than for texturized implants (Figure 3A). This finding indicates that if CC rates are lower than 31%, life years are higher for smooth implants than for texturized implants; however, that value is lower than the lower limit of the 95% CI of our meta-analysis and is therefore a very unlikely event.

For a probability of developing BIA-ALCL higher than 1:12,500, the number of life years becomes effective for smooth implants as well (Figure 3B). This value is within the probable range for the risk of developing BIA-ALCL.

Assuming a WTP of $100,000 per life year, breast augmentation with smooth implants becomes cost-effective with a probability of CC due to smooth implants equal to or less than 0.0947 (Figure 3C). If the risk of developing BIA-ALCL is 1:160 or greater, the alternative of utilizing smooth implants would be cost-effective (Figure 3D).

Assuming a WTP of $147,548.91 per avoided BIA-ALCL case, with a probability of CC due to smooth implants equal to or less than 0.096, breast augmentation with smooth implants becomes cost-effective compared with that with texturized implants (Figure 3E). To avoid 1 case of BIA-ALCL, the use of smooth implants would be cost-effective for a risk of developing BIA-ALCL equal to or greater than 1:196 (Figure 3F).

Table 1. Selected Input Values Per Health State for the Cost-Effectiveness Model

Probability of	Base case value
Successful surgery	
Developing BIA-ALCL	1/16,909
Capsular contracture from smooth implants	40.69%
Capsular contracture from texturized implants	9.17%
Reoperation from capsular contracture	73.46%
Death during surgery	1/50,000
Death from BIA-ALCL (excluding death during surgery)	5,76%
Receiving only surgery as treatment for BIA-ALCL	30.28%
Receiving surgery and chemotherapy as treatment for BIA-ALCL	37.14%
Receiving surgery and radiotherapy as treatment for BIA-ALCL	1.71%
Probability of receiving surgery, chemotherapy and radiotherapy as treatment for BIA-ALCL	30.87%
Costs	
Surgery for BIA-ALCL	$8546 (6335 + 2211)
Breast augmentation surgery	$6335
Capsular contracture surgery	$8546 (6335 + 2211)
Death of a patient with BIA-ALCL[a]	$1,405,920 (17,342 + 1,388,578)
Cost of death during breast augmentation surgery[b]	$1,600,074 (17,342 + 1,582,732)
Cost of death during capsular contracture surgery[c]	$1,426,292 (17,342 + 1,408,950)
Chemotherapy	$161,394
Radiotherapy	$8600

[a]Death at 11 years after breast augmentation surgery. Legal services and average funeral costs were added. BIA-ALCL, breast implant-associated anaplastic large cell lymphoma. [b]Death during breast augmentation surgery. Legal services and average funeral costs were added. [c]Death at 10 years after breast augmentation surgery. Legal services and average funeral costs were added.

For the favorable smooth implant scenario, 3 measures of effectiveness (life years, avoided deaths, and avoided BIA-ALCL cases) demonstrated positive ICERs. Increasing 1 life year would cost $4,438,758, preventing 1 death due to BIA-ALCL would cost $70,344,283, and avoiding 1 case of BIA-ALCL would cost $3,060,448.

DISCUSSION

Based on the current information, the utilization of smooth implants is not a cost-effective strategy compared with the employment of texturized implants for subglandular breast augmentation. To prevent 1 case of BIA-ALCL, 2925.7 additional reoperations due to Baker grade III-IV CC must be performed and 0.02 additional deaths must occur with an incremental cost of $18 million.

Our results could be explained by several factors. First, the probability of CC due to smooth implants is 4.19 times higher than CC due to texturized implants. In breast augmentation procedures with a lower CC rate, this analysis could shift toward the utilization of smooth implants (ie, submuscular pocket).

Second, the probability of developing Baker grade III-IV CC from smooth implants that requires reoperation and death during the reoperation is 75% higher than the probability of developing BIA-ALCL from texturized implants and subsequent death as a result. Currently, it is not possible to perform a precise estimation of the risk and prevalence of BIA-ALCL due to the continuous changes in the number of confirmed cases.[3] The BIA-ALCL risks of 1:160 and 1:196 presented in this study are hypothetical values obtained from the sensitivity analysis in which the utilization of texturized implants for breast augmentation surgery would be cost-effective to gain 1 life year (Figure 3D) and to prevent 1 BIA-ALCL (Figure 3F), respectively. Compared with the current risk of BIA-ALCL (1:12,500), these values may be interpreted as distant and "extreme." Although the BIA-ALCL trend will probably increase due to better surveillance and diagnosis, it is unlikely that the risk increase to a rate of approximately 1/200 and the utilization of smooth implants would become cost-effective.

As a methodological decision, we include only RCTs in the meta-analysis, although the capsular contracture rate reported in the included studies is very high for smooth implants, we did not find any RCTs with a lower capsular contracture. Nevertheless, we address that potential bias in the sensitivity analysis (Figure 3A,C and E), showing that in order to be cost/effective, the capsular contracture rate in smooth implants must be 9% or lower.

Third, the expected cost associated with smooth implants ($8264.25) is $1469.40 higher than the expected cost associated with texturized implants ($6805.25), which is explained by the higher risk of reoperation due to smooth implants than texturized implants. The higher cost and lower effectiveness of smooth implants over texturized implants are reflected in the negative ICERs for saved life years, avoided deaths, and avoided reoperation.

Economic analysis is one of many variables to consider in the evaluation of any medical treatment. No

Table 2. Costs, Effectiveness, and Incremental Cost-Effectiveness for Smooth Implants vs Texturized Implants in Breast Augmentation Surgery in a Theoretical Population of 100,000 Breast Augmentation Patients

Strategy		Basal scenario		Smooth favorable scenario	
		Texturized implants	Smooth implants	Texturized implants	Smooth implants
Costs, dollars	Cost	680,525,457.22	827,425,340.05	699,366,605.25	785,666,920.63
	Incremental cost		146,899,882.83		86,300,315.38
Deaths avoided, n	Effect	99,997.52	99,997.40	99,996.31	99,997.53
	Incremental effect		−0.12		1.23
	ICER (dollars)		−1,199,434,082.89 (-)		70,344,285.58
Avoided BIA-ALCL, n	Effect	99,992.09	100,000.00	99.971.80	100,000.00
	Incremental effect		7.91		28.20
	ICER (dollars)		18,562,003.01		3,060,448.41
Life years	Effect	2,526,612.42	2,526,610.12	2,526,592.87	2,526,612.31
	Incremental effect		−2.30		19.44
	ICER (dollars)		−63,982,807.88 (-)		4,438,758.11
Avoided reoperations, n	Effect	93,260.54	70,106.95	90,751.47	76,651.90
	Incremental effect		−23,153.59		−14,099.57
	ICER (dollars)		−6344.58 (-)		−6120.78 (-)

BIA-ALCL, breast implant-associated anaplastic large cell lymphoma; ICER, incremental cost-effectiveness ratio; (-), negative ICER.

single threshold exists for deciding whether a cost-effectiveness ratio is acceptable. Traditionally, in the United States, cost-effectiveness ratios of less than $50,000 per life year gained are generally considered attractive and greater than $100,000 per life year gained are generally considered unattractive, but these are rough guidelines at best and have been criticized as outdated and artificially low.[43] In this study, the higher incremental cost reflects the lower effectiveness of smooth breast augmentation to prevent 1 BIA-ALCL, gain 1 life year, and avoid 1 reoperation. Instead, smooth implants produce 1 additional death by 50 patients and approximately 3000 reoperations. The implication for patients is that the choice of smooth implants for subglandular breast augmentation surgery (instead of choosing texturized implants), in an attempt to avoid BIA-ALCL, will involve additional operations and a higher risk of death due to reoperations given higher CC rates. On the other hand, patients with texturized implants may need to cope with the shadow of the risk of BIA-ALCL. The decision should be shared and informed based on the current knowledge and preferences of the patient and surgeon.

Cost-effectiveness analysis is a powerful tool to resolve dilemmas regarding competing intervention in healthcare. Based on the analysis of probabilities, costs, and measures of effectiveness, it is possible to provide information for decision-making.[41-43] We adopted a societal perspective for our analysis because of the current changes in public policies related to breast implant surface and its impact on the development of BIA-ALCL. From this perspective, even though smooth implants are not cost-effective, a different viewpoint may reveal results in favor of smooth implants (eg, health payers who do not pay for aesthetic procedures but pay for BIA-ALCL treatment). Further research is needed to explore different scenarios and interventions in the field.

There are some limitations to our study. Only information about subglandular implants is included; there are no RCTs reporting rates of submuscular complications, so these rates may not be extrapolated to submuscular or subfascial implants. For the purpose of the study, we decided to utilize only level 1 evidence. The probability of CC was obtained from a meta-analysis of RCTs with a moderate heterogeneity, moderate risk of bias, and short follow-up; however, the probability of CC in these RCTs agrees with that reported in large cohort studies.[27,28] Further analysis could address the utilization of submuscular implants. Evidence from 1 study[51] indicates that the CC rate in a submuscular pocket may be the same for texturized and smooth implants. The authors did not find any differences at 1-year follow-up (5/58 in texturized and 8/52 in smooth implants), with a RR of 1.78 (95% CI = 0.62 to 5.11, P = 0.2726). The

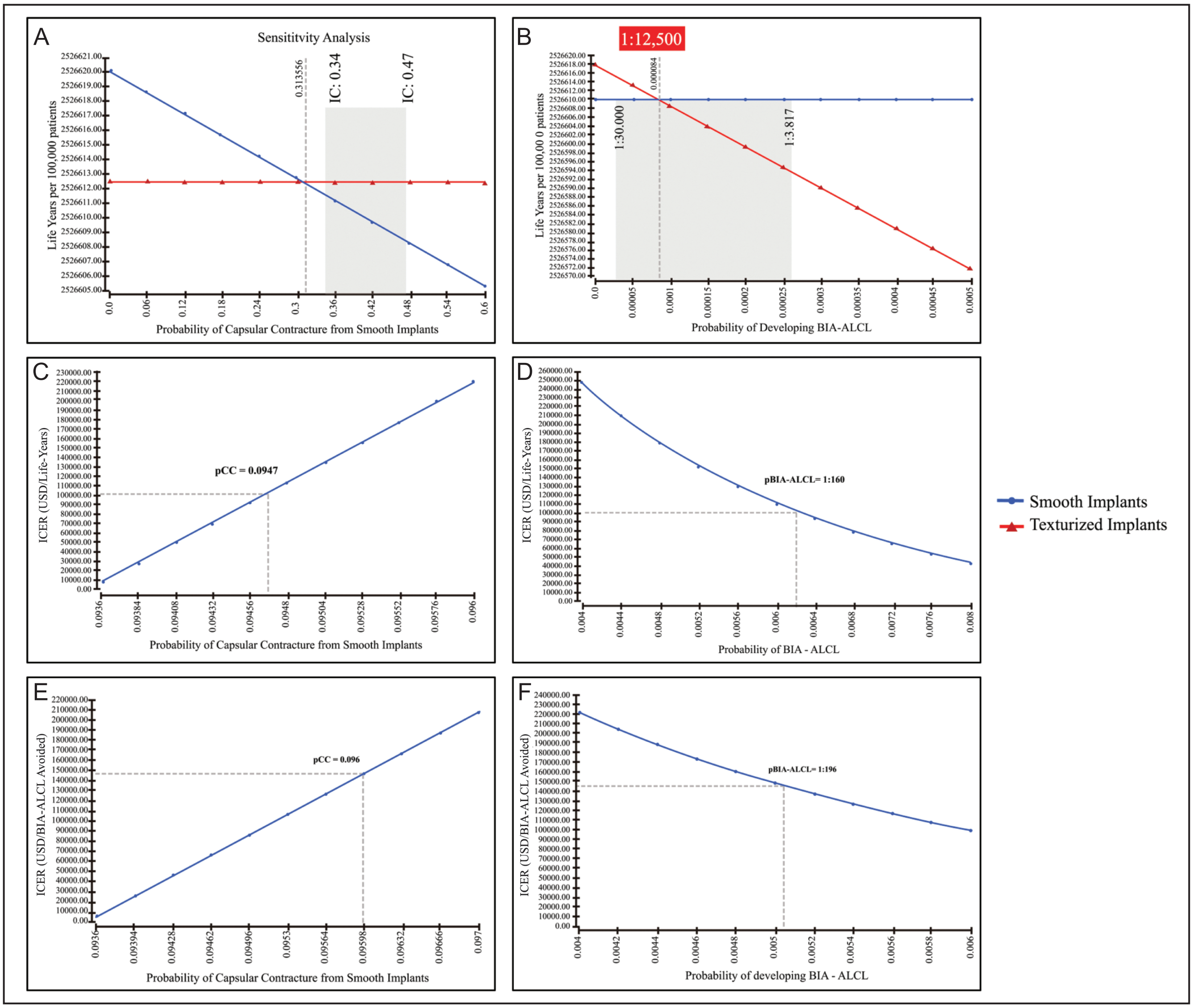

Figure 3. One-way sensitivity analysis. (A) Sensibility of life-years related to the probability of CC in smooth implants. Life years are influenced by the probability of die because a BIA-ALCL or die by surgery. The gray area corresponds to the 95% CI of the smooth implants CC rate, in all that area the smooth implant causes more deaths than texturized implants, the pivotal point occurs when the CC rate of smooth implants is lower than 31.3%, in that scenario there will be less death by BIA-ALCL than because of surgery case-fatality. (B) Sensibility of life-years related to the probability of BIA-ALCL in texturized implants. Life years are influenced by the probability of die because a BIA-ALCL or die by surgery. The gray area corresponds to the 95% CI of BIA-ALCL rate, in all that area the smooth implant causes more deaths than texturized implants, the pivotal point occurs when the BIA-ALCL rate is higher (more frequent) than 1/12500, in that scenario there will be less death by BIA-ALCL than because of surgery case-fatality. (C) ICER of US Dollars to gain 1 life-year related to CC rate in smooth implants. If the CC rate in smooth implants equal or lower than 9.47%, then the cost to gain 1 life-year is $100,000 or less. (D) ICER of US Dollars to gain 1 life-year related to BIA-ALCL rate in texturized implants. If the BIA-ALCL rate in texturized implants equal or higher than 1 in 160, then the cost to gain 1 life-year is $100,000 or less. (E) ICER of US Dollars to avoid 1 BIA-ALCL related to CC rate in smooth implants. If the CC rate in smooth implants equal or lower than 9.47%, then the cost to avoid 1 BIA-ALCL is $150,000 or less. (F) ICER of US Dollars to avoid 1 BIA-ALCL related to BIA-ALCL rate in texturized implants. If the BIA-ALCL rate in texturized implants equal or higher than 1 in 196, then the cost to gain 1 life-year is $150,000 or less.

post hoc power for the Asplund et al[51] study was 12.52%. An adequate study to detect a 20% difference rate of Baker grade III-IV CC should have at least 119 patients per side (90% power, alpha 0.0500, with a 2-sided proportion test). Other studies[27,28] suggest that there is no statistically significant difference between the probability of CC from smooth and texturized implants in the submuscular pocket; however, this corresponds to evidence level 3 and thus was not included in the study. The probabilities of submuscular CC reported in those studies were included in the sensibility analysis; therefore, our cost-effectiveness analysis reflects the results of a wide range of CC probability in different scenarios.

In this study, a decision tree model was utilized to perform the analysis. This evaluation method has some limitations. The value of the information obtained relies strongly on the assumptions to perform the economic evaluation, and the results might be not representative if the model variables (eg, costs) are unreliable. Differences between countries regarding implant placements manifest the significant international variability in breast augmentation approaches. Heidekrueger et al[2] reported the results of a survey sent to over 5000 active breast surgeons in 44 countries worldwide, evidencing the international predominance of partial submuscular pockets in the United States and in most other countries worldwide. However, Latin American surgeons utilize subglandular implant placement in approximately one-half of their patients. Therefore, extrapolations to other communities must be carefully analyzed.

Although more complex models with transition probabilities between events exists (Markov Analysis), currently there are no enough evidence to generate that models. Despite the stated limitations of our study, current model provides reliable answers with the available evidence.

CONCLUSIONS

From a societal viewpoint, shifting from texturized implants to smooth implants to avoid BIA-ALCL is not cost-effective for subglandular breast augmentation surgery. To prevent 1 case of BIA-ALCL, 2925.65 additional reoperations must be performed, 1 additional death must occur for every 50 cases of BIA-ALCL prevented, and $18 million must be spent. Banning texturized implants to prevent BIA-ALCL may involve additional consequences, such as increased reoperations and deaths, which should be considered in light of the higher CC rates associated with smooth implants than texturized implants.

Supplementary Material

This article contains supplementary material located online at www.aestheticsurgeryjournal.com.

Disclosures

Dr Danilla has received airplane tickets, lodging, and inscription costs for medical congress assistance from Polytech. Dr Albornoz has received travel expenses from Allergan for a medical conference. Dr Erazo has received airplane tickets from Allergan and Polytech. The other authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

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