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Breast Augmentation Surgery: How Do We Do It? Results of a Joint Survey from European Association of Societies of Aesthetic Plastic Surgery

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Abstract

Introduction The purpose of this study was to evaluate the current perceptions, preferences, and practice of plastic surgeons in Europe regarding breast implant surgery after the controversy on macrotextured implants and BIA-ALCL and the voluntary recall of all biocell implants.

Methods A survey comprising 15 questions about implant selection and postoperative routines associated with breast augmentation was sent to all society members of the EASAPS.

Results Out of 1473 correspondents, 416 completed the survey with response rate being 28.2%. Countries with less than ten respondents were not included in the analysis. A total of 359 respondents (24.4%) were included in the analysis. Twenty-one respondents (5.8%) had a clinical experience < 5 years, 43 (12%) had 5–10 years' experience, and 295 (82.2%) had > 10 years' experience. Regarding the type of implant, only 6.1% would use a macrotextured implant. Fourteen per cent of surgeons would recommend to change a biocell implant in any case, even without symptoms or problems (rupture, seroma, and capsular contracture), 99.7% would send the capsule for histopathological study (99.7%), 98.9% would perform bilateral implant replacement in case of a unilateral problem of rupture, contracture, or seroma, and 80.8% of respondents considered capsulectomy as a technique for managing capsular contracture degree III/IV.

Conclusions The main conclusion is the heterogenicity of answers and practice, due to the lack of guidelines and scientific evidence on breast implants. Although 22 (6.1%) respondents would use a macrotextured implant (either round or anatomic), 71.6% of respondents considered that there is not enough information for removing macrotextured implants from the market and that they should be allowed to be used unrestrictedly or under close surveillance of the regulatory agencies.

Level of Evidence III This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

Keywords Breast implant · Breast augmentation · Capsular contracture · Seroma · Rupture · Texturization

Introduction

According to the survey on aesthetic–cosmetic procedures of the International Society of Aesthetic Plastic Surgery, more than 1.8 million women worldwide underwent a breast augmentation procedure in 2018, making this the most common aesthetic procedure in women. Moreover, the number of breast augmentation procedures increased 27.6% from 2014 to 2018 [1].

Since the first silicone gel implant was introduced in 1962 [2], new generations of silicone implants have been developed in an attempt to minimize the incidence of complications [3].

Today, silicone gel implants dominate the world market [4], with 91% of plastic surgeons performing breast augmentation with them [1].

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Despite the scientific evidence suggesting long-term safety and efficacy of the breast implants, localized and distant inflammatory reactions have been observed, demonstrating the immunogenic potential of silicone [5–7]. Moreover, over the last years there have been an increasing number of reported cases of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) in the literature [8, 9].

Textured implants have been in the midst of the current implant crisis, and biocell was recalled worldwide after the latest Food and Drug Administration (FDA) update on the disease [10, 11].

Because there is new and controversial information about different issues regarding breast augmentation surgery, there is, from our point of view, the need to know how things in breast implant surgery are being made and what the impact of these new findings in the clinical practice of plastic surgeons has been.

The purpose of this study was to evaluate the current perceptions, preferences, and practice of plastic surgeons in Europe regarding breast implant surgery.

Methods

The study was conducted in November–December 2019, followed a descriptive and cross-sectional survey design. The target population for the survey was members of the European Association of Societies of Aesthetic Plastic Surgery (EASAPS).

The questionnaire comprised 15 questions about implant selection and postoperative routines associated with breast augmentation. The survey was sent to all society members of the EASAPS. The participants were notified of the voluntary nature of participation, confidentiality, and non-compensation for participation. Countries with less than ten respondents were not included in the analysis.

The results from the questionnaire were confidential, and no associations were made between the results and any specific surgeon.

Data were analysed by using version 19.1.5 of the MedCalc Statistical Software package (MedCalc Software bv, Ostend, Belgium; https://www.medcalc.org; 2020).

Before the study, it was determined that at least 305 surgeons need to answer the questionnaire, at a significance level of 0.05, with a statistical margin error of 5%.

Statistical analysis was performed by an independent statistician, who was blinded to the question, response options, and society.

Results

Out of 1473 correspondents, 416 completed the survey with response rate being 28.2%. According to the protocol requirements, respondents from Armenia (1), Austria (1), Belarus (1), Belgium (2), Bosnia and Herzegovina (2), Denmark (3), Finland (2), Georgia (1), Hungary (5), Latvia (2), Lithuania (1), Malta (2), The Netherlands (1), North Macedonia (2), Norway (3), Poland (1), Russia (6), Serbia (1), Sweden (3), Turkey (1), Ukraine (4), UK (6), and others (6) were not included in the analysis.

A total of 359 respondents (24.4%) were included in the analysis. Amongst all the respondents, 76.3% (274) were men. Most of the respondents (66.6%) were between ages $> 45 \leq 65$ years; 24.5% ≤ 45 years, and the remaining 8.9% over 65 years. Regarding clinical experience, 21 respondents (5.8%) had a clinical experience < 5 years, 43 (12%) had 5–10 years' experience, and 295 (82.2%) had > 10 years' experience.

Question 1. After recent controversies, what type of breast implant do you think should be used as of now? (multiple choice).

The median (95% confidence interval, 95% CI) number of answers was 2.0 (2.0–2.0), with 13.6% of respondents giving ≥ 4 answers. The 59.3% of respondents selected round smooth/nano-implants, 52.6% round microtextured ones, and 33.7% anatomic microtextured implants. Only 22 (6.1%) selected macrotextured implants, either round or anatomic ones (Fig. 1).

Question 2. What is, from your point of view, the ideal plane for smooth/nano-implants?

A total of 40.5% of respondents thought that it depends on patient characteristics. Other answers included (in order of number of responses): submuscular placement (24.8%), dual plane (24.2), subglandular placement (6.4%), and subfascial placement (4.2%).

Question 3. What is, from your point of view, the ideal plane for microtextured implants?

The results were, in general term, similar to those reported for smooth/nano-implants. A total of 45.7% of respondents answered that it depends on patient characteristics, 24.0% answered dual plane, 18.7% answered submuscular placement, 7.2% selected subglandular placement, and 4.5% chose subfascial placement.

Question 4. What is, from your point of view, the ideal plane for macrotextured/micropolyurethane implants?

A total of 51.3% of respondents chose "depends on patient characteristics", 18.4% selected a dual-plane

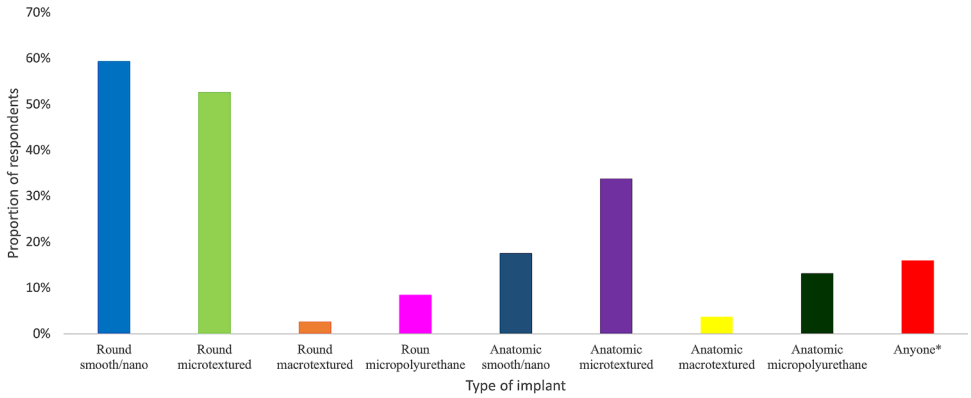

Fig. 1 Overview of the proportion of respondents to question 1: after recent controversies, what type of breast implant do you think should be used as of now? (multiple choice). *Dependent on patient characteristics

placement, 14.2% submuscular placement, 9.5% subglandular, and 6.7% subfascial placement.

Comparing the results of the questions 2, 3, and 4, it was possible to address that placement depends on type of implant ($p = 0.0026$) (Table 1).

Question 5. What should be the attitude in the presence of axillary siliconomas?

Amongst the 359 respondents, 140 (39.0%) chose an expectant-management/follow-up, 124 (34.5%) selected to perform surgical excision of the bigger ones, 79 (22.0%) chose to remove as many as possible, and 16 (4.5%) chose to perform a lymphadenectomy.

Question 6. When faced with a unilateral problem of rupture, contracture, or seroma: when, in your opinion, the two implants should be changed?

37.6% answered that always both implants should be changed, while only 1.1% chose that never should be indicated a bilateral removal of the implants (Fig. 2). Thirty-five per cent would change both depending on the time elapsed since implantation and 26% depending on this plus the cause originating the reoperation.

Question 7. How much time should span since the augmentation/mastopexy surgery for changing the two implants? (multiple choice).

The median (95% CI) number of answers was 1.0 (1.0–1.0), with 57 respondents giving two answers and one giving three. A total of 48.7% of respondent answered that only in implants older than 10 years, 43.5% would do at any time for any implant, 12.3% at any time, but only with biocell implants, and the 12.0% only in implants older than 5 years.

Question 8. When, in your opinion, total capsulectomy should be done? (multiple choice).

The median (95% CI) number of answers was 2.0 (2.0–2.0), with 72 respondents giving three answers and one giving four ones. A total of 80.8% (290/359) respondents considered that capsulectomy should be done if capsular contracture is present. On the contrary, 25 (7.0) respondents answered that capsulectomy should never be done (Fig. 3).

Question 9. Should the capsules be sent to histopathological study?

Only one (0.3%) respondent thought that it was not necessary to send the specimen for histological exam. On the contrary, 241 (67.1%) respondents thought that it is mandatory to send "every specimen obtained and, in any circumstance", while 117 (32.6%) respondents answered that only macroscopically altered areas should be sent to histological examination.

Question 10. If you send the capsule to histopathological study, in which of the following situations would you do it? (multiple choice).

Table 1 Comparison of the implant placement according to the type of implant

	Smooth/nano	Microtextured	Macrotextured/micropolyurethane	p^a
Subglandular [*n* (%)]	23 (6.4)	26 (7.2)	34 (9.5)	0.0026
Subfascial [*n* (%)]	15 (4.2)	16 (4.5)	24 (6.7)	
Submuscular [*n* (%)]	89 (24.8)	67 (18.7)	51 (14.2)	
Dual plane [*n* (%)]	87 (24.2)	86 (24.0)	66 (18.4)	
Depends on patient [*n* (%)]	145 (40.4)	164 (45.7)	184 (51.3)	

[a]Chi squared test

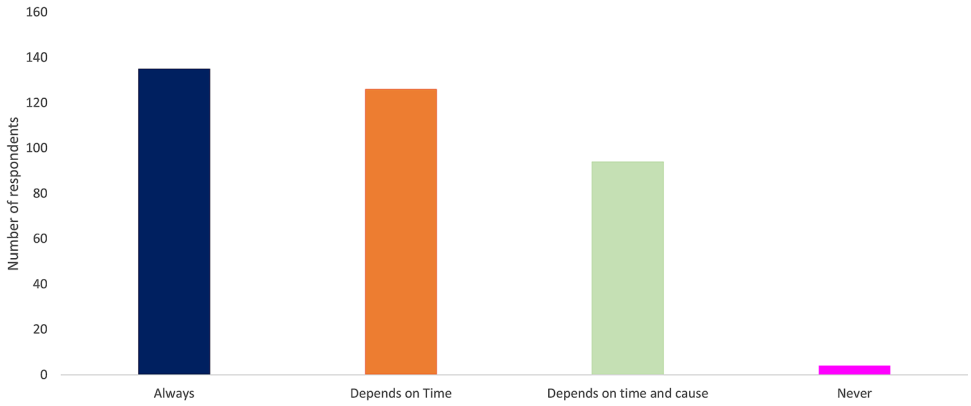

Fig. 2 Overview of the number of respondents to question 6: when faced with a unilateral problem of rupture, contracture, or seroma: when, in your opinion, the two implants should be changed?

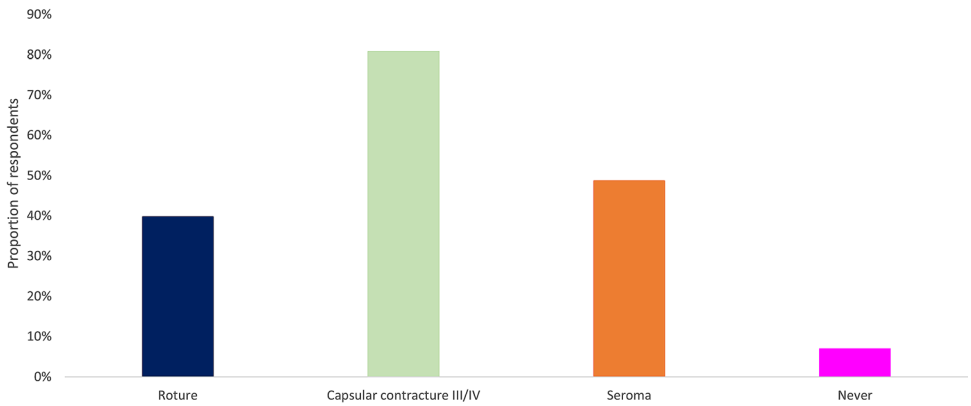

Fig. 3 Overview of the proportion of respondents to question 8: when, in your opinion, total capsulectomy should be done? (multiple choice)

The median (95% CI) number of answers was 2.0 (1.0–2.0), with 96 respondents giving two answers and 96 giving ≥ 3 ones. Most of the respondents (71.9%) would send the capsule if seroma was present, 54.0% would do in capsular contracture, 30.4% in case of capsular rupture, and the 28.4% of the respondents would never send the capsule to histopathological study.

Question 11. In a seroma, if the cytological analysis is negative for ALCL, if you need to perform a replacement surgery, do you think that it is justified to send the capsule to histological study?

Two-hundred and eighty-one (78.3%) respondents would send the capsule to histological exam in any case, while 61 (17.0%) ones would do it only if an altered area is present. Interestingly, 17 (4.7%) respondents would not send the capsule to histological study in any case.

Question 12. In patients with biocell implants, what would have been your recommendation? (multiple choice).

In this question, there are two missing answers, so the sample is 357 respondents. The median (95% CI) number of answers was 1.0 (1.0–1.0), with 57 respondents giving two answers and one giving three ones. A total of 55.7% (199/357) would replace the implant only if there were adverse events, as in any other, 46.8% (167) would maintain an expectant attitude, while 50 (14.0%) respondents would change the implant, even without adverse events.

Question 13. In a replacement, how should the replacement implant be?

The answer to this question was really very heterogeneous. One-hundred and thirty-seven respondents would select a round smooth/nano-implant, 89 chose a round microtextured one, and 81 did not have any preference (they discuss the options with the patient) (Fig. 4).

Question 14. How often should ultrasound control or magnetic resonance imaging (MRI) of implants be done?

A total of 20.9% of respondents considered that it is not necessary to do either an ultrasound or MRI control of the implants. Regarding the 79.1% that considered it necessary to do ultrasound or MRI examinations, 36.2% would do it every year and the remaining 42.9% every 2 years.

Question 15. What do you think the position of the regulatory agency in relation to macrotextured/microp-olyurethane implants should be?

Amongst the 359 respondents, 150 (41.8%) would allow their use, but as long as periodic and truthful information about their safety profile was available, 107 (29.8%) would

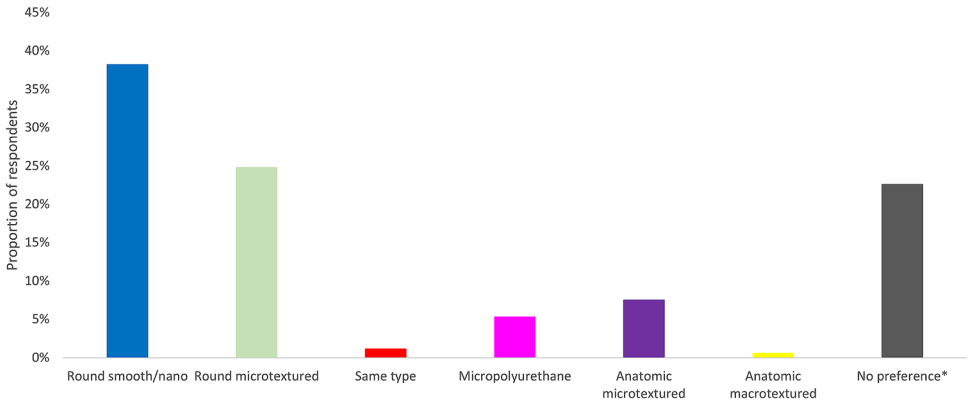

Fig. 4 Overview of the proportion of respondents to question 13: *In a replacement, how should the replacement implant be?* *They discuss the options with the patient

allow their use without restrictions while register of the European community or FDA was valid, and 102 (28.4%) respondents considered that these type of implants should be prohibited.

Discussion

Breast augmentation and reconstruction mammaplasty have been performed for decades and boast high patient satisfaction rates [12]. In 1997, Keech and Creech reported the first case of ALCL linked to breast implants [13], and in 2011 the FDA warned to have identified 60 cases worldwide [14]. In 2016, the World Health Organization recognized breast implant–associated ALCL as a type of lymphoma that can develop following breast implants [15]. Awareness about this disease grew up worldwide so many different cases of BIA-ALCL have been described [8, 9, 16, 17].

This brought us to the question of whether these findings have had any impact on the decision-making process of plastic surgeons in Europe, and, if so, how important such impact was on the actual practice of plastic surgeons in Europe.

Implant Characteristics

An essential part of the implant selection process is considering the physical characteristics of the implant itself. Texturing has become an important issue regarding effectiveness and complications. Implants have been classified depending on their roughness as smooth (0–10 μm), microtextured (10–50 μm), and macrotextured (> 50 μm) [18, 19]. About this issue, the results of the survey showed the heterogeneous results. Although round smooth/nano- and round microtextured implants were the preferred options, none of them reached the 60% of votes. Nevertheless, in implant selection, the new evidence about BIA-ALCL seemed to impact significantly on the decision-making process, because only 22 (6.1%) respondents would select a macrotextured implant (either round or anatomic).

When comparing our results with those published by Benito-Ruiz in 2017, it is possible to see some changes in the pattern and preferences of the plastic surgeons in this field. In a survey, conducted on members of the Spanish Society of Plastic, Reconstructive and Aesthetic Surgery, it was reported that the 33.1% of respondents were using macrotextured implants (either round or anatomic ones) [20]. That figure was significantly greater ($p < 0.0001$) than that observed in the current survey (6.1%). A national survey throughout the UK and Ireland in 2018 found a shifting trend to surgeons offering patients the choice of either a smooth or textured implant after informed counselling on the risk-to-benefit ratio. A total of 77.8% of surgeons were using textured implants at that time. At this stage, up to a third of surgeons surveyed had either already changed their implant practice to smooth, nano-, or microtextured implants or had plans to do so [21].

Textured implants have been used in Europe much more than in the USA. The shift in behaviour regarding the use of textured implants in Europe gives much more information about the impact of the BIA-ALCL in surgeon's practice.

Implant Placement

Breast implants have been traditionally placed either submuscular (beneath the pectoralis major muscle) or subglandular (over the pectoralis but beneath the glandular breast parenchyma) [22].

Independently of the type of implant, most of the respondents considered that anatomic placement depends on patient characteristics.

According to the results of a consensus from experts in breast augmentation surgery in Australia and New Zealand, the dual-plane technique was the most commonly used [23]. The "dual-plane" is a modification of submuscular

placement, which implies the creation of a surgical dissection plane between the pectoralis major fascia and the subglandular tissue, so the muscle covers more or less the surface of the implant [22].

The results of the current survey found that the dual-plane technique was selected by 24.2%, 24.0%, and 18.4% of the respondents in round smooth/nano-, microtextured, and macrotextured/micropolyurethane implants, respectively. Although it was, in microtextured and macrotextured/micropolyurethane implants, the second most voted option, our results are far away from those reported by the Australia and New Zealand survey [23].

Postoperative Complications

Implant rupture and capsular contracture are two common complications of breast augmentation [22, 24].

The rate of silicone lymphadenopathy is unknown but is strongly associated with implant rupture and subsequent gel migration although it can happen as well from leaking with intact implants [22, 25]. The recommendation is not to remove the nodes, unless they provoke symptoms [25, 26], due to the comorbidities and the lack of real benefit. The results of the current survey revealed that 39% of the respondents maintained an expectant attitude, but the rest advocated a partial removal and even a radical lymphadenectomy (4.5%).

It seems that the incidence of capsular contracture is decreasing as surgical techniques are refined [27]. Therapeutic strategies for capsular contracture include capsulectomy, capsulotomy, and implant replacement [22].

According to the results of the current survey, 98.9% of respondents would perform a bilateral implant replacement in case of a unilateral problem of rupture, contracture, or seroma. Only four (1.1%) respondents would never perform a bilateral replacement if unilateral complications occurred.

Regarding capsulectomy, most of the respondents (80.8%) selected this technique in case of capsular contracture degree III/IV, while only 7% of respondents would not perform capsulectomy in any case.

Regarding the question: Should the capsules be sent to histopathological study? Only one (0.3%) respondent would never send the capsule to histopathological study, while 99.7% of respondents would. This is, in our opinion, an important point that put on the table the awareness about BIA-ALCL and it is in line with recent recommendations [28]. Moreover, the results observed in question 11 confirmed this finding, since 78.3% of respondents would send the capsule to histological study in case of seroma, even if the cytological study was negative.

A point that, in our opinion, merits a special consideration is question 10. While in question 9, 99.7% of respondents would send the capsule to histological examination, and in question 10 28.4% of respondents answered that "in no case" would they send the capsule to histological study. Question 10 considered four different answers: implant rupture, capsular contracture, seroma, and "in no case". The question is: Did the respondents consider the option "in no case" as "none of the above" or "would send the capsule never"? Since it is not possible to fully elucidate the underlying reason of these answers, we should be very cautious when interpreting the results of this question. This point should be taken into consideration for future research.

Regarding the question: In a replacement, how should the replacement implant be? The survey showed a tremendous heterogeneity. It should be commented that only four (1.1%) respondents would select the same type of implant that the patient has and two (0.6%) respondents would select an anatomic macrotextured implant.

The FDA recommends nowadays follow up of the implants but not how often [29]. Interestingly, in this survey, 20.9% of respondents considered that it is not necessary to perform either ultrasound or MRI examinations in breast augmentation surgery patients, while 79.1% considered it necessary to do either ultrasound or MRI examinations. Our survey did not ask about what the first-choice imaging method should be, but rather about the follow-up period. It would be interesting for future investigations to have this issue into consideration.

We asked as well about the position of the regulatory agencies regarding to macrotextured/micropolyurethane implants. Although according to the results of question 1, only 6.1% of respondents would select macrotextured implants for their patients, 71.6% of respondents considered that there is not enough information for removing macrotextured implants from the market.

Several options emerge from these results: First: Has the scientific evidence suggesting BIA-ALCL enough quality? Second: If currently available scientific evidence did not have enough quality, why are they not used? and Third: If currently available scientific evidence has high quality, why allow its use? (but do not use them).

Limitations

Survey research has inherent limitations, which includes discrepancy, validity, and reliability of respondents. A possible limitation of this investigation is the low response rate, only 28.2%. Nevertheless, the number of respondents was enough for assuming a statistical margin error of 5%. A second limitation is the fact that three countries (France, Italy, and Spain) account for almost 62% of the participants

in our survey, leading to an overrepresentation of these countries.

Nevertheless, despite these limitations, we think that this study has shed some light and provided valuable baseline information on the current practice amongst plastic surgeons in Europe.

Conclusions

This survey provided some relevant information about real-life breast augmentation management. A total of 99.7% of respondents considered the capsule should be sent to histopathological study. Additionally, 98.9% of respondents would perform a bilateral implant replacement in case of a unilateral problem of rupture, contracture, or seroma. Finally, 80.8% of respondents considered capsulectomy as a technique for managing capsular contracture degree III/IV.

However, most of the questions provided the heterogeneous results, which makes it extremely difficult to draw recommendations or conclusions. In fact, from our point of view, the results of this survey might suggest the need to constitute an expert consensus group for developing recommendations.

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Compliance with Ethical Standards

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

Ethical Standards This article does not contain any studies with human participants or animals performed by any of the authors.

Informed Consent For this type of study, informed consent is not required.

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