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**Letter to the Editor to Cheng F, Cen Y, Liu C, Liu R, Pan C, Dai C. Round versus Anatomical Implants in Primary Cosmetic Breast Augmentation**

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### DISCLOSURE

None of the authors has a financial interest in any of the products or devices mentioned in this communication.

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## Round versus Anatomical Implants in Primary Cosmetic Breast Augmentation: A Meta-Analysis and Systematic Review

Sir:

With great pleasure and interest we have read the systematic review article by Cheng et al. entitled “Round versus Anatomical Implants in Primary Cosmetic Breast Augmentation: A Meta-Analysis and Systematic Review,”<sup>1</sup> in which the authors conclude that anatomical implants do not seem to have an aesthetic superiority compared with round implants. The discussion about the shape aspect has been going on for many years and, in our opinion, has also significantly been influenced by personal belief, marketing, and financial incentives; the latter two aspects definitely also play a certain role in the daily life of every active plastic surgeon performing breast augmentations (including us), not just the key opinion leaders of breast implant–producing and –selling companies. Isn't it perfect to have a product like an anatomically shaped breast implant that specifically solves the specific demand and cosmetic problem of our clients?

But how have we come so far to develop an anatomical implant that is rigid and still in its shape and form like that of the Allergan Gummy Bear Implant (style 410)? Although nice in shape and design, it is fully unnatural in its feel and dynamic behavior. The rising worldwide belief in rigid anatomical breast implants, such as the Allergan style 410 and 510, is that they have fallen from their pedestal, as already witnessed by the problem of breast implant–associated anaplastic large cell lymphoma<sup>2</sup> and now by this excellent review proving no evidence of superiority of anatomical implants over round ones.<sup>1</sup>

The development of rigid, form-stable anatomical implants had something to do with the demand for more cohesive silicone gel to prevent silicone bleeding and reduce widespread leakage in case of envelope rupture, thereby (suggesting) increasing patient safety. Although the second and third generation of breast implants felt soft upon palpitation, after implantation, their drawbacks were lack of projection and silicone bleeding through the envelope. The demand for increased projection of breast implants

with significantly less silicone bleeding has resulted in these form-stable anatomical breast implants, which unfortunately lack many of the aspects of a natural-feeling breast, that is, softness, anatomical shape when standing up, but roundness when lying on the back and moving sideways (laterally or medially) when moving to one side.

Fortunately, a paradigm shift is going on now, from rigid anatomical breast implants with stiff, highly cohesive silicone gel to dynamically behaving (round to anatomical) breast implants.<sup>3</sup> These are, in our opinion, the sixth generation of breast implants: round shaped breast implants that are either under-filled with a highly cohesive gel in a regular envelope (slightly thicker, less elastic) or fully filled with an elastic (mobile), highly cohesive gel in an elastic envelope. Obviously, both of these implants have inhibited gel bleed due to the highly cohesive soft silicone gel filling and barrier layer technology. Thus they feel soft and behave in a natural and similar way to breasts: anatomical in shape when standing up, because of gravity and gel behavior, and round when lying on the back or moving to one side. Two examples of breast implants (that we know) to date that already meet these criteria are the Motiva Ergonomix implants (Establishment Labs Holding, Inc., Alajuela, Costa Rica) and the Nagor IMPLEO implants (GC Aesthetics Limited, Dublin, Ireland). Time will prove the definitive place of these next-generation, dynamically behaving, round-to-anatomical breast implants (both companies are initiating U.S. Food and Drug Administration approval studies), but our clinical experience and the technical data provided with these implants already show that highly cohesive silicone gels do not need to be stiff anymore and can behave significantly more naturally upon breast augmentation. These new types of dynamically behaving round-to-anatomical breast implants announce and indicate the present paradigm shift in silicone breast implants, from stiff, form-stable (mostly associated with anatomical envelope and shape form), highly cohesive, silicone gel-filled breast implants to dynamically behaving, round-to-anatomical, highly cohesive, yet soft-feeling breast implants of the sixth generation.

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### DISCLOSURE

*Dr. van der Lei is a paid consultant for GC Aesthetics Limited. Dr. Stevens has no financial interest in any of the products or devices mentioned in this communication.*

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### Reply: Round versus Anatomical Implants in Primary Cosmetic Breast Augmentation: A Meta-Analysis and Systematic Review

*Sir:*

We have read with great interest the letter by van der Lei and Stevens regarding our article, “Round versus Anatomical Implants in Primary Cosmetic Breast Augmentation: A Meta-Analysis and Systematic Review.”<sup>1</sup> Holding similar views with the authors, we do think safety and patient outcomes are the key points of breast augmentation surgery.

Since the use of silicone breast implants for either cosmetic augmentation or reconstruction, the safety issue has been shadowed in controversy. The risks of silicone implants include local complications, such as rupture, infection, and capsular contracture, and even certain severe diseases (connective-tissue disease and cancer). In 2008, de Jong et al.<sup>2</sup> reported the first study indicating an increased risk of breast implant–associated anaplastic large cell lymphoma (BIA-ALCL) associated with breast implants. Since then, several studies were implemented to illustrate the risk of BIA-ALCL in women with implants. According to the Australian Therapeutic Goods Administration, the risk of developing BIA-ALCL was between 1/1000 and 1/10,000 among women with breast implants.<sup>3</sup> However, with the limitations in the worldwide reporting, we find it difficult to determine the exact number of cases worldwide. Despite this, we can still make some efforts in choosing the optimal type of breast implants to maximize patient outcomes and minimize complications.

Numerous innovations have been involved in the design and engineering of breast implants, from outer shell to breast implant fill to shape and projection. To date, breast implants are divided into different types

(round and shaped implants, smooth and textured implants, saline and silicone gel implants, and cohesive silicone gel implants). As for smooth and textured implants, it is now widely believed that smoother devices have higher capsular contracture rates, leading to the fact that some surgeons prefer to choose textured breast implants. Meanwhile, the development of BIA-ALCL is associated with textured devices,<sup>4</sup> and there are no confirmed cases of BIA-ALCL having something to do with smooth devices. According to this, some countries have already taken measures to decrease the occurrence of BIA-ALCL. The French national Agency for the Safety of Medicines and Health Products proposed to stop the use of textured implants<sup>5</sup> in February of 2019. Studies have confirmed that the feel and shape of silicone implants are much more natural compared with saline implants, with lower capsular contracture rates. The gel of the newest generation of silicone implants is more cohesive, making the implants free from silicone bleeding and leakage, while feeling firmer<sup>6</sup> at the same time. Resources have to be invested in the industry continually to produce a more sophisticated device to maximize patient outcome and to guarantee patient safety. DOI: [10.1097/PRS.00000000000006448](https://doi.org/10.1097/PRS.00000000000006448)

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1. Cheng F, Cen Y, Liu C, Liu R, Pan C, Dai S. Round versus anatomical implants in primary cosmetic breast augmentation: