Response to "Clarification About 'Expert Consensus on the Use of a New Bioengineered, Cell-Friendly, Smooth Surface Breast Implant'"

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This note is intended to respond to and acknowledge our appreciation of our esteemed colleagues for their constructive letter[1] regarding our recent paper "Expert Consensus on the Use of a New Bioengineered, Cell-Friendly, Smooth Surface Breast Implant."[2]

We live in an era in which the breast implant industry is being disrupted by major regulatory changes, patients' unlimited access to information through digital channels, and the promise of new technologies coming to market. The lack of innovation over the last 25 years has created an environment that is the preamble to a great transformation. Nevertheless, evolution is the key, and as Charles Darwin is supposed to have stated: "It is not the strongest of species that survives, nor the most intelligent that survives. It is the one that is most adaptable to change." There is no doubt that the breast implant industry has shifted towards implanting smooth devices in recent years and it is our duty as educators to teach a generation of plastic surgeons that never used traditional and advanced "smooth devices" how to use them to their advantage and how to avoid complications and pitfalls during this transition.

The major objective of this paper was to explain the technological contributions of Motiva to next-generation breast implants and to address best practices in the use of these devices. As a result, we brought together a group of early-adopter plastic surgeons, now Motiva "experts," to share their best practices in this endeavor. The paper made no claims or statements and only shared the experiences of these surgeons with Motiva devices.[3-5] It was not a scientific study, but had a validated level of evidence of 5 as clearly defined by the Centre for Evidence-Based Medicine, Oxford University as "first principles" according to expert opinion.[6]

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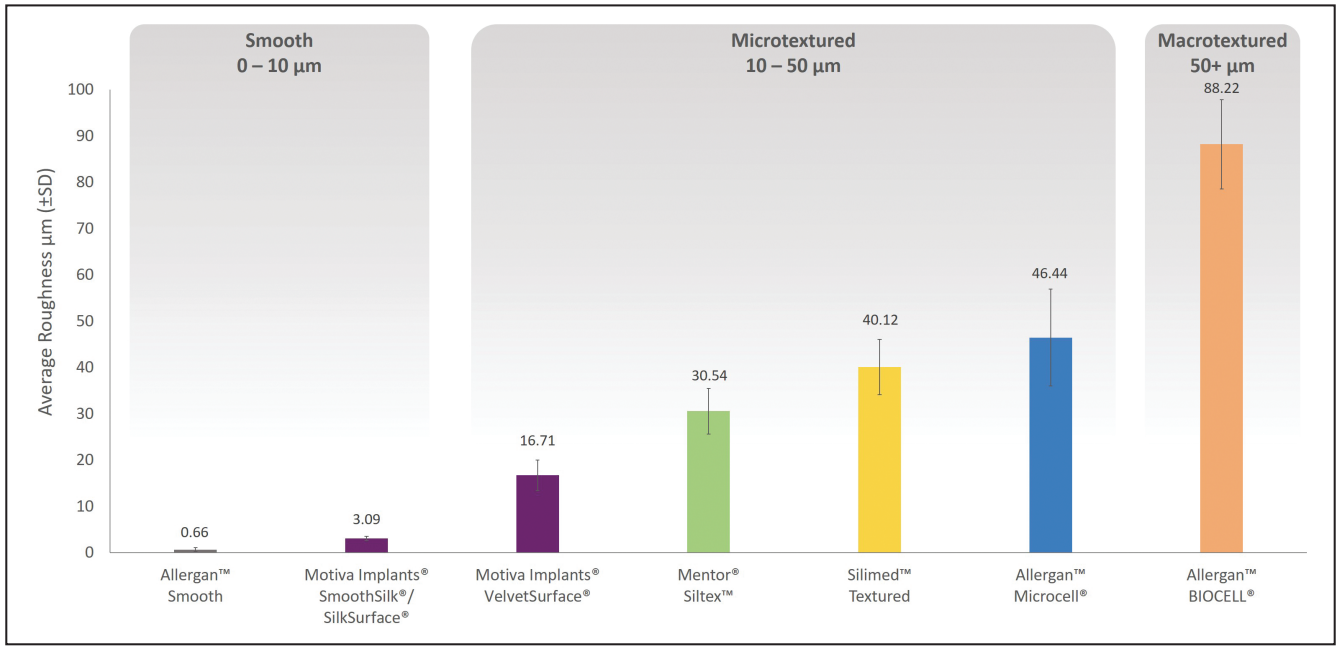

Figure 1. Surface characterization of different breast implants available on the market based on Establishment Labs data generated internally per ISO-14607:2018.

In April 2018, the International Organization of Standardization (ISO) published a new version of ISO-14607 "Non-active surgical implants—Mammary implants—Particular requirements"[7] (the "Standard"). Annex H, "Test for surface characteristic," states that the objective of adding a description of a surface is to generate data to improve knowledge on the correlation between breast implant surface characteristics, performance, and safety. Before the publication of this latest version of the Standard, there was no applicable internationally accepted standard that regulatory bodies could objectively use to classify implant surfaces. The new classification included in the Standard establishes a series of objective parameters to classify surfaces.

It is our understanding that Establishment Labs engaged an independent and internationally recognized French laboratory, Laboratoire national de métrologie et d'essais (LNE), to conduct an independent, blinded evaluation of the SmoothSilk/SilkSurface surface in accordance with ISO-14607:2018. We requested a copy of the LNE report, the conclusions of which state: "According to the ISO 14607-2018 categorization and the obtained results in this study, the SmoothSilk®/SilkSurface® in Motiva® Round is considered a smooth surface"[8] (Figure 1) (Establishment Labs, unpublished data). Moreover, the data provided by LNE, which were representative of all SmoothSilk/SilkSurface product families, unequivocally state that the surface characterization of all the Motiva SmoothSilk/SilkSurface breast implants falls into the "smooth" classification (< 10 µm), based on the average roughness measurement of the finished devices.[6] The term "nanosurface" best describes a surface that is within the "smooth" category, although they differ from the surfaces traditionally described as smooth that date back to 1962. The term is not meant to be nanometric (< 1 µm); rather, we use the term instead to mean the smallest in surface topography of nontraditional smooth devices—from Latin *nanus* meaning dwarf.

Regarding conflicts of interest (COIs), it is true that several authors have financial interests as consultants in the sponsoring company, but this does not exclude them from sharing their extensive experience as long as these COIs are properly disclosed. It is important to consider the issue of COIs, as it is virtually impossible to include every potential COI in a publication.

To date, there are no reported primary cases of pure smooth breast implant–associated anaplastic large cell lymphoma (BIA-ALCL).[9] Long-term data from Motiva implants can soon be gathered as they are now in their ninth year on the market, but undeniably more data need to be collected. Motiva fully intends to continue collecting data for many years to come. The Motiva SmoothSilk®/SilkSurface® is regarded as a smooth surface (and to date no cases of pure smooth implants with ALCL have been reported). Nevertheless, there was a strong consensus among these expert surgeons in regard to a probable reduced risk of BIA-ALCL with Motiva implants. Regarding long-term prospective data, Motiva is now in the second year of an investigational device exemption clinical trial with the US Food and Drug Administration, which will provide the highest level of evidence to all surgeons and colleagues.

The paper was intended to provide guidance and best practices for surgeons when transitioning to Motiva implants and to offer surgical "tips and tricks." There is a dire need to assist surgeons, especially in countries with limited or no experience in breast augmentation with smooth implants.

Furthermore, we would like to express our gratitude to Drs Nava, Rancati, de Vita, Catanuto, and Rocco for contributing to our collective understanding of these new devices. Your valuable input is appreciated. Together we must continue educating and helping all surgeons who need support as we all have at some point. Our colleagues across the world should be motivated and encouraged to put their patients' safety at the center of their practices.

Disclosures

Dr Sforza serves as coordinator of the Medical Advisory Board (MAB), has a consulting agreement with Establishment Labs Holdings, Inc, is a US clinical trial investigator, has received an option grant in September 2016 for 36,953 Class A Ordinary Shares and a restricted share grant in April 2018 for 68,233 Class A Ordinary Shares in Establishment Labs Holdings, and the author's institution on April 17, 2014 entered into a Supply Agreement with Establishment Labs Holdings, Inc. Dr Hammond has consulting agreements with Mentor Corporation, the Musculoskeletal Transplant Foundation, Establishment Labs Holdings, Inc, and Nova Plasma Ltd; receives book royalties from Elsevier; is a member of the MAB at Establishment Labs Holdings, Inc; has a development agreement, including royalties for future products, has shares in Establishment Labs Holdings, Inc, and is also an investigator in Establishment Labs Holdings, Inc's US clinical trial. Dr Botti declared no potential conflicts of interest with respect to the research, authorship, and publication of this article. Dr Hedén has consulting agreements with Establishment Labs Holdings, Inc, Allergan, and Mentor, has shares in Establishment Labs Holdings, Inc, and is also an investigator in Establishment Labs Holdings, Inc's US clinical trial. Dr Chacón-Quirós is a member of the MAB and consultant for Establishment Labs Holdings, Inc, and has shares in Establishment Labs Holdings, Inc. Dr Munhoz is a member of the MAB at Establishment Labs Holdings, Inc, and has shares in Establishment Labs Holdings, Inc. Dr Kinney is a member of the Scientific Advisory Board at Establishment Labs Holdings, Inc, and has shares in Establishment Labs Holdings, Inc, and is also an investigator in Establishment Labs Holdings, Inc's US clinical trial. Dr Corduff has a consulting agreement with Establishment Labs Holdings, Inc, is a member of the MAB, and has shares in Establishment Labs Holdings, Inc.

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