Response to: Nano-Surface Implants: Indications and Limitations

Marcos Sforza, MD; Giovanni Botti, MD; Per Hedén, MD, PhD; Renato Zacheddu, MD; Alexandre Mendonça Munhoz, MD, PhD; Federico Mayo, MD; Brian M. Kinney, MD; Dennis C. Hammond, MD; Niamh Corduff, MD; Humberto Uribe Morelli, MD; Demetris Stavrou, MD; and Jesús Centeno, MD

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We would like to respond to the letter entitled "Nano-Surface Implants: Indications and Limitations,"[1] which was recently accepted in *Aesthetic Surgery Journal*. We also would like to congratulate Dr Montemurro and Dr Tay on their recently published paper "Transitioning from Conventional Textured to Nanotextured Breast Implants: Our Early Experience and Modifications for Optimal Breast Augmentation Outcomes,"[2] which retrospectively describes Dr Montemurro's own experience with different implant brands and aims to compare early complications in 2 primary augmentation groups: 161 patients with Motiva SilkSurface implants (Round and Ergonomix) vs 254 patients with a mixture of different textured implants.

Nevertheless, it was with great surprise that we read this letter, which may mislead readers about the conclusions of this retrospective experience at a time when the options for textured devices are become scarcer every day, and as a result, surgeons around the world are seeking education on the use of smooth devices as a priority.

The original paper from Montemurro and Tay describes complication rates (at 1 year) of 3.5% for smooth nanosurface (SilkSurface) and 0.8% for the "conventional textures" group. It also states that the overall complication rate was 8.7% (at 24 months) for the smooth nanosurface group and 3.5% (at 28 months) for the "conventional textures" group. The authors note that the complication rate within the smooth nanosurface group significantly declined over time.

Unfortunately, the data presented by Montemurro and Tay relate to early complications in "comparable" groups at 1 year but then they also introduce a second time point to measure the "overall" complication rates, extending the follow-up period to an average of 26.9 months for the same population. This may confuse readers between

Dr Sforza is head of the elective internship in plastic surgery, Dolan Park Hospital, Bromsgrove, UK; and examiner of the Royal College of Surgeons (RCSEd). Dr Giovanni Botti is a plastic surgeon in private practice in Salo, Italy. Dr Hedén is an associate professor, Akademikliniken, Stockholm, Sweden. Dr Zacheddu is a consultant surgeon, Dolan Park Hospital, Bromsgrove, UK. Dr Munhoz is the chief of the department of plastic surgery, Division of Breast Reconstruction, Cancer Institute of São Paulo, Faculdade de Medicina da Universidade de São Paulo, São Paulo, Brazil. Dr Mayo is a plastic surgeon in private practice in Madrid, Spain. Dr Kinney is a professor, Division of Plastic Surgery, Keck School of Medicine, University of Southern California, Beverly Hills, CA, USA. Dr Hammond is an associate program director, Plastic and Reconstructive Surgery Spectrum Health/Michigan State University Plastic Surgery Integrated Residency Partners in Plastic Surgery, Grand Rapids, MI, USA. Dr Corduff is a plastic surgeon in private practice in Geelong, Australia. Dr Morelli is a plastic surgeon in private practice in Bogotá, Colombia. Dr Stavrou is an assistant professor at the St George's University of London, London, UK. Dr Centeno is a plastic surgeon in private practice in Valencia, Spain.

Corresponding Author:
Dr Marcos Sforza, Dolan Park Hospital, Stoney Lane, Bromsgrove B60 1LY, UK.
E-mail: marcos@marcossforza.com

Table 1. New Complications Table According to the 1-Year Follow-Up and Groups Originally Described and Excluding Technical Related Complications

Overall complications	Conventional textures group	SilkSurface group
Capsular contracture		
0-12 months	0	0
12-26.9 months	4	2
Seroma		
0-12 months	1	0
12-26.9 months	1	0
Implant rotation		
0-12 months	1	0
12-26.9 months	2	0
Total (%)	9/254 (3.54%)	2/161 (1.24%)

device-related complications and technique-related complications, and the purpose of this letter is to provide clarity.

If we segment the data according to the two main safety endpoints established for FDA breast studies, namely capsular contracture and rupture, it becomes clear that the group with conventional textures has double the complications related to capsular contracture at 26 months with no implant ruptures for either group. Furthermore, no seromas or implant rotations were observed in the group with smooth nanosurface at 26 months. The final result of device-related complications is 3.54% for the conventional texture group and 1.24% for the smooth nanosurface group, which tells a completely different story: the aforementioned "statistically significant increase" in complications disappears across the study (Table 1).

We identified other deficiencies among the methods and concepts. For instance, matching a group that received exclusively round and ergonomic SilkSurface implants with a heterogeneous group comprising round and shaped implants produced by a different manufacturing process (salt-loss textured, microtextured implants), resulting in dissimilar roughness, cannot, in our opinion, be considered a correct controlled observational exercise.

If we now turn our attention to the other complications, we understand that 100% of the reported adverse outcomes with SilkSurface implants at 1 year consist of technical mistakes such as displacements and "bottoming-outs," rather than direct device-related complications. A learning curve determined by technical inexperience comprised more than half the total complications of implant displacement that were reported in the early period of usage.

It is acknowledged that implant displacement and bottoming-out could be related to the positive phenomenon of low tissue reactivity on smooth nanosurface implants, but we have also seen this with different types of smooth and textured implants. However, if we take into consideration that this complication can be significantly minimized and even eliminated with specific surgical techniques and postoperative care management, in our experience, it is reasonable to characterize them as technically dependent.

The reported high complication rate described for the initial learning curve period in Dr Montemurro's paper should come as no surprise as the description of the technique, although brief, clearly states that the author used the same surgical technique with different implants and different surfaces. The fact that the author did not adapt his technique to a new device with which he had no experience clearly increased the learning curve and resulted in a larger number of complications at the beginning. However, the surgeon's good skills permitted a technical correction that generated fewer complications over time.

The same issue was also reported by Huemer et al,[3] who declared 4 malpositions in their first 6 months of usage and none in the next 2.5 years with more than 200 implants used. It is important to clarify that the senior author had exclusively used textured devices for many years and had no experience with smooth devices. More recently, D'Onofrio[4] reported 100 breast augmentations with smooth nanosurface implants over 18 months and no malposition complications when employing a technique specific to these implants.

We do appreciate the honesty showed by Montemurro et al in clarifying that the majority of their reported complications were indeed related to their learning curve, and we definitely believe that this early experience is probably linked to an educational gap rather than poor decision-making in creating the surgical pocket with a "macrotextured" mindset.[5]

Therefore, stating that these smooth nanosurface implants, or any smooth devices for that matter, are associated with a higher number of complications is an inappropriate conclusion that does not derive from the premises of their data and constitutes an invalid interpretation of their observational study. It is a general consensus that displacements with smooth implants are more likely to occur in women with thin subcutaneous tissue, lax dermal elements, and intramammary fold disruption, for example,[6,7] but can be treated successfully by technical adjustments. Sforza et al, in an expert consensus,[8] published guidelines to facilitate the learning curve and prevent these complications.

The real question here for the readers is a straightforward one: at a time of concern about the safety of textured breast implants, can plastic surgeons trust this innovative smooth surface for most of their patients? We believe the answer is a confirmable yes—for safety and aesthetic reasons. We have been educating surgeons worldwide

on a successful transition from macrotextured implants to smooth nanosurface implants. Anecdotally, when we add the data for all the authors of this letter, we can offer 9 years of experience with smooth nanosurfaces, during which time we have used over 11,000 implants and altogether have seen only 9 cases of capsular contraction in primary cases and 17 in secondary cases. We have experienced 62 cases of displacement, and all the authors declare that after their own learning curve, they have not seen displacements after 18 months, including bottoming-out of implants. Altogether we have reported 3 cases of rupture implant. These real-world numbers are highly comparable to the published scientific data, confirming a complication rate of <1%.[9]

Finally, it is essential to confirm that we have all used these devices not only in primary cases but in secondary, revision, and complex cases, including breast implant replacements with Baker 3 and 4 capsular contraction and mastopexies. The difference is a simple one: we have all adapted our technique to this type of surface, and because we have done so, we are successfully placing these implants in the large majority of our patients, often to solve complications created by conventional textured and polyurethane-coated implants.

Hence, the statements from Dr Hamdi could possibly mislead a surgeon who is seeking alternatives to textured implants to think smooth devices may have higher absolute complication rates, which is evidently debatable in the literature.[10] It has been 10 years since smooth nanosurface implants were brought to market, and more than 1 million devices have been implanted with impressive safety and aesthetic outcomes. There is a wealth of scientific evidence that explains why there is an improvement in device-related complications.[3,4,8,9,11-21] These devices are now under clinical investigation in an FDA trial, whereas no new textured or polyurethane implants are undergoing such rigorous scrutiny.

We thank Dr Hamdi because his letter inspired us to review our data, prepare a manuscript, and submit to this prestigious journal to mitigate doubts about the usage of smooth devices and to encourage plastic surgeons to learn new techniques as means of promoting safety and trust in breast aesthetics and reconstruction devices.

Disclosures

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