Motiva®

Motiva Implants® Literary Shelf

50 ARTICLES

5
years

100+
Authors

Sponsored collaborations established with

- MIT, Massachusetts, USA
- Medical University of Innsbruck, Austria
- Center for Biofilm Engineering, Montana, USA
- MacQuarie University, Sidney, Australia
- University of Manchester, UK

Investigator initiated studies from

- Fleury Imaging Center, Sao Paulo, Brazil
- Akademikliniken, Stockholm, Sweden
- University of Minnesota Medical School, MN, USA
- University Hospital Ghent, Belgium

This collection of articles summarizes and evaluates key aspects of the performance and safety profile of Motiva Implants® published during the last five years.

Since the first calls made to the scientific community in 2016-2017[1,2] by surgeons with scientific vocation and with an enormous trajectory, foreshadowing the advent of a device with differentiated characteristics, more than a hundred authors, independent contributors, researchers from prestigious academic centers, MotivaEDGE® educators, and even first time users have been building the trust and confidence that supports the solid growth of Motiva® in the global marketplace, with high-quality evidence through a diverse repertoire of experiences showcased in some of the most trusted journals of plastic surgery, bioengineering and radiology.

In figure 1, we can see the constant growth that the literary shelf of publications that have analyzed crucial aspects of Motiva Implants® has experienced.

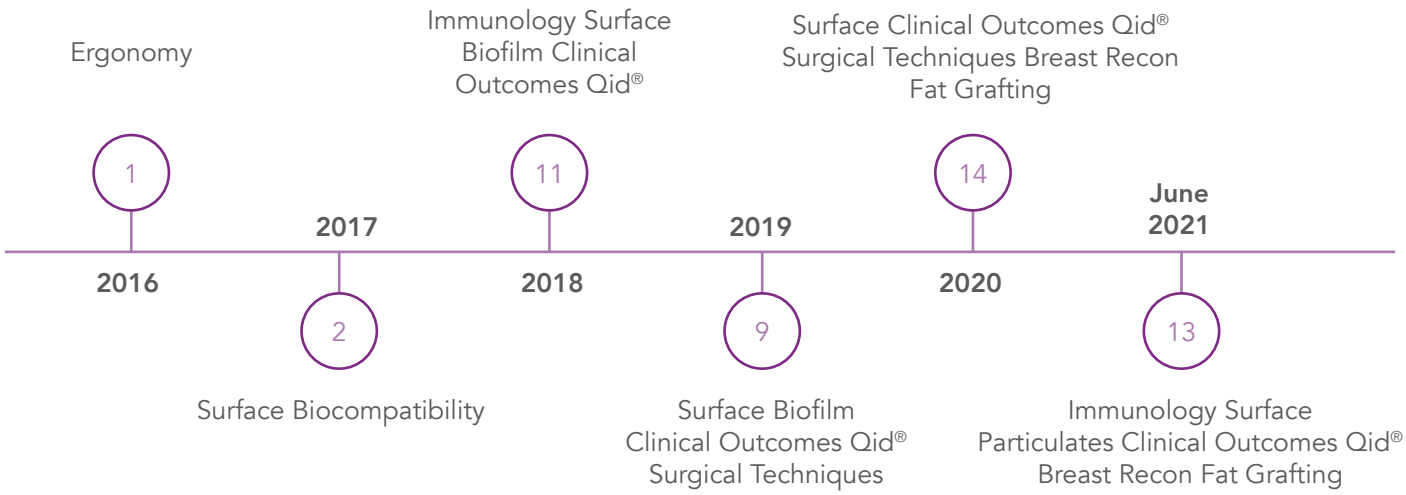


Figure 1. Number of publications over time and topics covered

A NEW PARADIGM OF INTERACTION BETWEEN THE IMMUNE SYSTEM AND THE BREAST IMPLANT

The traditional vision based on the duality – smooth surface and textured surface – has been disarticulated, and the claims of superiority of one over the other have become obsolete as research focused on key drivers of the early reaction of the organism make evident the relevance of multiple factors that impact the response to a foreign body on a chemical and physical level[3].

The biocompatibility of the device with its surrounding environment is a multifactorial phenomenon. One of the essential components is the cellular activity induced by the architecture of the surface.

Barr and Bayat noticed it since the early 2000s. Improving the biocompatibility of implantable materials is possible with surfaces that contain key cues at the cellular level that will influence the inflammatory and fibrotic process. Those findings can be correlated with the physical-chemical characteristics of the implants[4,5].

It is also possible to measure the influence exerted by the surface on the immune system. Cappellano carried out one of the first in vitro studies that proved a downregulation of specific pro-fibrotic and pro-inflammatory markers with SmoothSilk®[6]. Capsule thickness is also connected with specific fibrosis markers showing significant reduction[7].

Other researchers, while comparing the host response to different commercially available devices by characterizing the force required to break the tissue-implant interface, confirmed from another angle an edge that would eventually have a crucial clinical significance: The area of the surface and the absence of pores hinder the growth and adherence of capsular tissue on the surface[8].

THE STUDY OF SEVERE COMPLICATIONS ASSOCIATED WITH CHRONIC INFLAMMATION

Since the beginning of the century, the occurrence of phenomena such as double capsules and late seroma would herald the configuration of a cycle that has centralized discussion and debate in the community around a new clinical dimension: the advent of the inflammatory process that persists.

Implants with intermediate to high roughness surfaces have also been associated with a lymphocytic and potentially malignant proliferation due to multiple factors:

The coexistence of a bacterial plaque

High surface areas and roughness correlate with a greater risk of bacterial growth and association with this entity[9]. SmoothSilk® has a controlled and consistent low roughness surface[10], on the other hand, promotes significantly less bacterial growth when studied in vitro compared to micro and macro textured surfaces[11]. SmoothSilk® also remains with lower bacterial counts at different timepoints[12].

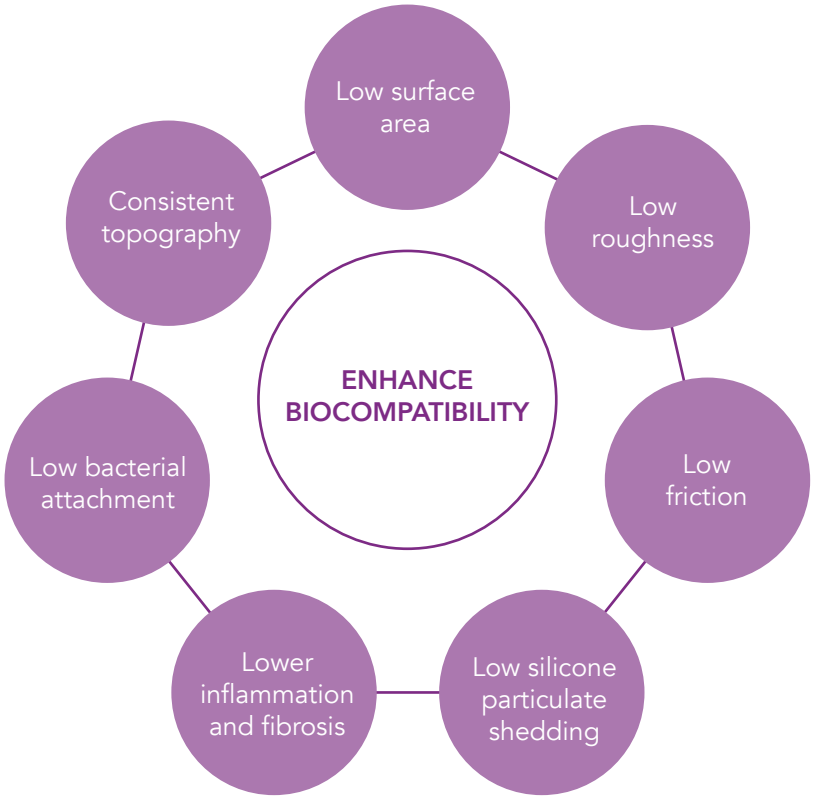
The detachment of particles of silicone from the surface

Surface topography and erosion quotient could perpetuate a stress response in the immune system, potentially leading to fatigue and cell damage[13]. The studies proposed by Hallab, Samelko and Hammond[14,15] studied the quantity and unique traits of the particles detached from different commercially available breast implant surfaces. During their experiments, they could objectively determine that the number of silicone particles that detaches from SmoothSilk® is below the limits of detection[15].

Genetic susceptibility

Individual genetics predispose long-term responsiveness. However, it is striking that when analyzing the cell populations of healthy capsules related to certain surfaces (macro-textures made with salt-loss), the expression of genes is similar to that of capsules with BIA-ALCL exposed to the same type of surface[16].

The balance in the expression of pro-inflammatory and anti-inflammatory gene clusters also seems to be directed to respond in a individual manner to the type of breast implant placed.



FROM BENCH TO BEDSIDE

Research that transforms scientific discoveries from laboratory and pre-clinical studies into new tools improves women's health by reducing drawbacks from old technologies.

Study	Post-op mean follow-up (years)	Number of cases	Bottoming out	Hypermobility	Flipping	Capsular Contracture	Seroma	Infection	Hematoma	Rupture
Sforza M et al.	2	2502	N/A	N/A	N/A	0	1	1	0	0
Chacón M et al.	6	35	0	0	0	0	0	0	0	0
Huemer G et al.	1 (n=71)	100	2	2	0	1	0	0	1	1
Sim HB	1	76	0	0	0	0	0	0	0	0
Stillaert F et al.	2	33	0	0	0	0	0	2	0	0
Rigo M et al.	1	387	2	1	1	1	0	0	0	0
Yoon S & Chang JH	1	152	3	0	0	2	1	1	0	0
Montemurro P & Kay VTS	2	161	12	0	0	2	0	0	0	0
Maximiliano J et al.	1.5	30	0	0	0	0	0	0	0	0
Munhoz AM et al.	1.5	42	0	0	0	1	0	0	0	0
Hong P et al.	1.5	87	0	0	0	18	24	6	18	0
Moon DS et al.	0.33	76	0	1	0	0	4	0	1	0
Zeplin PH	1	252	0	0	0	0	1	0	0	0
Lam MC et al.	2	103	1	0	0	2	1	1	1	0

* SmoothSilk cases

A series of individual and collective experiences[17–30] have been published in plastic surgery journals with the most significant impact in recent years, linking the science behind the implant with pleasing outcomes. Of special note is that 10 of these 14 articles are completely independent.

In general, although the differences in methodology and follow-up make it challenging to combine the results, surgeons obtain robust data[31] that consistently demonstrate low rates of device-associated complications, as can be seen in Table 1.

A closer analysis will also uncover the high educational value that some of these articles carry, for example the optimal thought process when planning the surgery[32], the precise and careful execution aimed at creating a narrow surgical pocket[26,28,33], the adaptations that allow improvement of the surgical procedure and implant support[30,34], or combining advanced techniques, such as the calculated use of fat to sculpt accurate results[29,35].

Our literary shelf outlines the continuous learning of the active surgeon.

OPENING SPACES FOR NEW DISRUPTIONS

Innovation accompanied by a relentless desire to overcome the status quo and improve the experiences of all kinds of patients[36] and surgeons alike was always at the core of our vision.

After a decade of consistently reforming our industry and imposing new safety standards in cosmetic breast surgery, today, we focus our efforts on reconstructive breast surgery.

Relevant members of the surgical community have shined the spotlight on the Ergonomix® family of implants, precisely on the benefits they can add to reconstructive surgery targeted to achieve a natural looking result[25]. A challenge to the form-stable highly cohesive alternative is being led by the behavior of our gels and the dynamic adaptation[33,37] of our implants.

The unique and carefully designed properties of Motiva Implants® have enabled surgeons to find new ways to achieve the full potential of their technical skills. One of these changes is moving forward to pre-pectoral placement, leaving behind the drawbacks of the submuscular plane.

In the hands of surgeons like Dr. Scheflan and others, the Ergonomix® implants have demonstrated to be suitable for planes that are more aesthetically pleasing, more comfortable and feel more natural to patients[25,38,39].

The adding of a first-of-its-kind tissue expander to the current two-stage breast reconstruction portfolio is another example that reflects our effort to combine novel technology with some of the legacy features that have brought great success to the Motiva® breast implants. Its magnet-free infusion port does not generate the distortion expected in MRI with the other expanders, making it even the first device of its kind to be labeled as MR Conditional[40].

GOING THAT EXTRA MILE FOR SAFETY

At Establishment Labs®, we are transparently[41] and proactively looking for solutions to improve the safety and satisfaction of the procedures performed with our products[42]. This search made us turn our attention to the issue of fast, easy, and long-term implant authentication.

The Qid®, a Radiofrequency Identification Device (RFID) technology, is a modern device unique in its category, that allows quick identification of our implants at any time with a non-invasive, inexpensive, and time-saving procedure, thus achieving a level of traceability incomparable with formerly used methods.

Innovation brings questions, and these have been studied to provide useful insights to attend the challenges associated to the RFID technology in medical imaging[44–50].

With ongoing prospective trials and new technologies in the fields of reconstructive and minimally invasive breast surgery, Establishment Labs® opens the door for a new era of revolution. Our continuous support to surgeons and researchers to publish these experiences is key to divulgate new knowledge.

Questions? Comments? do not hesitate to contact us at

medicalaffairs@establishmentlabs.com

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