

Usefulness of Radio Frequency Identification Device in Diagnosing Rotation of Motiva SmoothSilk Implants after Augmentation Mammoplasty

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Summary: Breast implant displacement has been described as a significant risk following augmentation mammoplasty. Magnetic resonance imaging (MRI) is considered the method of choice for diagnosing implant complications, but it has its limits in assessing correct implant position and displacement. Motiva SmoothSilk/SilkSurface® Implants (MSS) are the first to incorporate a radio frequency identification device (RFID), which produces an imaging artifact in MRI sequences. Given the frequency of breast augmentation procedures and the recent US Food and Drug Administration prospective trial involving SS with RFID, further analysis of implant stability and diagnostic imaging methods to evaluate implant positioning is necessary. The objective of this study was to assess the use of MRI with this new RFID-containing implant as a new tool to assess correct implant positioning. The authors performed this technique in 5 patients (10 implants) undergoing primary breast augmentation or revision surgery with MSS implants (255–385 cc, mean = 325 cc). The average area and volume of the artifact were 15.7 cm² and 31.75 cm³, respectively. All cases presented satisfactory results, with 1 case of implant displacement. Our clinical and radiological outcome demonstrated that RFID technology is a useful tool for correct visualization of the implant position and diagnosis of complications such as slight displacements or rotation. To our knowledge, this is the first RFID breast implant that has been objectively evaluated for MRI issues. (*Plast Reconstr Surg Glob Open* 2019;7:e2497; doi: [10.1097/GOX.0000000000002497](https://doi.org/10.1097/GOX.0000000000002497); Published online 28 November 2019.)

INTRODUCTION

Breast augmentation remains the most common aesthetic surgery procedure worldwide.^{1,2} Despite satisfactory outcomes, implant displacement and implant rotation are significant risks.³ Although these complications are more frequently observed in shaped implants (with incidence as high as 14%⁴), upside-down rotation of round implants has been reported in some cases.^{5,6} Although implant rotation is clinically diagnosed by asymmetry or deviation from breast shape (self-described by the patient or detected by

surgeon), round implant displacement is more difficult to recognize clinically, especially in patients with adequate soft tissue coverage. Furthermore, no breast implants currently on the market feature a specific radiopaque marker that can be easily and precisely recognized by imaging techniques.

Motiva SmoothSilk (MSS) implants (Establishment Labs Holdings, Alajuela, Costa Rica) were introduced in 2011 and are the first generation to incorporate a radio frequency identification device (RFID). Like any metallic foreign body, this device is composed of an integrated circuit and ferrite core and usually produces an imaging void artifact during magnetic resonance imaging (MRI) sequences, permitting precise identification of the position of round or shaped implants through simple noncontrast MRI examinations.^{7–11}

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Given the frequency of breast augmentation procedures^{1,2} and the recent US Food and Drug Administration prospective trial involving SS with RFID,¹² further analysis of implant stability and diagnostic imaging methods to evaluate implant positioning is necessary. This paper describes this simple and new tool which uses RFID to identify proper implant position in the pocket as well as to diagnose rotation and even minimal displacement.

MATERIALS AND METHODS

A single-center study of breast augmentation with SS implants was performed. All cases were assessed at a single outpatient facility by 2 surgeons (AMM and AMF). The local institutional review board approved retrospective review of these patients' clinical records, and patients signed an informed procedural consent form explaining the objective of the radiological procedure.

Radio Frequency Identification Device-Motiva (RFID-M) Technology

MSS implants feature the "Q Inside Safety Technology," an RFID measuring 2.1 mm × 9 mm (JAMM Technologies, Minneapolis Minnesota, USA). The RFID contains a specific integrated circuit and ferrite core/copper antenna and is enclosed in a sealed biocompatible glass tube. This tube is located on the posterior inner surface of the implant and produces an imaging void artifact during MRI sequences (See Video [online], which displays Motiva SmoothSilk Implant with RFID-M System).

MRI

Imaging Protocol

Noncontrast MRI was performed with the patient lying prone, using a 1.5-T MRI unit (Optima MR450w GE Medical Systems, Milwaukee, Wisconsin) with a dedicated 8-channel breast coil. The protocol consisted of a sagittal/axial T2-weighted fat-suppressed fast spin-echo sequence (repetition time: 3,860–3,374 ms; field of view: 21–32 cm; matrix size: 288 × 256; section thickness: 3.0 mm with 0.3 mm of gap).

MRI Analysis

The examinations were reviewed in a dedicated workstation (Advantage Workstation GE 4.1-4.2) by 3 breast imaging radiologists (with at least 7 years of experience), independently and by consensus. The MRIs were analyzed for safety, implant integrity, and position (subglandular, submuscular, or subfascial), displacement/rotation (0°, <45°, 45–90°, 90–180°), dimensions of artifact [area (L × anterior-posterior [AP]) and volume (L × T × AP × 0.5)], and its relation with the area and volume of implant. To analyze the adequate position of the implant, the following points of reference were standardized: medium sternal line (MSL); left medium breast line (LMBL) and right medium breast line (RMBL); left elastomer line (LPE) and right elastomer line (RPE). To identify changes in position and symmetry of the implant within the pocket, the following measures were used: distance between MSL and medium breast line (MBL; right and

left) (D-MBL-MSL); distance between the artifact and lateral elastomer (D-ALE) and distance between the artifact and medial elastomer (D-AME) (see figure, Supplemental Digital Content 1, which displays Axial T1 image of the breasts from an MRI with the main parameters such as MSL, LMBL, RMBL, LPE, RPE, D-MBL-MSL, D-ALE, D-AME, and D-AAE, <http://links.lww.com/PRSGO/B249>) (see figure, Supplemental Digital Content 2, which displays sagittal T1 image of the breasts from an MRI with the main parameters such as MSL, LMBL, RMBL, LPE, RPE, D-MBL-MSL, D-ALE, D-AME, and D-AAE, <http://links.lww.com/PRSGO/B250>).

RESULTS

The authors performed MRIs as described earlier on 5 patients (10 implants), with implants ranging from 255 to 355 cc (mean = 295 cc). All were smooth, Ergonomix® style (ProgressiveGel®, Motiva, Coyol, Alajuela, Costa Rica), which presents low viscosity with great increase of its elasticity for a very natural soft feeling. This gel (Nusil, Santa Barbara, CA) due to the high elasticity and elevated point of plasticity is designed to shift the maximum point of projection to the lower pole when the patient is standing (Figs. 1 and 2). In all cases but 1, the artifact was located entirely inside the silicone gel and the thoracic wall. The average area and volume of the artifact was 15.7 cm² and 31.75 cm³, respectively (Table 1). All implants properly positioned in the pocket demonstrated similar measurements between the left and right sides and between the lateral and medial distances in the same implant. In this group, the MBL was concordant with the posterior area of the nipple areola complex (NAC), demonstrating alignment of the implant with the central region of the breast. As of this writing, no complications have been observed, except 1 case of implant displacement in a postbariatric patient who underwent a secondary breast augmentation. In this case, the medial and lateral distances were significantly different and there was no concordance of MBL with the central region of the NAC (Fig. 2).

DISCUSSION

Breast implant malposition is one known complication following augmentation mammoplasty and may be secondary to the type of implant surface, individual patient anatomy, or overdissection of the pocket.^{3,4} Other aspects contributing to implant displacement include capsular fluid, double capsule, and breast massage.^{3,14}

MRI can be used to identify silicone implant complications and may be considered the method of choice for folds, capsular contracture, and rupture due to its high specificity and sensibility.¹³ However, this method is less adequate for assessing minor displacement of shaped implants or even rotation of round implants. Although studies have shown that MRI can be safely performed on patients with implants containing RFID,¹¹ as of this writing no research has focused on the potential of RFID artifacts to identify the precise location of implants. And although breast MRI for implant screening has been previously studied,¹³ a search of the medical literature does not yield any data on image quality in breasts with RFID implants.

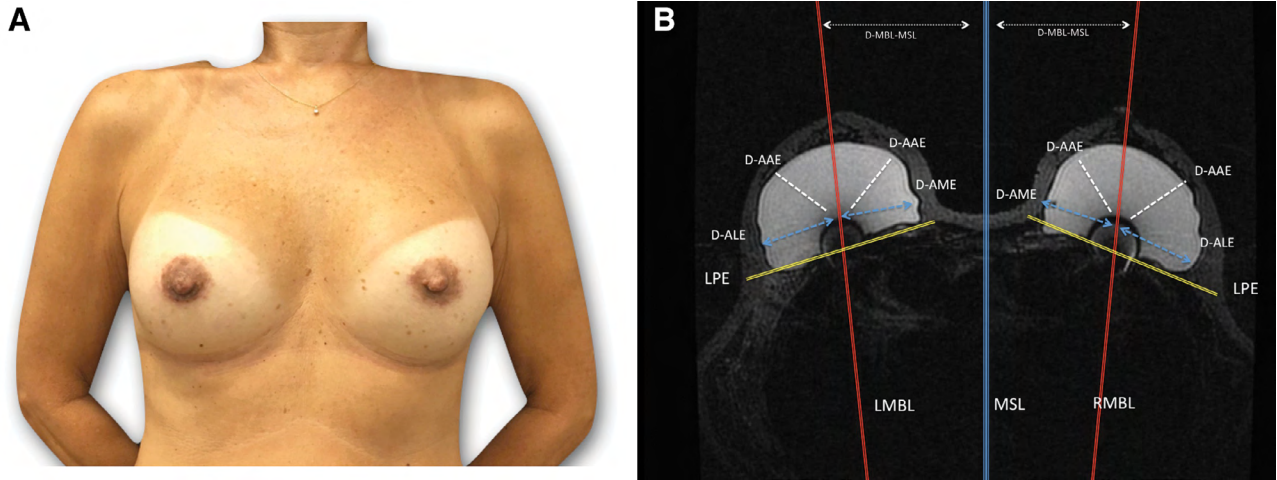


Fig. 1. Clinical example of a 49-year-old female patient who underwent to a secondary breast augmentation using the periareolar approach and 275 cc MSS. A, Two years postoperative of secondary breast augmentation with 275 cc SS Motiva Surface. B, Axial T1 image of the breasts from an MRI in the same patient with a clinically well-positioned breast implant.

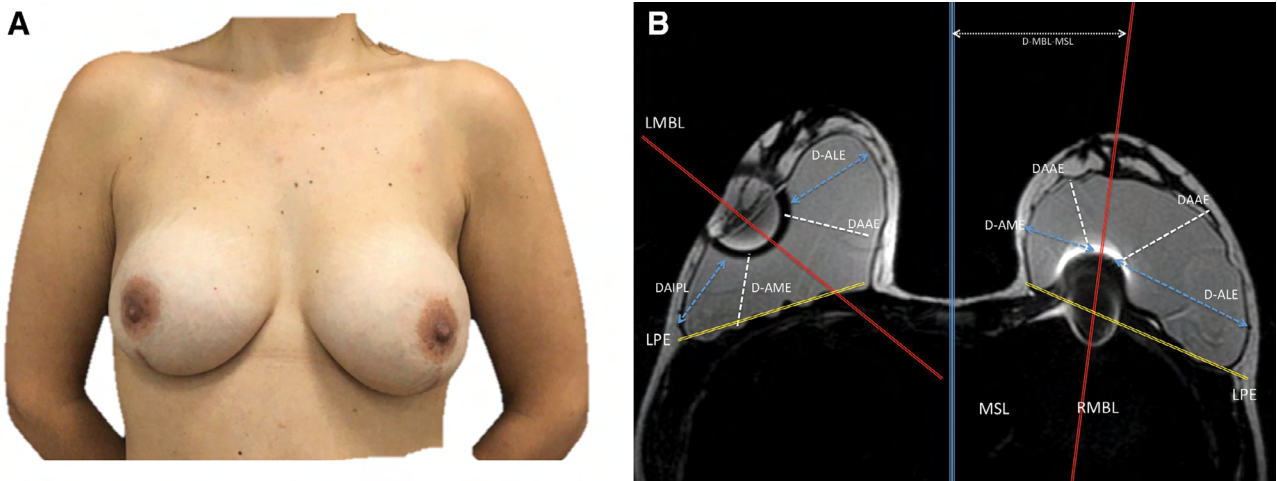


Fig. 2. Clinical example of a 35-year-old female patient who underwent to a secondary breast augmentation using the vertical and inframammary approach and 315 cc MSS. A, One year postoperative of primary breast augmentation with 315 cc SS Motiva Surface. B, Axial T1 image of the breasts demonstrating a partial rotation of the right implant and medial displacement of the left breast implant.

Table 1. Artifact Dimensions, Area, Volume Calculations of the Motiva SS Ergonomix Implants

Artifact Characteristics	Average (Min–Max)
Area (cm ²)	15.75 (11.6–26.8)
Volume (cm ³)	31.75 (19.1–50.2)
Percentage of artifact area size of implant area size	26.5 (25–29.1)
Percentage of artifact volume size of implant area size	11.4 (6.8–21.8)

Max, maximum; min, minimum.

The SS implants feature an RFID device located on the posterior inner surface of the implant. This micro-transponder is a passive device containing an electronic serial number that can be read by a handheld reader tuned to the same frequency.¹¹ This technology was originally introduced to track large animals, but now is mainly utilized

for medical product traceability.¹¹ After the Poly Implant Prothèse scandal and, more recently, anaplastic large-cell lymphoma (ALCL) in association with different implant types and surfaces, this new technology has been introduced for more precise tracking of silicone implants in response to concerns among regulatory authorities, manufacturers, plastic surgeons, and patients.¹¹ In addition to traceability information, there is currently RFID with localization sensors that will be useful for tissue expanders and making MRI safer in patients undergoing breast reconstruction with no magnetic ports. Future research shows the possibility of temperature, pressure, and chemical analysis sensors as additional information for the RFID system.

In our study of breast MRI, the most common artifact was the single void observed in all sequences. This appears as a region of signal void with neighboring increased signal that is larger than the RFID itself and has been described

as “black hole artifact.” The RFID device allows surgeons to accurately identify the implant’s position in the pocket and consequently diagnose slight implant displacement or even total rotation. The clear identification of the artifact in the central and posterior regions of the implant allows the measurement of distances from this region to the lateral and medial ends of the implant (D-MBL-MSL, D-ALE, and D-AME). In addition, it is possible to visualize the alignment of the central region with the NAC, allowing the correct diagnosis of small displacements or even rotations of the implant.

Despite the clear benefits in terms of traceability, the RFID system is a metallic foreign body constituted by an integrated circuit and a ferrite core and usually produces an artifact during MRI sequences.¹¹ As observed in any implanted metallic device, these artifacts are secondary to local magnetic field changes that are created by the ferromagnetic aspects of the implant and can potentially prejudice the quality of the magnetic resonance images.¹⁵ Up to now, no prospective data are available that evaluate the impact of silicone implants with RFID-M technology and artifacts in MRI during the follow-up of aesthetic and breast cancer patients. Although beyond the scope of this study, at the present moment, we are finalizing a prospective controlled study in which we will approach this subject, in terms of reduction in the quality of the MRI images or even impediment in the evaluation of the breast tissue due to the presence of the artifact. Thus, a full report is expected but these early results are promising.

Up to this point, our clinical and radiological impression is that the RFID permits more precise and objective analysis of breast augmentation/revision and could be a useful tool for correct visualization of the implant’s position and diagnosis of possible complications such as slight displacements or cases of rotation, but further controlled studies are required to corroborate this effect and assess artifact interference in the breast tissue images.

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REFERENCES

1. American Society of Plastic Surgeons (ASPS). 2017 Plastic Surgery Statistics Report. Available at <https://www.plasticsurgery.org/documents/News/Statistics/2017/plastic-surgery-statistics-report-2017.pdf>. Accessed November 9, 2018.
2. International Society of Plastic and Regenerative Surgeons (ISPRES). Available at <https://www.isaps.org/blog/isaps-statistics>.
3. Khan UD. Back-to-front flipping of implants following augmentation mammoplasty and the role of physical characteristics in a round cohesive gel silicone breast implant: retrospective analysis of 3458 breast implants by a single surgeon. *Aesthetic Plast Surg*. 2011;35:125–128.
4. Baeke JL. Breast deformity caused by anatomical or teardrop implant rotation. *Plast Reconstr Surg*. 2002;109:2555–2564; discussion 2568.
5. Irkoren S, Sivrioglu N. Can excessive breastfeeding be the cause for the upside-down rotation of a breast implant? A case report. *Breastfeed Med*. 2013;8:515–516.
6. Lee WS, Kang SG. Upside-down rotation of a breast implant with double capsule formation after aesthetic breast augmentation: a case report. *Arch Aesthetic Plast Surg* 2018;24:75–77.
7. Munhoz AM, Santanelli di Pompeo F, De Mezerville R. Nanotechnology, nanosurfaces and silicone gel breast implants: current aspects. *Case Reports Plast Surg Hand Surg*. 2017;4:99–113.
8. Sforza M, Zaccheddu R, Alleruzzo A, et al. Preliminary 3-year evaluation of experience with Silksurface and Velvetsurface motiva silicone breast implants: a single-center experience with 5813 consecutive breast augmentation cases. *Aesthet Surg J*. 2018;38(suppl_2):S62–S73.
9. Quirós MC, Bolaños MC, Fassero JJ. Six-year prospective outcomes of primary breast augmentation with nano surface implants. *Aesthet Surg J*. 2018;39:495–508.
10. Sforza M, Hammond DC, Botti G, et al. Expert consensus on the use of a new bioengineered, cell-friendly, smooth surface breast implant. *Aesthet Surg J*. 2019;39(Supplement_3):S95–S102.
11. Nelson MT, Brattain KA, Williams JM. Does electronic identification enablement for silicone gel implants impact patient safety? *J Surg Open Access* 2018;4:1–6.
12. Study of the safety and effectiveness of the Motiva implants silicone gel-filled breast implants SmoothSilk/SilkSurface in subjects who are undergoing primary breast augmentation, primary breast reconstruction, and revision surgery. Available at <https://clinicaltrials.gov/ct2/show/NCT03579901>. Accessed May, 2019.
13. Berg WA, Caskey CI, Hamper UM, et al. Diagnosing breast implant rupture with MR imaging, US, and mammography. *Radiographics*. 1993;13:1323–1336.
14. Munhoz AM, Gemperli R, Sampaio Goes JC. Transaxillary sub-fascial augmentation mammoplasty with anatomic form-stable silicone implants. *Clin Plast Surg*. 2015;42:565–584.
15. Jones RW, Witte RJ. Signal intensity artifacts in clinical MR imaging. *Radiographics*. 2000;20:893–901.