

Editorial Manager(tm) for Plastic and Reconstructive Surgery
Manuscript Draft

Manuscript Number:

Title: Should the Style 410 be called a form stable breast implant?

Article Type: Reply: Letter to the Editor

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Should the Style 410 be called a form stable breast implant?

Sir:

We enjoyed reading the letter written by Dr Tebbetts regarding our article (1) and are pleased with the opportunity given by the Editor to respond to this letter. Dr Tebbetts deals with an important issue in plastic surgery, namely the term *form stable* with respect to breast implants. This term has been circulating in plastic surgery articles for almost a decade, including several interesting articles written by Dr Tebbetts (2, 3). Although one might intuitively have an opinion on what the term implies, until 2007 when the Style 410 U.S. Core Clinical Study Group published their article by Bengtson et al. in the *Journal* (4), there were to our knowledge no scientific papers that provided a definition of form stability related to breast implants. The study group defined form stability as the maintenance of implant dimensions and form in any position.

We would like to quote Dr Tebbetts from an earlier letter to the Editor (5). Here he states that "if we are scientific, we must insist that conclusions and statements in peer-reviewed articles and presentations must be based on data". We could not find any data that supported the definition given by Bengtson et al. The results from our study clearly showed that there is a marked increase in implant projection when the body position is changed from supine to prone. Support for these findings are given in the elegant pilot study by Dr Hammond in his discussion of our article (6).

Dr Tebbetts criticizes the use of magnetic resonance imaging (MRI) in our study. MRI is an established imaging method giving excellent visualization of breast implants and body tissue, and its use is well documented in the literature. It is interesting that the implant dimensions as provided by the manufacturer are almost identical to those obtained from the MRI examinations in the supine position. This provides an indication of the accuracy of the measurements based on the MRI images. The measurements made in the prone position were completely different.

We explain this as a result of the implant's plasticity that allows significant changes in dimensions as a response to gravity and changes in the surrounding soft tissues. From a clinical point of view, such plasticity could in fact be considered as an advantage. In the prone position a normal breast would also show an increase in projection when compared to the supine position. An augmented breast with the Style 410 breast implant appears to behave in a natural way.

It is the opinion of Dr Tebbetts that the MRI examinations show "what any surgeon who has ever held a 410 in hand should be able to see with the naked eye" and that the patients were unnecessarily examined with MRI. However, it has little clinical value to know how the implant behaves in your hand without knowing how it behaves after implantation. Of course everyone is entitled to have an opinion. We are, however, surprised that Dr Tebbetts came up with such a statement. In a former letter to the Editor, he writes that "opinions are interesting, and we all have them, but "conclusions" based on opinions instead of data are also just opinions, not scientifically valid conclusions" (5).

It is interesting that the term form stable implant has been used during a long period without knowledge on how the implant behaves after implantation. As we see from our results, the implant is not form stable in respect to maintaining its dimensions in all positions. It has never been our intention to provide a scientific definition of the term form stable. Given the results from our study, we do not feel that there is a need to come up with a more accurate definition. We feel that the use of the term form stable as related to the Style 410 should be avoided as it may cause confusion.

One of the characteristics of the Style 410 breast implant is lower pole fullness which gives the implant its anatomical shape. We see from our study that the lower pole fullness is maintained in both the supine and prone positions. In addition the pilot study by Dr Hammond shows that lower pole fullness is maintained also in the upright position. In that respect, it is perhaps enough to say that the Style 410 is an

anatomically shaped breast implant that keeps its lower pole fullness in at least three body positions; the supine, the prone and the upright.

We see no reason to comment on the statements made by Dr Tebbetts regarding the motives, rhetorics and marketing policies of manufacturer of the Style 410 implant.

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