Measurement of Breast Prosthesis Contour Irregularities

P. T. Weatherall[1], Y. Ding[2], A. L. DeFatta[3], Q. Peng[4], and W. Adams[5,6]

[1]Radiology, Univ Texas Southwestern Medical Center, Dallas, Texas, United States, [2]Radiology, Univ Texas Southwestern Medical Center, [3]Radiology, Univ Texas Southwestern Medical Center, Dallas, Texas, [4]Radiology, Univ Texas Health Center San Antonio, San Antonio, Texas, United States, [5]Plastic Surgery, Univ Texas Southwestern Medical Center, Dallas, Texas, United States, [6]Dallas Plastic and Cosmetic Surgery

Introduction

Millions of women have undergone silicone breast augmentation or reconstruction worldwide. Many studies indicate a high percentage (>20%) of eventual prosthesis rupture requiring replacement or other surgery (average ~10 years), a significant physical and financial cost to patients and society. Multiple studies have been performed to evaluate various types of prosthesis, but necessarily take many years to determine whether the implant design is improved, with less chance of rupture. One of the causes of rupture is reported to be increased friction and mechanical deformity relating to implant folds [1]. A means of in-vivo detection and quantification of these folds in an accurate and reproducible fashion would provide manufacturers and other interested groups with useful information concerning the implants, much sooner. Manufacturers could determine whether their prosthesis was resistant to enfolding. It may enhance the ability of researchers to assess the properties of various types of prosthesis and potentially predict their likelihood of rupture. Surgeons would rapidly determine whether the size of tissue pocket or amount of filling was causing excess implant infolding. We present a way of rapidly extracting important implant contour features such as prominent undulation (concavity), deep fold, and edge (focal convex) creation. The measurements are based on two parameters, compactness index (CI) and bending energy (BE); both quantify the distortion of breast implant contour.

Methods

We evaluated 28 cohesive gel silicone breast prostheses in 14 women with one and two-year follow-up MRI exams using identical techniques on each occasion. A silicone-only axial sequence (6mm, 36cm FOV, 154x256 matrix) with water saturation and inversion recovery nullification of fat was utilized for subsequent analysis by a human observer and a contour analysis computer program developed at this institution (YD). The silicone only images produced striking contrast between the prosthesis and adjacent tissues allowing computation of BE and CI values without need of region of interest drawing (after threshold value was determined). Human observer correlation values were created by having a radiologist (AD) measure the depth of contour undulations and folds. Undulation depths of less than 2mm were considered normal and not included in the calculations. We compared the average total number of undulations, the number of deep undulations (at least 2.5:1 diameter vs. depth), and actual folds (< 1.0 ratio) determined by human measurement, with the computer program calculations. Only representative (every third) slices were actually measured by the human observer in this current pilot-study. The total number of deep undulations and folds determined by measurement was compared with the BE and CI values for each prosthesis. The trend (stable, increased or decreased enfolding) of implant contour was noted between 1st and 2nd year imaging studies. Values within 2% were considered stable and increased/decreased enfolding or BE/CI values greater than 20% were labeled as prominent change.

Results

When using simple total index values for each implant, CI was better able to detect the number of folds and acute corner angles in individual slices, whereas BE better approximated the number and severity of deep undulations over the entire surface area. Assessment of BE continuous rate change plot also detected individual folds and their location, although this information was not used in the current study. A higher or lower than average number of undulation/folds determined by human measurement correlated positively with the BE calculation in over 94% of the implants. Assessment of changes in implant contour undulation between year 1 and year 2 exams indicated stronger correlation between BE and Human measurement (only ~5% definite discordance) whereas a nearly 25% discordance with CI was noted. The CI was still noted to have value in detecting individual deep folds as shown in figure 1. The BE for the right implant (containing obvious fold) is high (5.03) but less than that detected for the left implant (5.27) where no fold is present. The corresponding CI values of 3.25 and 2.29 a 1/3 difference in the ratio clearly indicate greater sensitivity to focal/deep folds. Figure 2 shows right implant smooth contour with mild angulation and left implant with two areas of moderate undulation and enfolding; corresponding BE (3.57 / 7.95) and CI (2.13 / 2.62) for right and left sides demonstrate that BE has much greater sensitivity to deep undulations. A 10% increase in deformity was detected the one year interval, but no implant rupture occurred in 14 patients evaluated to date to allow testing of the true value of this tool.

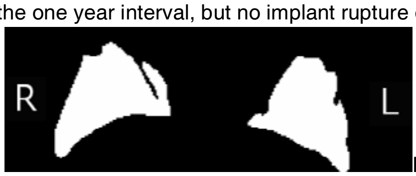

Figure #1

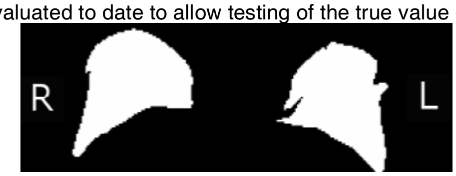

Figure #2

Discussion

Comparison among breast implants used a type of "bending energy" [2], which is the amount of energy required to deform a contour representing the breast implant from a normal state into its present shape. Mathematically, Bending energy (BE) is defined as the integral over of the squares of the curvatures along a border. Since curvature is a measure of the rate of change in orientation at each point along a curve, BE is more sensitive to the sharpness of corners and deep undulations. A more popular measurement is compactness index (CI), which estimates *roundness* of a 2D object [3] computed by the equation: $P^2/4piA$ (P= perimeter, A= area). Simplicity of CI limits detection of complex structure allows detection of the implants deep folds, an important characteristic. The deficiencies of both methods of computational evaluation of implant surface irregularity can be seen in figures 1 and 2. The single prominent fold in the left breast in figure #1 is mostly "lost" in the otherwise predominantly smooth contour of the rest of the prosthesis using only the BE-value, whereas it is registered as a significant difference when assessed from the CI point of view. The ability to assess the amount of deformity of any implant (similar techniques can be used for saline prostheses) accurately with minimal human input and bias, will be valuable for groups that need to assess the probability of subsequent rupture, early capsular contraction, or success of anatomic positioning. The relatively mild progression of implant enfolding detected in this limited follow-up pilot study is to be expected considering that the properties of the cohesive silicone gel are more resistant to focal deformation than the more fluid-like silicone or saline implants.

Conclusions

1. A new computational program developed for evaluation of breast implant deformity allows rapid accurate detection of folds and deep undulation
2. The new technique is used to confirm progressive implant deformity during the one year follow-up interval, potentially increasing likelihood of rupture

References

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