Evidence Based Perspectives on Rupture

Rupture is a long-recognized complication of breast implants and the risk of rupture increases over time after implantation.[1] In the MemoryGel® Breast Implants Core Study, the cumulative Kaplan-Meier confirmed rupture rate in the Primary Augmentation MRI Cohort is 9.8% at 10 years.[2] The 10-year core study demonstrates the safety and effectiveness of MemoryGel® Breast Implants. It is also important to note that MemoryGel® Breast Implants have consistently been backed by a free lifetime product replacement in the event of an unexpected rupture.[3]

Excerpt from the 2019 FDA Executive Summary: Breast Implants Special Topics

The 10-year Core study rupture data from Allergan, Mentor, and Sientra for silicone implants were analyzed. Due to the differences in the methods in which ruptures were detected and confirmed, the types of data that were collected, length and frequency of patient follow-up, and the methods for analyzing and presenting the data greatly limited the comparisons that can be made between manufacturers.

The results of the completed Allergan and Mentor Core studies indicated that comparable numbers of silent and symptomatic rupture were found in the MRI and non-MRI cohorts. Due to the design of the Sientra study it was not possible to determine the comparative number of silent and symptomatic ruptures in the MRI and non-MRI cohorts.[4]

MemoryGel® Breast Implants Core Study Rupture Data by Patient

9.8%

Kaplan Meier Confirmed Rupture Rate at 10 years*[2]

*11 Confirmed Ruptures, by Patient, out of 202 Total Patients in the MRI cohort for Primary Augmentation study subgroup.[5,6]
Confirmed ruptures are confirmed by examining the implant for those patients that underwent implant removal.

Understanding Kaplan-Meier Estimates

While numerous studies report Kaplan-Meier (KM) estimates, there are a number of statistical considerations that can impact the accuracy of Kaplan-Meier analyses. The cumulative incidence of rupture increases over time; therefore, any meaningful calculation must account for duration of follow-up. For example, in the MENTOR® MemoryGel® core clinical study, there were 202 Primary-Augmentation (PA) patients enrolled in the MRI cohort with a 46% follow-up rate. **The 9.8% Kaplan-Meier confirmed rupture rate is a more reliable reference than the 24.2% Kaplan-Meier suspected† or confirmed rate for primary augmentation patients because confirmed ruptures are verified as ruptured by physical examination of the implant upon explantation.[1,5]**

MemoryGel® Core Clinical Study: Suspected vs. Confirmed Rupture		
	24.2%*	9.8%†
Kaplan-Meier	✓	✓
By Patient	✓	✓
MRI Cohort	✓	✓
Primary Augmentation	✓	✓
46% Follow Up	✓	✓
	Suspected & Confirmed	Confirmed Only

*25 Suspected or Confirmed Ruptures, by Patient, out of 202 Total Patients[5]
†11 Confirmed Ruptures, by Patient, out of 202 Total Patients[5,6]
Suspected ruptures are those identified on an MRI as potential ruptures, but have not been confirmed by physical examination of the explanted implant as patients often chose not to have these implants removed.
Confirmed ruptures are confirmed by examining the implant for those patients that underwent implant removal.

Conclusion

There are multiple methods for calculating long term rupture rates and each methodology must be considered when evaluating a device. As demonstrated with our long term clinical data, MemoryGel® Breast Implants have proven to be a safe and reliable choice for millions of women.

1. Handel N, Garcia ME, Wixtrom R. Breast implant rupture: causes, incidence, clinical impact, and management. Plast Reconstr Surg. 2013;132(5):1128-1137.
2. Cumulative Incidence rate of confirmed rupture in the primary augmentation cohort of MRI Cohorts A and B.
3. MentorPromise Protection Plan Terms & Conditions 2017.
4. FDA Executive Summary: Breast Implant Special Topics. Advisory Panel March 25 & 26, 2019.
5. Mentor Worldwide LLC. MemoryGel® Breast Implants Mentor Worldwide LLC. 10-Year Core Gel Clinical Study Final Report. April 2013.
6. Mentor MemoryGel Rupture Stats Confirmed and Iatrogenic, Reported January 2020.

Important Safety Information:

MENTOR® Breast Implants are indicated for breast augmentation, in women who are at least 18 years old, or for breast reconstruction. Breast implant surgery should not be performed in those women with active infection anywhere in their body, those with existing cancer or pre-cancer of their breast(s), those who have not received adequate treatment for these conditions or those who are pregnant or nursing. There are risks associated with breast implant surgery. Breast implants are not lifetime devices and breast implantation is not necessarily a one-time surgery. Patients may require additional unplanned surgeries on the breast(s) because of complications or unacceptable cosmetic outcomes. Many of the changes to the breast(s) following implantation are irreversible (cannot be undone) and breast implants may affect the ability to breastfeed, either by reducing or eliminating milk production. The most common complications with MENTOR® MemoryGell® Breast Implants include re-operation, implant removal, capsular contracture, asymmetry, and breast pain. A lower risk of complication is implant rupture, which is most often silent (meaning neither you nor your doctor will know you have a rupture). The health consequences of a ruptured silicone gel breast implant have not been fully established. MRI screenings are recommended three years after initial implant surgery and then every two years after to detect silent rupture.

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