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Mammary implants: laboratory simulation of recreational diving conditions

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SUMMARY. To ascertain whether mammary implants are prone to changes in conformation or structure if they are submitted to recreational dives, eight mammary implants were submitted to 40 simulated dives to imitate an average recreational diving schedule. Matching implants were used as a control group. Photographs were taken before and after completion of the protocol. All implants were observed for changes in volume and checked for integrity. Variations in density were evaluated using a Tc scan. No changes in volume occurred after each dive. None of the implants showed ruptures, and Tc scanning failed to reveal any differences in density between tested and control implants. Cohesive-gel implants submitted to the simulated dives showed some morphological alterations. This study indicates that the mammary implants tested could be implanted in a sports diver, but raises concern about whether the increased exposure to stress could negatively affect their durability. © 2002 The British Association of Plastic Surgeons

Keywords: breast implant, diving, simulated dive, hyperbaric chamber.

Diving is becoming an increasingly popular sport for women. This has created a group of patients with breast implants who are diving. In salt water, the body of a diver is subjected to compression during the descent, due to an increase in pressure of one atmosphere every 10 m of depth, and to a corresponding decompression when ascending toward the surface. There has been misleading news in the lay press concerning breast-implant rupture due to changes in pressure and altitude. This has created concern among women considering augmentation mammaplasty.

There is little data in the literature regarding the performance of breast implants in divers.[1] In 1988, Vann et al exposed mammary implants to seven simulated dive profiles, of which two, if executed in real life, would result in life-threatening decompression sickness for the diver. They followed these dives by altitude exposure, and looked for changes in volume and bubble formation. Their study detected a significant change in volume when the implants were flown at 30 000 feet in an unpressurised aircraft after a deep saturation dive lasting 24 h or more – an unlikely situation for a recreational diver.[1] Minimal changes in volume occurred after each dive at sea level, and when implants were exposed to commercial airline cabin pressure.

The aim of this study was to ascertain whether mammary implants are prone to changes in conformation or structure if they are submitted to 20 days of repetitive recreational dives – a typical holiday schedule for a sports diver. A recreational dive is defined as a dive no deeper than 40 m; a second dive in close succession is called a repetitive dive. Commercial and recreational diving frequently have a repetitive schedule and use a dedicated decompression table to guarantee a very low risk of decompression illness.

Materials and methods

The research protocol was submitted to various implant manufacturers, asking them to offer matching pairs of implants for this project. Two of them, McGhan and Mentor, agreed to enter the study.

To assess the behaviour of mammary implants during a series of dives, seven new silicone-gel and bilumen (saline and gel) implants were tested, together with an implant inserted 2 years previously and removed when the patient requested a larger breast. These eight implants were submitted to 40 simulated recreational dives in the hyperbaric air compression facilities at the University of Rome 'La Sapienza'. Four matching implants were used as controls (Table 1). For the purposes of this study, the two McGhan implants, Style 110 and Style 120 Biocell, were matched, because both devices are manufactured with the same textured silicone-gel filler and Intrashiel shell, the only difference between them is the moderate (110) or high (120) profile. The four McGhan Style 410s were matched: one was placed in the control group and three, of which one was the only used implant in the study, were placed in the immersion group. The only McGhan Style 150 FH Biodimensional expandable breast implant was placed in the immersion group. The three Mentor Siltex round gel implants were matched, although one of the two implants assigned to the immersion group had a different profile (high rather than moderate) from the implant assigned to the control group. One of the two Mentor Siltex Becker 50 expander/mammary implants was placed in the control group and one in the immersion group.

The experimental model was designed to simulate an average holiday diving schedule, in which two immersions per day are usually planned. In total, 20 dives were performed in the morning and 20 dives in the afternoon. All dives were planned according to the US Navy tables,[2]

Table 1 Breast implants tested in the study

Control group	*Immersion group*
McGhan	
Style 110 Biocell textured silicone gel-filled Intrashiel barrier shell 27-110211	Style 120 Biocell textured silicone gel-filled Intrashiel barrier shell 27-120341
Style 410 Biodimensional 27-FM125-350	Style 410 Biodimensional 27FL120-250
	Style 410 Biodimensional 27FM115-270
	Style 410 Biodimensional 27FM115-270 (explanted)
	Style 150 FH Biodimensional 27-150351 expandable breast implant, silicone gel with adjustable saline-fill inner lumen, mini remote port
Mentor	
Siltex round gel moderate profile 354.2257	Siltex round gel moderate profile 354.1507
	Siltex round gel high profile 354.2754
Siltex Becker 50 expander/mammary implant, 50% silicone gel in outer lumen, 50% saline in inner lumen, 354.1515	Siltex Becker 50 expander/mammary implant, 50% silicone gel in outer lumen, 50% saline in inner lumen, 354.2020

For the purposes of this study, the two McGhan breast implants Style 110 and 120 Biocell were matched, because both devices are manufactured with the same textured silicone-gel fill and Intrashiel shell, the only difference between them being the moderate (110) or high (120) profile. The McGhan Style 150 FH Biodimensional 27-150351 expandable breast implant did not have a matching implant in the control group. The three Mentor Siltex round gel implants were matched, although one of the implants in the immersion group had a different profile (high rather than moderate) to the one in the control group.

and were calculated with repetitive decompressor schedule. The maximum depth and bottom time were 39 m and 30 min, respectively, while the compression rate was 7.8 m min^{-1} in both dives. Decompression schedules were calculated, according to US Navy tables, at different levels: −6 m for 3 min and −3 m for 18 min in the morning dive, and −6 m for 10 min and −3 m for 25 min in the afternoon dive (Fig. 1).

The simplest and safest form of compressed-gas diving is called no-decompression or no-stop diving, and does not require decompression stops during the ascent to the surface. Bottom times greater than the no-stop limits can be achieved without excessive risk of decompression illness if the diver ascends to the surface slowly with planned stops, so that nitrogen is eliminated from the body without producing symptoms. This type of dive is often chosen by expert divers. In our study, we planned a 40 m dive with a bottom time greater than the no-stop limits, necessitating a very slow ascent rate and a first decompression stop at −6 m for 3 min, with a second stop at −3 m for 18 min, according to the US Navy tables (Fig. 1A).

A second dive in close succession is called a repetitive dive, and is very common in all diving communities. It requires special decompression profiles to minimise the risk of nitrogen bubbles. During a repetitive dive, the bottom time must be reduced or the decompression time increased to allow for the residual inert gas remaining in the body from the previous dive. In our protocol, the afternoon dive was a repetitive dive with the same bottom time and, therefore, a longer decompression profile. Of the many methods for determining repetitive-dive bottom times and decompression requirements, that of the US Navy is one of the most flexible and the most common.[2] According to their decompression tables, our afternoon dive required a first decompression stop at −6 m for 10 min, with a second stop at −3 m for 25 min.

The temperature in the hyperbaric chamber was kept close to 21 °C with continuous ventilation. The atmospheric humidity varied between 60% and 70%.

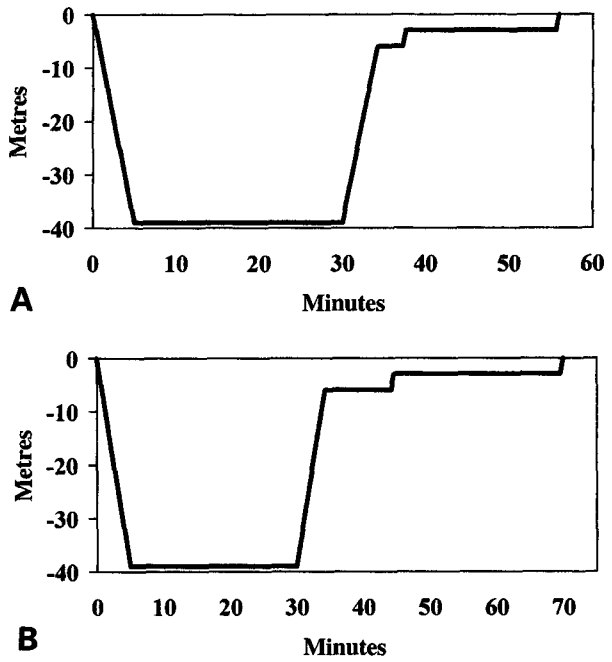

Figure 1—(A) Profile of the morning dive. Maximum depth: 39 m; time: 30 min; standard decompression profile. (B) Profile of the afternoon dive, which took place 8 h after the end of the morning dive. The dive profile differs from that of the morning dive because this is a repetitive dive, according to the US Navy dive tables.

Photographs were taken of all the implants in the study at the beginning and the end of the experiment. The volumes of the implants were assessed at sea level before and after each simulated dive by immersing the implants in a closed water-filled container, where volume changes were determined by variations in the water level in a capillary tube. After each simulated dive, the integrity of the implants was checked.

To complete the study, a Tc scan of each implant was performed after completion of all the simulated dives, to

assess variations in the density of the gel. All the implants were evaluated using a Somaton Plus machine (Siemens, Erlangen, Germany), and for each implant five scans of 5 mm thickness were taken at 1 cm intervals. The implants were evaluated separately, each sitting directly on the scan table. Density was assessed using the densimetric Hounsfield Unit (HU) scale, which is the Tc density measure scale.[3] The X-ray beam, when passing through tissues, is attenuated in proportion to the tissue density. The HU value indicates the density of the tissue submitted to the X-ray beam, and depends on the atomic numbers of the tissue elements. The HU scale has a conventional reference value, which is 0 HU for an X-ray beam attenuated through water. High-density structures have high HU values (up to 1000 HU), while gas conventionally has a value of −1000 HU.

Results

None of the implants used in this study showed shell ruptures. None of the implants showed a variation in volume at sea level after each dive or at the end of the test. None of the implants showed a variation in the density of the gel or saline. The densities inside the silicone-gel implants varied between 95 HU and 105 HU. All double-lumen implants had a density of between 95 HU and 105 HU in the outer silicone-gel chamber and between 15 HU and 20 HU in the inner saline-filled chamber, with bubbles of air inside the inner chamber whose density was −1000 HU.

Some of the implants submitted to the simulated dives showed morphological changes (Fig. 2). The cohesive gel implants did not retain their original shape. This was confirmed by the Tc scans: a morphological examination showed marked irregularities of the profiles of all implants tested in the hyperbaric chamber when compared with the matching control implants (Fig. 3). The explanted Style 410 Biodimensional implant showed an irregular oval area of increased density inside the implant (Fig. 4). This was confirmed by an ultrasound scan using a 7.5 MHz probe with a Toshiba Sonolayer SSA250A. The inner shells of the two double-lumen implants tested in the hyperbaric chamber showed some irregularities (Fig. 5).

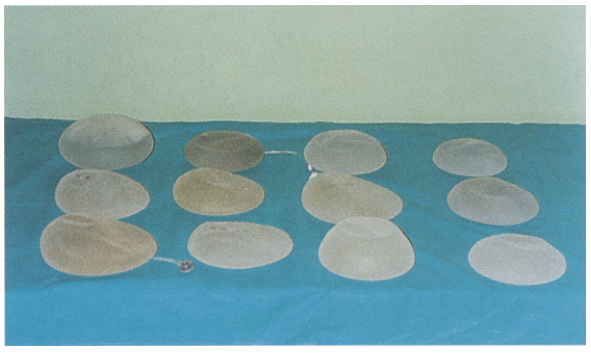

Figure 2—The appearance of each of the implants (tested and control) at the end of the simulated dives. Air can be seen in the Siltex Becker implant (which was completely emptied of air at the beginning of the study), and the shape of all the cohesive-gel implants has altered. Front row, from left to right: McGhan Style 150 FH 27-150351; Style 410 27FL120-250; Style 120 27-120341; Style 110 27-110211. Middle row: McGhan Style 410 27FM115-270; Style 410 27FM115-270 (explanted); Style 410 27-FM125-350; Mentor Siltex 354.2257. Rear row: Mentor Siltex Becker 354.2020; Siltex Becker 354.1515; Siltex 354.2754; Siltex 354.1507.

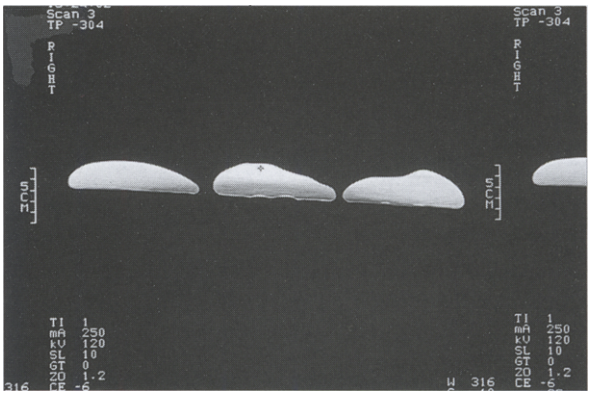

Figure 3—Imaging of three Style 410 McGhan implants by Tc scanning. The leftmost implant was used as a control; the middle and rightmost implants were submitted to the simulated dives. The implants submitted to the simulated dives have changed shape. There are no differences in gel density between the three implants.

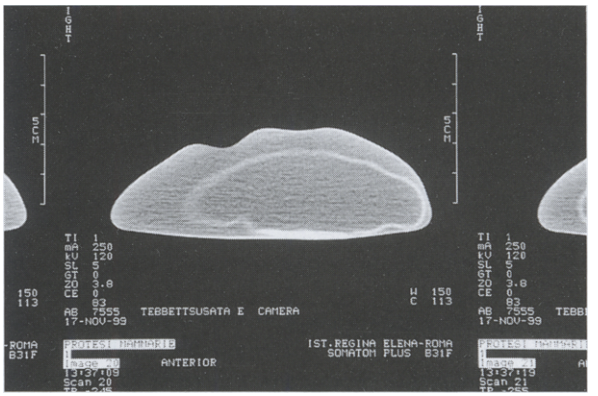

Figure 4—Tc scan of the McGhan implant explanted after 2 years and submitted to the simulated dives. The implant is unbroken after completion of the test, but a hyperdense profile can be seen inside the implant.

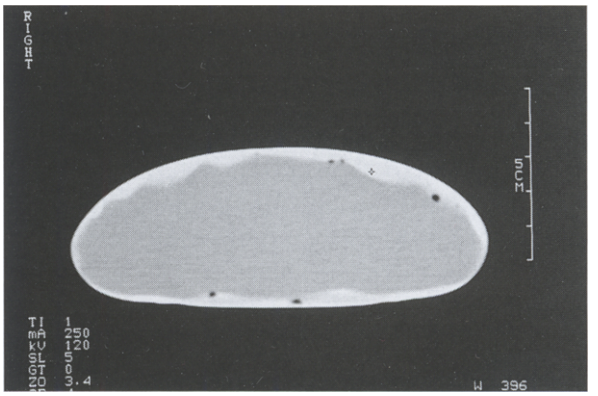

Figure 5—Tc scan of the McGhan expandable breast implant submitted to the simulated dives. The implant is unbroken after completion of the test, but tiny bubbles of air can be seen inside the inner chamber of the device.

Discussion

In this study, no variations in the volumes of the implants were observed after each simulated dive or at the end of the protocol. These data differ from those of Vann et al,[1] who used a different experimental model and reported variations in volumes of breast implants after a longer and deeper simulated dive followed by a simulated flight.

In 1988, van Rappard et al tested the breaking pressure of silicone-gel-filled breast implants, and showed that there is a negative correlation between the pressure resistance of breast implants and the duration of implantation.[4]

Even though none of the mammary implants tested were broken by the procedure used in this study, some alterations occurred as a result of the compression and decompression process of the simulated dive. The tested implants showed some distortions in shape, and some irregularities of the inner shell were observed in the double-lumen implants. The distortion of the cohesive gel implants remained 12 months after the completion of the study, although the prostheses had a tendency to go back to their original shapes.

These observations raise some concern about the safety of breast implants in sports divers, particularly in relation to the stress resistance during immersions exceeding 40 m in depth. It may be advisable not to recommend double-lumen implants to a female diver, because of the recurring stress of the alternating pressure forces during each dive, which may produce a crease near the valve or a failure of the continence of the valve, leading to deflation.

Our series of 40 dives represents a limited number for a sports diver, yet changes in shape were observed in the tested implants when compared with the control group. This could affect the lifespan of the prostheses, which may be shortened by repetitive stress correlated with the number and depth of dives. As a result of this study we can report that it is safe to perform augmentation mammaplasty in a sports diver using the tested implants, although long-term follow-up may be advisable.

The authors have no financial interest in the products used in this study.

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