Effects of radiation therapy on silicone prostheses with different gel cohesivity

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Statement of Purpose: In spite of widespread use of breast-conserving therapy for early breast cancer, a large number of patients still undergoes mastectomy. Post-mastectomy radiation (PMRT) is indicated in selected breast cancer patients. Currently, number of patients receiving PMRT is increasing, as many women would pursue breast reconstruction with benefit for self-image [1]. Even if breast reconstruction does not contraindicate radiotherapy, irradiation treatment to implant-based reconstruction remains highly controversial. Criticism of the technique has focused on possible compromised radiation design and potential for increased complication rates with inferior cosmetic outcomes [2-3]. When RT is given to patients with permanent implants, the irradiation technique does not vary from that for intact breast, using ^{60}Co, to administer 45-50 Gy to the chest wall with daily fractions of 1.8-2 Gy. Many published data indicate that prostheses do not affect the quality of radiation treatment: in fact the linear absorption coefficient for silicone gel and water are comparable and, behaving like tissue, silicone prostheses or water filled expanders do not affect the photon or electron beam distribution with no significant alterations of depth doses [4]. Vice versa, data on alteration of shape and consistence of the implants due to radiation are occasionally reported.

The aim of this work is the study of morphological and mechanical modification of three types of prostheses (namely FM, MM and MX), occurred after an irradiation dose similar to the radiotherapy on patient affect of breast cancer.

Methods: The investigated models of breast prosthesis, kindly provided by Allergan Co., are ST410 FM 360g (FM0), 410 MM 360 g (MM0), 510 MX 360 g (MX0). The main difference among the three models is the silicon gel cohesivity, 510 MX model has a double gel with different cohesivity, while the ST410 FM is a soft touch model with a less cohesive gel. All prostheses (one for each model) were treated under γ-rays emitted by ^{60}Co source of the Cobalt Treatment Unit Theratron 780C (AECL, Canada) operating at the S.C. Radioterapia A, Fondazione IRCCS Istituto Nazionale Tumori, Milan, Italy. Two integral dose levels were investigated 50Gy and 80Gy; samples were irradiated in fractionated regimen, 2Gy/fraction. The first one was selected to simulate the radiation treatment of breast cancer and the second one to study the effects of high dose level on breast prosthesis.

For studying the morphological change, the volume of the prosthesis was obtained for every CT scans acquired before and after prostheses irradiation with a CT Scanner Unit (Picker PQ 2000). For each untreated and radio-treated prostheses, photos of front and back side, and lateral profile were acquired by digital photo camera. To investigate change in the mechanical properties, 6 dumbbell specimens were cut out from the front (n = 3) and back (n=3) side of the silicone shell of each examined prosthesis. Tensile tests were performed using a MTS1/MH electromechanical system with a 5 kN load cell equipped with high capacity pneumatic grips, evaluating secant moduli at different elongation values (10 ÷ 400%) and stress and strain at break.

Results: In Figure 1 the volume change after irradiation therapy are reported. Among the investigated implant models, MM model exhibited the lowest change in volume, whereas FM and MX showed a higher increase of volume at 50Gy irradiation and a lower increase at 80Gy.

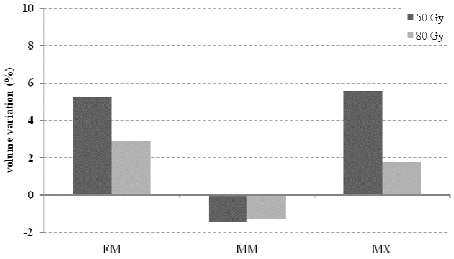

Figure 1. Volume variation after 50 and 80 Gy irradiation compared to the volume of untreated implant

These results were confirmed by macroscopic images, that evidenced a remarkable change in shape after the two dose irradiation for the 510 MX prostheses (Figure 2); no variation was observed for the other implant models.

Figure 2. Photos of lateral profile of 510 MX prostheses (a) not irradiated, (b) treated at 50 Gy, and (c) treated at 80 Gy.

For ST410 FM model, significant differences ($p<0.05$) were detected in σ_b and ε_b values after the irradiation treatments. For 510MX implants no significant difference ($p>0.05$) was evidenced after 50Gy treatment, while a significant decrease ($p<0.05$) in σ_b and ε_b values after 80Gy treatment was observed. For 410 MM model no significant differences ($p>0.05$) were detected.

Conclusions: The preliminary results on radiation therapy effects on silicone gel breast implants demonstrate that the irradiation affects the properties of the materials, depending on the gel cohesivity. Further investigations are still in progress to better understand the effects of the radiotherapy commonly used for the treatment of breast cancer on the implant materials, especially on the silicone gel used as filler.

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