Results: In the previous 12 months to 2010 April, we have recorded 146 SLND in patients with breast cancer, and 156 in the 12 month after that date. Both groups have similar patients characteristics.

There is no significative differences in micrometastasis detection between the intraoperative OSNA method (21/156) and the classical HEintraoperative plus delayed method (18/146) − p = 0.3.

In the same period the macrometastasis fall down a 30% due to a better preoperative evaluation by means of axillary echography ± puncture, that exclude from SLND cytological positive axillary nodes.

Conclusions: The OSNA method provides similar results, about micrometastasis, than manual intraoperative plus delayed HE method.

Conclusions of the recently published ACOSOG Z0011 trial, as well as many papers that are questioning the therapeutic value of complete axillar dissection after sentinel lymph node positive, let's safety avoid it In most of cases of micrometastasis. When the result is a macrometastasis we proceed conform the patient wishes, after discuss the possibilities with her, before surgery, and after to analyze the theoretical benefit in each real circumstances.

Further studies are necessary to analyze the cost-efficacy of OSNA method in expertise pathologist centers.

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Development of New Generation of Breast Implant Using Silsesquioxane Nanocomposites Shell

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Introduction: Silicone implants are being used increasingly worldwide, in breast reconstruction after cancer surgery or breast augmentation procedures. Various complications have been associated to the use of breast implants in which capsular contracture and implant failure are the most common.

To overcome the complications, our group have developed a novel nanocomposite material based on polyhedral oligomeric silsesquioxane-poly (carbonate-urea) urethane (POSS-PCU) for use as tissue implants.

Method: To investigate capsular contracture, we performed in vitro and in vivo experiments as follows:

In vitro: Human monocyte derived macrophages (MDMs) were seeded on the wells of culture plates that were already covered with nanocomposite; equal number of wells covered with silicone used as control. These culture plates were maintained in culture for up to 4 days.

In vivo: we implanted nanocomposite polymers in six healthy sheep for 36 months and a silicone implant served as control. After explantation, we looked for signs of surface degradation on the polymer by performing attenuated total reflectance Fourier transform infrared spectroscopy analysis. Histopathologic and electron microscopic examinations were performed in order to study the interaction between the biomaterial and the host environment in greater detail.

All mechanical property experiments (Shell ultimate elongation, Tensile and Tear test) were conducted with an Instron electromechanical testing system for nanocomposite and silicone with the same protocol in the same environment.

Result: macrophage stimulation on the samples exposed to silicone was more than the nanocomposite, implying more foreign body reaction with silicone. The viability of macrophages cultured on different substrates was not affected.

In vivo tests showed minimal inflammatory reaction of the nanocomposite within the sheep model as compared with the silicone control. The increased fibrinogen adsorption on POSS-PCU, its amphilicity, and large contact-angle hysteresis indicated that our nanocomposite inhibits inflammation by adsorbing and inactivating fibrinogen on its surface. In complete contrast, the control silicone in the same setting demonstrated very significant inflammation and degradation, resulting in capsular formation. Naturally, there was no evidence of degradation of the nanocomposite compared with the silicone control.

Tensile test showed that mechanical strength of our nanocomposite polymer is about 7 times higher than silicone control with half the silicone thickness.

Conclusion: POSS-PCU nanocomposites have enhanced interfacial biocompatibility, better biological stability and stronger mechanical properties as compared with conventional silicone biomaterials, thus making them safer as tissue implants.

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Validation of Three Different Nomograms to Predict the Risk of Non-Sentinel Lymph Node Involvement in Turkish Breast Cancer Patients with Sentinel Lymph Node Metastasis

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Background: The sentinel lymph node biopsy after having proven it's efficacy and reliability by many randomized controlled studies has become an alternative of axillary lymph node dissection (ALND) in convenient patients. ALND still remains as 'the gold standard" for patients with positive SLN. However only 30−50% of the breast cancer patients with positive sentinel lymph nodes (SLN) have non-sentinel lymph node involvement in the axilla. Nomogram accuracies for predicting non-SLN involvement vary between different patient populations. Our aim is to put these nomograms to test on our patient population and determine our individual predictive parameters effecting SLN and non-SLN involvement for our patient population.

Methods: Data collected from 932 early breast cancer patients who underwent SLN biopsy between 2003 and 2011 was retrospectively analyzed. Nomogram values calculated for each patient utilizing Memorial Sloan Kettering Cancer Center (MSKCC), Tenon and MHDF (Turkish) models. Nomograms' accuracies were tested with the calculation of AUC values of ROC curves. Moreover, using our own patient and tumor depended parameters, we established a unique predictivity formula for SLN and non-SLN involvement. Statistics Package for Social Sciences version 16.0 was utilized for statistical analyses. The tests used for statistical analyses were; Chi Square, analysis of variance (ANOVA), receiver-operating characteristic (ROC) curve, Fisher's exact test, Mann-Whitney test and logistic regression. P values under 0.05 were accepted as statistically significant.

Results: All the patients except one were female. Median age was 51.9±11.6 (19−85) years. A total of 2565 SLN were excised. A median number of 2.75 (1−10) SLN was found to have been excised for each patient. Median tumor size was 18±8.9 mm (0.1−50 mm).SLN invasion was present in 271 of the patients. Complementary AD was performed in 244 of these patients and 100 (40.9%) had non-SLN metastasis. The median follow up time was 34 (1−93) months. The calculated AUC values for MSKCC, Tenon and MHDF models were 0.727 (95% CI 0.64−0.8), 0.665 (95% CI 0.59–0.73) and 0.696 (95% CI 0.59–0.79) respectively. In the multivariety regression analyses of the factors effecting the positivity of SLN and non-SLN; tumor size (p = 0), presence of lymphovascular invasion (p = 0) and progesterone receptor positivity (p = 0.012) were found to be correlated with SLN positivity while Cerb-2 positivity (p = 0.004) and size of the metastasis in the lymph node (p = 0.006) were found to correlate with non-SLN involvement in our study group. The AUC value of the predictivity formula established using these parameters was 0.722 (95% CI 0.63–0.81).

Conclusion: The most accurate nomogram for our patient group was the MSKCC nomogram. Our unique predictivity formula using only two predictive variables, proved to be as equally effective and competent as the MSKCC nomogram. However, likewise other nomograms our predictivity formula needs future validation studies.

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A New Predictive Model for Predicting the Non-sentinel Lymph Node Metastases in Breast Cancer Patients with Positive Sentinel Lymph Node Biopsy

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Background: Completion Axillary Limph Nodes Dissections (CALND) performed in breast cancer (BC) patients with positive Sentinel Lymph Node (SNL) at definitive histology show additional nodal metastases in only 35% to 50%. Some institutions proposed statistical methods to identify patient's risk for non-SLN metastases. Aim of this paper was developing a new tool with the final goal of avoiding unnecessary CALND.

Materials and Methods: We retrospectively evaluated 593 primary BC patients. 139 positive SLN underwent CALND. The predictive accuracy of five published nomograms (MSKCC, Tenon, Cambridge, Stanford and Gur) was measured by the AU ROC curve. Then we developed a new logistic regression model comparing the performances. Our model was validated by the leave-one-out cross validation method.

Results: In 53 cases (38%) we found at least one metastatic Non-SLN. All the selected nomograms showed values greater than the 0.70 threshold, and our model reports a value equal to 0.77 (CI = 0.69–0.86 and ER = 0.28), and equal to 0.72 (CI 0.63–0.81, ER = 0.28) after the validation. With a 5% cutoff value, sensitivity was 98% and specificy 9%, for a cutoff of 10%, 96% and 2%, respectively.

Conclusions: All the nomograms were good discriminator; however the alternative developed model shows the best predictive accuracy in this Italian BC sample. We still confirm that these models, very accurate in the institution of origin, require a new validation if used on other populations of patients.

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Factors in Decision Making of Breast Conservation in Early Breast Cancer: a Study in Northern India

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Background: Breast cancer is the commonest cancer in urban Indian female and second commonest in rural Indian female. Breast conservation surgery (BCS) followed by radiotherapy (RT) to breast has not been widely adopted in our country. Aim of present study is to evaluate factors responsible in decision making regarding type of surgery in early breast cancer (clinical stage I, II).

Material and Method: Patients with stage I, II breast cancer who had definitive surgical procedure (BCS or Mastectomy) and were either on RT or follow up were eligible treated at department of Surgery CSM medical university hospital from July 2007 to July 2011. A questionnaire was prepared to assess various factors responsible for decision making regarding surgery:

1. Patients related: age (< or >60 yrs), literacy status, anxiety of recurrence of tumor.
2. Adjuvant RT related: non availability of RT facility in city of patients, waiting period of RT in the hospital (6−10weeks), anxiety of RT as painful treatment, duration of RT (6 weeks).
3. Interaction between surgeon and patients related: decision making of surgery (made by surgeon alone, surgeon and husband together, patients alone), time spent in communication between surgeon and patients (<15minute, 15−30 minute, 30−60 minute).
4. Patient satisfaction related: Satisfaction with cosmetic body images, overall satisfaction with outcome of treatment.

Result: Sixty patients of stage 1 and 2 out of 182 patients were eligible and answered the questionnaire (BCS n = 10, Mastectomy n = 50).

Mean age was 38 years. 100% were literate in BCS group while 60% were literate in mastectomy group. Anxiety of tumor recurrence after BCS was 100% in mastectomy group while 20% in BCS group.80% in Mastectomy group not opted BCS because of facilities of radiotherapy was not available in their city. Significant waiting period of RT after surgery and duration of RT (6 weeks) were found to be a factor in decision for mastectomy in 66%, 50% respectively. 100% in mastectomy group had anxiety of RT as a painful treatment while 80% in BCS group. Anxiety regarding duration of RT was 80% in BCS group while 40% specifically preferred mastectomy as they may be spared of RT.100% in BCS group told that surgeon had spent more time while 20% in mastectomy group told surgeon spent less time. In all patients of BCS group decision was taken by both doctor, husband, 40% decision in mastectomy group were taken by doctors alone and rest 60% were taken by both surgeon and husband. Patients were satisfied in both groups with overall treatment. But 40% patients were not satisfied with body image in mastectomy group.

Conclusion: Significant factors which influenced the decision regarding BCS were anxiety regarding recurrence, non availability, waiting period of RT facility in their city. Significantly two factors duration of RT treatment leading to work loss hours and after mastectomy they may be spared of RT were observed not described earlier.

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Feasibility of 3D Intraoperative Freehand SPECT Probe Imaging for Radioguided Tumour Excision and Sentinel Node Biopsy in Breast Cancer

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Background: The purpose of this study is to evaluate the feasibility of 3D intraoperative imaging with a freehand single photon emission computed tomography (SPECT) probe to guide tumor excision and sentinel node biopsy in patients with impalpable breast cancer.

Methods: The study was designed to evaluate 20 patients with impalpable breast cancer scheduled for radioguided occult lesion localization (ROLL) using an intratumoural radiocolloid deposit or radioactive iodine 125 seed (radioactive seed localization, RSL) with or without sentinel node biopsy. In case of ROLL, the radiocolloid (99mTc-nanocolloid) was intratumourally injected (40MBq) guided by ultrasound. When a sentinel node biopsy was also performed, a dose 120Mbq was injected, followed by lymphoscintigraphy at 15 minutes and 3 hours post injection for sentinel node identification. In case of RSL, a 125I-seed (8.5MBq) was implanted in the tumour prior to neoadjuvant chemotherapy (2−4 months before operation) guided by ultrasound. Intraoperatively, a device combining a spatial localization system and two tracking targets fixed respectively on the gamma probe and on the patient was used. 3D images were generated and displayed in real time following a protocol based on freehand SPECT probe movements.

Results: To date, 11 patients with an average age of 63 years (range 51−73) have been included (6 ROLL, 2 ROLL+SNB and 3 RSL). Freehand SPECT enabled visualization of the preoperatively marked primary lesions in all 11 patients. During surgery, freehand SPECT also provided distance estimations to the lesions, facilitating their retrieval. Freehand SPECT image acquisition took 131.5s for ROLL, 155.5s for ROLL+SLNB and 69.2s for RSL on average. *Ex-vivo* real time display of the radioactivity in the excised tissue specimen in relation to the margins of the specimen was performed in all patients. Histopathologic margins were tumour negative in all 11 cases, in accordance with the *ex-vivo* images.

Conclusion: 3D intraoperative imaging using freehand SPECT may add valuable information to perform minimally invasive radioguided surgery in breast cancer. This technique may also be of value in other radioguided surgical applications involving tumour excision and sentinel node biopsy.

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Transparent Plastic Device; a New Tool for Near Infrared Guided Indocyanine Green Sentinel Node Biopsy in Breast Cancer

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Background: A novel method of using near infrared (NIR) guided indocyanine green (ICG) for sentinel lymph node biopsy (SLNB) in breast cancer has shown true potential. However, one of the major limitations of using this method has been the inability to transcutaneously visualize the sentinel lymph nodes (SLNs). A new compression technique using a transparent plastic device (TPD) has emerged as a possible solution in resolving this aforementioned problem. The aim of this study was to compare the usefulness of the TPD in SLNB of patients with breast cancer using NIR guided ICG and radiocolloid (RC) method.

Materials and Methods: A group of 28 consecutive breast cancer patients underwent SLNB using RC. From this group, the first 15 patients underwent NIR guided ICG without the TPD, while the next 13 patients underwent NIR guided ICG with the TPD. The number of patients with visible fluorescent path and nodes was recorded. Furthermore, the number of transcutaneous SLNs detected by the fluorophore and the total number of SLNs detected by fluorophores and/or RC were noted.

Results: In the first group without the TPD, RC method and NIR guided ICG method detected a total number of (mean = 1.6; range = 1−4) and (mean = 2.16; range = 1−4) SLNs respectively. In this group, NIR guided ICG allowed visualization of SLNs transcutaneously in 2/15 patients (13.3%). In the second group with the TPD, RC method and NIR guided ICG method detected a total number of (mean = 1.69; range = 1−3) and (mean = 2.15; range = 1−5) respectively. With the utilization of the TPD, NIR guided ICG allowed transcutaneous visualization of the SLNs in 12/13 patients (92.3%).

Conclusions: The simple employment of the TPD allowed for much higher transcutaneous visualization of the SLNs. However, it did not affect the total number of nodes harvested. Although further research is required, use of TPD seems to a crucial component in optimizing the NIR guided ICG SLNB in breast cancer patients.

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Oncological Safety of the Peri-areolar Incision for Wire Guided Excisions of Breast Lesions

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Background: In breast conserving surgery the challenge to combine safe excision and excellent cosmesis for benign and malignant lesions continues. Oncological safety is paramount; however a highly visible scar on the breast can cause psychological distress to the patient. The aim of this study was to investigate the oncological safety of using the peri-areolar