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AIM:
The Breast Lesion Excision System by Intact®(B.L.E.S) is a novel stereotactic, vacuum-assisted breast biopsy device that utilizes radiofrequency in order to completely excise any suspicious (BIRAD ≥4) non palpable mammographic lesion. The purpose of this clinical study is to evaluate the efficiency and success rate of the B.L.E.S system in the accurate diagnosis of any suspicious non-palpable mammographic lesions.

MATERIAL AND METHODS:
This study included 105 patients with suspicious non palpable mammographic lesions that visited the Breast Unit of the First Propaedeutic Surgical Clinic at Ippocation hospital from January 2008 to April 2010. The mammographic findings included suspicious microcalcifications, solid lesion and radial scars, all classified as BIRAD ≥4. The method was performed by the same surgical-radiologist team utilizing the Fisher's stereotactic table which includes a breast compression plate, incorporated digital mammography device, a robotic arm that carries the biopsy needle and a vacuum apparatus. The system is controlled by a central computer that performs the stereotactic localization. We utilize the 15mm or the 20mm tissue basket depending on the size of the lesion, trying to completely excise it with healthy margins, if possible. The procedure is performed under local anaesthesia (20ml of 2% Lydokaine) and is completed with a single needle pass. A 5-6 mm skin incision is performed and a retrieval basket is deployed to circumscribe the lesion, while radiofrequency is used to ablate the surrounding breast tissue. The basket containing the captured specimen is removed through the incision and the wound is dressed with steril strip. We routinely perform mammography on the specimen to insure the success of the biopsy and we place a titanium clip in the biopsy cavity to mark the area.

RESULTS:
One hundred and five patients with non palpable mammographic lesions underwent biopsy with the BLES - Intact® system. All lesions were excised completely, but not all with healthy margins especially in cases of DCIS with intraductal component. The histological findings included: Fibroadenoma:38 (36.1 %), Invasive Ductal Breast Cancer with associated DCIS 14 (13.3 %), papilloma: 11 (10.4 %), Fibrocystic changes 11 (10.4 %), Papillary Apocrine Metaplasia 7 (6.6 %), Stromal Fibrosis: 7
(6.6%), mammary duct ectasia: 6 (5.71%), DCIS :5 (4.7%), Liponecrosis: 2 (1.9 %), Intramammary lymph node: 2 (1.9%), Invasive Ductal Carcinoma: 1 (0.95%), Invasive Ductal Carcinoma with associated lobular in situ (LCIS): 1 (0.95%).

CONCLUSION:
Suspicious non palpable mammographic lesions can be safely removed for histologic diagnosis utilizing the BLES - Intact® system. The method has the unique advantage of completely removing the lesion without cutting through it. This way the specimen retains its original architectural structure intact, which means even more accurate histologic diagnosis and thus lower underestimation rates. Furthermore, the BLES system alliviates all concern for possible tumor dissemination through the needle tract since it comes in no contact with the tumor and can remove the lesion with healthy margins.