

Nano Technology :

Can this Replace the Gold Standard Histopathological Examination with the Help of the K. J. Oncotracker in Breast Lesions?

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Abstract

Breast cancer is so very common in India but unfortunately goes undetected till it gets advanced many a times in our country due to two main reasons. One being the less awareness among population about the self-screening method i.e., the self-breast examination that can catch up the disease early and the other being the economic status of many in our country that people can't afford to spend for the series of tests and examinations available to make a definite diagnosis itself, let alone the expenditure involved for the treatment. To bring down the agony of many and to catch the diseases at their early stages we have now invented a device called the K.J. Oncotracker designed specially and skilfully considering the comfort of the patient, safety from radiation exposure, non-invasiveness and thus causing zero degree pain to the patient.

Key words: Zetapential, Non-invasive, K.J. Oncotracker, Breast cancer.

Introduction

The breast is an exocrine gland. Structurally the breast has an areola which surrounds the nipple forming the nipple areola complex. Usually during development, the breast overlies the pectoralis major muscles and extend from the level of the second rib to the level of the sixth rib anterior to the rib cage. Vertically the breast tissue can extend from clavicle to the middle of the sternum. Horizontally it can extend into the axilla and can reach as far as to the latissimus dorsi muscle. The breast can develop anywhere in the mammary line ie; extending from mid clavicle to the medial aspect of the thigh at the level of mid groin in human beings.[1] Accessory rudimentary nipple – polythelia/

accessory fully developed breast – polymastia. The principal author had the opportunity to witness one case of a fully developed accessory lactating breast in the groin in a young woman who had come for some other comorbid condition and she wanted it to be removed.

The main function of the breast is to produce milk for the nourishment of the newborn. In early life, it remains rudimentary until puberty where the development takes place as a secondary sexual character. The breast gets fully functional during pregnancy. The breast development is brought about by the ovarian, adrenal and pituitary hormones. This sensitivity to hormones may play a role with susceptibility of the breast to both benign and malignant diseases.[2] Breast feeding, familial, genetic factors (bitners milk factor) and Partity has got relationship with the incidence of breast carcinoma and other lesions.[3] Breast cancer has ranked number one cancer among Indian females with age adjusted rate as high as 25.8 per 100,000 women and mortality 12.7 per 100,000 women.[4] It was estimated that 1,671,149 new cases of breast cancer were identified and 521,907 cases of deaths due to breast cancer occurred in the world in 2012. According to GLOBOCAN, it

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is the most common cancer in women, accounting for 25.1% of all cancers. Breast cancer incidence in developed countries is higher, while relative mortality is greatest in less developed countries.[5]

After the advent of oral hormonal contraceptive pills, there was a sudden spurt in the incidence of Ca breast in India 7% and globally 20%. [6] With the advent of surgical treatments, radiotherapy, chemotherapy, immunotherapy and genomic therapy the outlook has changed. Cure rate has very much improved to 90%. Till date man has been able to differentiate and diagnose malignancies and benign breast conditions only after clinical assessment, investigations like x-ray, ultrasound, computed tomography, mammogram, tissue diagnosis with fine needle aspiration cytology, fine needle aspiration biopsy with biopty gun and further treat

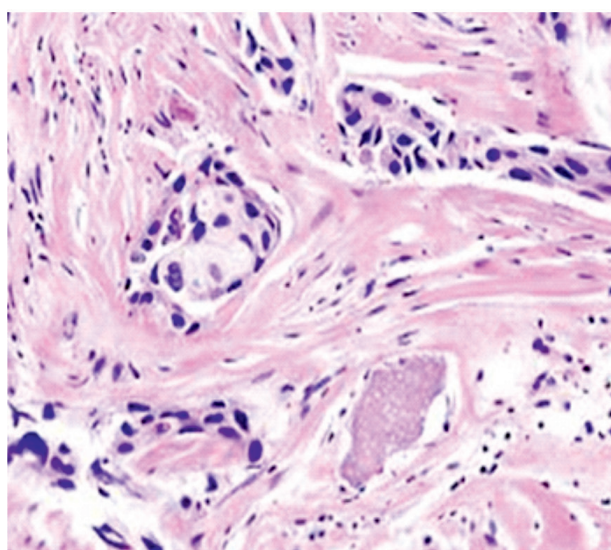
surgically.

Materials and Methods

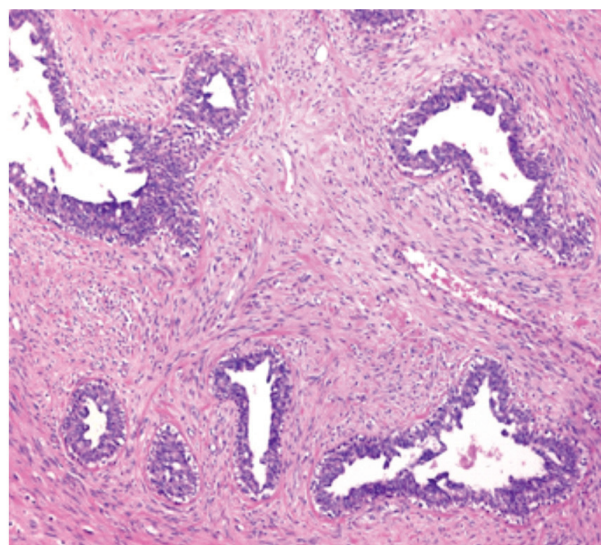
We have now innovated a simple non-invasive radiation free device called the K J Oncotracker (figure 1). It is a nano technology-based device which assesses the micro or nano potential of the tissue and based on two parameters that we are measuring, i.e., the zeta potential and temperature. We can differentiate if it is a normal breast tissue, a benign lesion or a malignant lesion. The main hardware of the system includes temperature sensor, electrical potential sensor, microcontroller and a liquid crystal display (LCD). It consists of two main parts namely the sensing system and the programming system. The sensing system consists of the temperature sensor and electrical potential sensor.



Figure 1: K. J. Oncotracker



Invasive Ductal Carcinoma H&E Stain



Fibroadenoma Breast H&E Stain

Figure 2: Fibroadenoma and Carcinoma of the breast

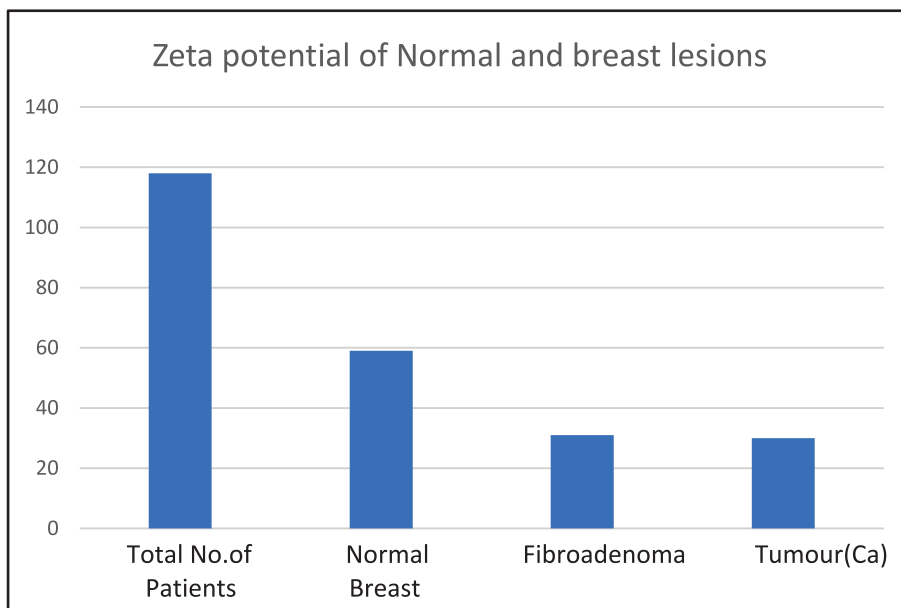


Figure 3: Zeta potential of Normal breast and breast lesions

Temperature in Fahrenheit

| Normal Breast | Fibroadenoma | Tumour(Ca) |
|---------------|--------------|------------|
| 96 to 99 | 100 to 103 | 104 to 109 |

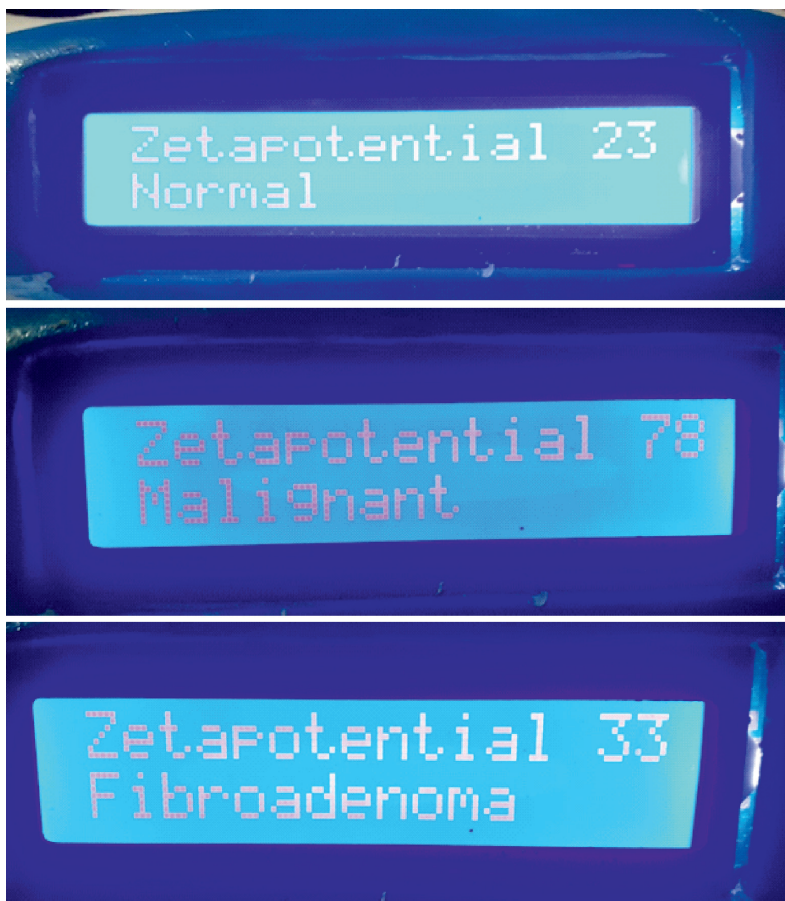


Figure 4: Zeta potential range of the normal breast, fibroadenoma and carcinoma

The output voltage of the sensor is given to the circuit which as an analog to digital converter through a microcontroller to an LCD. The LCD displays the outputs of the sensor. The device is directly placed on the breast and the sensors identify whether the lesion is benign or malignant.

With the proper consent of the patient, we have compared the results with histopathological examination as gold standard.

Initial work encouraged us to proceed further and this study involved about 118 patients inclusive of fibroadenoma and carcinoma of the breast, with their histology and grading (figure 2). This equipment can give the same without any form of invasion or radiation to the patient. It is a painless, precise and fast diagnostic procedure. On search of the literature, we found that this is the first of its kind. The women at high-risk age group should undergo testing using this device once in every 3-6 months which will help with early detection and prompt treatment and intervention to cure the underlying disease and thus make the life of the patient more comfortable.

The instrument measures the zeta potential as well as the temperature of the lesion which is much higher than normal breast tissue / surrounding tissue. We are presenting here the reports of 118 patients on whom this device has been used and the biopsy of the lesion is taken as gold standard. This device apart from diagnosing can tell the grade of malignancy in the breast. Probably sooner the invasive procedure can be replaced with K J Oncotracker. Statistically we found 100% accuracy when taken with Histopathological examination diagnosis. We hope in the near future the outlook on diagnosis and management of carcinoma breast will change for the better. It will make a gulf of difference to the already suffering patients. Now in Hyderabad another major centre is doing a dedicated study in their breast unit. The zeta potential range of the normal breast is 23 to 25 mill volts, for fibroadenoma is 32 to 35 mill volts and for tumour (Carcinoma) is 60 to 80 mill volts (figure 3 & 4). The results are compared and statistically analysed. The statistical significance of K.J. Oncotracker with the current diagnostic methods was found to be extremely significant as its P value obtained is 0.0001.

Few years back we had estimated the nano potential of the breast with the consent of the patient. After intervening with surgical procedure and tissue diagnosis we tried to correlate with the control (opposite breast) and it showed marked difference. Further we ventured into a study in one of the major institutions in Chennai in a dedicated breast unit. Now a study for non-invasive zeta potential measurement and temperature is in progress.

Conclusion

The K. J. Oncotracker has been designed and innovated in such a way that the diagnosis of breast diseases can be made early and prompt interventions can be taken to avoid both the physical and

mental trauma that the patient has to undergo otherwise if the disease is diagnosed in the late stages. It is a simple, non-invasive, painless, free from radiation device which provides results within seconds of testing thus reducing the waiting time for the results allowing both the patient and the doctor to discuss and plan about what can be done next, in case the results are positive for breast diseases, hence proving cost effective and life saving for the patient. The earlier the diagnosis is made the better quality of life a patient can lead. This will be a blessing, changing the fates of millions of women in the years to come. It could be used for self-examination replacing mammogram and other screening tests involving radiation. Further study is on for the grading of malignant lesions using the K.J. Oncotracker.

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