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Ultrasound-guided percutaneous insertion of small vascular surgical clips versus dedicated breast mammoclips as markers for breast cancer prior to neo-adjuvant therapy: a prospective randomized controlled trial

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Abstract

Aim: To investigate the feasibility of applying small vascular surgical clips as tissue markers for breast cancer in patients scheduled for neoadjuvant chemotherapy (NAC) in comparison with the dedicated breast clips with assessment of their different complications.

Patients and methods: This prospective randomized controlled trial included 160 female patients with breast cancer whose neoadjuvant chemotherapy was required for their management. Patients were randomly allocated into 2 groups; group I for patients who were subjected to the insertion of the small vascular surgical clips, and Group II for patients who were subjected to the insertion of the dedicated breast clips (UltraClips®). Assessment of the feasibility of the application of the vascular surgical clips and detection of the complications of the vascular surgical clips compared to the UltraClip® commercial clips were the endpoints of this study.

Results: Vascular surgical clips application had significantly longer duration than the duration of application of the UltraClips® (9.10 ± 2.67 min, and 5.44 ± 1.09 min respectively, $P < 0.001$). The application of vascular surgical clips was feasible in all patients. There were more incidences of non-deployment (6 patients) and mal-deployment (4 patients) in group I, compared to one patient and 2 patients in group II, respectively. All patients of non-deployment and mal-deployment in both groups had reapplication of other clips successfully. There were no significant differences between the two groups regarding incidence of complications.

Conclusions: The spinal needle/surgical vascular clip technique seems to be a cheap and effective alternative to the dedicated commercial mammoclips when required, with convenient results and minimal complications.

Keywords: Surgical clips, Mammoclips, Breast cancer, Neo-adjuvant therapy

Introduction

In the last decade, neo-adjuvant chemotherapy (NAC) has become an established modality of treatment for various types of breast cancer subtypes, such as triple negative and Her2 positive [1, 2]. Placement of tumor markers is unavoidable prior to NAC treatment because of the variable responses of the different types of the tumors

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to NAC [3, 4]. These variable clinical and radiologic responses of the tumors make the surgical excision more challenging due to the difficulty to verify accurate localization of the site of the previous tumor [3].

The use of different sizes titanium surgical ligating clips in labelling breast cancer had been tested using different techniques [5–8]. Dedicated breast mammoclips (corMARC, Ultraclip, Hydroclip) are costly devices (cost ranges from 170 to 215 US $). This is considered as an overburden for patients who are not covered by medical insurance. Non-insertion of the dedicated clips prior to the NAC regimen complicates the surgical decision later on as excision of larger breast volumes, up to mastectomy, may be required [9]. The problem is augmented in multifocal breast cancer where insertion of multiple markers is requested [10].

It has been reported that breast markers may have immediate and delayed complications. Immediate complications include hemorrhage, infection, non-deployment and inaccurate initial deployment, while delayed post-marker problem is migrations [5, 10–13].

Vascular clips are small size clips just similar to the dedicated clip type size. They are made of titanium and MRI compatible. In contrast to the dedicated breast mammoclips, the small vascular surgical clips cartilage is much cheaper and contains multiple clips. It costs approximately 9.2 US $. The use of the small surgical clips as markers for breast cancer instead of the dedicated breast mammoclips was suggested as a cost-effective alternative to the expensive dedicated breast mammoclips [14]. However, there is a paucity of the studies supporting this suggestion.

Therefore, this study aimed to investigate the feasibility of applying small vascular surgical clips as tissue markers for breast cancer in patients scheduled for NAC in comparison with the dedicated breast clips with assessment of their different complications.

Patients and methods

This prospective randomized controlled study was conducted over a period of two years from April 2018 to April 2020. Minimal sample size needed for each group was calculated to be 76. The calculation was based on α of 0.05, power of 0.80, confidence level 95%, assumed incidence of complications to be 4% [15], and odds ratio 6. It was calculated by using the Epi Info [16] program, developed by the Centers for Disease Control and Prevention.

The study included female patients with breast cancer whose NAC was required for their management. Patients who refused NAC or did not complete the course were excluded from the study. Also, patients who did not undergo ultrasonography after they finished NAC were excluded from the study. All patients underwent complete blood picture (CBC), bleeding profile (INR, PT and PTT) within a week from the procedure. Careful medical and medication history were obtained. None of them had an absolute contraindication to the procedure according to ACR guideline [17].

A total of 160 patients were randomly allocated using closed envelop technique into 2 groups; group I (80 patients), who were subjected to the insertion of the small vascular surgical clips, and Group II (80 patients), who were subjected to the insertion of the dedicated breast clips (UltraClips ®). Two sets of opaque envelops were prepared (I and II) each containing 80 envelops. They were closed and shuffled. An assistant nurse with no relation to the research was asked to choose an envelope just before the procedure and to inform the radiologists about the type of the procedure.

Technique of clips application

Both techniques used in the study were applied by the same team of expert interventional radiologists with an experience of 15–19 years. All procedures were performed under a completely aseptic technique.

Group I

Ligating vascular clip (small Titanium Ligating EURO-CLIPS. Ackermann instrumente GmbH. Eisenbahn-Strasse Wellheim. Made in Germany) was taken by the clip dedicated applier (VITALITEC ® stainless PJ 120-EB small Manufactured by Peters Surgical CE 2018-11) and was bent manually using a needle holder. The stylet of a disposable 18 Gauge spinal needle (Sterile single use S.Q Introducer Needle with Trocar. Q for plastic Industries. Land Plot #25, 1st Industrial Zone. Badr City 11,829, Cairo, Egypt) was withdrawn for one cm and the bent clip was inserted within the outlet of the spinal needle (Fig. 1). Spinal needles (3 US $) were chosen rather than coaxial needles (35 US $) as they were cheaper with same effectiveness, and achieve the target of having a cost-effective technique.

The patient lied down in the proper position either supine or oblique according to the tumor site and the breast was prepared with antiseptics. At the selected site for skin incision, the skin was infiltrated with xylocaine to form a bulla. With the ultrasound-guidance more xylocaine infiltration was performed through the course of needle to the mass. A puncture in the skin was done using a scalpel (size 11) then the ultrasound-guided spinal needle was introduced until its tip was immediately related to the center of the mass. The stylet was advanced to push the bent clip into the mass center or the desired location then the whole spinal needle was withdrawn smoothly (Fig. 2).

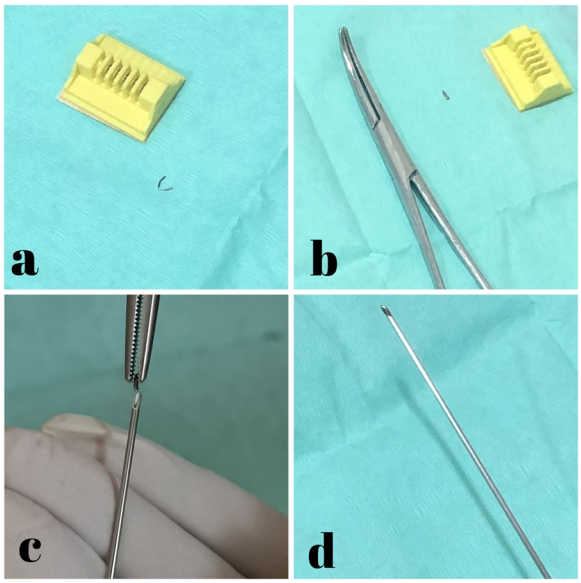

Fig. 1 Technique of surgical clip preparation. **a** Surgical clip cartilage and the opened clip. **b** The clip is closed by sterile needle holder and ready for use. **c** The closed surgical clip inserted within the beveled end of the spinal needle. **d** The spinal needle with the clip within

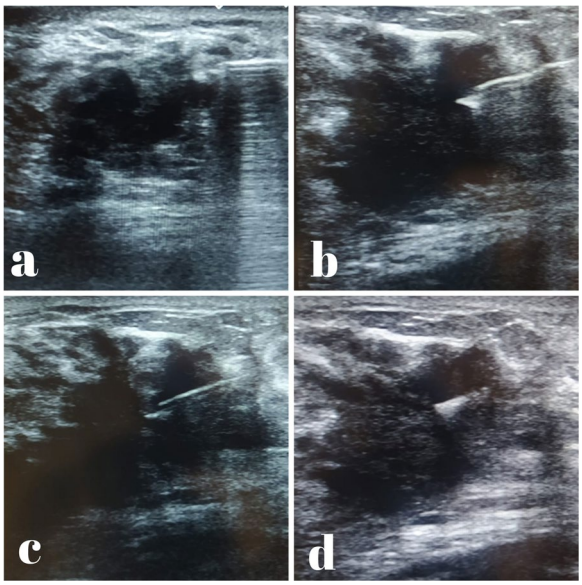

Fig. 2 A case of pathologically proved infiltrating ductal carcinoma (IDC). **a** The spinal needle at the margin of the mass. **b** The spinal needle enters the malignant mass. **c** The needle at the center of the mass and **d** The clip at the center of the mass after withdrawal of the needle

Group II

UltraClips® (Bard BIOPSY SYSTEMS. Bard Peripheral Vascular, Inc. 1625 West 3rd street. Tempe, AZ 85,281. USA) were used as tissue markers in group II. Insertion of the UltraClips® had the same preparations of the patient and the site of insertion as in group I. Ultrasound-guided advancement of the needle was performed till reaching above the center of the mass. Then, the firing button was pressed and kept in the pressed position while retracting the needle.

The position of the clip[s] was/were assessed by ultrasound (Fig. 3) and mammography (MLO and CC views) in all patients to ensure proper localization (Figs. 4, 5). Non-deployment and mal-deployment (when the marker deployed initially ≥ 1 cm away from the accurate location) were detected and reapplication of other clips was performed (Fig. 6). In case of multifocal lesions, either the clips were inserted in the center of each mass or bracketing technique was performed (Fig. 7). After assuring successful marking of the tissues, patients received their neoadjuvant chemotherapy.

All patients had MRI before the NAC and after finishing their NAC for assessment of the post-NAC response (Fig. 8). Patients were subjected to another mammography preoperatively for detection of late complications, such as migration of the clips.

Outcomes

Primary endpoints

- Assessment of the feasibility of the application of the vascular surgical clips as markers for breast cancer prior to NAC by determination of the success rate of its application.
- Detection of the complications of the vascular surgical clips as markers for breast cancer prior to NAC compared to the UltraClip® commercial clips by the radiologists immediately after performing the procedure and through follow-up radiological studies.

Statistical analysis

The statistical analysis of the data was done using the Statistical Package for Social Sciences (SPSS version 25; SPSS Inc., Chicago, Illinois, USA). Descriptive statistics were applied (frequency and percentage for categorical variables, mean and SD for quantitative variables). To test significance of differences between the studied groups, independent sample t-test was applied for quantitative

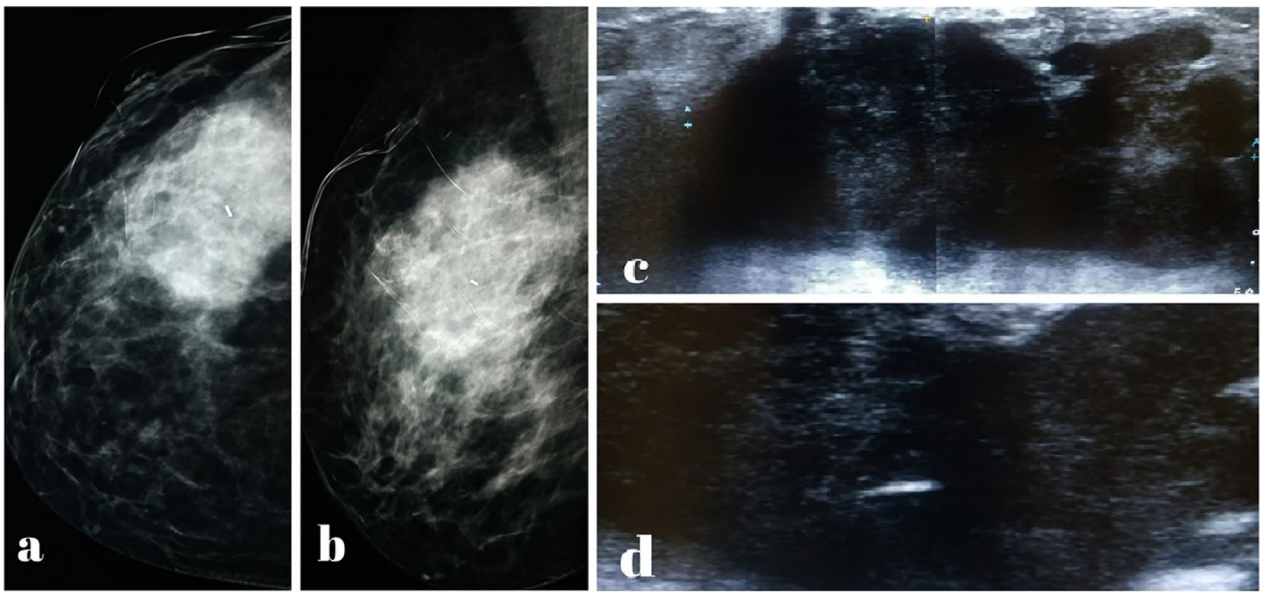

Fig. 3 Sixty years old lady diagnosed as locally advanced breast cancer (LABC) of not otherwise specified (NOS) infiltrating ductal carcinoma [IDC] type. **a**–**b** The CC and MLO views showing the centrally located surgical clip. **c**–**d** show the ill-defined, heterogeneously hypoechoic mass with centrally located hyperechoic surgical clip

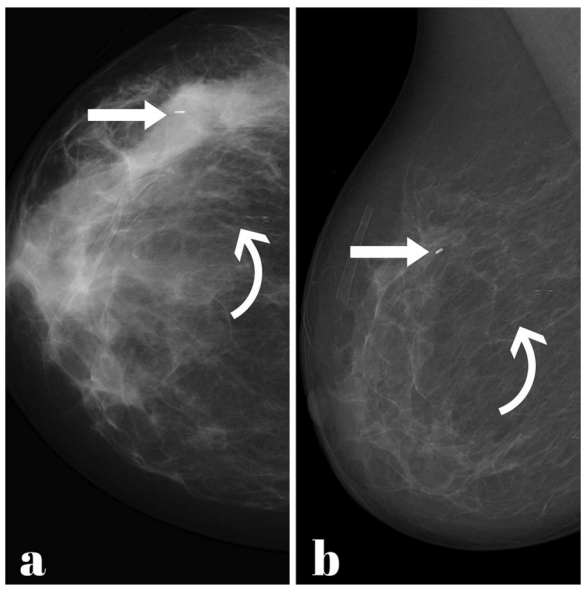

Fig. 4 Fifty-two years old lady diagnosed as right IDC. **a** MLO and **b** CC views show a central clip [straight arrow] within the speculated right upper outer breast mass. Linear calcifications are seen [curved arrow]

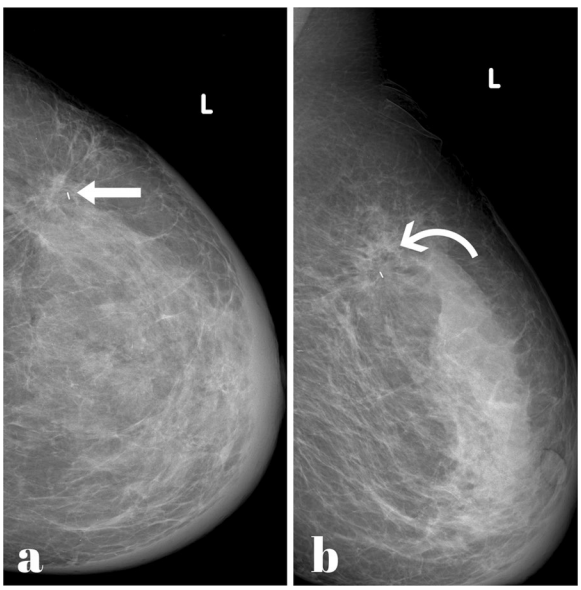

Fig. 5 Fifty-seven years old lady diagnosed as NOS IDC. **a**–**b** shows left CC and MLO mammograms with an upper outer quadrant isodense speculated mass [curved arrow] associated with architecture distortion and diffusely thickened breast skin. The clip is inserted within the mass [straight arrow]

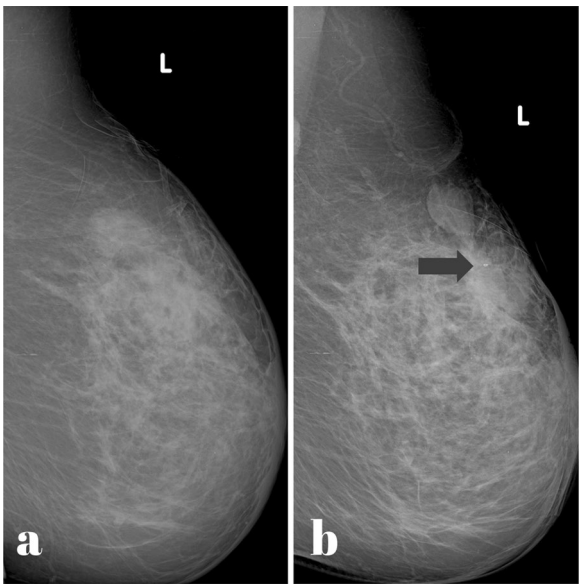

Fig. 6 Forty-eight years old lady diagnosed as IDC. MLO views show irregular shape hyperdense mass with distortion. **a** MLO after first trial to insert the clip showing non-deployment of the clip. **b** The clip marker is seen [arrow]. Curvy superficial dense lines are attributed to the bandage after trial [curved arrow]

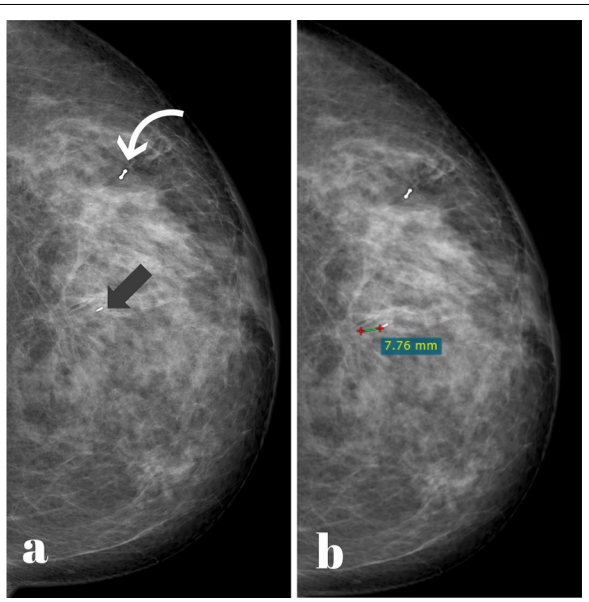

Fig. 7 Forty-five years old lady had a bicentric breast masses with initially diagnosed unifocal mass. **a** A dumbbell shape commercial clip [curved arrow] outside the institution. A second focus was identified and a surgical clip was applied [straight arrow]. **b** the clip is applied 7mm from the second focus

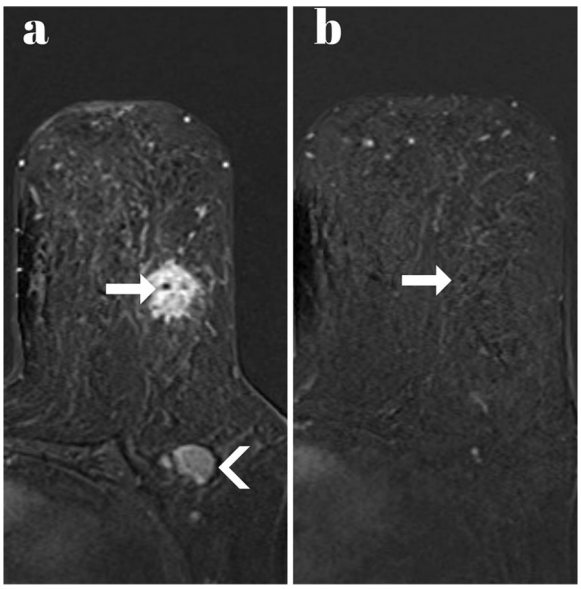

Fig. 8 Left breast T1 post-contrast subtracted images with pathologically proved 3 o'clock axis IDC on NAC. **a** A signal void artifact from the inserted surgical clip is seen at the center of the mass. **b** Complete radiological response after completion of the NAC cycles, still with the signal void clip artifact in place

data, whereas the χ^2-test was applied for qualitative data. A statistically significant P value was considered at P less than 0.05.

Ethical approval

The study was approved by the Institutional Research Board of the Medical Research Institute, Alexandria University (IORG#0,008,812). All precautions were taken to conceal the identity of the patients.

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Written informed consents were obtained from all patients participating in this study regarding the steps of the procedures, potential complications, and participation in the study.

Table 1 Demographic and preoperative clinical data of the patients

	Group I (Surgical clips) ($n=80$)	Group II (Commercial clips) ($n=80$)	*P* value
Age *n* (%)			
< 40 years	39 (50.6%)	38 (49.9%)	0.293
40–50 years	27 (44.3%)	34(55.7%)	
> 50 years	14 (63.6%)	8(36.4%)	
BMI *n* (%)			
Normal	8 (80.0%)	2 (20.0%)	0.138
Overweight	23 (46.0%)	27 (54.0%)	
Obese	49 (49.0%)	51 (51.0%)	
Tumor size *n* (%)			
< 40 mm	11 (44.0%)	14 (56.0%)	0.715
40–49 mm	23 (56.1%)	18 (43.9%)	
50–59 mm	26 (46.6%)	30 (53.6%)	
> 59 mm	20 (52.6%)	18 (47.4%)	
Tumor site *n* (%)			
Central	12 (54.6%)	10 (45.4%)	0.882
Lower Inner Quadrant	6 (42.9%)	8 (57.1%)	
Lower Outer Quadrant	7 (58.3%)	5 (41.7%)	
Upper Inner Quadrant	11 (55.0%)	9 (45.0%)	
Upper Outer Quadrant	44 (47.8%)	48 (52.2%)	
Clinical staging *n* (%)			
IIA	10 (41.7%)	14 (58.3%)	0.701
IIB	16 (45.7%)	19 (54.3%)	
IIIA	27 (54.0%)	23 (46.0%)	
IIIB	27 (52.9%)	24 (47.1%)	
Histopathological type *n* (%)			
Infiltrative ductal carcinoma	64 (49.6%)	65 (50.4%)	0.841
Infiltrative Lobular carcinoma	16 (51.6%)	15 (48.4%)	
Molecular Subtype *n* (%)			
HER-2 Positive	25 (51.0%)	24 (49.0%)	0.980
Luminal-A	20 (47.7%)	22 (52.3%)	
Luminal-B	8 (53.3%)	7(46.7%)	
Triple Negative	27 (50.0%)	27 (50.0%)	
ARC Classification *n* (%)			
A	17 (51.5%)	16 (48.5%)	0.550
B	25 (51.0%)	24 (49.0%)	
C	34 (52.3%)	31 (47.7%)	
D	4 (30.8%)	9 (69.2%)	

Results

The study included 160 female patients who fulfilled the inclusion criteria. They were randomly allocated in to group I (80 patients) who were subjected to vascular surgical clips application and group II who were subjected to UltraClips®. The demographic and the preoperative clinical data of the patients are shown in Table 1.

The procedure of vascular clips application had an average duration of 9.10 ± 2.67 min, which was significantly longer than the duration of application of the UltraClips® that had an average of 5.44 ± 1.09 min ($P < 0.001$). The application of vascular surgical clips was feasible in all patients. Nevertheless, there were more incidences of non-deployment (6 patients) and mal-deployment (4 patients) in group I, compared to one patient and 2 patients in group II, respectively. All patients of non-deployment and mal-deployment in both groups had reapplication of other clips successfully. Neither infection nor migration were reported in our study. There were no significant statistical differences between the two groups

Table 2 Comparison between the two groups regarding duration and complications

	Group I (Surgical clips) ($n=80$)	Group II (Commercial clips) ($n=80$)	*P* value
Duration of the technique (minutes)			
mean ± SD	9.10 ± 2.67	5.44 ± 1.09	< 0.001
Complications of clips application			
Non-deployment *n* (%)			
No	74 (48.4%)	79 (51.6%)	0.053
Yes	6 (85.6%)	1(14.3%)	
Mal-deployment *n* (%)			
No	76 (49.4%)	78 (50.6%)	0.405
Yes	4 (66.7%)	2 (33.3%)	
Hemorrhage *n* (%)			
No	77 (50.0%)	77 (50.0%)	1.000
Yes	2 (50.0%)	2 (50.0%)	

regarding incidence of complications. Data regarding complications of clips applications, response to neoadjuvant chemotherapy and surgical procedures among the two groups are shown in Tables 2, 3.

Discussion

Using clips after stereotactic breast biopsy was first described in 1996 [18]. Before that, biopsy site was identified by residual disease in various imaging modalities with the resultant of high rates of false positive and post-operative positive margins [13]. Since that time, the procedure of post-biopsy markers for breast cancer has been developing until becoming a routine practice nowadays [12, 19, 20]. Nevertheless, the relatively high cost of the dedicated commercial breast markers has limited the usage of these clips in the developing countries in which large number of patients are not covered by medical insurance. This situation created the necessity to provide a cheaper alternative to serve these patients and provide them with the best practice in management of their breast cancer. Unfortunately, limited studies evaluated the usage of the titanium based surgical clips in breast cancer and their comparability to the available dedicated commercial clips [8, 9, 14, 21–23].

In our study, the procedure of the surgical clips in group I took significantly longer time than that needed for the UltraClip® in group II. A similar finding was reported by Margolin et al. [24], who studied insertion of the surgical clips after stereotactic core biopsy for breast cancer, and required about 4 min for loading the clip into the needle. This finding seems logic due to the steps required to prepare the vascular clips. However, we noticed that this duration was reduced when the learning curve of the procedure was achieved.

In the current study, we used ultrasonography as a guiding imaging modality for insertion of the clips. Fora long time, ultrasonography has been known as a useful imaging modality for marker deployment [11]. Being cheap, available and with no radiation hazards added to the concept of our study by fulfilling our aim of offering an effective and cheap technique. Moreover, the development of the ultrasound high resolution machine aided to better visualization of the breast clip and pathological details [25, 26].

In this study, we experienced a perfectly successful visualization of all patients in both study groups. Koo et al. [10] conducted a study on 15 patients to compare the ultrasound visibility of surgical clips and ultra-clips. They stated that the visibility of the surgical clips was even better than the ultra-clips and owed that to the thickness of the surgical clip. This is matching with the current results, where the 18-gauge spinal needle and the bent clip were clearly visible on ultrasound with appropriate deployment of the clip in most cases.

We had found the visualization of the surgical clip better than the Ultraclip initially on firing. After completion of the NAC course, both clips are hardly

Table 3 Response to the neoadjuvant chemotherapy and operative procedures performed for both groups

	Group I (Surgical clips) ($n=80$)	Group II (Commercial clips) ($n=80$)	*P* value
Response to neoadjuvant therapy *n* (%)			
Complete response	9(40.9%)	13(59.1%)	0.358
Partial response	71(51.4%)	67 (48.6%)	
Surgical procedure *n* (%)			
Breast Conservative Surgery	38(61.3%)	24(38.7%)	0.094
Modified Radical Mastectomy	10(32.3%)	21(67.7%)	
Skin Sparing Mastectomy and expander	14 (53.8%)	12(46.2%)	
Skin Sparing Mastectomy and LD flap	10(41.7%)	14(58.3%)	
Skin Sparing Mastectomy and TRAM flap	8 (47.1%)	9 (52.9%)	

visualized on ultrasound when a complete radiological response had been achieved. Therefore, the mammogram was the modality of choice for wiring in case of complete radiological response.

Regarding the complications encountered in our study, there was a higher incidence of non-deployment among patients in group I [6 patients, 7.5%], compared to one patient [1.25%] in group II. This could be attributed to the complex technique of manual firing of the clip into the breast tissue if compared with the mechanical firing system of the UltraClip® commercial clip. Furthermore, two out of six patients with non-deployment in group I showed non-major hemorrhage after skin incision, despite their normal prothrombin time and International Normalized Ratio. None of the patients needed hospitalization or blood transfusion. They had large tumor sizes with increased tumor vasculature, which may be the cause of the bleeding. These two patients had non-deployment after advancement of the stylet. Margolin et al. [24] suggested that hemorrhage can wash out the clips with the resultant of non-deployment. Smith et al. [13] reported two device deficiencies, including one non-deployed CorMARK clip.

Mal-deployment was noted in 4 patients (5%) in group I, compared to 2 patients (2.5%) in group II. Such difference could be attributed to the complex sequence of the deployment of the vascular clips compared to the usual commercial clips. A similar incidence was reported by Rosen et al. [27].

The application of vascular surgical clips was feasible in all patients in group I, either in the initial application or in the second trial after initial non- or mal-deployments.

None of the procedures in our study was complicated by infection or allergy. These complications are quite rare and were only detected in case reports [23, 28]. Furthermore, migration of the clips (delayed marker movement from its initial placement location to a different breast site) was not encountered in any of our two study groups. Migrations of the clips were detected more frequently among clips deployed on stereotactic technique and attributed to the release of the compression plate that leads to accordion effect in the z axis direction [29]. Hematoma was also described as a cause for the migration after stereotactic guided clip placement [27, 30, 31]. Burnside et al. [32] suggested that reduction of the tissue resistance in a fatty breast may be a cause of breast migration.

The UltraClip® commercial clips system costs more than 20 folds than the spinal needle/surgical clip technique, which showed convenient results. Since the spinal needle/surgical clip technique was applied, almost all patients who were not covered by medical insurance had their chance for accurate management.

Conclusions

The spinal needle/surgical vascular clip technique seems to be a cheap and effective alternative to the dedicated commercial mammoclips when required, with convenient results and minimal complications.

Abbreviations

NAC: Neoadjuvant chemotherapy; US $: US dollars; SPSS: Statistical package for social sciences.

Acknowledgements

Not applicable.

Author contributions

All authors contributed to the study conception and design. Material preparation, data collection was performed by [EA.El-b], [MHS], [YNEl], and [AAM]. Analysis was performed by [YS.A], [MA.B] and [WM.AEl M]. The first draft of the manuscript was written by [EA.El-b], and [WM.AEl M]. All authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Availability of data and materials

Data will be available with the corresponding author to be provided on reasonable request.

Declarations

Ethics approval and consent to participate

The study was approved by the Institutional Research Board of the Medical Research Institute, Alexandria University (IORG#0008812). All precautions were taken to conceal the identity of the patients. All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Written informed consents were obtained from all patients participating in this study regarding the steps of the procedures, potential complications, and participation in the study.

Consent for publication

The authors give their consent for the publication of identifiable details, including photograph(s) details within the text ("Material") to be published in the Journal and Article.

Competing interests

The authors declare that they have no competing interests.

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