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ORIGINAL ARTICLE

Comparing tissue adhesive (2-octylcyanoacrylate) to subcuticular vicryl 3/0 skin closure following excision of benign breast masses

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Abstract

Background: Most breast lumps occur in females. They are a course of anxiety because of the fear of cancer and the distortion of the shape of the affected breast. Most women wish to remove such lumps but are also anxious about the resulting scar on their breast. The final arbiter for the optimal management of breast lumps is histology. This involves a biopsy which often requires an incision and consequently, a surgical scar. Several studies comparing various methods of skin closure after open biopsy, and illustrating varying cosmetic results have been reported. However, there is paucity of such studies on breast surgery in our environment.

Aim: This study compared 2-octylcyanoacrylate (OCA) and vicryl 3/0 subcuticular skin closure following excision of palpable benign breast lumps in terms of cosmetic outcomes, wound complication and patient satisfaction.

Methodology: This was a prospective randomised controlled study in which 70 patients were randomly allocated for skin closure of their wounds with either OCA or vicryl 3/0 subcuticular wound closure following breast lump excision biopsy. Cosmetic outcome was assessed using the Hollander wound evaluation scale (HWES) and the visual analogue scale (VAS). Wound management and complication rates, and patients' satisfaction were also compared. Data was collated and analysed using the statistical package for the social sciences (SPSS) version 23.

Results: A total of 67 patients completed the study and the outcome of 71 wounds was analysed: n = 34 for the tissue adhesive group (OCA) and n = 37 for the vicryl group (SVC). There was no statistically significant difference in age distribution, or educational status between both groups. Both groups had similar cosmetic outcomes when assessed using the Hollander wound evaluation scale (P=0.535) and visual analogue scale (P=0.232) with no statistically significant difference found between both groups. Similarly, patients' satisfaction and wound complication rates were the same, but OCA had a statistically significant faster skin closure time when compared to SVC (p=0.000).

Conclusion: The use of OCA did not give superior cosmetic results following excision of benign breast lumps when compared to SVC but was found to have a faster skin closure. OCA also had similar wound complication rates and thus can be incorporated into the practice of wound closure in our environment.

Keywords: Benign breast lumps, octylcyanoacrylates, wound closure.

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INTRODUCTION

There has been an increase in the number of patients attending the general surgery breast clinic with complaints.[1,2] The most common complaints are breast pain and palpable breast masses.[3] Breast masses are a heterogenous group consisting of both benign and malignant lesions. Benign masses are more common especially among younger patients.[3,4,5] This is corroborated by a study done in Zaria Nigeria, where out of the 428 breast biopsies reviewed, 71.3% were benign.[3] Other studies in different parts of Nigeria also reported similar findings.[1,2,5]

Of importance for the optimal management of breast lumps is the differentiation of benign, atypical and malignant tumours which require biopsy and histology.[6] A cosmetic approach to biopsy is recommended as aesthetics is essential in maintaining a healthy body image, especially in young females who are sensitive about their body appearance.[7] Cosmesis can be improved by apposing the wound edges in a manner that enhances healing by primary intention. If a continuous subcuticular suture is applied meticulously, the wound edges will be approximated accurately.[8] This type of suturing is preferred in linear and curvilinear wounds because it does not cause the crosshatch stitch marks produced by interrupted sutures.[8] Both absorbable and non-absorbable sutures can be used and have similar outcomes,[9] but absorbable sutures do not require removal.[10] Although wound closure with sutures is safe and effective, it can be time consuming, operator-dependent, and requires specialised instruments. It also carries the risk of a needle prick injury to the practitioner and may require a return visit for suture removal.[8] The advantages of cyanoacrylate adhesive over the conventional methods of suturing include rapid application and painless removal as it sloughs off spontaneously. They also reduce the risk of needle stick injury and do not form suture marks on either side of the wound. Cyanoacrylates are applied topically and do not tear through tissue or strangulate them.[11] The basic cyanoacrylate monomer is a low viscosity fluid, and on contact with various anionic substances such as blood, the cyanoacrylates polymerise into long chains forming a solid film that bridges the wounds and holds the apposed wound edges together.[12] The adhesive film generally sloughs off within 5 to 10 days as the epidermis regenerates, so there is no need to remove the adhesive.

Several studies have been done comparing tissue adhesive wound closure with other conventional methods of wound closure.[11,13] In a study of 25 women with bilateral breast reduction surgery in which one breast incision was closed with octylcyanoacrylate, while the other was closed with sutures, 95% of the women felt that the side closed with octylcyanoacrylate looked better than the other side closed with sutures and preferred closure with octylcyanacrylate.[14,15] Only a few studies have investigated octylcyanoacrylate in breast surgery in our environment. This study aimed to determine whether the physical properties of octylcyanoacrylates makes it comparable to sutures for closure of wounds following excision of palpable benign breast lumps in our environment and if it results in a superior cosmetic appearance.

MATERIALS AND METHODS

This study was conducted within the Department of Surgery at the University of Benin Teaching Hospital (UBTH) Benin City, Edo state.

INCLUSION CRITERIA

Female patients 18yrs and above with breast lumps which had both clinical and radiological features (BIRADS II and III) of benign breast

lesions, presenting at the surgical breast clinic,
who consented to be included in the study.

EXCLUSION CRITERIA

Patients with known blood clotting disorders. Positive personal or family history of keloids or hypertrophic scar formation. Patients who have lumps measuring 5cm or above. Known allergy to cyanoacrylate or formaldehyde. Patients who had histology of malignant disease following biopsy.

RANDOMISATION

A total of seventy (70) patients were recruited for this study by balloting technique while the concurrent parallel study design was used for patients with bilateral breast lumps. Patients who met the study criteria from the general surgery units were assigned to study (Group A) or control groups (Group B) by making them ballot from an opaque bag that contained forty pieces of wrapped paper marked 'A' and another forty pieces marked 'B'. Patients who had bilateral lesions were made to pick two separate pieces of paper, one for each breast. The papers picked were not returned to the bag. Randomization was revealed to the surgeon by the research assistant only after the subcutaneous stitches were applied. Patients in group A had their wounds closed using 2-octylcyanoacrylate, while those in Group B that had their wounds closed with subcuticular vicryl 3/0 suture.

PROCEDURE

After a detailed history, the breast was examined by the researcher to ensure the benign nature of the mass. This was further assessed radiologically mainly by ultrasound scan of the breast and by mammography in women 40 years and older. All excised lumps were submitted for histopathological confirmation of their benign nature.

Patients had excisional biopsies under local anaesthesia (10mls of 2% xylocaine + adrenaline diluted with 10mls of sterile water to give a 20mls solution) using either the circumareolar incisions for lesions within 5cm of the nipple areolar area, or a curvilinear incision on the lump for lesions further away. An incision 5cm in length (measured with the use of a tape rule and skin marker) was made to access lumps in all patients.

After excising the lump, adequate haemostasis was achieved by pressure packing and ligating bleeding vessels. For all patients, buried subcutaneous sutures (3-0 Vicryl) were applied to aid in apposition of the wound edge margins, relieve tension, ensure adequate skin edge eversion and prevent deposition of 2-octylcyanoacrylate (OCA) into the wound. The skin closure was done based on the patient's randomisation revealed by the research assistant just before skin closure, to avoid bias during the closure of the subcutaneous layer. Patients randomised into the control group had their wounds closed using a continuous subcuticular vicryl 3/0 suture, and then a dry dressing was applied. The wounds of patients in the study group were closed with OCA. The vial was crushed, and the adhesive was expressed through the tip and painted over the approximated wound edges. Care was taken to avoid pushing the tip of the introducer into the wound, and two coatings were applied 2 minutes apart. Dry dressings were then applied.

The time required for epidermal closure were recorded for both groups. This time included only the time required for applying the skin closure device, excluding time spent applying subcutaneous sutures, as this is independent of the method of epidermal closure. Timing was done with a stopwatch and started once the suture was mounted on the needle driver or the adhesive vial was crushed and ended once the closure device was placed down following closure.

Patients in both groups were placed on diclofenac tablets 50mg twice daily, paracetamol tablets 1g thrice daily, both for three days, and vitamin c tablets 100mg thrice daily, for two weeks. They were instructed to keep their wounds clean and dry for at least 72 hours after surgery. At each post-operative visit, three days, seven days, three weeks, and thirty days following surgery, the wound was inspected for infection, inflammation, wound dehiscence and scarring. The researcher carried out 75% of the surgeries, with other cases done by other senior registrars in general surgery who knew the protocol for carrying out the surgeries included in the study.

OUTCOME MEASURES

I. **Wound infection**. On the third and seventh post-operative day, wounds were examined for features suggesting infection (redness, swelling, differential warmth, undue tenderness, and discharge) and wound dehiscence (separation of the wound edges). Clinical suspicion of surgical site infection was confirmed by laboratory evaluation to isolate the aetiological agent using a swab of the wound discharge sent for microscopy, culture, and sensitivity pattern. Appropriate wound care and antibiotics if indicated, was then instituted. In addition, patients in the study group were instructed to allow the polymer to slough off from the wound site.

II. **Cosmesis.** On the twenty-first- and thirtieth-day follow-up visits, patients had bedside assessment of their wounds done by a plastic surgeon (who did not participate in the surgery and was blinded to the method of skin closure) using the Hollander wound evaluation scale (HWES)[16]. HWES is a descriptive measure that helps to define the VAS's numerical values and improve its validity. The wound score addresses clinical variables; absence of step-off borders, contour irregularities, scar width > 2mm, edge inversion excessive inflammation and overall cosmetic appearance. Each of these points is graded on a 0 or 1 point scale. A total cosmetic score is derived by adding up the six categorical variables. A score of 6 is considered optimal, while a score of < 5 is suboptimal. Step-off borders was noted to be present if the wound edges were on different planes. Scars with this characteristic were scored zero for that variable. If any puckering was noted along the length of the wound (contour irregularity), the wound was scored zero for that variable. The scar widths were measured with a measuring tape. If it was more than 2mm, the wound was scored zero. Edge inversion was identified by any sinking or depression along the length of the wound. If it was present, the wound was scored zero. If there was any discharge from the wound, it was scored zero. The total score for each wound was collated and recorded. In addition, patients blinded to the physician score assessed their degree of satisfaction with the cosmetic outcome of the wounds using a visual analogue scale (VAS).[16] The VAS for cosmesis is a 100mm line with 'worst scar' at the right end (0mm) and 'best scar' at the left end (100mm). Wound evaluation scores for both groups were then compared to determine if any significant difference was evident.

III. **Patient satisfaction**. A satisfaction score was also rated by the patient at three weeks, which included practical aspects of everyday living (degree of pain, ease of managing the wound) in the first three weeks after surgery. The score was on a scale of 1-10 with >5 for satisfied and < 5 as not satisfied.

RESULTS

A total of 70 patients who met the inclusion criteria during the study period were recruited into the study. However, two (2) patients were lost to follow – up at three weeks post-operatively, and 1 patient who had a histologic diagnosis of invasive ductal carcinoma was excluded. Thus 67

patients were included in the study, with an attrition rate of 4.3%. Sixty-three (94.0%) patients had unilateral breast lesions and 4 (6.0%) patients had bilateral lesions so a total of 71 breast lesions were operated on. Each of the 71 wounds were randomized individually with 34 wounds closed using tissue adhesive (OCA) and 37 wounds closed using subcuticular vicryl 3-0 suture (SVC).

DEMOGRAPHICS

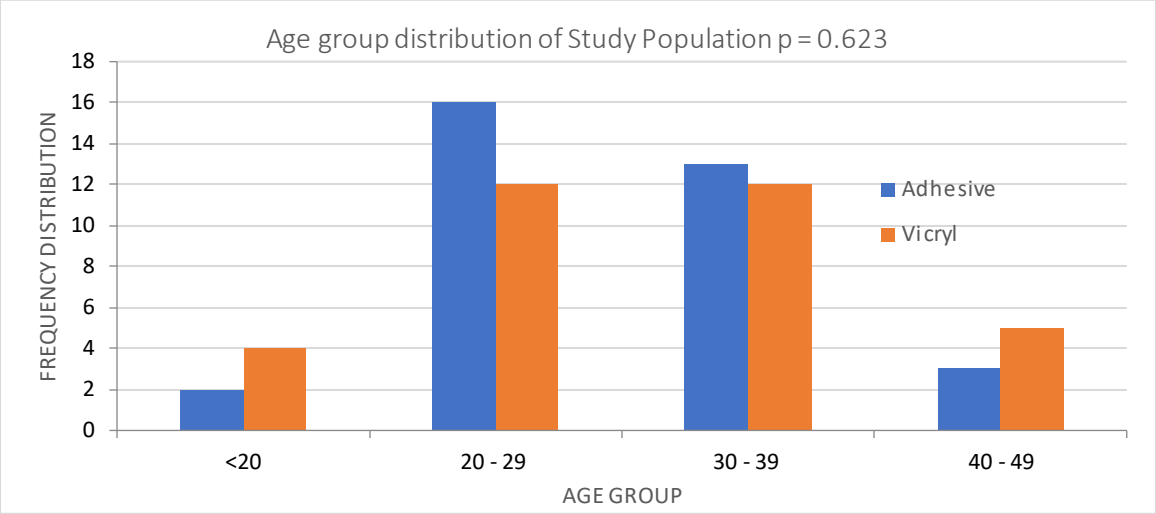

Figure 1: Age distribution of the patients in years.

Figure 1 above shows that most of the patients in the study were less than 40 years. Twenty-eight (41.8%) patients were between the ages 20 – 29, while 25 (37.3%) were aged between 30 - 39 years. The mean age of patients in the OCA group was 29.9 years while that for the SVC group was 30.3 years. There was no statistically significant difference between both groups (p = 0.623).

Table 1: Visual analogue scale (VAS) score for both groups.

VAS score	Adhesive n = 34	Vicryl n = 37	Total n = 71
6	0 (0.0%)	1 (2.7%)	1 (1.4%)
7	11 (32.4%)	15 (40.5%)	26 (36.6%)
8	21 (61.8%)	20 (54.1%)	41 (57.7%)
9	2 (5.9%)	1 (2.7%)	3 (4.2%)
10	0 (0.0%)	0 (0.0%)	0 (0.0%)

Table 1 above, shows that 20 (54.1%) wounds in the subcuticular vicryl group, had a visual analogue score (VAS) of 8 and 15 (40.5%) had a score of 7. One (2.7%) wound was scored 9 and another (2.7%), 6. The median score was 8 (interquartile range 6 - 9). In the tissue adhesive group, 21 wounds (61.8%) had a VAS score of 8, 11 (32.4%) wounds had a score of 7, and 2 (5.9%) wounds had a score of 9. The median was 8 (interquartile range 7 - 9).

Table 2 : Hollander wound evaluation score (HWES) for both groups.

HWES (0 – 6)	Adhesive n = 34	Vicryl n = 37	Total n = 71
3	0 (0.0%)	0 (0.0%)	0 (0.0%)
4	2 (5.9%)	1 (2.7%)	3 (4.2%)
5	20 (58.8%)	25 (67.5%)	45 (63.4%)
6	12 (35.3%)	11(29.7%)	23 (32.4%)

Table 2 above shows the scores of scars in both groups, using the Hollander wound evaluation scale (HWES), 12(35.3%) wounds in the tissue adhesive group had a score of 6, 22 (64.7%) wounds had a score less than 6. In the subcuticular vicryl group, 12 (32.4%) wounds had a score of 6, 25 (67.6%) wounds had a score less than 6.

Patients' satisfaction scores for both groups.

Satisfaction Score	Adhesive n = 34	Vicryl n = 37	Total n = 71
5	0 (0.0%	1 (2.7%)	1 (1.4%)
6	2 (5.9%)	4 (10.8%)	6 (8.5%)
7	15 (44.1%)	18 (48.6%)	33 (46.5%)
8	15 (44.1%)	14 (37.8%)	29 (40.8%)
9	2 (5.9%)	0 (0.0%)	2 (2.8%)
10	0 (0.0%)	0 (0.0%)	0 (0.0%)

As shown in table 3 above, fifteen (44.1%) patients in the tissue adhesive group had a satisfaction score of 8 and another 15 (44.1%), a score of 7. Two (5.9%) patients had a score of 9, and 2 (5.9%) had a score of 6.

In the subcuticular vicryl group, 18 (48.6%) patients had a score of 7 and 14 (37.8%) had a score of 8. Four (10.8%) patients had a score of 6, and 1 (2.7%) patient a score of 5.

Table 4: Comparing the mean values of duration of skin closure, cosmesis scores and patients' satisfaction score for both groups.

	Adhesive (n = 34)		Vicryl (n = 37)		P value
	Mean ± SD	95% CI	Mean ± SD	95% CI	
Duration	3.5 ± 0.5	3.3 – 3.7	6.3 ± 1.2	5.9 – 6.7	0.000
WES	5.3 ± 0.6	5.1 – 5.5	5.2 ± 0.5	5.1 – 5.4	0.535
VAS	7.7 ± 0.6	7.5 – 7.9	7.6 ± 0.6	7.4 – 7.8	0.232
Satisfaction	7.5 ± 0.7	7.3 – 7.7	7.2 ± 0.8	7.0 – 7.5	0.106

The mean duration of wound closure in the tissue adhesive group was 3.5 ± 0.5 minutes while that of the subcuticular vicryl group was 6.3 ± 1.2 minutes. The difference in the mean was statistically significant (p = 0.000). There was no statistically significant difference in mean of HWES scores between both groups (p-value = 0.535). The difference in the mean VAS scores and patients' satisfaction scores for both groups were also not statistically significant as shown in the table above.

Table 5: Complication rate in both groups

	Adhesive n = 34	Vicryl n = 37	Total	Stat	P value
Reaction	1 (2.9)	4 (10.8)	5 (6.9)	Fishers	0.359
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Haematoma	1 (2.9)	3 (8.1)	4 (5.6)	Fishers	0.615
Discharge	0 (0.0)	1 (2.7)	1 (1.4)	Fishers	1.000

As shown in table 5 above, one wound (2.7%) in the subcuticular vicryl group had a wound-related complication, which was serous discharge. The other complication noted was haematoma seen in 4 (5.6%) wounds. There was no statistically significant difference in the wound complication rates between both groups, as shown in the table above.

DISCUSSION

The mean age in the OCA group was 29.9 years, and that in the SVC group was 30.3 years. This mean age was similar to the study conducted by Umoke et al. (2019) in Gwagwalada, Nigeria[13]. This was the cluster age group for benign breast diseases**.** Data from the study showed that skin closure using OCA provided good cosmetic results and is comparable to SVC as shown in table 2. There was no significant difference between cosmetic outcomes of

healed incisions in the two groups. Cosmetic evaluation of

the wound was done 30 days post-operatively using the cosmetic visual analogue scale (VAS) assessed by the patient and the Modified Hollander Wound Evaluation Scale (HWES) assessed by the plastic surgeon, who was blinded to the method of closure. Overall, the cosmetic appearance of the scars in both arms of the study was judged to be good (>5), with a mean score of 5.3 ± 0.6 in the OCA group and 5.2 ± 0.5 in the SVC group. There was no statistical difference between them with a p-value of 0.535. There was also a good agreement between the surgeon (HWES) and patient (VAS) in rating the wounds. The mean VAS score in the OCA group was 7.7± 0.6, and that in the VAS group was 7.6 ± 0.6.

Dinakar et al. (2019)[17] reported similar results, finding no significant difference between wounds that were closed using tissue adhesives and those that were closed with sutures as evaluated using the HWES (p-value = 0.97). In the comparative study of OCA and sutures in skin closure following breast excisional biopsies conducted by Umoke et al. (2019)[13], similar cosmetic results were found between both closure methods (mean HWES scores: OCA, 4.9 ±1.3, SWC, 5.4 ±0.9; p = 0.262) with no statistically significant difference between them. Gennari et al. (2004)[16] studied the use of tissue adhesives versus sutures in skin closure following breast surgery, some of which included wounds created during mastectomy with reconstruction surgery and axillary dissection. They also found no differences in the wound evaluation scale as rated by the patient or plastic surgeon. with OCA, their comparison was to closure with staples, not sutures.

As shown on table 4, it took half the time to close wounds with OCA (mean of 3.5 ± 0.5) when compared to SVC (mean of 6.3 ± 1.2). This difference was significant with a p-value <0.05. This finding is similar to results reported by Umoke et al. (2019) in which it took a quarter of the time to close wounds of similar length with OCA compared to sutures.[13] Gennari et al. (2004) found that using OCA significantly decreased the time required to close breast incisions.[14] Other studies have reported a similar superior wound closure time using OCA.[18-21] The more the wound length, the greater the time saved as the application of OCA unlike sutures, does not require more time as the length of the incision increases.[14] This reduced time in closing skin wounds translates to shorter operating time as well as increased efficiency[14].

The difference in mean patient satisfaction scores between the OCA (7.5 ± 0.7) and SVC (7.2 ± 0.8) groups was not statistically significant, with a p-value of 0.106 in this study. The study by Gennari et al. (2004) showed that the patient's satisfaction score in the OCA group was significantly higher than that of the suture (SWC) group (OCA, 9.5 vs SWC, 7.45; P <0.0001).[14] One of the major advantages the OCA group had over the suture group, as noted by the authors, was the possibility of participants in this group to shower immediately after surgery. No dressings were applied over their wounds in contrast to participants in the suture group. A similar finding was observed by Hall et al.

(2005) who conducted their study in a similar fashion.[22]

The safety of OCA for skin closure has been reported in multiple studies that showed it had a similar infection and wound dehiscence rates as suture closure.[13,14,19]

Most patients in this study had satisfactory healing as evaluated on day seven follow-up. One (2.7%) patient in the SVC group had wound discharge. One (2.9%) patient in the OCA group and three (8.1%) patients in the SVC group had haematomas. The difference between both groups was not statistically significant, with a p-value of 0.615. The haematomas were not likely related to the method of skin closure but reflect inadequate control of haemorrhage prior to skin apposition. The wound infection rate (1.4%) in this study may be attributed to the fact that the study was on clean breast surgeries in otherwise healthy patients. Martin et al. (2017)[21] conducted a study that included patients predisposed to impaired wound healing secondary to chemotherapy, tumour-related cachexia and effect of chronic disease. They had three cases of wound infection (two in the suture group, and one in the tissue adhesive group) with no statistical difference between them.

CONCLUSION

There was no statistically significant difference in cosmetic outcomes between OCA and SVC used for wound closure following excision of benign breast lumps.

Tissue adhesive (OCA) had a statistically significant faster skin closure time when compared to closure using SVC.

The use of OCA for wound closure is safe, with both OCA and SVC having similar wound dehiscence and infection rates following use for wound closure.

Patient satisfaction following the closure of wounds using OCA was similar to that following SVC with no statistically significant difference between both groups.

LIMITATIONS OF THE STUDY

Follow-up was limited to 30 days in an attempt to complete the study within the stipulated time. Cosmetic appearance continues to evolve for up to a year following surgery[18] and so a longer follow-up may have influenced the results obtained for cosmesis of the scar.

Patients in the OCA group had their wounds dressed like those in the SVC group so as to standardise wound care and blind participants to the method of skin closure. However, this prevented patients in this group from taking a shower in the first three post-operative days and required them to return for wound inspection. Similar studies have reported superior

patient satisfaction in patients who had tissue adhesive applied for wound closure with their wounds left open because they were able to take a bath on the day following surgery.[16]

OCA is not readily available in Nigerian pharmacies and can only be procured online or with the assistance of a pharmaceutical representative.

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