



## Randomized Controlled Trial comparing Dressing and No Dressing of Surgical Wound after Cleft Lip Repair

<sup>1</sup>Olalere Omoyosola Gbolahan, <sup>2</sup>Stella Amiede Ogunmuyiwa, <sup>3</sup>Babatunde Babasola Osinaike

### ABSTRACT

**Background:** Cover wound dressings are regarded as important postoperative care following surgical intervention. Opinions differ on whether the cleft lip repair wound should be routinely covered by dressings or not. Therefore, a well designed randomized controlled trial is required to determine if routine cover dressing offers a better outcome.

**Aim:** The aim of this study was to compare the outcome of wound and cosmetic appearance of cleft lip repair in a randomized controlled trial between cover wound and no wound dressing groups.

**Materials and methods:** Forty consecutive patients requiring cleft lip repair were randomized prospectively to receive the traditional wound dressing cover (n = 20) or had the wound left exposed without any dressing cover (n = 20), after the completion of cleft wound closure. The main outcome measures were wound infection and dehiscence rates in the two groups, in addition to the scar cosmetic outcomes.

**Result:** The two groups were comparable in terms of age and sex. The incidence of wound infection was 0% (0/20) in cover dressing group as compared to 5% (1/20) in no cover dressing group (p = 0.31). No statistical significant differences in the wound dehiscence rate between the wounds that received dressing (15%) and those with no dressing (20%) were observed. The mean diameter of scar at the 5th to 8th week review appointments was almost similar between the group with dressing (3.29 ± 1.26 mm) and no dressing (3.62 ± 1.28 mm). The patient reported outcome in relation to the cosmetic appearance of the scar after repair was similar in the two groups.

**Conclusion:** There was no difference in the main outcome measures between the group that had cover dressing and those with exposed wound after cleft lip repair surgery. This study demonstrates that dressing of cleft repair wound may be unnecessary.

**Keywords:** Cleft lip, Wound dressing, Surgical outcomes.

**How to cite this article:** Gbolahan OO, Ogunmuyiwa SA, Osinaike BB, Alabi A. Randomized Controlled Trial comparing Dressing and No Dressing of Surgical Wound after Cleft Lip Repair. *J Contemp Dent Pract* 2015;16(7):554-558.

**Source of support:** Nil

**Conflict of interest:** None

### BACKGROUND

Traditionally, covering of surgical wound with a sterile dressing is usually considered a routine conclusion to an aseptic operation.<sup>1</sup> Varieties of dressing agents and materials are available depending on the wound, site and the surgeon's preference among other factors. One of the agents employed for dressing after surgical repair of cleft wound is antibiotic ointment (the commonest example being gentamicin ointment).<sup>2</sup> Other materials and agents include wet sterile gauze, dry sterile gauze held in place with an adhesive tape used alone or with antibiotic ointment.<sup>3,4</sup> The rationale for placing these dressings is based on the assumption that they provide a barrier to microbial contamination and thus reduce the risk of surgical site infection (SSI), which could be a major source of morbidity and increased cost following surgery.<sup>1,3</sup> Other potential benefits of wound dressing are: offering physical barrier, preventing tension over the site of repair, absorption of exudates, moisture retention or rehydration, antimicrobial activity, odor absorption, thermal insulation and meeting patient's desires for wound coverage.<sup>2,3,5</sup> Despite these potential benefits, some authors have actually shown that not only might dressing of clean surgical wound be unnecessary, but

<sup>1</sup>Department of Oral and Maxillofacial Surgery, University of Ibadan/University College Hospital, Ibadan, Oyo, Nigeria

<sup>2</sup>Oral and Maxillofacial Surgery Unit, Federal Medical Centre Abeokuta, Ogun, Nigeria

<sup>3</sup>Department of Anesthesia, University of Ibadan/University College Hospital, Ibadan, Oyo, Nigeria

**Corresponding Author:** Olalere Omoyosola Gbolahan  
Department of Oral and Maxillofacial Surgery, University of Ibadan/University College Hospital, Ibadan, Nigeria, e-mail: gbolahanlere@yahoo.com

also that it might actually have a number of detrimental effects on the wound.<sup>4,6</sup> Some of the problems reported in published work include adverse skin reaction to the dressing materials, additional cost, increased nursing time, barrier to easy visualization and monitoring of the wound; potentially prolonging the hospital stay.<sup>1,4</sup> It is also claimed that application of cover dressing on the facial wounds may draw unnecessary attention from the public causing embarrassment. In particular, it may constantly draw the attention of the patients especially the infants to the presence of the wound with the constant urge to fiddle with the dressing and wound and thereby risking wound disturbance with potential adverse consequences. In spite of these controversies about the role of dressing of surgical wounds, most surgeons working on cleft continue to use some form of dressing at the completion of cleft lip repair surgery.<sup>7-9</sup> The choice of placing a formal wound dressing or not, and the particular type of dressing on cleft repair wound is at the discretion of the attending surgeon.<sup>3,10</sup> There is a need to always justify the choice of treatment modality on whether it has a net beneficial effect to the patient [patient oriented evidence that matters (POEM)].<sup>11</sup> To the best of our knowledge, no study has compared the outcome of 'dressing' vs 'no dressing' of cleft repair wound in a randomized controlled fashion.

The main aim of this study was to compare the outcome of wound and cosmetic appearance of cleft lip repair in a randomized controlled trial between cover wound and no wound dressing.

## MATERIALS AND METHODS

The study was a prospective, single blind, randomized controlled one carried out between September 2012 and August 2013 at sacred heart hospital, Lantoro, Abeokuta (a tertiary health facility in south western Nigeria). Ethical approval was obtained from the hospital ethics committee and informed consent obtained from the patients in case of adults, and parents or guardians of the minors. Forty consecutive pediatric and adult patients who presented to the cleft unit of the hospital, requiring cleft lip repair, were randomized equally into two groups (groups A and B) with a computer generation of random numbers. Group A (dressing) had gentamicin ointment applied over the cleft repair wound and this was covered with dry gauze and held in place with an adhesive tape for the first 72 hours postoperatively. Gentamicin ointment alone was thereafter applied for the next 4 days. Group B (no-dressing) had a gauze dressing placed over the cleft repair wound for the first 6 hours postoperatively. Thereafter, the gauze dressing was removed without further dressing. In this

study, gentamicin cream was applied as part/form of cover dressing in the study group.

A doctor blinded to the objectives of the study assessed the wound daily, while the patient was on admission for any sign of infection (based on 'modification of the criteria developed by center for disease control (CDC) for defining SSI' by Horan et al reaction to dressing or suture breakdown.<sup>12</sup> This observation was continued during weekly review after discharge for the next 6 weeks and data were collected. Between the 6th and 8th week postoperation, the quality of the scar was assessed by measuring the scar width with the use of vernier calipers, and thereafter the satisfaction with surgical outcome was sought from the patients or their guardians. In cases of wound discharge, the characteristics of discharge were noted, swab taken with a sterile swab stick and subsequently sent for microscopy culture, and sensitivity testing where indicated.

Data analysis was done using statistical package for social sciences (SPSS, version 17.0, Chicago IL). The continuous data is presented as mean with standard deviation or as median with interquartile range (IQR) and categorical variables presented as counts (percentage). Categorical variables were compared using a Chi-square test while normally distributed continuous variables were compared using the student's t-test. Statistical significance was set at  $p \leq 0.05$ .

## RESULTS

A total of 40 patients participated in the study. The median age for those in the dressing group was 4.5 months (3 months and 65 years), while that for the non-dressing group was 6.5 months (3 months and 55 years) ( $p = 0.42$ ). Unilateral cleft lip plus or minus cleft palate (UCL +/- P) was the commonest type of cleft in the two groups. All unilateral cleft lips were repaired using the Millard's rotational advancement flap technique, while all the bilateral clefts were repaired using the forked flap technique. The two groups were comparable in terms of age, sex, type of cleft and the surgical procedure. Table 1 shows the patients' characteristics and type of surgical repair.

The duration of surgery ranged from 40 to 155 minutes with mean values of  $60.00 \pm 21.08$  and  $76.40 \pm 29.03$  minutes for the dressing group and no-dressing groups, respectively.

Wound infection occurred in one patient in the no-dressing group and none in the dressing group, giving an overall infection rate of 2.5%. The culture of the swab taken from the only infected wound yielded Gram positive *Staphylococcus aureus*, sensitive to ofloxacin and ciprofloxacin.

**Table 1:** Patient characteristics

|   | Dressing group<br>(n = 20) | No dressing group<br>(n = 20) | p-value |
|---|----------------------------|-------------------------------|---------|
| Age (median) months                         | 4.5                        | 6.6                           | 0.42    |
| <b>Gender</b>                               |                            |                               |         |
| Male  | 15 (75%)                   | 10 (50%)                      | 0.19    |
| Female                                      | 5 (25%)                    | 10 (50%)                      |         |
| Weight (mean) kg                            | 10.74 ± 14.60              | 17.32 ± 22.44                 | 0.28    |
| Duration of surgery (mean) minutes          | 60.00 ± 21.08              | 76.40 ± 29.03                 | 0.36    |
| <b>Type of cleft</b>                        |                            |                               |         |
| Right unilateral cleft lip +/- cleft palate | 10 (50%)                   | 6 (30%)                       | 0.59    |
| Left unilateral cleft lip +/- cleft palate  | 7 (35%)                    | 9 (45%)                       |         |
| Bilateral cleft lip +/- cleft palate        | 2 (10%)                    | 4 (20%)                       |         |
| Tessier 7: Orofacial cleft                  | 1 (5%)                     | 1 (5%)                        |         |
| <b>Type of surgical repair</b>              |                            |                               |         |
| Millard's rotational advancement flap       | 17 (85%)                   | 15 (75%)                      | 0.62    |
| Forked flap                                 | 2 (10%)                    | 4 (20%)                       |         |
| Direct closure in layers                    | 1 (5%)                     | 1 (5%)                        |         |

Minor wound dehiscence occurred in three patients (15%) in the group that had dressing and in four patients (20%) in the no-dressing group. All wounds except one that dehisced in the no-dressing group had healed by the 5th postoperative week. The mean diameter of scar between the 6th and 8th week was 3.29 ± 1.26 mm in the dressing group as compared to 3.62 ± 1.28 mm in the no-dressing group. However, this difference was not statistically significant (p = 0.49) (Table 2). Patient-reported outcome showed that one patient in the no dressing group and none in the dressing group were dissatisfied with the outcome of surgery. However, this difference was also not statistically significant either. The mean scar diameter and patient satisfaction with outcome of repair is depicted in Table 2. There was no reported local skin reaction to the dressing materials in the two groups.

**DISCUSSION**

This study has shown no difference in surgical outcome and patient satisfaction following cleft lip repair, whether dressing is applied or not. Similar to previously published works, our result has shown no statistical significance in the rate of infection between the wounds that had dressing and the ones that had no dressing.<sup>1,4,13</sup>

**Table 2:** Mean scar diameter and patient satisfaction with outcome of repair

|                      | Dressing<br>(n = 14) | No dressing<br>(n = 19) | p-value |
|----------------------|----------------------|-------------------------|---------|
| <b>Scar diameter</b> |                      |                         |         |
| Diameter of scar     | 3.29 ± 1.26          | 3.62 ± 1.28             | 0.491   |
| <b>Satisfaction</b>  |                      |                         |         |
| Satisfied            | 14                   | 18                      | 0.383   |
| Not satisfied        | 0                    | 1                       |         |

The routine use of dressing following cleft repair to prevent SSI may have some benefit, either real or imaginary, in some clinical settings. Such clinical settings include a situation, where cleft repair patients are nursed on the same ward with all other categories of surgical wounds (clean, dirty and infected wounds), thereby preventing the exposure of such wound to the risk of SSI. Anecdotally, it is argued that in such a setting, applying a form of dressing in the first 2 to 5 days allows healing to have progressed enough to seal off the wound from outside contamination. Although this argument sounds logical, it does not have much real scientific evidence in the literature to support it. It has been shown in experimental studies that healing wounds rapidly develop a coagulum of blood and fibrin within 2 to 6 hours of closure which is impenetrable to bacteria.<sup>4,14</sup> Therefore, if the wound could be kept free of bacteria until coagulum has formed, then infection is unlikely. Most of the cleft patients do not get to the ward earlier than 3 hours after closure because of the time spent between the theater, recovery room and the ward. If proper hemostasis is achieved at the time of surgery, coagulum must have formed before the patient gets to the ward, thereby making infection unlikely. This view is supported by the works of Law and Ellis, who found no increase in the incidence of wound infection by exposure to potential pathogens when dressings are omitted; and the work of Ajao done in a general surgical ward showing no significant difference in rate of infection between dressed and undressed wound.<sup>4,6</sup>

Other perceived benefits that researchers have claimed for placing a form of dressing on surgical wound after closure include—protecting the site of repair against trauma and tension, and acceleration of angiogenesis due to hypoxic environment under occlusive dressing, all of which are said to reduce healing period and result in



esthetic scar.<sup>8,15,16</sup> However, these are assumptions that have not been substantiated and as observed in previous reports, dressing or no dressing does not influence wound dehiscence or quality of scar.<sup>3,4,17,18</sup>

Similarly, in our study there was no statistically significant difference in the rates of wound dehiscence as well as the quality of scar between the dressed and undressed wounds. One of the rationale for placing dressings on surgical wounds is the assumption that they provide a barrier to microbial contamination and thus reduce the risk of SSI, which could be a major source of morbidity and cost, following surgery.<sup>1,3,19</sup> Different rates of SSI have been reported in published literature and is influenced by several factors among which are; the surgical procedure, the degree of bacterial contamination (clean, clean-contaminated, contaminated and dirty wounds), amongst others.<sup>19,20</sup>

Cleft lip repair wound can be regarded as clean-contaminated wound and the reported infection rate is between 1.7 and 12%.<sup>19</sup> The infection rate of 0 (dressed wound) to 2.5 % (no dressed wound) found in our study is in the lower limit of the rate (1.7–12%) generally reported for clean-contaminated wounds in other parts of the body, but similar to values (0–2.6%) previously reported for cleft lip repair wound.<sup>3,9,19,21</sup> Orofacial tissues generally have a higher resistance to infection due to the abundant vascularity and this may well explain the lower rates of SSI in the orofacial region compared to other regions of the body.<sup>22</sup>

When the patients were assessed for satisfaction with outcome of treatment, all except one in the group that had no dressing were satisfied. This finding is similar to the findings in previous studies that reported no significant difference in outcome of treatment between dressed undressed wounds.<sup>18,23</sup> The only patient that expressed dissatisfaction with outcome of treatment was the one, who still had wound dehiscence at the period of assessment for outcome of treatment. It is conceivable that the dehisced wound would have caused some form of esthetic detractor that may make the patient dissatisfied with the outcome of treatment. The small sample size of our study may be a limitation.

## CONCLUSION

Dressing a cleft repair wound at the completion of closure does not seem to reduce the rate of SSI. Quality of scar as well as patient satisfaction with outcome of treatment does not seem to be influenced by dressing or not dressing a cleft repair wound. There is a need for randomized control trials with a larger sample size in future, which should also evaluate the cost-benefit ratio of dressing or not dressing a cleft repair wound.

## List of Abbreviations

- SSI: Surgical site infection
- POEM: Patient oriented evidence that matters
- CDC: Center for disease control
- SPSS: Statistical package for social sciences
- IQR: Interquartile range
- UCL +/- P: Unilateral cleft lip plus or minus cleft palate

## AUTHORS' CONTRIBUTIONS

Olaere Omoyosola Gbolahan was involved in the conception and design of the study and participated in the analysis and write-up of the manuscript. Stella Amiede Ogunmuyiwa was actively involved in the design of the study and participated in recruiting the subjects, obtaining information from the subjects and writing the manuscript. Babatunde Babasola Osinaike was involved in designing the study as well as statistical analysis and write-up of the manuscript. All authors read and approved the final manuscript.

## ACKNOWLEDGMENTS

Dr Ayantunde A Abiodun and Dr Adisa Akin for reading the manuscript and offering valuable advice.

## REFERENCES

1. Merei JM. Pediatric clean surgical wound: is dressing necessary? *J Pediatr Surg* 2004 Dec;39(12):1871-1873.
2. Royal Pharmaceutical Society of Great Britain and others. *British National Formulary 61 In*. London: The Society; 2011. p. 1036.
3. Walter CJ, Dumville JC, Sharp CA, Page T. Systematic review and meta-analysis of wound dressings in the prevention of surgical-site infections in surgical wounds healing by primary intention. *Br J Surg* 2012;99(9):1185-1194.
4. Law NW, Ellis H. Exposure of the wound—a safe economy in the NHS. *Postgrad Med J* 1987;63(735):27-28.
5. Musgrave, RH, Garrett WSJ: The unilateral cleft lip. In Converse JM (Ed), *Reconstructive plastic surgery*. Philadelphia Saunders, 1964. Pp. 1360-1388 accessed at <http://premak.tripod.com/ENT/Converse/conv43.pdf> on 13-03-2015. In.; 2015.
6. Ajao OG. Surgical wound infection: a comparison between dressed and undressed wounds. *J Trop Med Hyg* 1977 Sep;80(9):192-196.
7. Chen PKT, Noordhoff MS, Liou EJW. Treatment of complete bilateral cleft lip-nasal deformity. *Semin Plast Surg* 2005 Nov;19(4):329-342.
8. Elhadidy AM and Eldeen AM, Elbassiouny L. An improved technique for repair of bilateral cleft lip deformities through extensive muscle dissection in one stage surgery. *Egypt J Plast Reconstr Surg* 2006;30(2):131-137.
9. Nagy K, Mommaerts MY. Postoperative Wound Management after Cleft Lip Surgery. *Cleft Palate Craniofac J* 2011 Sep;48(5):584-586.
10. Kannon GA, Garrett AB. Moist wound healing with occlusive dressings: a clinical review. *Dermatol Surg* 1995;21(7):583-590.

11. Hague J. Patient-oriented evidence that matters: POEMS. *EJHP* 2004;11(42):56-57.
12. Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG. Center for disease control definitions of nosocomial surgical site infections, 1992: a modification of CDC definitions of surgical wound infections. *Infect Control Hosp Epidemiol* 1992;13(10):606-608.
13. Lunca S, Romedea NS, Moroşanu C: Surgical site infection; is surgical wound dressing really necessary? *J Surg* 2005;1(4): 401-406.
14. Schauerhamer RA, Edlich RF, Panek P, Thul J, Prusak M, Wangenstein OH. Studies in the management of the contaminated wound. *Am J Surg* 1971;122(1):74-77.
15. Katz MH, Alvarez AF, Kirsner RS, Eaglstein WH, Falanga V. Human fluid from acute wounds stimulates fibroblast and endothelial cell growth. *J Am Acad Dermatol* 1991;25(1): 1054-1058.
16. Nemeth AJ, Eaglstein WH, Taylor JR, Peerson LJ, Falanga V. Faster healing and less pain in skin biopsy sites treated with an occlusive dressing. *Arch Dermatol* 1991;127(11):1679-1683.
17. Shinohara T, Yamashita Y, Satoh K, Mikami K, Yamauchi Y, Hoshino S, Noritomi A, Maekawa T. Prospective evaluation of occlusive hydrocolloid dressing regarding the healing effect after abdominal operations: randomized controlled trial. *Asian J Surg* 2008;31(1):1-5.
18. Holm C, Petersen JS, Grønboek F, Gottrup F: Effects of occlusive and conventional gauze dressings on incisional healing after abdominal wounds. *Eur J Surg* 1998;164(3):179-183.
19. Gottrup F, Melling A, Hollande DA. An overview of surgical site infections: aetiology, incidence and risk factors. *EWMA J* 2005;5(2):11-15.
20. Culver DH, Horan TC, Gaynes RP, Martone WJ, Jarvis WR, Emori TG, Banerjee SN, Edwards JR, Tolson JS, Henderson TS, et al. Surgical wound infection rates by wound class, operative procedure, and patient risk index. National Nosocomial Infections Surveillance System. *Am J Med* 1991;91(3B):152S-157S.
21. Mourougayan V. Sutureless skin closure for cleft lip repair. *Cleft Palate Craniofac J* 2006 Nov;43(6):656-658.
22. Miranda-Rius J, Brunet-Llobet L, Eduard Lahor-Soler E, Mendieta C. An unexpected presentation of a traumatic wound on the lower lip: a case report. *J Med Case Rep*. 2014 Sep 7;8:298.
23. Moshakis V, Fordyce MJ, Griffiths JD, McKinna JA. Tegaderm versus gauze dressing in breast surgery. *Br J Clin Pract* 1984;38(4):149-152.

