

UNILATERAL CLEFT LIP REPAIR: A COMPARISON OF TREATMENT OUTCOME WITH TWO OPERATIVE METHODS

By

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ABSTRACT

Background: Several researches that matched cleft lip operative managements were achieved and they comprise assessment of dentofacial growing and progress, facial look, speech, nasal breath, quality of life (QoL), scars, and case satisfactions. While, these studies as well show that there is deficiency of agreement on matching procedure cleft lip repair for evaluating outcome through different research centers.

Aim and objectives: Evaluation and comparison of treatment outcomes following repair of uni-lateral cleft lip (UCL) defects via the Tennyson-Randall (triangular) (TR) method or the modified Millard rotation-advancement (M) method.

Subjects and methods: This was a prospective cohort randomized controlled trial (RCT) that had been performed at plastic Surgery departments at Nasr City Insurance Hospital, Beni Suef Insurance Hospital and Al-Azhar University (Al-Hussein and Sayed Galal) Hospitals and included 40 subjects with uni-lateral cleft lip (UCL).

Results: According to Cupid's bow symmetry post-operatively and on following-up in every group. At Day - 30 after surgery, most of the patient was evaluated as symmetrical (70% in-group M and 85% in-group T) with nonsignificant change among both groups, also nonsignificant change among both groups according to Evaluator assessment of operative outcome of the nose.

Conclusion: the present work revealed that there is no main change in the general consequences amid the Tennyson-Randall (TR) and Millard rotation advancement (M) repairs. Consequently, either method can be utilized for uni-lateral clefts, considering the strength and weakness of every method.

Keywords: Tennyson-Randall, Millard rotation, cleft lip, cleft palate, outcomes.

INTRODUCTION

CLP is the second most common congenital birth defect in the U.S. trailing only Down syndrome. There are roughly 7,000 infants born with orofacial clefts in the U.S. annually (*Shkoukani et al., 2013*).

Cleft lip and palate is the fourth most common congenital malformation and the

first most common craniofacial anomaly. The incidence of cleft lip and palate varies from one per 750 live births to one per 650 live births depending on the geographical area. Cleft palate is a feature of over 200 well-defined syndromes of congenital malformations (*Ysunza et al., 2015*).

Various problems are observed in the patients such as dental disorders, poor occlusion, deformation of the face and nose and nutritional, respiratory, hearing and articulation problems (*Noorollahian et al., 2015*).

Currently, various surgical techniques are used for the repair of unilateral cleft lip defects. Straight-line closure technique for the repair of unilateral defects was introduced in 1840s. Since then, various techniques have been implemented for such procedures (*Hoghoughi and Habibagahi, 2019*).

The treatment begins soon after the child's birth and continues until adulthood. The purpose of cleft treatment is aesthetic and functional rehabilitation. The surgical repair is important for facial growth preservation, normal speech formation and development of proper dentition. The less number of interventions, the less the scarring results and hence, growth retardation (*Farronato et al., 2014*).

Successful repair of cleft lip deformity is a challenging as well as rewarding task. Though localized to a small anatomic area, the face it demands more attention and priorities (*Gadre et al., 2016*).

Tennison and Marcks (1950-1960) and colleagues introduced triangular flap which created a Z-plasty at lower part of lip. Subsequently, Randall used the same design as Tennison but reduced size of triangular flap (*Gadre et al., 2016*).

Each technique has its advocates, and both techniques address the importance of repositioning the lip muscle (orbicularis oris) in the correct anatomic orientation for optimal aesthetic and functional outcomes (*Adebayo et al., 2018*).

PATIENTS AND METHODS

This was a prospective cohort RCT that had been performed at plastic Surgery departments at Nasr City Insurance Hospital, Beni Suef Insurance Hospital and Al-Azhar University (Al-Hussein and Sayed Galal) Hospitals and included 40 subjects with UCL who allocated into 2 groups: **Group (I):** That comprised twenty UCL cases who had undergone Tennison-Randall (triangular) technique. **Group (II):** That included twenty UCL patients who had undergone Millard rotation-advancement technique.

Inclusion criteria: UCL presenting for primary surgery that had satisfied general conditions of the baby starting at age of one month.

Exclusion criteria: Bi-lateral cleft lip, patients who had a previous early cleft operation, syndromic cranio-facial anomalies and blood diseases or other cardio-vascular anomalies

Methods: Eligible cases had been subjected to:

History taking and Physical examination including Ages, gender, weights, heights, and cleft kind. Cleft lip and palate were sorted in accordance to classification with alterations stated by the International Confederations for Plastic and Re-constructive Surgery in 1967 (*Khan et al., 2013*).

Pre-operative assessment: Routine pre-operative blood examinations involving value of Hb, urea, electrolyte, and creatinine, and electro-cardiography was accomplished for every case. Echocardiography when showed. Cases had been directed to their pediatrician for clinical assessment to rule out cardio-

vascular inborn irregularities, higher respiratory tract infections, ear infections, and other inborn irregularities that can be clinically significant. Pre-operative photographs had been captured for all cases.

Operative technique: A team of senior specialists handled the cases, but their operative variances were lessened in the current work by trailing a standard protocol of operative procedures. A standard hygienic basis and best degree of sterilizations of tools followed in all the operations. Standard TR-Technique (**Figure 1**) and M-Technique (**Figure 2**) have been done for 20 cases. Lip closure

has been done in layers constituting of muscles and sub-cutaneous suturing via 4-0 Vicryl suture correspondingly and 6-0 Prolene suture have been located in the vermilion and the mucosa of the lip finalizing the closures. The nostril sill was locked with Prolene suture. The alar cartilage on the cleft-side was repositioned non-dependently of the covering alar skin by locating a through-and-through sutures tied over a bolster for period of 7-days. Suture elimination was performed on 7th-day post-operatively, trailed by discharge and advices on wound care. **Figure 1 (d), Figure 2 (d).**



(A) Pre-operative



(B) Standard markings



(C) Intra operative



(D) Post-operative 7th day



(E) Post-operative 1 month

Figure (1): Tennison- Randall technique



(A) Pre-operative



(B) Standard markings



(C) Intra operative



(D) Post-operative 7th day



(E) Post-operative 1 month

Figure (2): Millard's rotational advancement technique.

Evaluation of surgical outcome: The subjects had been followed-up every week for 2-wks, and then one time monthly for 3-mths; the operative-outcomes assessment had been accomplished at the last 3rd-mth following-up. Quantitative assessments had been done on anthropometric measures, as defined by (Haddock & McRae, 2012). Anthropometric measures were documented from a 2D facial photo of cases. Each measurement had been taken three times, and the average of the three measures had been determined.

Ethical approval: Approval of ethical committee from the ethics unit at faculty of medicine Al-Azhar University, Cairo. An informed consent had been obtained from all cases before participation in this study.

Statistical Analysis: Statistical analysis of the collected data has been done via SPSS 22.0 (Chicago, IL, USA). All statistical comparing were two tailed. At $P\text{-value} \leq 0.05$ the difference judged significant, $p < 0.001$ data has high significance while, $P > 0.05$ indicates non-significant change.

RESULTS

A prospective cohort randomized controlled study included 40 patients divided into: Group (T): Include twenty UCL patients who will undergo Tennison-

Randall (triangular) technique. Group (M): Include twenty UCL patients who will undergo Millard rotation-advancement technique.

Table (1): Comparison between both groups as regard preoperative and postoperative anthropometry measurement

		Group M (n=20)	Group T (n=20)	p value
		Mean (SD)	Mean (SD)	
Horizontal lip length (mm)	Preoperative	13.63 (5.21)	14.25 (5.92)	0.182 (NS)
	Postoperative	16.28 (7.13)	16.12 (6.21)	
	P1 value	0.001* (S)	0.015* (S)	
Vertical lip length (mm)	Preoperative	11.52(4.75)	12.28 (5.11)	0.518 (NS)
	Postoperative	15.22 (5.19)	14.72 (5.7)	
	P1 value	0.001* (S)	0.002* (S)	
Nasal width (mm)	Preoperative	23.71 (7.13)	24.38 (9.11)	0.311 (NS)
	Postoperative	18.26 (6.21)	20.53 (6.91)	
	P1 value	0.001* (S)	0.001* (S)	

P value: comparison between group M & T

P1 value: comparison between preoperative and postoperative

Table (2): Cupid’s Bow symmetry postoperatively and on follow-up in each group

Post Op. Day	CUPIDS BOW SYMMETRY	Group M (n=20)	Group T (n=20)	p value
Day -7	Symmetry	16 (80%)	18 (90%)	0.217 (NS)
	Asymmetry	4 (20%)	2 (10%)	
Day -30	Symmetry	14 (70%)	17 (85%)	0.341 (NS)
	Asymmetry	6 (30%)	3 (15%)	

Fisher’s Exact Test

Table (3): Assessor evaluation of surgical outcome of the nose

		Group M (n=20)	Group T (n=20)	p value
		No (%)	No (%)	
Nostril symmetrical	Yes	11 (55%)	13 (65%)	0.318 (NS)
	No	9 (45%)	7 (35%)	
Centrality of columella	Central	14 (70%)	16 (80%)	0.427 (NS)
	Deviated	6 (30%)	4 (20%)	
Ala on the cleft side	Normal	12 (60%)	15 (75%)	0.255 (NS)
	Flattened	8 (40%)	5 (25%)	

Table (4): Patients satisfaction regarding scar quality in each group

Post Op. Day	Group M (n=20)	Group T (n=20)	p value
Very happy	17 (85%)	16 (80%)	0.117 (NS)
Happy	3 (15%)	3 (15%)	
Okay	0 (0%)	1 (5%)	
Unhappy	0 (0%)	0 (0%)	

DISCUSSION

Measurement of treatment outcome is vital to evaluate the success of cleft management and the degree of improvement, especially in the present age of evidence-based medicine where treatment guidelines for best practice are becoming an integral part of contemporary clinical practice. Many studies that compared cleft lip and palate surgical treatments have been performed and they include evaluation of dentofacial growth and development, facial appearance, speech, hearing, nasal breathing, quality of life, and patient satisfaction. However, these reports also indicate that there is lack of consensus on

agreed methodology for assessing outcomes across various research centers (*Abdurrazaq et al., 2013*).

The purpose of this study was to evaluate and compare the treatment outcome from surgical repair of UCL using either the Tennison-Randall or Millard techniques. They evaluated outcomes according to using preoperative and postoperative anthropometry measurements (*Hakim et al., 2014*).

Our prospective cohort randomized controlled study included 40 patients divided into Group (M): Include twenty UCL patients who will undergo Millard rotation-advancement technique and Group (T): Include twenty UCL patients

who will undergo Tennison-Randall (triangular) technique.

As regarding Demographic and clinical data of studied groups,

There was no statistically significant difference between both groups as regarding demographic data, most of them were between 3-6 MS (60% in group M and 75% in group T), Male s (65% & 55% respectively), on Left side (75% & 65%), and finally most of them were of the Complete (70% & 80%) type.

Unilateral Clefts and Laterality Cleft lip only (CL) tends to be unilateral (around 90%) and approximately two-thirds occur on the left side regardless of sex, ethnic group and severity of defect (*Mossey et al., 2012*).

Sex Distribution Among the accepted epidemiological differences between CL/P and isolated CP is the now well-accepted male predilection to CL/P and female tendency towards CP, and the sex ratio varies with severity of the cleft, presence of additional malformations, the number of affected siblings in a family, ethnic origin and possibly paternal age. In white populations, the sex ratio for CL (P) is about 2:1 [1]. In Japanese populations, there is a significant male excess in the CLP group but not in the cleft lip only group (*Sivapathasundharam, 2020*).

The goals of UCL repair include the creation of an intact upper lip with appropriate vertical length and symmetry, repair of the underlying muscular structures to achieve normal function, and the management of the associated nasal deformity. The Tennison – Randall and Millard’s rotational advancement flap technique remains the most accepted

techniques. With the need of time and situation, certain modifications in both techniques are made and combinations of both have been utilized (*Adetayo et al., 2018*).

In our study as regarding Comparison between both groups as regard preoperative and postoperative anthropometry measurement, there was a significant improvement between Preoperative and Postoperative anthropometric measurements, but there was no significant difference regarding comparison between both techniques separately (Horizontal lip length $P=0.182$, Vertical lip length 0.518, and Nasal width 0.311). This means that both procedures had same efficacy in correcting anthropometric measurements.

In agreement with our results, (*Gadre et al., 2016*) concluded that the total lip length, in both the groups remained approximately same on 7th postoperative and one month follow up day. The lip length reduced more in Group T postoperatively than that to preoperative analysis. The cleft side lip height increased postoperatively in both groups. But, no significant change in lip height was observed on the analytic days.

In addition, our findings are consistent with those of (*Tse & Lien et al., 2015*) and (*Hakim et al., 2014*) who independently evaluated Millard’s and Tennison-Randall techniques, respectively. Hakim et al. performed postoperative digital anthropometry on 18 patients who received UCL repairs with rotation-advancement and they compared these to normal controls. They found that there were improvements in the lip and nasal measurements. Similarly, *Bilwatsch et al.*

reported improvements after repair with the Tennison-Randall and Millard's techniques similarly.

As regarding Cupid's Bow symmetry postoperatively and on follow-up in each group. At Day -30 after surgery, most of the patient was evaluated as symmetrical (70% in-group M and 85% in-group T) with no statistically significant difference between both groups. Also no statistically significant difference between both groups as regarding Assessor evaluation of surgical outcome of the nose (Nostril symmetrical, Centrality of columella, and Ala on the cleft side).

In the study of (*Adetayo et al., 2018*), Cupid's bow in the TR group was more similar to those of the controls than the Millard group, but both were similar in comparison to each other.

In the study of (*Gadre et al., 2016*) the alar base symmetry showed improvement postoperatively with most of patients presenting with symmetrical alar base in both Groups. They suggested that both Millard's rotational advancement and Tennison –Randall technique gave similar kind of results with respect to white roll match, alar base symmetry, Cupid's bow symmetry and the lip length.

These results match the study conducted by (*Abdurrazaq et al., 2013*) where in, they found out that overall appearance of lip and nose postoperatively in Millard's and Tennison –Randall techniques was same.

As regarding Assessor evaluation of surgical outcome of the scar, there was no statistically significant difference as regarding thickness of the lip scar, thickness of scar at the nostril of sill, scar

transgression of the philtral ridge, hypertrophic scar. Also regarding satisfaction, most of the patients were reported to be Very happy (60% in-group M and 85% in-group T).

In the study of (*Gadre et al., 2016*), the postoperative scar appearance in 27 and 19 patients of Group T and M respectively was satisfactory. However, difference was noticed on 1-month follow up, the satisfactory scar quality was seen in 21 and 27 patients of group M and T, respectively with no statistically significant difference. This suggests that the scar remained constant in Group T on postoperative 7th day and on follow up of one month.

The Millard rotation-advancement technique, introduced in 1957, is the most widely used procedure for cleft-lip repair because it places most of the scar along the natural philtral border and is more flexible than geometric closure techniques. Furthermore, the Millard technique allows for complete muscular repair and minimizes discarding of normal tissue. Its disadvantages include the need for extensive undermining, risk of nostril stenosis on the cleft side and the potential to cause contraction with its consequent decrease in vertical lip height (*Demke et al., 2011*).

From all the aforementioned data we can concluded that, Our study findings show no major difference in the overall results between the Tennison-Randall and Millard rotation advancement repairs. Thus, either technique could be used for unilateral clefts, taking into consideration the strength and weakness of each technique. And, whichever repair is used, the end result is a function of individual

preference, surgeon skill level, and the extent of cleft deformity.

CONCLUSION

The current work revealed that no main change in the total outcomes amid the Tennison-Randall and Millard rotation advancement techniques. Consequently, either method can be utilized for unilateral clefts, considering the strength and weakness of both techniques.

Conflict of Interest: no any conflicts of interests were present among authors.

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اصلاح الشفاه الأرنبية أحادية الجانب: مقارنة بين نتائج العلاج باستخدام طريقتين مختلفتين من العمليات الجراحية

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خلفية البحث: تعد الشفة الأرنبية هي واحدة من أكثر العيوب الخلقية بالوجه في المواليد والتي يتم تشخيصها بشكل متكرر. وثاني أكثر العيوب الخلقية شيوعاً في الولايات المتحدة التي تتبع متلازمة داون فقط.

ويتم استخدام تقنيات جراحية مختلفة لإصلاح عيوب الشفة المشقوقة أحادية الجانب. وحيث تم إدخال تقنية إغلاق الخط المستقيم لإصلاح العيوب من جانب واحد في أربعينيات القرن التاسع عشر. ومنذ ذلك الحين يتم تطبيق تقنيات مختلفة لمثل هذه الإجراءات.

الهدف من الدراسة: تهدف هذه الدراسة الي تقييم ومقارنة نتائج العلاج بعد إصلاح عيوب الشفة الأرنبية أحادية الجانب باستخدام إما تقنية هما تينيسون راندال (المثلثة) أو تقنية ميرالد المعدلة.

طرق الدراسة: هذه دراسة جماعية عشوائية محكمة تم إجراؤها في أقسام الجراحة التجميلية بمستشفى مدينة نصر للتأمين ومستشفى بني سويف للتأمين ومستشفى جامعة الأزهر (الحسين وسيد جلال) وتضمنت 40 شخصاً مصابين بشفة مشقوقة من جانب واحد. إلى مجموعتين:

- المجموعة (ت): تضمنت عشرين مريضاً من الشفة المشقوقة احادية الجانب خضعوا لتقنية تينيسون راندال - (المثلثية).
- المجموعة (م): تضمنت عشرين مريضاً من الشفة المشقوقة احادية الجانب خضعوا لتقنية ميرالد المعدلة.

النتائج:

- لا يوجد فرق ذو دلالة إحصائية بين المجموعتين فيما يتعلق بتقييم المقيم للنتيجة الجراحية للأنف (فتحة الأنف المتناظرة، مركزية العمود الفقري).
- فيما يتعلق بتقييم المقيم للنتيجة الجراحية للندبة، لم يكن هناك فرق ذو دلالة إحصائية فيما يتعلق بسمك ندبة الشفة، سماكة الندبة عند فتحة الأنف، تجاوز الندبة في الندبة، الندبة الضخامية. أيضاً فيما يتعلق بالرضا، تم الإبلاغ عن أن معظم المرضى سعداء جداً.

الاستنتاج: يمكننا أن نستنتج أن نتائج دراستنا لا تظهر أي فرق كبير في النتائج الإجمالية بين إصلاحات الشفة المشقوقة أحادية الجانب تينيسون راندال وميرالد. وبالتالي، يمكن استخدام أي من الطريقتين في الشقوق أحادية الجانب، مع مراعاة قوة كل تقنية وضعفها.

الكلمات الدالة: تينيسون راندال، ميرالد المعدلة، الشفة الأرنبية، شق سقف الحلق.