

TREATMENT OF PREPUBERTAL LABIAL ADHESIONS: A RANDOMIZED,  
DOUBLE BLINDED TRIAL COMPARING TOPICAL EMOLLIENT  
VERSUS TOPICAL ESTROGEN

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TAZIM DOWLUT-MCELROY

B.A., Indiana University, 1992  
M.D., Indiana University School of Medicine, 1997

Kansas City, Missouri  
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Tazim Dowlut-McElroy, Candidate for Master of Science Degree  
University of Missouri-Kansas City, 2016

ABSTRACT

Labial adhesions are a common finding estimated to occur in 22% of prepubertal girls. Symptoms are related to the accumulation of urine behind partially fused labia and include urinary tract infections, vulvovaginitis, pain with activity, post-void dripping of urine, and, in cases of complete labial fusion, urinary retention. Although topical estrogen had traditionally been considered first-line therapy, this method of treatment can be associated with alarming side effects in prepubertal girls including breast budding and vaginal bleeding. This clinical study aimed to assess the need for estrogen for treatment of prepubertal labial adhesions.

A single site, randomized, double-blinded, 21-month clinical trial was performed. Prepubertal girls ages 3 months to 12 years with labial adhesions and without underlying dermatologic disorders, systemic conditions that can have vulvar manifestations, disorders requiring immunosuppressant treatment, and previous surgical separation of labial adhesions were included in the study. A computer-generated block randomization design with blocks of 10 was used to randomize participants into the topical estrogen or topical emollient group. The topical estrogen group received Estrace® Cream (Estrace vaginal

cream, USP, 0.01%; Warner Chilcott). The topical emollient group received Cetaphil® Moisturizing Cream to resemble Estrace® cream. The participants' parents or guardian were instructed to apply the preparation to the labial adhesion with lateral traction twice daily. The principal investigator, study staff and patients were blinded throughout the trial.

The primary outcome was the comparative the effectiveness of topical emollient with lateral traction as compared to topical estrogen with lateral traction on the resolution of labial adhesions in prepubertal girls. The secondary outcome was the change in severity of labial adhesion over time between the two groups. Sample size calculations indicated 20 girls per group would be sufficient ( $\alpha = 0.05$ , power = 80%).

Of the 43 prepubertal girls randomized, 38 (88%) completed the study. Although almost twice as many patients treated with estrogen (37%) had complete resolution of the labial adhesion as compared to those treated with emollient (19%), this difference was not statistically significant ( $p = .206$ ). In addition, although there was a decrease in severity of labial adhesions with time for both groups, the magnitude of the improvement did not depend on treatment assignment. Seventy-five percent of the variance in severity of labial adhesions between the 2 treatment groups was explained by time alone versus only 2 percent of the variance explained by the interaction between treatment and time. The difference in severity of labial adhesions between the 2 treatment groups over time (interaction effect) and main effect of treatment were not statistically significant ( $p = .425$  and  $.370$  respectively).

Topical emollient with lateral traction can be recommended for treatment of prepubertal labial adhesions.

## APPROVAL PAGE

The faculty listed below, appointed by the Dean of the School of Medicine have examined a thesis “Treatment of Prepubertal Labial Adhesions: A Randomized, Double-blinded Trial Comparing Topical Emollient versus Topical Estrogen,” presented by Tazim Dowlut-McElroy candidate for Master of Science degree, and certify that in their opinion it is worthy of acceptance.

### Supervisory Committee

Karen Williams, PhD., Committee Chair  
Department of Biomedical and Health Informatics

Julie L. Strickland, M.D., M.P.H.  
Department of Obstetrics and Gynecology

Timothy P. Hickman, M.D., M.P.H., M.Ed.  
Department of Biomedical and Health Informatics

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CHAPTER 1  
INTRODUCTION

Labial adhesions are an acquired condition of prepubertal girls in which the labia are partially or completely fused over the vaginal opening, and, in severe cases, the urethra. The diagnosis is made by visual inspection of the vulva. A thin line of fusion can be seen in the midline of the labia fused over the vaginal opening.<sup>1</sup>



Figure 1. Labial Adhesion

Labial adhesions are estimated to occur in 22% of prepubertal girls and are most frequent in ages 3 months to 6.<sup>2-4</sup> As labial adhesions typically resolve spontaneously with estrogen production at puberty, treatment is recommended only for prepubertal girls who are symptomatic.<sup>1</sup> Symptoms are related to the accumulation of urine behind partially fused labia and include recurrent urinary tract infections and vulvovaginitis, pain with activity, post-void dripping of urine and, in cases of complete fusion of the labia, urinary retention.<sup>1,2,5</sup> Some parents also request treatment for concerns about the appearance of their child's external genitalia including that their child's vagina appears "absent."<sup>1,6</sup> The

etiology of labial adhesions is unclear but is presumably related to hypoestrogenism in combination with vulvar irritation.<sup>1</sup> Labial adhesions are not seen in newborn girls as the vulva are well estrogenized from maternal hormones. The persistence of labial adhesions in early adolescence in the presence of endogenous pubertal estrogen levels is uncommon. In pubertal girls, labial adhesions are extremely rare in the absence of underlying conditions such as genital trauma.<sup>7</sup>

For many years, first-line treatment for labial adhesions in prepubertal girls has been topical estrogen. This recommendation was based on early reports that treatment with topical estrogen resolved labial adhesions in 88% to 90% of cases.<sup>4,8</sup> However, these were observational studies with small patient populations. In one case series of 50 patients, the authors included in their success rate of 90% those girls who required manual separation of fine adhesions after treatment with topical estrogen.<sup>4</sup> A prospective cohort study of only 30 patients including five patients in a control group treated with a topical emollient reported a success rate of 88% for girls treated with topical estrogen.<sup>8</sup> In contrast, a later retrospective case series in which 259 symptomatic girls with labial adhesions were treated with topical estrogen reported a success rate of only 47% with a 14% recurrence rate after successful treatment.<sup>1</sup> Although regimens vary, topical estrogen is typically applied with gentle lateral traction to the adhesion site once or twice daily for 4 to 8 weeks. However, multiple courses may be necessary before resolution of labial adhesions and there have been reports of use of topical estrogen cream for up to 36 months.<sup>9</sup> This method of treatment is not without risk as estrogen is systemically absorbed. Although transient, there have been reports of breast budding, vulvar hyperpigmentation and vaginal bleeding with the use of topical estrogen.<sup>6,9,10</sup> In addition there is a high risk of recurrence of labial adhesions of up to 35%

after treatment with topical estrogen.<sup>11</sup> For labial adhesions that do not respond to medical therapy, manual separation with a cotton-tipped swab after application of local anesthesia can be attempted.<sup>1</sup> Patients who do not tolerate separation in the office or who have dense labial adhesions require separation in a surgical setting.

Recently, the role of low estrogen levels as the etiology of labial adhesions and the use of topical estrogen for treatment of labial adhesions has been questioned. Caglar found no statistically significant difference in the serum estradiol levels of prepubertal girls mean age 12 months with and without labial adhesions.<sup>10</sup> Papagianni reported the case of a 2 year old girl with elevated serum estradiol levels and premature thelarche who also had a labial adhesion.<sup>12</sup> In a recent study comparing the use of topical estrogen therapy verses manual separation followed by topical estrogen for the treatment of labial adhesions in patients with no previous therapy, Soyer reported a statistically significant higher success rate with the use of manual separation followed by topical estrogen (100%) when compared to topical estrogen alone (55.5% to 66.6%).<sup>13</sup> In addition, the rate of recurrence was higher (11%) in the patients treated with estrogen alone when compared to the other treatment group in which there was no recurrence during a 9-month follow-up.

Although hypoestrogenism persists in children and the level of estrogen does not increase in girls until puberty, the peak incidence of labial adhesion in girls is at 13 to 23 months of age.<sup>14</sup> Typically, most girls no longer use diapers after the age of 3 years and are more mobile and active. Caglar proposes that the decreased local irritation that accompanies decreased use of diapers and the increased activity which causes frequent opening of the labia minora prevents approximation of denuded labial epithelium and decreases the incidence of labial adhesions in girls older than two years.<sup>10</sup>

There is no conclusive evidence that estrogen has a lytic effect on labial adhesions.<sup>10</sup> However, estrogen has been shown to accelerate cutaneous wound healing, inhibit local inflammatory response and enhance wound reepithelialization.<sup>15,16</sup> Generally, for medical treatment of labial adhesions, topical estrogen is applied with gentle lateral traction to the adhesion site. It is, therefore, plausible that the lateral traction results in the separation of labial adhesions while the use of estrogen improves healing after mechanical separation.

The primary aim of this randomized clinical trial was to compare the effectiveness of topical emollient with lateral traction as compared to topical estrogen with lateral traction on the resolution of labial adhesions in prepubertal girls. The secondary aim of this study is to evaluate the change in severity of labial adhesion over time between the two groups.

CHAPTER 2  
METHODOLOGY

**Procedures**

This was a single site, randomized, double-blinded, 21-month clinical trial evaluating the comparative effectiveness of topical emollient with lateral traction versus topical estrogen with lateral traction for the treatment of labial adhesions in prepubertal girls.

A block randomization design with blocks of 10 was generated by SPSS software (Version 22.0 SPSS Inc, Chicago, IL) and used to maintain balance of treatment assignments. Treatment allocation was directed by a list of participant study ID numbers and corresponding random assignments prepared in advance by the study statistician and followed by the investigational drug services (IDS) pharmacy as each new participant enrolled and was assigned the subsequent study identification (ID) number. Only the statistician and the pharmacy staff were aware of the assignments. The principal investigator, study staff and patients were blinded throughout the trial. Group 1 received Estrace® Cream (Estrace vaginal cream, USP, 0.01%; Warner Chilcott). Group 2 received Cetaphil® Moisturizing Cream formulated by the IDS pharmacy at Children's Mercy Hospital, Kansas City Missouri to resemble Estrace® cream. Study medication was packaged in identical containers dispensed directly to the patient by the IDS pharmacy staff.

Potential subjects from the Pediatric and Adolescent Gynecology Clinic at Children's Mercy Hospital & Clinics meeting inclusion/exclusion criteria were invited to participate and written consent was obtained from a parent or legal guardian. Following baseline measurements, study participants were randomly assigned to either the topical estrogen with traction group or the topical emollient with traction group. The participants'

parents or guardian were instructed to apply the preparation to the labial adhesion with lateral traction twice daily. The technique for application of the topical preparation as well as the technique for lateral traction was demonstrated to the participants' parent or legal guardian and written instructions were provided. After randomization, participants returned for assessments at 3 and 6 weeks. Evaluations at baseline, 3 weeks and 6 weeks were chosen as 50% of labial adhesions resolve in 2 to 3 weeks and most labial adhesions resolve with 6 weeks of treatment with topical estrogen.<sup>2</sup>

This study was submitted to the Children's Mercy Hospital institutional review board and was approved after full review. This study was also registered on ClinicalTrial.gov (Identifier: NCT02218463).

### **Sample**

At the time of study initiation, there were no data from which to estimate the potential effect size between the two treatment groups, therefore a clinically meaningful failure rate was used for the power analysis. Data suggest that 50% of labial adhesions treated with estrogen will resolve within the 3 week study period.<sup>1</sup> A meaningful failure rate for the emollient would be a rate of only 10% resolution at 3 weeks. Therefore, a sample size of 20 completed participants per group was determined to have 80% power to detect a difference in resolution of that magnitude in labial adhesions between the two groups at the 3 week follow-up point. Taking into account a 20% attrition rate, the goal was to enroll 50 patients to have 40 completed subjects.

Inclusion criteria were as follows: prepubertal girls ages 3 months to 12 years with labial adhesions. Exclusion criteria were as follows: presence of underlying dermatologic conditions such as lichen sclerosis, severe atopic dermatitis, psoriasis or vitiligo; presence of

systemic conditions that can have vulvar manifestations such as Crohn's disease and Behçet disease; presence of disorders requiring immunosuppressant treatment; and, previous surgical separation of labial adhesions.

### **Measures**

The age of all enrolled patients was obtained from the chart and recorded. At the initial evaluation, baseline severity and thickness of the labial adhesion was determined by examination by either the principal investigator or the gynecology advanced practice nurse practitioner using the following scales:

- Rating of closure of the introitus at presentation was assigned a ordinal value as follows:
  - 0=Resolved
  - 1=25%
  - 2=50%
  - 3=75%
  - 4=100%.
  
- Rating of degree of thickness of the labial adhesion was measured as:
  - 0=Resolved
  - 1=Thin
  - 2=Intermediate
  - 3= Thick.

Additionally, the following symptoms were obtained from the participants' parents: urinary tract infection (UTI), vulvovaginitis, pain, post void dribbling, and urinary retention. After the initial evaluation, follow up examinations were performed at 3 weeks and again at 6



weeks. The same criteria used at baseline were used to assess severity and thickness and whether labial adhesions were not resolved at the 3 week visit. If complete resolution was observed at the 3 week visit, subject's participation in the trial was concluded. At each follow up examination, the presence of symptoms were recorded as were the following potential side effects: breast budding, vulvar hyperpigmentation, vulvar irritation, and vaginal bleeding.

### **Statistical Analysis**

All statistical analysis were performed using SPSS version 23.0. Descriptive analyses were used to characterize the two treatment groups at baseline. For the inferential analysis, an intention-to-treat principle was employed. For the measurement of percent closure of the introitus, median values for each study group at 3 and 6 weeks respectively were imputed for the 4 drop outs. Three-week data was pulled forward to the 6 week visit for the participant who had missing data at 6 weeks and for those that had complete resolution at 3 weeks.

To assess the primary outcome, complete resolution of labial adhesions between the two treatment arms, Fisher's Exact test was used as one cell had counts of less than 5. A p-value of less than 0.05 was considered significant.

To assess the effect of treatment over time on extent of resolution, a composite measure was created by creating a cross product of the severity and thickness ratings. For the secondary analysis, the composite score was compared using a two-factor repeated measures ANOVA to assess the main effects of treatment group, time, and the interaction of time by treatment. For this analysis, a p-value of less than 0.05 was considered significant. To ensure statistical conclusion validity, since the composite score was a function of ordinal

data, data were also analyzed using non-parametric statistics (Mann-Whitney and Friedman's Chi Square) and segmenting the design. For this assessment a Bonferroni approach was used to control for family-wise error rate and a p-value of less than 0.01 was considered significant for each test.

## CHAPTER 3

### RESULTS

A total of 99 children were assessed for eligibility between August 2014 and March 2016. Of these children, 76 were eligible for the study, 43 were randomized and 38 (88%) completed the study (Figure 2). Two study participants dropped out after randomization and 2 study participants dropped out after the 3 week assessment. Of these 4 drop outs, 2 had been randomized to the topical estrogen group and 2 to the topical emollient group. One study participant, who had been randomized to the topical emollient group, had no data recorded at her 6 week visit although her records indicated that she had been examined.

Table 1 displays the baseline characteristics of study participants in each of the treatment groups. As this is a randomized controlled trial which, by definition, reduces selection bias and eliminates bias in treatment assignment<sup>17</sup>, statistical analysis of differences in baseline characteristics between the two groups was not performed. The mean age of participants was 33 ( $\pm$  20) months in the topical emollient group and 26 ( $\pm$  21) months in the topical estrogen group. Approximately half of the participants in both groups were characterized as having 100% closure of the introitus which, in this study, denoted the presence of only a pin-point opening of the adhesion which allowed passage of urine. The majority of participants in both groups had a labial adhesion of intermediate thickness. Prior to randomization, urinary tract infections were present in only 2 patients both of whom were subsequently randomized to the topical estrogen group, none of the patients had vulvovaginitis, only 2 patients noted pain with activity with subsequent randomization of 1 to each treatment group, and postvoid dribbling was endorsed by only 1 patient who was subsequently randomized to the topical emollient group.

Table 2 depicts symptoms and side effects at 3 and 6 weeks after intervention. Only 2 study participants reported pain with activity at baseline. One was randomized to each study group. Both reported resolution of pain at 3 weeks post intervention. Only 1 patient reported postvoid dribbling at baseline. She was randomized to the topical emollient group and had persistent postvoid dribbling at 6 weeks post intervention. Her labial adhesion did not resolve by the end of the study. There were no report side effects of breast budding, vulvar hyperpigmentation and vaginal bleeding thorough the study period. Two patients, one randomized to each study group, reported vulvar irritation at only at 6 weeks post intervention. There were no serious adverse events during the study.

The difference in complete resolution between participants randomized to the topical emollient group as compared to those randomized to the topical estrogen group is depicted in Table 3. For this analysis, intention-to-treat was used wherein dropouts were assigned as not completely resolved. Although almost twice as many patients treated with estrogen (37%) had complete resolution of the labial adhesion as compared to those treated with emollient (19%), this difference was not statistically significant ( $p = .206$ ).

Response to treatment of labial adhesion is dependent not only upon the size of the adhesion but also the thickness. A more accurate measurement of response to treatment would, therefore, incorporate both measurements. For this study, the percentage of closure of the introitus at presentation was assigned an ordinal value as follows: 1=25%, 2=50%, 3=75%, and 4=100%. The degree of thickness of the labial adhesion was also measured in a similar fashion: 1=thin, 2=intermediate and 3= thick. Those that were resolved received a rating of 0 on both scales. A composite severity scale was created by multiplying the value assigned to the percentage of introital closure by that assigned to the thickness of the

adhesion for each of the 3 study visits. This allowed a comparison of treatment effect between each group over time wherein a lower composite severity score corresponded to a less severe labial adhesion (Table 4). Although there was a decrease in severity of labial adhesions with time for both groups, the magnitude of the improvement did not depend on treatment assignment (Figure3). Seventy-five percent of the variance in severity of labial adhesions between the 2 treatment groups was explained by time alone versus only 2 percent of the variance explained by the interaction between treatment and time. In addition, the difference in severity of labial adhesions between the 2 treatment groups over time (interaction effect) and main effect of treatment were not statistically significant ( $p = .425$  and  $.370$  respectively).

To confirm that the use of parametric analysis was a valid statistical decision for the assessment of degree of severity of labial adhesions over time, a non-parametric analysis was also performed (Table 5). As 5 analyses were performed, a Bonferroni correction was applied and each analysis tested at significant  $p$  value of  $.01$ . Again, the difference in severity of labial adhesion at baseline, 3 weeks and 6 weeks was not statistically significant between groups. However, the difference in the composite severity score over time within each treatment group was statistically significant ( $p < .0001$ ). These findings validate the use of parametric analysis to assess the resolution of labial adhesions over time.

## CONSORT 2010 Flow Diagram

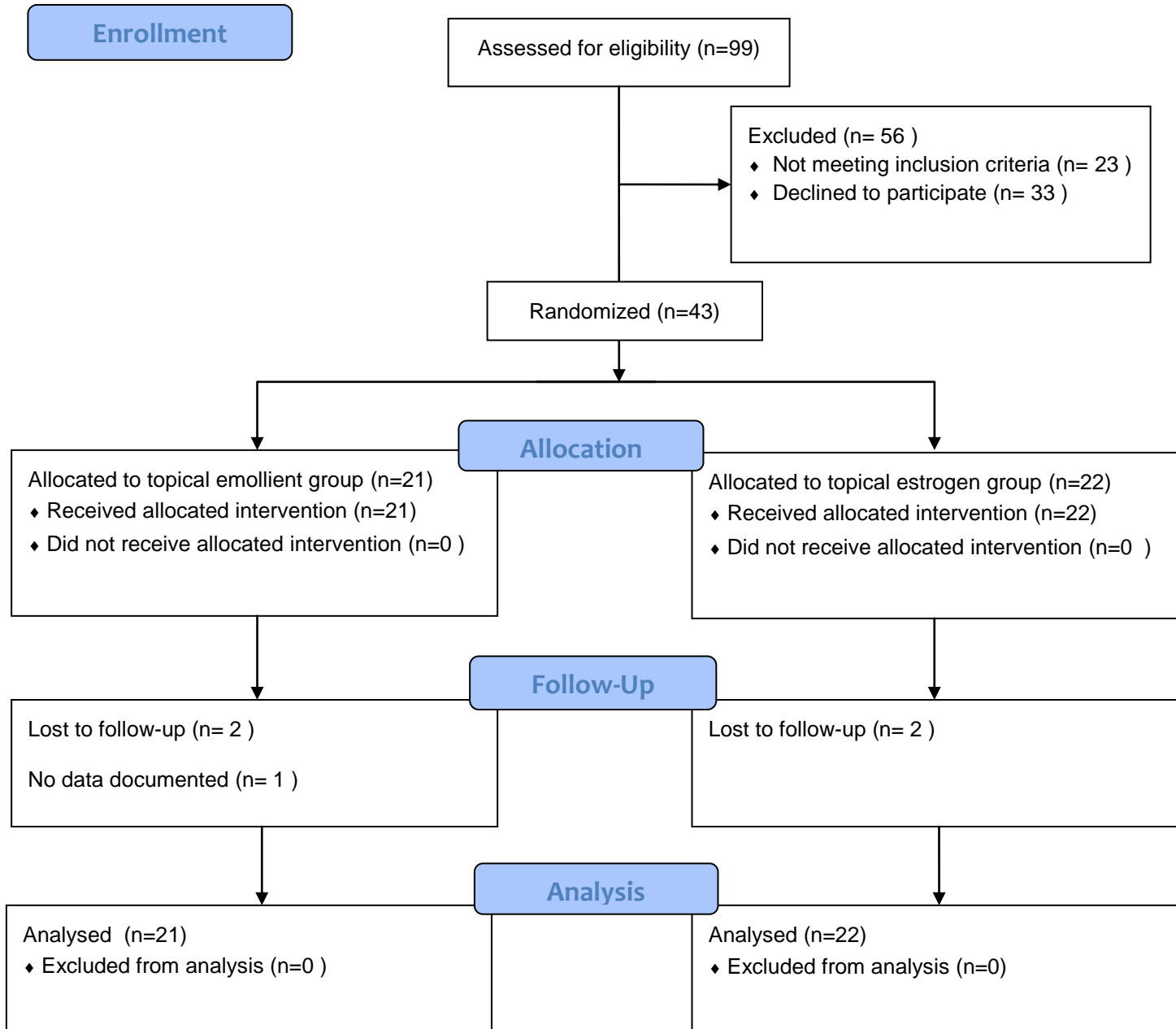


Figure 2. CONSORT Flow Diagram

Table 1 Baseline Characteristics of Study Participants

Characteristics	Topical Emollient N = 21, n (%)	Topical Estrogen N = 22, n (%)
Mean age in months $\pm$ SD	33 $\pm$ 20	26 $\pm$ 21
n (%) introital closure		
25%	1 (5)	0 (0)
50%	5 (24)	4 (18)
75%	4 (19)	7 (32)
100%	11 (52)	11 (50)
Thickness of labial adhesion		
Thin	5 (24)	4 (18)
Intermediate	14 (67)	17 (77)
Thick	2 (10)	1 (5)
UTI	0 (0)	2 (9)
Vulvovaginitis	0 (0)	0 (0)
Pain with activity	1 (5)	1 (5)
Postvoid dribbling	1 (5)	0 (0)

Table 2 Symptoms and Side Effects After Intervention

Variable	Topical Emollient N = 21, n (%)	Topical Estrogen N = 22, n (%)
At 3 weeks		
UTI	0 (0)	0 (0)
Vulvovaginitis	0 (0)	0 (0)
Pain with activity	0 (0)	0 (0)
Postvoid dribbling	1 (5)	0 (0)
Urinary retention	0 (0)	0 (0)
At 6 weeks		
UTI	0 (0)	0 (0)
Vulvovaginitis	0 (0)	0 (0)
Pain with activity	0 (0)	0 (0)
Postvoid dribbling	1 (5)	0 (0)
Urinary retention	0 (0)	0 (0)
At 3 weeks		
Breast budding	0 (0)	0(0)
Vulvar hyperpigmentation	0 (0)	0 (0)
Vulvar irritation	0(0)	0(0)
Vaginal Bleeding	0(0)	0 (0)
At 6 weeks		



Breast budding	0 (0)	0 (0)
Vulvar hyperpigmentation	0 (0)	0 (0)
Vulvar irritation	1 (5)	1(5)
Vaginal Bleeding	0 (0)	0 (0)

Table 3 Complete Resolution

Complete Resolution	Topical Emollient N = 21, n (%)	Topical Estrogen N = 22, n (%)	P value
Yes	4 (19)	8 (36)	.206
No	17 (81)	14 (64)	

Table 4 Composite Severity Scale of Labial Adhesion Over Time (Parametric Analysis)

Variable	Topical Emollient N = 21	Topical Estrogen N = 22	P value <sup>^</sup>
Composite Severity Scale			Treatment: .370 Time: .0001 Interaction: .425
Baseline	6.3 (3.1)	6.2 (2.0)	
3weeks	2.3 (2.4)	1.5 (1.7)	
6weeks	1.9 (2.1)	1.6 (1.9)	

Data presented as mean  $\pm$  SD

<sup>^</sup> Repeat measure ANOVA: main effects are for treatment (emollient versus estrogen), time (baseline, 3 weeks and 6 weeks after intervention) and treatment by time interaction.

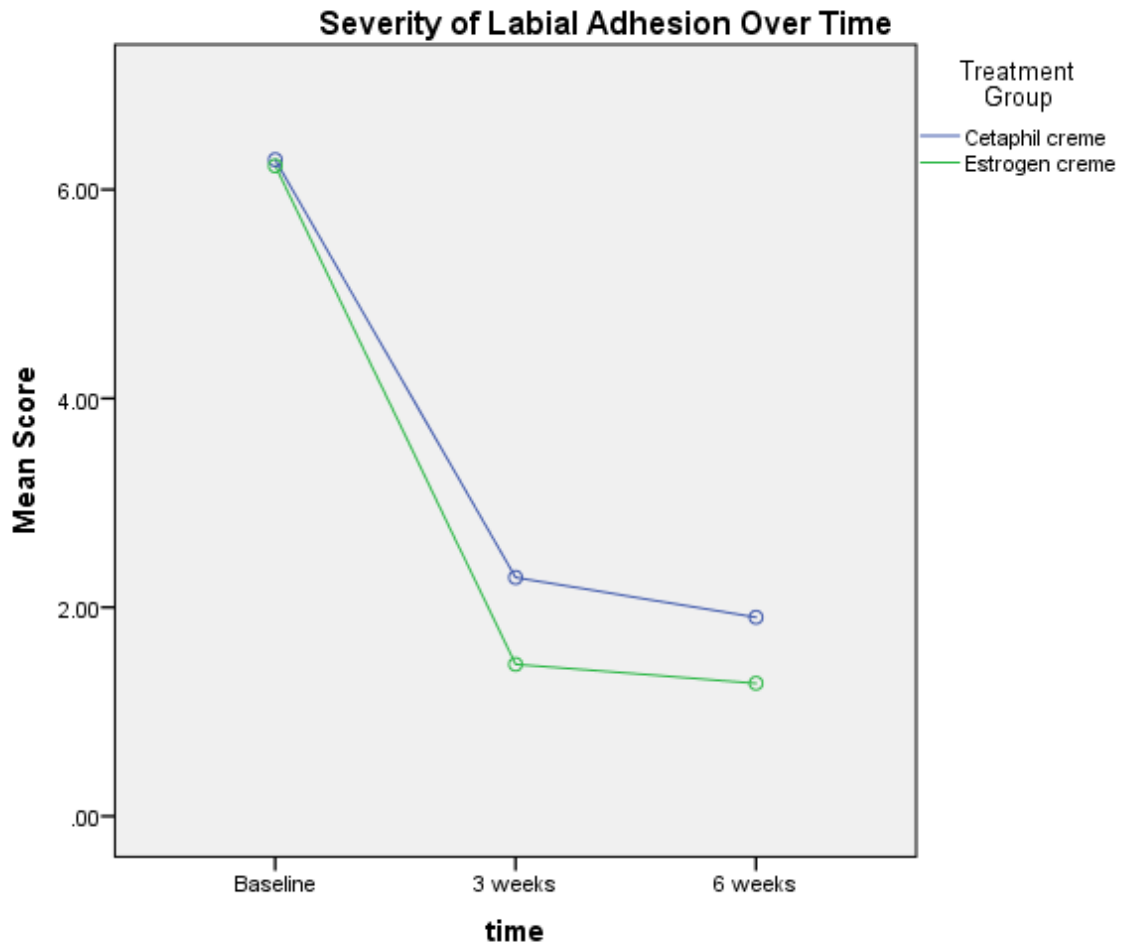


Figure 3. Composite Severity Scale of Labial Adhesion Over Time

Table 5 Means (SD) of Composite Severity Scale of Labial Adhesion Over Time (Non-Parametric Analysis)

Composite Severity Scale	Baseline	3 weeks	6 weeks	P value <sup>^</sup>
Topical Emollient N = 21	6.3 (3.1)	2.3 (2.4)	1.9 (2.1)	.0001
Topical Estrogen N = 22	6.2 (2.0)	1.5 (1.7)	1.3 (1.6)	.0001
P value <sup>^^</sup>	.898	.250	.281	

<sup>^</sup> Friedman Chi-Square, <sup>^^</sup>Mann-Whitney

## CHAPTER 4

### DISCUSSION

Although the exact etiology of prepubertal labial adhesions is unknown, vulvar inflammation in a hypoestrogenic milieu is the prevailing hypothesis.<sup>1,18</sup> The traditional treatment for labial adhesions has been the application of topical estrogen with or without manual separation.<sup>19</sup> There is, however, no evidence that estrogen has a lytic effect on labial adhesions. In addition, topical estrogen can cause alarming side effects such as breast budding and vaginal bleeding in prepubertal girls. The question remains as to whether lateral traction with the use of a topical emollient would have comparable results as lateral traction with the use of estrogen. This clinical trial was primarily undertaken to assess the need for estrogen for treatment of prepubertal labial adhesions. In this study, only 36% of patients treated with twice daily application of topical estrogen with lateral traction during 6 weeks had complete resolution of labial adhesions. This is considerably lower than previously reported resolution rates as high as 100% with use of topical estrogen. Carpraro and Greenberg described a retrospective case series including 66% of patients with adhesions “involving the entire length of the labia minora.”<sup>4</sup> Forty-two of 47 patients (89%) had good results with a 2 to 4 week course of once daily topical estrogen. However, included in the success rate were patients with “fine adhesions” who were treated with manual separation. Aribarg reported a prospective cohort study in which 22 of 25 patients (88%) were successfully treated with once daily topical estrogen for 1 to 4 weeks.<sup>8</sup> All patients had adhesions “involving the entire length of the labia minora.” This study, however, lacked blinding of treatment method and the control group consisted of only 5 patients treated with a topical emollient for 1 month. Leung et al described a prospective

case series of 20 patients with labial adhesions in which all patients (100%) responded to treatment with topical estrogen applied twice daily.<sup>20</sup> Although the authors described the severity of the adhesions as covering at least 50% of the vaginal opening, it is possible that lower success rate in the current study is attributable to a higher percentage of more severe labial adhesions amongst the study population wherein 51% (22 of 43) of participants had 100% closure of the introitus with only a pin-point opening. In addition, patients in Leung's series were treated with topical estrogen for up to 14 weeks as compared to up to only 6 weeks of treatment in the current trial.

With regards to the complete resolution of labial adhesions in this study, the difference between the two groups was clinically significant (37% treated with estrogen versus 19% treated with emollient) albeit not statistically significant. It would not be surprising for a parent made aware that estrogen is almost twice as likely as emollient to result in complete resolution of labial adhesions to choose the former for their child. This is especially so given the equally low (5%) side effect rate of vulvar irritation between the two groups, the only side effect of treatment noted in this study. The lack of statistical significance in complete resolution in this study may be attributable to the use of previously reported treatment success rates to estimate a meaningful difference between the two treatment groups. The relatively small sample size of this study likely contributed to the inability to obtain statistically significant results for a relatively small difference in treatment outcomes between the two treatment groups.

Interestingly, in a retrospective case series of 259 patients wherein patients were treated with topical estrogen for 10 to 14 days, Muram reported a success rate of only 47% despite the fact that 76% of these girls were reported to have thin, translucent labial

adhesions.<sup>1</sup> In the current study, there was a 36% complete resolution rate despite a much smaller percentage of patients (21%) with thin adhesions. The relative difference in results between these two studies reflects the importance of using both thickness and size of labial adhesions as a measure of severity in assessing treatment response. When comparing the relative effect of treatment with estrogen as compared to emollient in this study, use of the composite severity score showed that time alone rather than method of treatment explained the majority of the variance in severity of labial adhesions between the two groups. However, many parents may have found it difficult to be completely compliant with the recommendation to apply topical estrogen twice daily. Thus, the lack of a statistically significant difference in the severity of labial adhesions when evaluating treatment effect alone may reflect lack of adherence to the recommended frequency of treatment.

In a recent review of clinical recommendations for the treatment of labial adhesions topical estrogen was still described as “the best initial therapeutic recommendation.”<sup>18</sup> However, the results of this study suggest that topical estrogen is not essential in the treatment of labial adhesions. The use of a topical emollient with lateral traction does result in a decrease in severity of labial adhesions over 3 and 6 weeks of treatment. This finding has clinical significance in that families who are unwilling to use topical estrogen due to fear of potential side effects of hormonal therapy or are unable to purchase topical estrogen due to cost have the option of treating labial adhesions using a relatively inexpensive topical emollient with lateral traction.

This study does have limitations. The adherence to treatment was obtained through parent report rather than weighing the returned medication initially provided by the IDS pharmacy at the end of the study period. As parents may not have been willing to admit a

lack of compliance with recommended therapy, the lower resolution rates of labial adhesions described in this study may be a function of lack of adherence to the treatment protocol. In addition, although all study participants were evaluated by one of two investigators, as neither intra- nor inter-observer variability in the assessment of labial adhesions were assessed, the measurements must be considered subjective.

Future studies with larger sample size should include more objective means of assessing the severity of labial adhesions as with photo documentation and assessments of both intra- and inter-observer variability.



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## VITA

Tazim Dowlut-McElroy was born on November 14<sup>th</sup> 1971 in Mauritius. She was educated in public schools and graduated from Tell City High School in 1988. She received a Bachelor of Arts degree in Chemistry from Indiana University from which she graduated Phi Beta Kappa in 1992. She then received a medical degree from the Indiana University School of Medicine in 1997. She was an obstetrics and gynecology resident at the Grand Rapids Medical Education and Research Center in affiliation with Michigan State University and completed her residency program in 2001. Dr. Dowlut-McElroy became a diplomate of the American Board of Obstetrics and Gynecology in 2003.

After completion of her residency, she has practiced obstetrics and gynecology in a variety of institutions including private practice, a federally-qualified health center, and academic medical centers. In addition, from 2011 to 2013, she served first as assistant director followed by director of the medical student obstetrics and gynecology clerkship at the Michigan State University College of Human Medicine.

In 2013, she joined the University of Missouri-Kansas City Department of Obstetrics and Gynecology when she began her fellowship in Pediatric and Adolescent Gynecology and also served as part-time faculty to the residency program. She also elected to pursue a Master of Science degree through the Biomedical and Health Informatics program during her fellowship. Upon completion of her fellowship requirements, Dr. Dowlut-McElroy accepted a faculty position at the University of Missouri-Kansas School of Medicine Department of Obstetrics and Gynecology in conjunction with a position in the Department of Surgery at Children's Mercy Hospitals in Kansas City, Missouri.

Dr. Dowlut-McElroy is a member of the American Congress of Obstetricians and Gynecologist and the North American Society for Pediatric and Adolescent Gynecology.