



# Cerclage Outcome Depending On Suture Material Choice, Effects on Birth Week, Infant Weight, Intensive Care Requirement, and Infection Rates

## Sütür Materyal Seçimine, Doğum Haftasına, Bebek Kilosuna, Yoğun Bakım İhtiyacı ve Enfeksiyon Oranlarına Bağlı Olarak Serklaj Sonuçları

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### Abstract

**Aim:** A preterm birth (PTB) is one that occurs before the full 37th week of pregnancy. Our theory is based on the possibility that braided mesh sutures made of Mersilene could lead to more complications and undesirable outcomes.

**Material and Method:** There were 46 pregnant women who had cervical insufficiency. Mersilene sutures were used in 26 cases and prolene sutures in 20 cases. The cervical lengths were comparable.

**Results:** Each case involved a pregnancy with a single fetus. Mersilene and prolene were the suture types in 26 cases and 20 cases, respectively. During the monitoring period, no problems, including infections, were noted.

**Conclusion:** Prolene sutures appear to be related with decreased PTB and improved neonatal results, despite the fact that mersilene sutures are the conventionally chosen material for cerclage. Prolene sutures continue to offer an option to conventional mersilene sutures, notwithstanding the need for more thorough randomized clinical trials to identify any potential associations between suture material and cerclage outcomes.

**Keywords:** Cerclage, suture material, preterm

### Öz

**Amaç:** Preterm doğum (PTB), gebeliğin tam 37. haftasından önce meydana gelen doğumdur. Teorimiz, Mersilene'den yapılan örgülü meş sütürlerin daha fazla komplikasyona ve istenmeyen sonuçlara yol açabileceği ihtimaline dayanmaktadır.

**Gereç ve Yöntem:** Servikal yetmezliği olan 46 gebe vardı. 26 olguda mersilen, 20 olguda prolene sütür kullanıldı. Servikal uzunluklar benzerdi.

**Bulgular:** Her vakada tek fetüslü bir gebelik vardı. 26 olguda mersilen ve 20 olguda prolene sütür tipi idi. İzleme süresi boyunca enfeksiyonlar da dahil olmak üzere herhangi bir sorun kaydedilmedi.

**Sonuç:** Mersilen sütürlerin serklaj için geleneksel olarak seçilen materyal olmasına rağmen prolene sütürler PTB'de azalma ve neonatal sonuçlarda iyileşme ile ilişkili görünmektedir. Prolene sütürler, sütür materyali ile serklaj sonuçları arasındaki herhangi bir potansiyel ilişkiyi belirlemek için daha kapsamlı randomize klinik çalışmalara duyulan ihtiyaca rağmen, geleneksel mersilen sütürlere bir seçenek sunmaya devam etmektedir.

**Anahtar Kelimeler:** Serklaj, sütür materyali, preterm



## INTRODUCTION

Preterm birth (PTB) is defined as birth before thirty-seven completed weeks of pregnancy (less than 259 days after the last menstrual period).<sup>[1]</sup> Gestational age at delivery is inversely proportional to mortality, so that the earlier the gestation at delivery the higher the mortality and requirement for intensive care admission. One of the major obstetric interventions for preventing (PTB) in women with cervical insufficiency is the cervical cerclage.<sup>[2]</sup> Cervix may shorten and dilate afterwards due to cervical insufficiency or incompetence. Acquired incompetence may be due to previous obstetrical or gynaecological procedures that distort cervical anatomy or cause trauma to the cervix. Rarely cervical weakness can be due to congenital causes leading again to anatomical or sometimes histological defect. Cervical anatomy can also be distorted by the presence of intramural pathology such as low-lying myomas or fibromas. There are no objective investigations or tests that can be performed before pregnancy to predict or diagnose subsequent cervical insufficiency. Diagnosis historically has almost always been clinical and retrospective depending on history and exclusion of other causes of the preterm birth. Hysterosalpingography and use of cervical dilators have been used in the past as diagnostic procedures prior to pregnancy but are no longer used.

Cervical cerclage, vaginal and intramuscular progesterone, a cervical pessary, or a combination of cervical pessary and vaginal progesterone have all been tried as treatments for cervical insufficiency. Still cervical cerclage seems as the most appropriate treatment option. Despite these results, some researchers continue to search for evidence supporting those methods of PTB prevention with in a single setting, randomising patients to pessary, progesterone or cerclage arms

Cervical cerclage has been offered to treat cervical insufficiency for over 60 years. One of the reasons for its continuous use is the lack of reliable evidence to support an alternative. Several suture materials have been used to perform the cervical cerclage procedure including Mersilene 5mm tape, Mersilene silk, metal wire, human fascia lata, Prolene and Nylon. Currently the most commonly used suture material is Mersilene tape (a braided suture material/mesh) because of its perceived strength, reduced likelihood of tearing through tissues and ease of removal. While it was reported that using different suture types showed no differences with regard to extending the period of gestation,<sup>[3]</sup> it was also reported that the braided polyester thread (MersileneR) suture type was more effective for extending the period of gestation compared to other suture types in emergency or physical examination induced cerclages.<sup>[4]</sup> However in certain animal and wound site studies, based on the hypothesis that bacteria would increase more in multifilament sutures and would lead to an ascendant infection risk, it was asserted that monofilament sutures would be less correlated with infection compared to mersilene.<sup>[5,6]</sup>

Our hypothesis depends on that braided mesh suture Mersilene might cause higher complication rates and unwanted results –like early delivery, low bir weight and intensive care unit requirement. Study was conducted in retrospective manner and included data of 46 pregnant diagnosed with cervical insufficiency. Suture material choices were decided by physician at time of cerclage procedure.

## MATERIAL AND METHOD

46 pregnant with cervical insufficiency were included. All data was collected in retrospective manner. We collected written consent of all cases during data collection. Mean age was  $32.5 \pm 5.1$  years and mean gestational age was  $18.1 \pm 5.1$  weeks (Median 17, IQR 8 weeks). All cases were pregnancies with single fetus. In 26 cases suture type was mersilene and in 20 cases was prolene. Cervical lengths were similar ( $8.2 \pm 3.8$  vs  $10.6 \pm 3$  cm). Data of birth week, infant weight, intensive care requirement and other complications including infections were collected retrospectively from patient charts. Patients < 18 years old, multiple pregnancies, who are unable to give informed consent, who do not want to join study group were excluded.

All surgical procedures were performed by same surgeon. The stitch was inserted using a McDonald technique. Main plan was to remove suture at  $37 \pm$  weeks of gestation yet as given in results some cases gestation was terminated by delivery before planned schedule.

Our study was approved as a thesis project by the Ethics Committee of Memorial Hospital in 2021, with the decision of the ethics committee numbered 003

### Statistical analysis

An IBM SPSS ver 21 was used for data analysis. Kolmogorov Smirnov test was used to define data homogeneity. Normally distributed data were expressed as mean  $\pm$  SD and nonnormally distributed data were expressed as median (IQR). Student's t test and Mann Whitney tests were used when appropriate. Categorical variables were analyzed by chi-square and Fisher tests. A p value < 0.05 was considered as statistically significant.

## RESULTS

46 pregnant with cervical insufficiency were included. Mean age was  $32.5 \pm 5.1$  years and mean gestational age was  $18.1 \pm 5.1$  weeks (Median 17, IQR 8 weeks). All cases were pregnancies with single fetus. In 26 cases suture type was mersilene (Group 1) and in 20 cases was prolene (Group 2). Groups' mean ages were similar ( $33 \pm 5.5$  vs  $32 \pm 4.9$  yrs). Gestational ages at cerclage were similar ( $18.4 \pm 3.8$  vs  $17.2 \pm 6.5$  wks). No complications including infection was observed during follow-up period. All babies were normal vaginally delivered. Birth times were significantly shorter in group 1, ( $34.4 \pm 6.2$  vs  $37.9 \pm 4.7$  weeks,  $p:0.02$ ). Birth weights

were significantly lower ( $1839\pm 878$  vs  $3257\pm 602$  grams,  $p:0.0001$ ) in group 1. Intensive care requirements were also significantly higher in group 1 (30% vs 10%,  $p:0.0001$ ). All findings are summarized in **Table 1**.

	<b>Mersilene group (n: 26)</b>	<b>Prolene group (n: 20)</b>	<b>P value</b>
Age	33±5.5	32±4.9	NS
Cerclage week	18.4±3.8	17.2±6.5	NS
Birth week	34.4±6.2	37.9±4.7	0.02
Birth weight (gr)	1839±878	3257±602	0.0001
Intensive care requirement (n, %)	8, 30.7%	2, 10%	0.0001

## DISCUSSION

In our study we observed that mersilene suture usage might be associated with higher preterm birth rates, lower birth weights and more requirement for intensive care unit.

Cervical cerclage has been offered to treat cervical insufficiency for over 60 years. One of the reasons for its continuous use is the lack of reliable evidence to support an alternative. It is used as an interventions to reduce rates of PTB. The placement of suture is currently only considered for singleton pregnancies and is not recommended in twin/multiple pregnancies.<sup>[7]</sup> According to NICE<sup>[8]</sup> guidelines there are three main indications for cerclage insertion: elective based history, proactive based on ultrasound criteria; and emergency/rescue cerclage. MRC multicentre study<sup>[9]</sup> which recruited 1292 women who were deemed to be at high risk of cervical insufficiency and randomised them to cerclage (647 women) versus no intervention (645 women) is also an other important source for selection of patients for cerclage. Results from this trial reported that woman who had cerclage were less likely to have PTB compared to patients who didn't have any intervention (13% versus 17%). Study could not demonstrate any difference in fetal or neonatal outcome.

Various materials have been used for cerclage. Among these materials, human fascia lata, Mersilene, Prolene, Tevdek, and metal wires can be mentioned. The most commonly used ones today are non-absorbable monofilaments such as Mersilene and prolene.<sup>[10,11]</sup> Mersilene (a braided suture material) is traditionally preferred suture material because of its perceived strength, reduced likelihood of tearing through tissues and ease of removal. On the other hand braided sutures have been associated with an increased risk of infection particularly when used in potentially contaminated surgical areas

In one study, Berghella et al reported that cerclage that suture type had no effect on delivery below 35 weeks or the age of pregnancy in a group of 138 patients.<sup>[1]</sup> Similarly Stafford et al reported that suture type has no effect on pregnancy results in a group of 108 pregnant women.<sup>[12]</sup> In contradiction in a study by Kindinger et al a group of 678 pregnant women were

evaluated and it was reported that the mersilene suture group had higher PTB rates and earlier birth weeks.<sup>[13]</sup> In another prospective study, the same authors applied ultrasound induced cervical cerclage to 49 patients and compared the mersilene and prolene suture usage. As a result, it was reported that the vaginal microbiome was corrupted in the mersilene suture group and that the pregnancy results were related to the corruption of the vaginal microbiome rather than the suture type.<sup>[13]</sup> Similarly Deger et al.<sup>[14]</sup> evaluated 151 pregnant women and found that pregnancy week was significantly lower in the mersilene suture group. They also reported that fetal weight, 1st and 5th minute APGAR scores in the mersilene suture group were significantly lower and intensive care requirement rates were significantly higher.

In the present study, it was observed that mersilene suture usage might be associated with higher PTB, lower birth weights and more requirement for intensive care unit. However, we did not perform any evaluation with regard to the vaginal microbiome. There are some animal models that reported monofilament sutures are associated with lower infection rates<sup>[4,6]</sup> but this association must still be analyzed with more detailed studies. It is not surprising that infants in mersilene group had lower birth weights and required more intensive care as their birth of week were significantly lower. The results of this study still indicate that the use of prolene sutures is recommended for better neonatal results and positive pregnancy results. Limitations of our study is small sample size and no evaluation of vaginal microbiome. More detailed randomized control studies with larger sample sizes are needed for evaluation of the effectiveness of different suture types in cerclage procedure. However, although the superiority of one suture materials over the other was not proven, the findings support the use of a thinner suture in women is correlated with lower PTB and better neonatal results.

## CONCLUSION

Although mersilene sutures are traditionally preferred material for cerclage, prolene sutures seems to be associated with lower PTB and better neonatal results. While more detailed randomized clinical trials are needed to reveal any possible association between suture material and cerclage outcomes, prolene sutures stand still as alternative for traditional mersilene sutures.

## ETHICAL DECLARATIONS

**Ethics Committee Approval:** The study was carried out with the permission Memorial Hospital Ethics Committee (Date: 30.04.2021, Decision No: 003).

**Informed Consent:** Because the study was designed retrospectively, no written informed consent form was obtained from patients.

**Referee Evaluation Process:** Externally peer-reviewed.

**Conflict of Interest Statement:** The authors have no conflicts of interest to declare.

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**Author Contributions:** All of the authors declare that they have all participated in the design, execution, and analysis of the paper, and that they have approved the final version.

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