22 February 2023

Identifiers: NCT06119113

Brief Title: Evaluation of Wound Infection Rates and Cosmetic Results of Different Suture Materials in Cesarean Skin Incision

STUDY PROTOCOL

1. Name of the study:

Evaluation of Wound Site Infection, Early and Late Wound Healing and Cosmetic Results of Vicryl (Polyglactin 910), Monocryl (Polyglecaprone 25) and Prolene (Polypropylene) Suture Materials Used in Pfannenstiel Skin Incision in Caesarean Section Surgery

2. Purpose and importance of the research (main purpose, secondary purposes):

Our primary aim with this study is to evaluate the early and late cosmetic results and patient preference of skin incision in a frequently performed surgery such as cesarean section.

Caesarean section is the most common surgery in women worldwide, and the incidence of cesarean section is increasing worldwide. 32% of pregnant women in the USA [1] and 48% in Turkey [2] give birth by cesarean section. Due to the high frequency of CS, it is essential to determine the surgical incision technique that yields the optimal cosmetic outcome of the incision scar. [4–5]. The incidence of wound complications following cesarean delivery has been reported to be between 3% and 30%; such wound complications include surgical site infection, hematoma, seroma, and wound dehiscence [6–7].

The skin is typically approximated with absorbable sutures, non-absorbable sutures, tissue adhesive or stapler after closing the abdominal layers and, if necessary, the subcutaneous fat tissue [8]. However, the suture material for optimal subcuticular skin closure is unclear, but the safest option is determined in terms of wound complications. It is important. Vıcryl (Poliglaktin 910), Monocryl (Poliglekapron 25) and Prolene (polypropylene) are the most commonly used suture materials for closing the skin incision.

The structure of the sutures may vary and their effects on biological healing processes may also vary [9]. Polyglactin 910 (Vicryl Rapide) is an absorbable, multifilament synthetic braided suture consisting of glycolide and L-lactide copolymer and its absorption period is 5076 days. Poliglekaprone 25 (Monocryl) is a monofilament synthetic absorbable suture made of glycolide and epsilon copolymer, its absorption period is 90-120 days. Polypropylene (prolene) monofilament is a non-absorbable synthetic suture with high tensile strength and minimal tissue reaction.

Clinical data in available studies are conflicting. In the animal studies of Sharp WV and colleagues comparing multifilament sutures with monofilament sutures, an increase in surgical site infection was found in multifilament sutures [10]. Tuuli et al. No significant difference was found in the risk of surgical site infection in patients treated with Vicryl compared with Monocryl (6.1% vs. 5.1%; P = .58). Buresch et al. In his study, he compared the wound complication rates of Monocryl (Poliglekapron 25) and Vicryl (Polyglactin 910), and closure with Monocryl was associated with a significantly reduced overall wound complication rate. (14.4% compared to 8.8%; P=0.04). Koroglu N, 2020 No statistically significant difference was observed between Vicryl (polyglactin 910) and prolene

(polypropylene) in terms of early wound complications or superficial infection. (8.3% in the polypropylene group vs 10.6% in the polyglactin 910 group, p = .642), but cosmetic results and patient satisfaction were not evaluated in this study. Cromi A et al. In his study, a total of 158 patients were evaluated with POSAS (Patient and Observer Scar Assessment Scale), VAS (Visual analog scale), VSS (Vancouver Scar Scale (VSS) scar evaluation scales, staple (40 patients), monocryl (45 patients), vicryl (40 patients).) and prolene (33 patients) sutures were used in 4 groups, and they determined that there was no significant difference in the cosmetic results of the wounds in the 2nd month and 6th month evaluations.

There are many scales used to evaluate the scar. The most important of these and the ones we will use in our work are; Vancouver Scar Scale (VSS) and Patient and Observer Scar Assessment Scale (POSAS) are scar assessment scales.

Vancouver Scar Scale (VSS), developed by Sullivan et al. in 1990 to evaluate scars, includes four parameters (elasticity, height, vascularity and pigmentation) and is scored between 0 and 14.

Patient and Observer Scar Assessment Scale (POSAS) is a comprehensive scale designed to evaluate all types of scars by patients and healthcare professionals. HGSAS is available as two separate scales (HSAS and GSDS). 6 items in the HSRS enable the patient to subjectively evaluate the scar and express his/her thoughts about the wound; GSDS has 5 items and helps the observer to evaluate the changes in the scar by applying the scale at different times, to evaluate the scar healing, and to express his/her thoughts about the scar (16). Each item is included in a 10-point Likert type scoring. An increase in the score obtained from the scale means that the scar has worsened.

3. **Expected benefits and risks from the research**

The aim of the study is to determine the safest option for optimum subcuticular skin closure, reduce wound complications and provide the best cosmetic result.

4. **Type, scope and design of planned research**

Single-center, three-arm prospective study

Our patients who gave birth by cesarean section in our hospital within a 6-month period and meet the study criteria will be included in the study.

The patients to be included in the study will be divided into three groups according to the Vicryl (Poliglactin 910), Monocryl (Poliglekapron 25) and Prolene (polypropylene) sutures preferred by the surgeon on the first post-operative day. In our clinic, cefazolin 2 g will be administered intravenously 1 hour before each operation as a prophylactic procedure. In routine cesarean section, a Pfannenstiel skin incision is made 2 cm above the pubic symphysis, and following the birth of the fetus, the uterus, peritoneum and fascia are closed sequentially. In the skin suture, according to the surgeon's preference, Vicryl (Polyglactin 910), Monocryl (Poliglekapron 25) and Prolene (polypropylene) sutures are selected and closed according to the patient's subcutaneous fat tissue and structure. In our study, patients hospitalized on the first post-op day will be grouped according to the suture preferred in the operation. The dressing will be removed on the first day after the surgery and the patients will be discharged on the second

post-op day if there is no problem after the surgery. Patients will be called for follow-up on the 10th post-operative day, 2nd month and 6th month. On the 10th post-operative day, the wound will be evaluated for infection (erythema, tenderness and purulent discharge will be considered as wound infection). If deemed appropriate, the sutures of the patients in the prolene suture group will be removed. All groups coming for follow-up will be evaluated for scar classification on the 10th day, 2nd month and 6th month post-op, first with the standardized scar evaluation scale (Sullivan T), then with the patient and observer evaluation scale (POSAS) and the Vancouver Scar Scale (VSS). and will be evaluated by the observing doctor. Additionally, patients will be categorized according to the classification recommended by the international scar management advisory panel at 2 months and 6 months.

The Patient and Observer Assessment Scale (POSAS) is a questionnaire developed to evaluate scar quality. Observer by rating scale based on clinically relevant scar characteristics consists of five patient six-item scales (Observer and Patient Scales) (Table 1) [13 , 14]. Observer ; It scores six items: vascularization, pigmentation, thickness, surface roughness, flexibility and surface area. Patient ; It scores six items: pain, itching, colour, thickness, relief and flexibility [14]. All items included are scored on a multiple 10-point scale, where 1 point is given when the scar characteristic is similar to 'normal skin' and 10 points are given when it reflects the 'worst scar'. All items are summed to determine the total scar score, with a higher score representing worse scar quality.

The Vancouver scar scale (VSS) consists of four variables: vascularity, height (thickness), elasticity and pigmentation. The total score varies between 0 and 14, with 0 points reflecting normal skin. (Table 2)

Table 1

Patient and Observer Scar Evaluation Scale (POSAS)

Observer Scar Assessment Scale (OSAS)

	Normal skin 1 2 3 4 5 6 7 8 9 10 worst scar imaginable
Vascullarity	O O O O O O O O O O
Pigmentatiion	O O O O O O O O O O
Thickness	O O O O O O O O O O
Relief	O O O O O O O O O O
Pliability	O O O O O O O O O O

Patient Scar Assessment Scale (PSAS)

	No, no complaints 1 2 3 4 5 6 7 8 9 10 Yes, worst imaginable
Is the scar painful ?	O O O O O O O O O O

Is the scar itching ?	O	O	O	O	O	O	O	O	O	O	
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	
No, as normal skin											**Yes, very different**
Is the color of the scar different?	O	O	O	O	O	O	O	O	O	O	
Is the scar more stiff ?	O	O	O	O	O	O	O	O	O	O	
Is the thickness of the scar different ?	O	O	O	O	O	O	O	O	O	O	
Is the scar irregular ?	O	O	O	O	O	O	O	O	O	O	

Table 2

Vancouver Scar Scale

Scar Characteristic	Puan
Vascularity	
Normal	**0**
Pink	**1**
Red	**2**
Purple	**3**
Pigmentation	
Normal	**0**
Hypopigmentation	**1**
Hyperpigmentation	**2**
Pliability	
Normal	**0**
Supple	**1**
Yielding	**2**
Firm	**3**

Ropes	4
Contracture	5

Height (mm)

Flat	0
<2 MM	1
2-5 MM	2
>5 MM	3

4. **Number of patients and volunteers to be included in the research, their nature and reason for selection (age ranges, gender, etc.).**

Women between the ages of 18-45 who had their first cesarean delivery in our hospital at 37 weeks and later will be included in the study.

5. **Parameters to be checked (must be written one by one and clearly),**

Preop:
- Age
- Gravida, parity, living child, pattern of previous births
- BMI
- Week of birth
- Caesarean section indication - Preop hemogram, htc Interop: − Operation time Postop:
- Maternal post-op 6th hour hemogram, WBC value
- Mother's hospital stay
- Post-op 10th day, 2nd month and 6th month, scar grading will be done with PSOAS and VSS. - scar length (cm)

6. **Where and by whom to look at the parameters**

The patients' incisions will be evaluated by the principal and assistant investigator during routine outpatient clinic checks.

7. **Which of the parameters to be used in the research are routine for that disease group and which are requested specifically for the research?**

Pregnant women who have undergone cesarean section will receive the follow-up and treatment we routinely do. In our clinic, Vicryl (Polyglactin 910), Monocryl (Poliglekapron 25) and Prolene (polypropylene) sutures are used, depending on the surgeon's preference and the

patient's subcutaneous tissue, for routine skin suturing. No research-specific examination will be required.

8. **Estimated working period, start and end dates,** The starting date is February 22, 2023 and the anticipated working period is 6 months.

9. **Criteria for inclusion in the study, exclusion from the study and withdrawal from the study,**

Inclusion criteria:

- Between 18-45 years old
- >37w patients who had primary cesarean section in our hospital
- Patients with Phannenstiel incision and subcutaneous closure

Exclusion criteria:

- Women <18 years and >45 years old
- Those with a history of Kelloids
- Those with suprapubic incision due to previous surgery
- Those with signs of infection at or near the incision line during cesarean section
- Known hypersensitivity to any of the suture materials used
- Having a medical disease that causes immune suppression, such as DM, chronic corticosteroid use
- Failure to obtain informed consent from the patient

10. The study will be terminated when patients meeting the inclusion criteria are reached.

11. **The statistical methods that will be used in evaluating the data obtained as a result of the research should be explained.**

G –Power 3 software package program was used to calculate the sample size of our study. Data from a similar study conducted by Cromi et al. were taken into account (18). For our study to be conducted in three arms, assuming Type 1 (alpha) error margin: 0.005 and Type 2 (beta) error margin: 0.20, the F value was calculated as 0.20 and the sample size was 243 cases. Considering the possibility of loss in 30% of the cases during the study period, the number of cases was planned to be at least 324.

SPSS 20 package program will be used to analyze the data obtained from our study. The Kolmogorov-Smirnov test will be applied to evaluate the distribution of continuous variables.

One-Way ANOVA and Kruskal-Wallis test will be used to compare groups in terms of parametric (homogeneous) and non-parametric (heterogeneous) continuous variables, respectively. Chi-square test will be used to compare groups for categorical variables (percentage). The change in scar evaluation criteria over time will be evaluated with the Wilcoxon matched pairs test, and the relationship between them will be evaluated with the Sperman's rho correlation test. $p<0.05$ will be considered statistically significant.

12. Resources

1. Martin JA, Hamilton BE, Osterman MJ, et al. Births: final data for 2015. Natl Vital Stat Rep. 2017;66(1):1.
2. Hacettepe University Institute of Population Studies. 2013 Turkey demographic and health survey. Ankara, Turkey: TR Ministry of Development and TUB_ ITAK; 2014.
3. Fleisher J, Khalifeh A, Pettker C, Berghella V, Dabbish N, Mackeen AD. Patient satisfaction and cosmetic outcome in a randomized study of cesarean skin closure. J Matern Fetal Neonatal Med. 2019 Nov;32(22):3830-3835. doi: 10.1080/14767058.2018.1474870. Epub 2018 May 24. PMID: 29739243.
4. Owen J, Andrews WW. Wound complications after cesarean sections. Clin Obstet Gynaecol. 1994;37(4): 842–855
5. Reilly J, Twaddle S, McIntosh J, et al. An economic analysis of surgical wound infection. J Hosp Infect. 2001;49(4):245–249.
6. Corbacioglu Esmer A, Goksedef PC, Akca A, et al. Role of subcutaneous closure in preventing wound complications after cesarean delivery with Pfannenstiel incision: a randomized clinical trial. J Obstet Gynaecol Res. 2014;40(3):728–735.
7. Vats U, Pandit Suchitra N. Comparison of Efficacy of Three Suture Materials, i.e., Poliglecaprone 25, Polyglactin 910, Polyamide, as Subcuticular Skin Stitches in PostCesarean Women: A Randomized Clinical Trial. J Obstet Gynaecol India. 2014 Feb;64(1):14-8. doi: 10.1007/s13224-013-0448-5. Epub 2013 Sep 4. PMID: 24587600; PMCID: PMC3931899. *
8. Sajid MS, McFall MR, Whitehouse PA, et al. Systematic review of absorbable vs nonabsorbable sutures used for the closure of surgical incisions. WJGS. 2014;6(12): 241– 247
9. Buresch AM, Van Arsdale A, Ferzli M, et al. Comparison of subcuticular suture type for skin closure after cesarean delivery: a randomized controlled trial. Obstet Gynecol. 2017;130(3):521–526.
10. Sharp WV, Belden TA, King PH, et al. Suture resistance to infection. Surgery. 1982;91(1):61–63.
11. Tuuli MG, Stout MJ, Martin S, et al. Comparison of suture materials for subcuticular skin closure at cesarean delivery. Am J Obstet Gynecol. 2016;215(4): 490.e1–490.e5.

12. Koroglu N, Temel Yuksel I, Aslan Cetin B, Aytufan Z, Deniz N, Akca A, Yetkin Yildirim G, Yuksel A. Skin closure at cesarean section, polypropylene versus polyglactin 910: a randomized controlled study. J Matern Fetal Neonatal Med. 2022 Mar;35(6):1088-1092. doi: 10.1080/14767058.2020.1743654. Epub 2020 Mar 30. PMID: 32228099.
13. Draaijers LJ, Tempelman FR, Botman YA, Tuinebveijer WE, Middlekoop E, Kreis RW, et al. The patient and observer scar assessment scale: a reliable and feasible tool for scar evaluation. Plast Reconstr Surg 2004;6:1960e7.
14. Van de Kar AL, Corion LU, Smeulders MJ, Draaijers LJ, van der Horst CM, van Zuijlen Paul PM. Reliable and feasible evaluation of linear scars by the patient and observer scar assessment scale. J Plast Reconstr Aesthet Surg 2005;2:512e4.
15. Ekin M, Dagdeviren H, Caypinar SS, Erdogan B, Ayag ME, Cengiz H, Yasar L, Helvacioglu Ç. Comparative cosmetic outcome of surgical incisions created by the PEAK Plasma Blade and a scalpel after cesarean section by Patient and Observer Assessment Scale (POSAS): A randomized double blind study. Taiwan J Obstet Gynecol. 2018 Feb;57(1):68-70. doi: 10.1016/j.tjog.2017.12.011. PMID: 29458906.
16. Ekin M, Dagdeviren H, Caypinar SS, Erdogan B, Ayag ME, Cengiz H, Yasar L, Helvacioglu Ç. Comparative cosmetic outcome of surgical incisions created by the PEAK Plasma Blade and a scalpel after cesarean section by Patient and Observer Assessment Scale (POSAS): A randomized double blind study. Taiwan J Obstet Gynecol. 2018 Feb;57(1):68-70. doi: 10.1016/j.tjog.2017.12.011. PMID: 29458906.
17. Yang J, Kim KH, Song YJ, Kim SC, Sung N, Kim H, Lee DH. Cosmetic outcomes of cesarean section scar; subcuticular suture versus intradermal buried suture. Obstet Gynecol Sci. 2018 Jan;61(1):79-87. doi: 10.5468/ogs.2018.61.1.79. Epub 2018 Jan 9. PMID: 29372153; PMCID: PMC5780325.

18. Cromi A, Ghezzi F, Gottardi A, Cherubino M, Uccella S, Valdatta L. Cosmetic outcomes of various skin closure methods following cesarean delivery: a randomized trial. Am J Obstet Gynecol. 2010 Jul;203(1):36.e1-8. doi: 10.1016/j.ajog.2010.02.001. Epub 2010 Apr 24. PMID: 20417924.
19. Sullivan T, Smith J, Kermode J, Mclver E, Courtemanche DJ. Rating the burn scar. J Burn Care Rehabil 1990;11(3):256–60.

INFORMED VOLUNTEER CONSENT FORM

Dear ..... (legal representative of volunteer candidate / volunteer candidate);

We will introduce you to the program "Vıcryl (Polyglactin 910, Multifilament-absorbable), Monocryl (Poliglekapron 25, monofilament-absorbable) and Prolene (polypropylene, monofilament non-absorbable), which are used to close the skin incision after cesarean section, at the gynecology and obstetrics clinic of Başakşehir Çam and Sakura City Hospital. We invite you to the research titled "Evaluation of early and late postoperative wound healing and cosmetic results of three different suture materials". Before deciding whether or not to participate in this research, you need to know for what purpose and how the research will be conducted, the possible benefits, risks and discomforts that this research will bring to the volunteer participants, and make your decision freely within the framework of this information. Therefore, it is of great importance to read and understand this form. This form contains the written form of the information conveyed to you verbally by us, the research officer. Before signing the form, take the time to carefully read the following information, which is explained to you verbally. If you wish, discuss this information with your family, relatives and/or doctor. If there are things you do not understand or are not clear to you, or if you would like more information, ask us. If you agree to participate, you will be given a copy of this form to keep, signed by you and the witness who was with you during the briefing.

Participating in the research is entirely voluntary. You have the right not to participate in the study or to withdraw from the study at any time after participating. We would like to inform you that in both cases you will not be subject to any sanctions or loss of rights.

Research Supervisor

The study we offer you to participate in voluntarily is a research project. When closing the skin after cesarean section in routine, Vicryl (Poliglactin 910), Monocryl (Poliglekapron 25) and Prolene (polypropylene) are the most commonly used suture materials to close the skin incision. The suture material for optimal subcuticular skin closure is uncertain, but determining the safest

option is important in terms of wound site complications. Our primary aim with this study is to determine the most useful suture to reduce complications due to skin incision in frequently performed surgery such as cesarean section, and our secondary aim is to evaluate the suture we use in terms of cosmetic results and patient preference.
In this research project, our patients who had a cesarean section for the first time will be grouped according to the skin suture used during the cesarean section, and the skin incision will be evaluated at the end of the 10th day, 2nd month and 6th month after the surgery. No extra blood will be taken from you for the study before, during or after cesarean section. You will receive routine follow-up and treatment before and after birth.
The results of the research will be used for scientific and educational purposes. All information obtained from you will be used solely for research purposes and will be kept confidential, and the confidentiality of your identity information, if any, will be protected when the research is published. If you exercise your right to withdraw or are removed before the research is completed, data about you will not be used, except for anonymized information.

You or the social security institution you are affiliated with will not be charged for any action taken within the scope of the research. The research budget will be covered by me.

CONTACT PERSON

Ayşenur ÇALIŞ ÖZBAYRAM (554) 9707052

CONSENT / APPROVAL / CONSENT

I have read the information section regarding the research whose subject and purpose are stated above, and I have been informed first verbally and then in writing by the relevant person who has signed below. I fully understand the scope and purpose of the study in which I am asked to participate and the responsibilities that fall on me as a volunteer. I had the opportunity to ask questions and discuss the study and received satisfactory answers. The possible risks and benefits of the study were also explained to me verbally. I know that I participated in the research voluntarily, that I can leave the research at any time, with or without justification, and that I can be excluded from the research by the researcher regardless of my own will, and that my current treatment will not be negatively affected when I leave the research.

In this conditions ;

1) I agree to participate in the Clinical Research in question with my own consent (for my child/guardian to participate in this study) without any pressure or coercion.

2) If necessary, my personal information can be accessed by individuals/institutions specified in the legislation.,

3) I consent to the use of the information obtained in the study (on the condition that my identity information remains confidential) for publication, archiving and, if necessary, to be transferred outside our country for the purpose of scientific contribution.

I hereby consent to participate in this clinical trial without any further explanation and without any pressure.

Volunteer's
Name and surname:
Signature:
Address:
(Phone Number, Fax Number, if any):
Date (day/month/year): …./…./….

I have made explanations to the volunteer/legal representative whose name is written above about the purpose, content, method, benefits and risks of the research, and the rights of the volunteer. The patient's questions were answered. In addition, the volunteer / legal representative was ensured to review this form in detail and sign it.

Person Making the Statements
Name and surname:
Signature:
Date (day/month/year):…/…./…..

This Informed Volunteer Consent Form, consisting of a total of 3 pages, was prepared in 2 copies and one copy was delivered to the patient/patient's relative.