Journal of Surgery
2021; 9(2): 63-68
http://www.sciencepublishinggroup.com/j/js
doi: 10.11648/j.js.20210902.14
ISSN: 2330-0914 (Print); ISSN: 2330-0930 (Online)

Research Article

Prospective, Observational Study to Assess a New Quick Absorbable Monofilament Suture for Skin Closure in Adults

Petra Baumann[1, *], Frank Gumpinger[2, 3]

[1]Department Medical Scientific Affairs, Aesculap, Tuttlingen, Germany
[2]Department of General Surgery, Benedictus Clinic Tutzing, Tutzing, Germany
[3]Department of General Surgery, Clinic Agatharied GmbH, Hausham, Germany

Email address:
petra.baumann@aesculap.de (P. Baumann)
[*]Corresponding author

To cite this article:
Petra Baumann, Frank Gumpinger. Prospective, Observational Study to Assess a New Quick Absorbable Monofilament Suture for Skin Closure in Adults. *Journal of Surgery*. Vol. 9, No. 2, 2021, pp. 63-68. doi: 10.11648/j.js.20210902.14

Received: January 28, 2021; **Accepted**: February 23, 2021; **Published**: March 26, 2021

Abstract: This is the first prospective, single centre study assessing the clinical outcome of a new quick, absorbable, monofilament suture for skin closure in adults after general surgical interventions. In total 50 patients were included in the study to apply Monosyn Quick suture to skin closure. Suture handling was evaluated by the surgeons using a 5-point Likert scale. The Visual-Analogue-Scale (VAS) was used to rate wound healing, pain and satisfaction. Adverse events were reported up to the day of discharge. The new suture material was judged good to excellent regarding its handling properties. Patients stayed in hospital for an average of 5.46 days. Wound healing assessment by the physician was excellent [mean (range) 94.94 (50.00 – 100.00)]. Low pain level was reported by the patients (mean (SD) 23.21±18.96; [range 0.00 – 95.00]) and persisted in mean for 2.56 days [range 0.00 - 7.00 days]. High satisfaction with the skin closure was reported by patients at discharge (mean (SD) 94.25±7.89 [range 70.00 – 100.00]). No wound healing-related adverse events were observed. Our results showed, that the new quick, absorbable, monofilament suture is appropriate for dermal wound approximation in general surgery and represents a good alternative option to other suture materials which are in common use to close the skin.

Keywords: Skin closure, Fast-absorbable monofilament, General surgery

1. Introduction

The ideal suture material to close the skin is characterized by an easy handling and sufficient tensile strength to support the healing phase [1]. In addition, its application should cause a minimal tissue reaction and should lead to an excellent cosmetic outcome [1]. Non-absorbable as well as absorbable sutures are in common use for skin approximation [1]. A disadvantage of non-absorbable sutures is that they must be removed approximately 7-14 days after surgery, which is time-consuming and unpleasant for the patient [1].
In contrast, absorbable suture are degraded by hydrolysis in the body after a certain period and suture removal can be avoided.

Currently, multifilament as well as monofilament absorbable sutures are applied to close the skin. Rapid absorbable, braided suture material which consists of polyglactin 910, is routinely used for wound edge approximation. This suture material supports the wound healing phase up to 14 days after surgery and is completely absorbed within 42 days [2]. In addition, an absorbable monofilament suture made of epsilon-caprolactone and glycolide, (polygelcaprone 25) is also applied to close the skin [3]. Complete absorption of this suture is seen 91 – 119 days after implantation with slight to minimal tissue reaction [4]. The absorbable monofilament can provide benefits regarding of aesthetic outcome and cost-effectiveness for skin closure compared to non-absorbable sutures. Increased versatility, ease of handling, and convenience are further advantages of this suture material [5]. In contrast to braided absorbable sutures, monofilament absorbable sutures are favourable for skin closure because of their smoother and lower surface

minimising the risk of infection which could be induced by the capillary properties of multifilament, braided sutures.

In 2015 a new quick-absorbable, monofilament suture (Monosyn® Quick) was introduced in the market. This suture is a copolymer made of 72% glycolide, 14% ε-caprolactone and 14% trimethylenecarbonate. The threads are gamma-irradiated for faster absorption. 50% suture strength is lost 7 days after implantation and 100% after 14-21 days. Monosyn® Quick absorption is completed approximately 56 days after implantation.

This study is the first research analysing clinical performance of a new quick-absorbable, monofilament suture for skin closure under daily clinical routine.

2. Methods

2.1. Study Design and Participants

A single centre, prospective, observational study was designed to evaluate the clinical performance of a new, quick, absorbable, monofilament suture for skin closure in patients undergoing general surgery. Assessment criteria were intrasurgical suture handling properties, the result of wound edge approximation, cosmetics and patient´s satisfaction. Study registration was recorded in ClinicalTrials.gov, registration number NCT03355001, before enrolment of the first patient.

Adult patients undergoing skin closure after general surgical interventions. (e.g. sigmoid diverticulitis, hernia surgery, colorectal surgery) who provided a written informed consent for data collection were included in one clinic located in Germany. No exclusion criteria were selected. Treatment was performed in daily clinical routine. The selected clinic applied Monosyn® Quick on a standard basis to align to the dermal wound. Patients were presurgically examined, operated and followed-up until the day of discharge for a total of three visitations (Figure 1). Data collection was performed in a case report form in a paper-based version (pCRF).

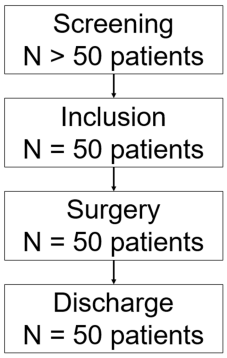

Figure 1. *Patients flow diagram.*

2.2. Outcomes

Intrasurgical handling properties of the suture were judged by the surgeons after skin approximation as a parameter of efficacy and a questionnaire was completed after each surgery. The following handling categories were assessed: knot security, tensile strength, tissue drag, and pliability of the suture and the different categories were judged from poor to excellent on a five-point Likert-type scale. As suture related complications we classified thread rupture, knots in the thread, bended thread and a defect in needle-thread attachment. Wound healing was assessed by the physician using the visual analogue scale (VAS), duration of pain assessed by the patients, as well as pain and satisfaction rated by the patient via the VAS served as efficacy parameters. The most frequently used method for pain intensity and other parameters such as satisfaction, was the VAS scale. This is a horizontal [6, 7] or vertical 10-cm scale [8], that at each end is labelled by descriptors such as '0=no pain' and '10=worst pain ever' for pain assessment. The patient's opinion in the moment of rating is equivalent to the mark on the line and the quantification of the distance in centimetres from 0 is the result. This method has been widely used and validated [9, 10]. To evaluate the safety of the suture material the incidence of wound dehiscence (defined as a gap in the wound), surgical site infections, tissue reaction, allergic reaction, seroma formation, fistula or abscess formation and haematoma as well as thread removal due to incomplete- or non-absorption of the suture material were monitored until day of discharge. In addition, the length of hospital stay was recorded.

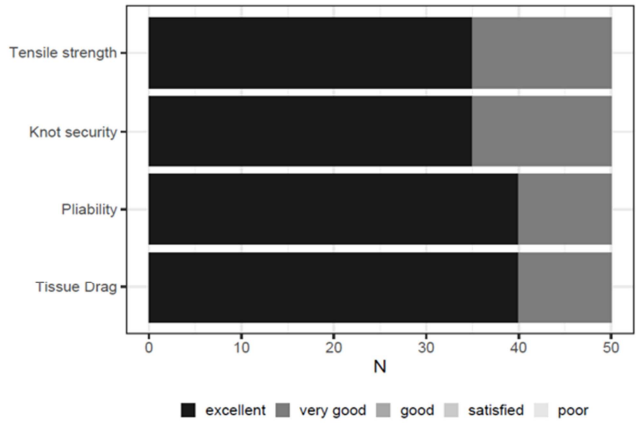

Figure 2. *Frequency in bar diagrams of assessed handling parameters of the suture.*

2.3. Statistical Methods

Adults who underwent general surgery and receiving the suture material for skin closure as described in the study protocol were included in the analysis. No sample size calculation was performed. The basis of the sample size determination was the number of patients that could be enrolled in the selected clinic within six months. In addition, we hypothesised that a population of 50 patients would be large enough to detect the absence of a high number of complications. The study was analysed descriptively and outcome was compared to historical literature data. The clinical performance of the new quick, absorbable, monofilament suture was evaluated as equivalent if the results correspond to the findings available for either fast-absorbable, multifilament sutures or standard absorbable, monofilament sutures.

To compare our results with corresponding literature ranges, 95% confidence intervals (Agresti-Coull method) were applied. SAS software version 9.4 (SAS Institute Inc., Cary, NC, USA) was used for statistical analysis. No replacement by estimates was done for missing data, these were analysed as such. We employed the t-test for statistical comparison.

2.4. Ethical Considerations

During the trial, no additional study-specific examinations or invasive measures were performed, because patients were treated under clinical routine setting. The suture material was applied according to its instruction for use. The ethics committee (Bayerische Landesärztekammer) was responsible for the participating clinic endorsed the study design prior to patient acquisition.

3. Results

3.1. Recruitment

The recruitment took place between the 10th of April 2018 and the 18th of September 2019. Many adults were checked for eligibility. In total 50 cases were included and, after different general surgical interventions, the skin was aligned using Monosyn® Quick suture material. All patients were followed up until discharge (Figure 1). The last mandatory discharge visit of the last enrolled patient was completed on the 21st of September 2019.

3.2. Patient Demographics and Other Baseline Characteristics

Patients receiving Monosyn® Quick suture for skin closure and whose fulfilled the inclusion criteria were included in the analysis. The population consisted of 18 females and 32 males. Demographic parameter of the included cohort are shown in Table 1. The patient population averaged 62.9±10.5 years of age. A mean weight of 79.3±14.2 kilogram (kg) and a mean height of 173.8±9.9 centimetres (cm) were reported for the total population. Average Body Mass Index was 26.3±4.2 kg/m^2. There were only minor differences between the female and male population in regards to demographic data like age, weight, height and BMI, which were not significant. The female population was slightly older, weighed less, was smaller and had a slightly increased BMI compared to the male population.

Table 1. *Demographic data of patients undergoing skin closure with Monosyn® Quick.*

Parameter	Subgroups	Number (N)	Median (Range)	Mean (SD)
Age (years)	All	50	61.5 (32.0 – 84.0)	62.9 (10.5)
	Female	18	63.5 (50.0 – 84.0)	65.1 (10.1)
	Male	32	60.0 (32.0 – 84.0)	61.6 (10.6)
Weight (kg)	All	50	79.0 (46.0 – 112.0)	79.3 (14.2)
	Female	18	71.5 (55.0 – 88.0)	72.7 (10.4)
	Male	32	84.0 (46.0 – 112.0)	83.0 (14.8)
Height (cm)	All	50	173.0 (155.0 – 198.0)	173.8 (9.9)
	Female	18	166.0 (155.0 – 183.0)	165.3 (6.8)
	Male	32	180.0 (160.0 – 198.0)	178.6 (7.9)
Body Mass Index (BMI) (kg/m^2)	All	50	25.7 (15.6 – 37.2)	26.3 (4.2)
	Female	18	27.4 (19.4 – 32.8)	26.7 (4.3)
	Male	32	25.6 (15.6 – 37.2)	26.0 (4.2)

Abbreviations: BMI, Body Mass Index; cm, centimetre; kg, kilogram; m^2, square metre; n, number; SD, standard deviation.

3.3. Surgery Details

The main reasons for surgery were sigmoid diverticulitis, followed by a hernia surgery, colorectal surgery, cholecystitis / cholecystolithiasis. In total, nine patients underwent surgery due to another reason (Table 2).

Table 2. *Reason for surgery in patients undergoing skin closure with Monosyn® Quick.*

Indication for surgery	N	Percentage (%)
All	50	100.0
Sigmoid diverticulitis	13	26.0
Hernia	12	24.0
Colorectal surgery	8	16.0
Cholecystitis/cholecystolithiasis	6	12.0
Sigmoid carcinoma	2	4.0
Others	9	18.0

Abbreviations: n, number; %, percentage.

Except for one patient, all other patients received an incision on the front of the body (Table 3). The length of the incision was a mean 7.2±3.3 cm (Table 4). The longest mean incisions were seen when sigmoid diverticulitis or sigmoid carcinoma was the reason for surgery, with 9.3±2.1 cm and 10.5±0.7 cm, respectively (Table 4). The mean time to close the incision was 5.9±2.7 min (Table 4). The longest closure time were reported after a sigmoid carcinoma surgery, with in

mean 11.0±1.4 min (Table 4).

Table 3. *Localisation of incisions in patients undergoing skin closure with Monosyn® Quick.*

Localisation	Indication for surgery	N	%
body – back side	All	1	2.0
	Other	1	2.0
Body – Front side	All	49	98.0
	Sigmoid diverticulitis	13	26.0
	Hernia	12	24.0
	Colorectal surgery	8	16.0
	Cholecystitis/cholecystolithiasis	6	12.0
	Sigmoid carcinoma	2	4.0
	Other	8	16.0

Abbreviations: n, number; %, percentage.

Table 4. *Length of incisions and duration of suturing in patients undergoing skin closure with Monosyn® Quick.*

Parameter	Indication for Surgery	N	Median (Range)	Mean (SD)
length of Incision (cm)	All	50	7.0 (3.0 – 17.0)	7.2 (3.3)
	Sigmoid diverticulitis	13	10.0 (3.0 – 11.0)	9.3 (2.1)
	Hernia	12	4.0 (3.0 – 7.0)	4.1 (1.2)
	Colorectal surgery	8	8.5 (4.0 – 13.0)	8.5 (3.3)
	Cholecystitis	6	4.5 (4.0 – 10.0)	5.5 (2.4)
	Sigmoid carcinoma	2	10.5 (10.0 – 11.0)	10.5 (0.7)
	Other	9	6.0 (4.0 – 17.0)	7.4 (4.0)
Suturing duration (min)	All	50	5.0 (2.0 – 12.0)	5.9 (2.7)
	Sigmoid diverticulitis	13	7.0 (4.0 – 11.0)	7.4 (2.5)
	Hernia	12	3.5 (2.0 – 7.0)	3.9 (1.7)
	Colorectal surgery	8	7.0 (2.0 – 10.0)	6.9 (2.9)
	Cholecystitis/cholecystolithiasis	6	5.0 (4.0 – 6.0)	5.0 (0.6)
	Sigmoid carcinoma	2	11.0 (10.0 – 12.0)	11.0 (1.4)
	Other	9	4.0 (3.0 – 10.0)	5.2 (2.3)

Abbreviations: cm, centimetre; min, minutes; n, number; SD, standard deviation.

Overall, 75 suture threads were applied in 50 surgeries to close the skin. The suture material was applied in the majority of cases (N=48, 96%) in the interrupted suture technique only in two operations (4%) the suture was used in the continuous suture technique. All sutures were implanted intracutaneously. The preferred United States pharmacopoeia (USP) size was 4/0 combined with a DSMP 19 needle.

3.4. Intrasurgical Handling of Suture Material

The knot security was rated with "very good" in 30% (N=15) and with "excellent" in 70% (N=35) of the surgeries. The same was observed for the tensile strength. Judgement of tissue drag, and pliability was very good in 20% of cases (N=10) and excellent in 80% (N=40). Therefore, all categories received a rating of 4 to 5 points, showing that the suture material is good to excellent to handle (Figure 2).

3.5. Complications

Neither intrasurgical adverse events nor suture-related adverse device effects (ADEs) occurred.

Two (4%) AEs were recorded before discharge.

A superficial wound infection was seen once (2%), which lead to a prolongation of hospitalisation and was therefore reported as serious. In this patient, a part of the incision was clamped by the surgeon during surgery and showed a redness postoperatively, whereas the sutured part of the wound was not affected. The clamps were removed to deal with this, but the suture remained in place. The patient recovered without sequelae. No causal relationship with the suture material was mentioned.

Necrosis was observed in the second case. No measures were taken, the wound was controlled, and the event was resolved without any sequelae. The reason for this event was electrocautery burning during surgery. Therefore the event was reported with a causal relationship with the surgical procedure.

3.6. Hospital Stay

An average of 5.5±3.0 days was reported for post-surgical length of hospital stay, (Table 5). Most of the patients left the hospital two days after surgery. The length of hospital stay ranged from 0 until 12 days after surgery.

3.7. Post-Surgical Assessment Using VAS Scale

Pain was reported by the patients at discharge using the VAS Scale (0 low-100 high). Mean pain intensity was 23.2±10.0 with a mean duration of 2.6±1.5 days (Table 5). In total, 14 patients (28%) had no pain. The majority of patients (N=32, 64%) recorded low pain, whereas only two patients (4%) reported high pain.

Patient satisfaction was measured using the VAS at discharge. A level of 94.3±7.9 was reported, indicating high

patient satisfaction with the clinical outcome (Table 5). In addition, physicians rated the wound healing as excellent 94.9±9.8, which indicates that the cosmetic outcome was also excellent.

Table 5. *Postoperative outcomes of patients undergoing skin closure with Monosyn® Quick.*

	Parameter	N	Median (range)	Mean (SD)
General	Hospital stay (days)	50	6.0 (0.0 – 12.0)	5.5 (3.0)
Physician assessed	Wound healing (VAS)	50	100.0 (50.0 – 100.0)	94.9 (9.8)
	Duration of pain (days)	48	2.0 (0.0 – 7.0)	2.6 (1.5)
Patient assessed*	Pain intensity (VAS)	48	20.0 (0.0 – 95.0)	23.2 (19.0)
	Satisfaction (VAS)	48	98.0 (70.0 – 100.0)	94.3 (7.9)

Abbreviations: VAS, visual analogue scale (0 low – 100 high); n, number; SD, standard deviation.
* Data only available in 48 patients.

4. Discussion

This is the first study analysing the clinical outcome of a new quick, absorbable, monofilament suture for skin closure. Our findings indicate high patient satisfaction, a low complication rate with no causal relationship to the applied device, an excellent wound healing assessment by the physician and a good suture handling judgement by the surgeon.

Skin closure using a rapidly, absorbable, multifilament suture based on polyglactin 910 (Vicryl Rapide) was evaluated in several publications [11–16], which confirmed that the application of a fast-absorbable suture is sufficient for cutaneous wound closures [13]. A randomized controlled study evaluating Vicryl Rapide versus a non-absorbable suture for wound approximation after open carpal tunnel release, found out that a fast-absorbable, braided suture is cost- and time efficient in comparison to non-absorbable sutures [12]. Vicryl Rapide is described as falling out spontaneously within 2–3 weeks. The most-frequent reported postoperative adverse events after skin closure are: wound infection 1–11% [11] and deferred wound cure 1–3.4% [3, 15, 17]. Seldom observed complications were suture removal, tissue reactions and abscess development [13, 15, 16]. The adverse event rate in the present study was very low. Only one wound infection (2%) was observed in the current study and was comparable with the rates published in the literature.

Our small series indicates that using a quick absorbable monofilament suture for wound approximation in adults is secure and reliable. In addition, the performance evaluation of the investigated suture was very good in regards to wound healing and patient's satisfaction and in line with published data [11, 12, 17, 18].

Limitations of this study were the rather short follow-up period until discharge that does not cover the whole wound healing phase as well as the complete absorption of the suture material. The use of a historical control group for comparison as well as a small size also weaken the results of this study.

5. Conclusion

Different reports indicate that rapid absorbable, braided sutures or absorbable monofilament sutures should be preferred to approximate dermal wounds.

Based on the current results, we conclude that our quick, absorbable, monofilament suture represents a reliable alternative for skin closure to common used sutures as such standard absorbable, monofilament or rapidly, absorbable, multifilament sutures. Several factors influence the tissue reaction after suture placement including the degradation, absorption and configuration of the suture. Due to their smooth and lower surface, absorbable, monofilament sutures reduce the risk for infections induced by capillary penetration of bacteria, in contrast to rapidly, absorbable braided multifilament sutures. In addition, monofilament sutures made of poliglecaprone have been described as having low tissue reactivity.

Therefore, randomised controlled trials comparing a rapidly, absorbable, multifilament suture versus a quick, absorbable monofilament suture for skin closure should be performed to increase the clinical evidence in regards to the best suture choice based on its filament structure.

Abbreviations

Percentage, frequency (%)
Adverse Device Effect, (ADE)
Adverse Event, (AE)
Body Mass Index, (BMI)
Centimetre, (cm)
Case Report Form, (CRF)
Three-eights, circle needle, cutting, micro point, precision cut (DSMP
For example, (e.g.)
Kilogramme, (kg)
Kilogramme / square metre (kg/m^2)
Square metre, (m^2)
Maximum, (Max)
Minimum, (Min)
Minutes, (min)
Number, (N)
Serious Adverse Event, (SAE)
Standard Deviation, (SD)
United States Pharmacopoeia, (USP)
Visual Analogue Scale,(VAS)

Declarations

Disclosure

The authors declare that they have no competing interests.

Funding

The sponsor of this study was B. Braun Surgical SA. Project management, data management, statistics and study registration were organized and managed by the Medical Scientific Affairs department of Aesculap AG.

Authors' Contributions

PB was involved in the study design and prepared the manuscript together with FG. Final manuscript was approved by both authors.

Acknowledgements

The authors thank the staff of the Benedictus Clinic, Tutzing, Germany for their interest and support. In addition, the authors address special thanks to the patients for their willingness to participate in the study.

References

[1] Gfroerer S, Baumann P, Schwalbach AK, Smirnoff A. Prospective international multicenter observational study of Novosyn® Quick for skin closures in adults and children (SKINNOQ). BMC Surg. 2019; 19 (1): 47.

[2] Matsumine H, Takeuchi M. Usefulness of Irradiated Polyglactin 910 (Vicryl Rapide) for Skin Suturing during Surgery for Lateral Ray Polydactyly of the Toes in Children. Plast Reconstr Surg Glob Open 2013; 1 (6): e42.

[3] Odijk R, Hennipman B, Rousian M, Madani K, Dijksterhuis M, Leeuw JW de et al. The MOVE-trial: Monocryl® vs. Vicryl Rapide™ for skin repair in mediolateral episiotomies: a randomized controlled trial. BMC Pregnancy Childbirth 2017; 17 (1): 355.

[4] Bezwada RS, Jamiolkowski DD, Lee I-Y, Agarwal V, Persivale J, Trenka-Benthin S et al. Monocryl® suture, a new ultra-pliable absorbable monofilament suture. Biomaterials 1995; 16 (15): 1141–8.

[5] Yag-Howard C. Absorbable poliglecaprone 25 sutures for both subcutaneous and transepidermal closure: a cosmetically and economically appealing option. Cutis 2013.

[6] Joyce CR, Zutshi DW, Hrubes V, Mason RM. Comparison of fixed interval and visual analogue scales for rating chronic pain. Eur J Clin Pharmacol 1975; 8 (6): 415–20.

[7] Huskisson EC, Sturrock RD, Tugwell P. Measurement of patient outcome. Br J Rheumatol 1983; 22 (3 Suppl): 86–9.

[8] Sriwatanakul K, Kelvie W, Lasagna L, Calimlim JF, Weis OF, Mehta G. Studies with different types of visual analog scales for measurement of pain. Clin Pharmacol Ther 1983; 34 (2): 234–9.

[9] Price DD, Dubner R. Mechanisms of first and second pain in the peripheral and central nervous systems. J Invest Dermatol 1977; 69 (1): 167–71.

[10] Rosier EM, Iadarola MJ, Coghill RC. Reproducibility of pain measurement and pain perception. Pain 2002; 98 (1): 205–16.

[11] Tejani C, Sivitz AB, Rosen MD, Nakanishi AK, Flood RG, Clott MA et al. A comparison of cosmetic outcomes of lacerations on the extremities and trunk using absorbable versus nonabsorbable sutures. Acad Emerg Med 2014; 21 (6): 637–43.

[12] Theopold C, Potter S, Dempsey M, O'Shaughnessy M. A randomised controlled trial of absorbable versus non-absorbable sutures for skin closure after open carpal tunnel release. J Hand Surg Eur Vol 2012; 37 (4): 350–3.

[13] Ekerot L. Correction of syndactyly: advantages with a non-grafting technique and the use of absorbable skin sutures. Scand J Plast Reconstr Surg Hand Surg 1999; 33 (4): 427–31.

[14] Parell GJ, Becker GD. Comparison of absorbable with nonabsorbable sutures in closure of facial skin wounds. Arch Facial Plast Surg 2003; 5 (6): 488–90.

[15] Howard K, Simison AJM, Morris A, Bhalaik V. A prospective randomised trial of absorbable versus non-absorbable sutures for wound closure after fasciectomy for Dupuytren's contracture. J Hand Surg Eur Vol 2009; 34 (5): 618–20.

[16] Duprez K, Bilweis J, Duprez A, Merle M. Etude expérimentale et clinique d'un matériel de suture cutanée à résorption rapide. Annales de Chirurgie de la Main 1988; 7 (1): 91–6.

[17] Tuuli MG, Stout MJ, Martin S, Rampersad RM, Cahill AG, Macones GA. Comparison of suture materials for subcuticular skin closure at cesarean delivery. Am J Obstet Gynecol 2016; 215 (4): 490. e1-5.

[18] Niessen FB, Spauwen PH, Kon M. The role of suture material in hypertrophic scar formation: Monocryl vs. Vicryl-rapide. Ann Plast Surg 1997; 39 (3): 254–60.