

# Scar quality examination comparing titanium-coated suture material and non-coated suture material on flap donor sites in reconstructive surgery

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## **Clinical Trial Register**

This study was registered retrospectively at the German Clinical Trials Register (DRKS) under the registration number DRKS00021767.

[https://www.drks.de/drks\\_web/navigate.do?navigationId=trial.HTML&TRIAL\\_ID=DRKS00021767](https://www.drks.de/drks_web/navigate.do?navigationId=trial.HTML&TRIAL_ID=DRKS00021767)

**Short running head:** Scar examination after use of titanium-coated suture material

## **Abstract**

### **OBJECTIVES**

Wound healing and scar quality after trauma are subject to impairment through excessive wound healing, chronic wound or even surgical site infections. Optimizing the process of scar formation and skin healing is crucial in virtually all fields of medicine. In this regard, we tested the possible usage and advantages of titanium coated suture material.

### **METHODS**

We performed a prospective observational cohort study including 30 patients who underwent soft tissue reconstruction. One half of the donor flap site was sutured with titanium coated suture material, while the other half was closed with non-coated sutures. Scar quality of the donor flap site was assessed by photographs and POSAS scores on days 2-5, 14, 42, 72 and 180 postoperatively.

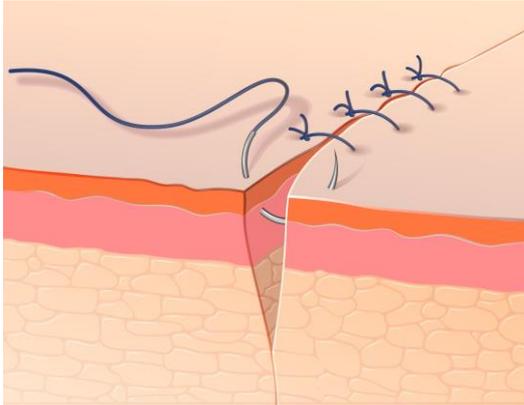
### **RESULTS**

No difference between the titanium coated sutures and non-coated sutures was seen in the POSAS assessment, neither for the patient scale at 14, 42, 72 and 180 days, nor for the observer scale on the same dates. Comorbidities like diabetes, chronic renal failure and smoking as well as the BMI of each patient affected the wound healing process to an equal degree on both sides of the suture.

### **CONCLUSION**

No difference between the titanium coated and non-titanium-coated suture material was seen in the POSAS assessment in regard to scar quality and wound healing. The titanium-coated suture material can be considered to be equally as effective and safe in all qualities as the non-titanium-coated suture material, even in patients with comorbidities.

## Graphical Abstract



**Key Words:** suture, titanium coated, wound healing, scar quality, POSAS score

## Introduction

As a result of trauma, either by accident or intent procedure, the skin is subject to a wound healing process resulting in the formation of a mature scar and therefore maintaining the integrity of the skin [1, 2].

Deviation from the physiological wound healing process, such as excessive wound healing, chronic wound or even surgical site infections, can impair the scar quality and the adequate physical function of the skin [2-4]. A surgical suture's tissue integration and biocompatibility are decisive factors for ideal wound healing, therefore the optimal choice of suture material is still up for discourse [5, 6].

Surgical site infection has been assessed to arise in 5% of all medical procedures in hospitals [7], resulting in pain and discomfort for the patients and prolonged hospitalization and additional costs to the health system [8]. Not only implanted foreign bodies, yet also suture material have to be taken into consideration as a host for biofilm and therefore a potential source of infection [7, 9, 10]. In order to surmount this issue, the coating of suture material not only with chemicals such as triclosan [11-16], yet also with metal legions is not

uncommon in medicine. Silver nanoparticle-coatings on silk suture for example have proven to be successful in the prevention of surgical site infections [17-20].

Titanium as a metal legion is renowned for excellent bone to implant bonding [21, 22], high biocompatibility due to low allergic potential [23], resistance to corrosion [24] and limited complications like wound dehiscence, infection and pain [25-27]. Therefore, titanium is commonly used for medical products, whether it be as orthopedic implants [28], titanium clips in cardiology and neurology [29-31], auditory ossicle replacements [32], endoprosthetic surgery and osteosynthesis in dentistry [24, 33], nickel-titanium wire for closure in cleft lip procedures [25] , titanium surgical tacks in gynecology [34] or as titanium coated meshes in abdominoplasty [35-38]. In the latter for example, it has shown to provoke less severe late inflammatory processes, greater tissue maturation and collagen disposition in comparison to a non-titanium-coated polypropylene mesh [37].

These qualities of titanium in medical products raise the question whether titanium, if used as a coating for suture material, could also be used to improve wound healing and scar quality.

Wound healing is an immensely difficult and interference-prone process which needs to be assisted at its best and optimized constantly, especially in patients with comorbidities that could compromise ideal healing and scar formation [1-3].

In this study, we therefore aimed to further evaluate the possible usage and advantages of titanium coated suture material with regard to wound healing, surgical site infections and scar quality in reconstructive and plastic surgery. This was exemplified on flap surgery donor sites.

## **Materials and Methods**

### *Patient collective*

We performed a prospective observational cohort study. The materials of this study have been drafted from patients aged 18 and older who had given their informed consent. All patients received soft tissue reconstruction via free flap surgery at the University Hospital Leipzig from August 2018 to October 2019. Flaps included ALT-, latissimus dorsi-, DIEAP-, parascapular- and gastrocnemius flaps. In total, 30 patients (7 females, 23 males) with a median age of 60 (26 to 92) were included. Baseline data comprised of gender, BMI, comorbidities, duration of hospitalization after surgical intervention and wound healing with Patient and Observer Scar Assessment Score/POSAS (Suppl. 1, 2).

After raising the flap, the donor site wound was sutured continuously and intracutaneously with titanium coated suture material (Seratan<sup>®</sup> 2-0, titanium coated [Serag Wiessner GmbH & Co. KG., Naila, Germany]) on one half and non-titanium-coated suture material (Seralon<sup>®</sup> 2-0, non-titanium-coated [Serag Wiessner GmbH & Co. KG., Naila, Germany]) on the other (Supp. 3). The study was performed in a single blinded design with patients not knowing which half was sutured with titanium coated or non-titanium-coated material.

### *Scar assessment via POSAS scores and clinical photography*

On days 2-5 post-surgery, wound visits were performed. On day 10, the stitches were removed and on day 14, POSAS (Patient and Observer Scar Assessment Scale) scores for both sides of the suture were executed by the patient and an observer. Wound visits and POSAS scores were again carried out on day 42, 72 and 180. Photographical documentation was performed continuously during inpatient and outpatient follow up dates (Suppl. 3, 4). The POSAS consists of both a Patient Scale and an Observer Scale. Both scales contain six items that are scored numerically on a ten-step scale with 10 indicating the worst imaginable

scar or sensation and 1 corresponding to the situation of normal skin. Together they make up the total score of the scale.

### *Statistical analysis*

Post-test analysis was done using SPSS for Windows V24.0 (IBM, Chicago, IL, USA). All data is reported as frequencies with percentages (%) or mean and standard deviation (SD) with ranges.

A paired t-test was used to detect differences in means between Seratan<sup>®</sup> and Seralon<sup>®</sup> for continuous data. The level of significance was defined as  $p < .05$ .

### **Results**

In total, 30 patients with a mean age of 60 years (SD 16, range, 26 to 92; 7 females, 23 males) were included into the final analysis. The most frequent flap entity was the anterior lateral thigh flap (n = 23), followed by latissimus dorsi flaps (n = 3), deep inferior epigastric artery perforator flaps (n = 2), gastrocnemius flaps (n = 1), and parascapular flaps (n = 1). The mean hospital stay after surgery was 13 days (SD 7, range 5 to 37).

The patients' mean Body Mass Index was 27.0 kg/m<sup>2</sup> (SD 5.9, range 18 to 44). Preexisting comorbidities that are known to affect wound healing were diabetes in 15 patients (50 %), smoking in 13 (43 %) and chronic renal failure in 10 patients (33 %). No patient received immunosuppressive medication.

All patients' donor site wounds were closed with above named suture material in a 50:50 fashion. The mean wound length per patient sutured with titanium-coated material was 11.2 cm (SD 2.6) and 10.9 cm (SD 2.1) for non-coated sutures ( $p = 0.293$ ). Complications occurred in four patients. This included one suture fistula (Seratan<sup>®</sup>), one superinfected hematoma (Seralon<sup>®</sup>), one superficial wound necrosis (Seralon<sup>®</sup> + Seratan<sup>®</sup>), and one hematoma which

had to be revised (Seratan<sup>®</sup>). All other complications were managed in a conservative fashion.

No significant difference between the titanium coated and non-titanium coated sutures was seen in the POSAS assessment, neither for the patient scale at 14 days ( $p = 0.161$ ), at 42 days ( $p = 0.787$ ), at 72 days ( $p = 0.433$ ) or at 180 days ( $p = 0.293$ ), nor for the observer scale at 14 days ( $p = 0.787$ ), at 42 days ( $p = 0.522$ ), at 72 days ( $p = 0.184$ ) or at 180 days ( $p = 0.375$ ). However, there is a tendency for a slightly better overall opinion in all follow-ups for the titanium coated material in both groups, patients and observers (Figure 1). When taking into consideration comorbidities like diabetes (Seratan<sup>®</sup>:  $p = 0.808$ , Seralon<sup>®</sup>:  $p = 0.484$ ), chronic renal failure (Seratan<sup>®</sup>:  $p = 0.297$ , Seralon<sup>®</sup>:  $p = 0.244$ ) or smoking (Seratan<sup>®</sup>:  $p = 0.459$ , Seralon<sup>®</sup>:  $p = 0.562$ ) while comparing the POSAS scores on day 180, no significant difference between the two suture materials could be detected (Figure 2-4). Furthermore, comparing overall patient satisfaction on day 180 on coated and non-coated wound closure sites in correlation to the BMI of each patient did not show any significant difference in scar quality (Seratan<sup>®</sup>:  $p = 0.541$ , Seralon<sup>®</sup>:  $p = 0.647$ , Figure 5).

## **Discussion**

Wound healing and scar quality are an important part of virtually every field of medicine. The choice of suture material, as an immense factor of impact for the scar formation and healing abilities, is of great importance when it comes to optimizing these processes. This is valid especially in patients with comorbidities which compromise ideal healing and scar formation, like diabetes mellitus, chronic renal failure or the indulgence in nicotine [1-3]. Our findings indicate that titanium coated suture material can be seen as equivalently effective and safe as non-titanium-coated suture material.

In this pilot study with 30 patients, scar quality was assessed on flap surgery donor sites with the help of POSAS score evaluation and photography, while comparing titanium coated sutures with non-titanium-coated sutures. The coating of medical material with titanium material can be seen as leadoff technique in medicine, therefore scientific literature on this topic is rare. Notwithstanding, our findings can be seen as consistent with the advantages of coating suture material with chemicals [11-16] or metal legions, like the prevention of surgical site infections [17-20]. They were also in accordance with beneficial qualities of titanium in medical products, like excellent bone to implant bonding, high biocompatibility due to low allergic potential, resistance to corrosion and limited complications like wound dehiscence, infection and pain [21-27].

The titanium coated suture material was equivalent to the non-coated-suture material in regard to scar quality and wound healing. Even the presence of comorbidities did not have any impact on these qualities. However, it should be emphasized that high satisfaction in regard to scar quality was achieved in both groups which also increased over the course of time. Additionally, titanium coated sutures presented slightly better results in regard to wound healing than non-titanium-coated sutures. This data suggests the possibility of using titanium coated material in surgical procedures for wound closure in the future. Our findings support the results of Saalabian et al. in which titanium coated suture material showed significantly lower signs of inflammation in small wounds of the hand and forearm[39].

The limitations of this study include its small sample size and the limited variability in surgical sites. A more extensive clinical study and a cost efficiency analysis would have to be planned to not only show clinical evidence, but also practicability in the long term. Nevertheless, titanium coated suture material can be considered as equally effective and

safe as non-titanium-coated suture material in regard to wound healing, scar quality and surgical site infection. Combining the advantages of titanium legions in medical products with benefits of coating suture material in order to minimize surgical site infections and therefore receiving optimum wound healing and scar formation was the intention behind the development of the suture material and also this study. However, our research suggests that the production of the titanium coated suture material will not be able to deliver superior results to the non-titanium-coated suture material.

### **Conclusions**

Titanium coated suture material brings forward as equally adequate results in scar quality and wound healing in flap surgery donor sites as non-titanium-coated suture material. The coating of medical products in general with titanium seems to have a positive impact on wound healing and provides decreased complications like wound dehiscence and surgical site infection [25-27]. Nevertheless, the utilization of titanium coated suture material on flap surgery donor sites, even in patients with comorbidities or immunocompromization, will not be superior to non-titanium-coated suture material.

### **Availability of data and materials**

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

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Figure 1

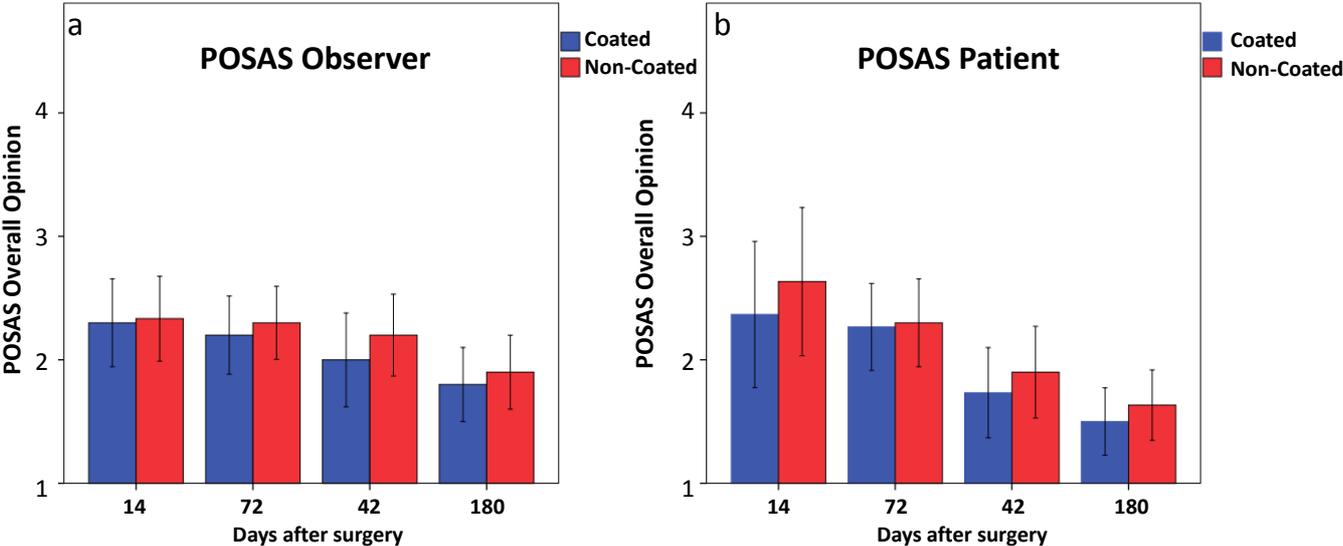


Figure 2

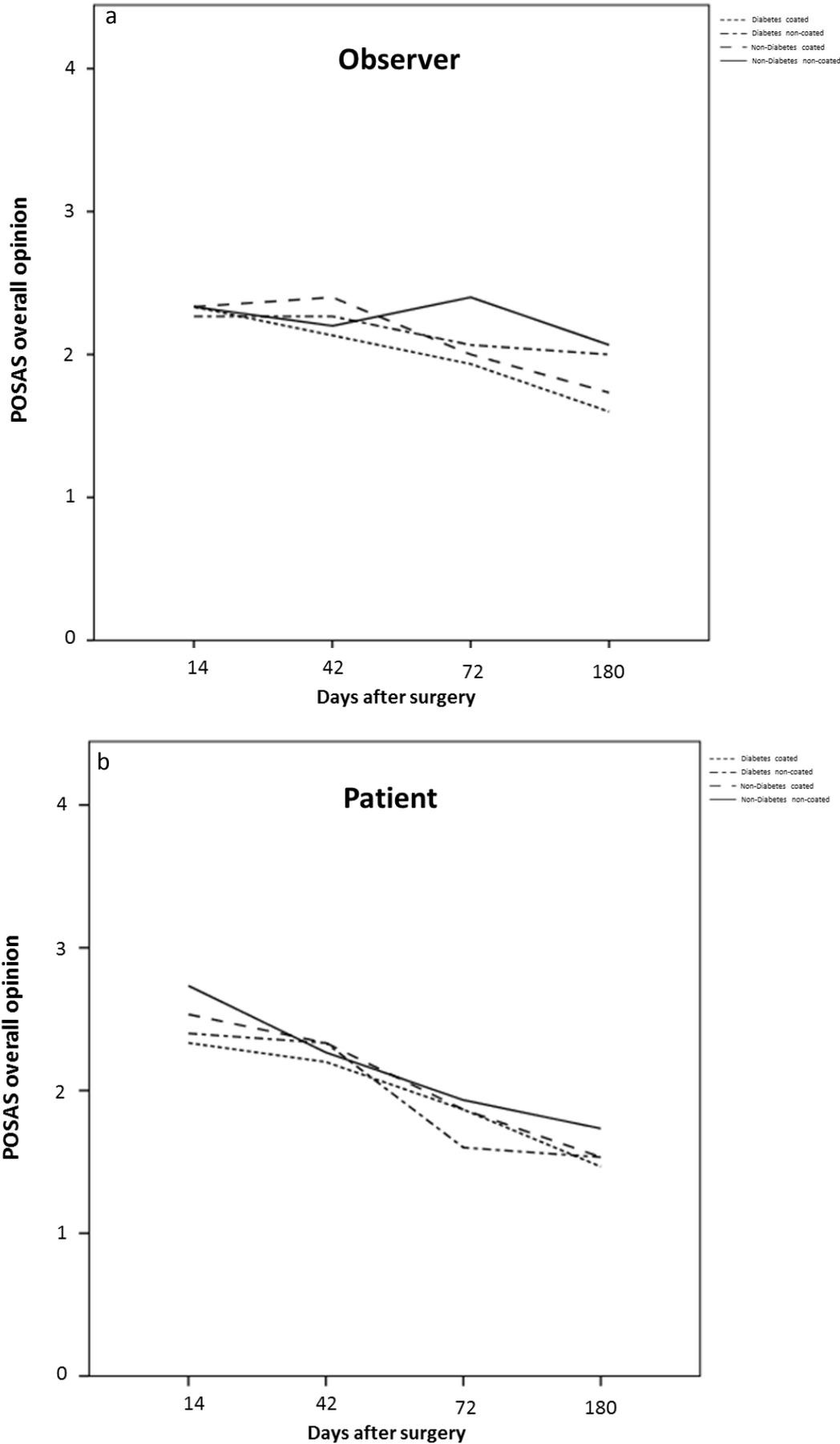


Figure 3

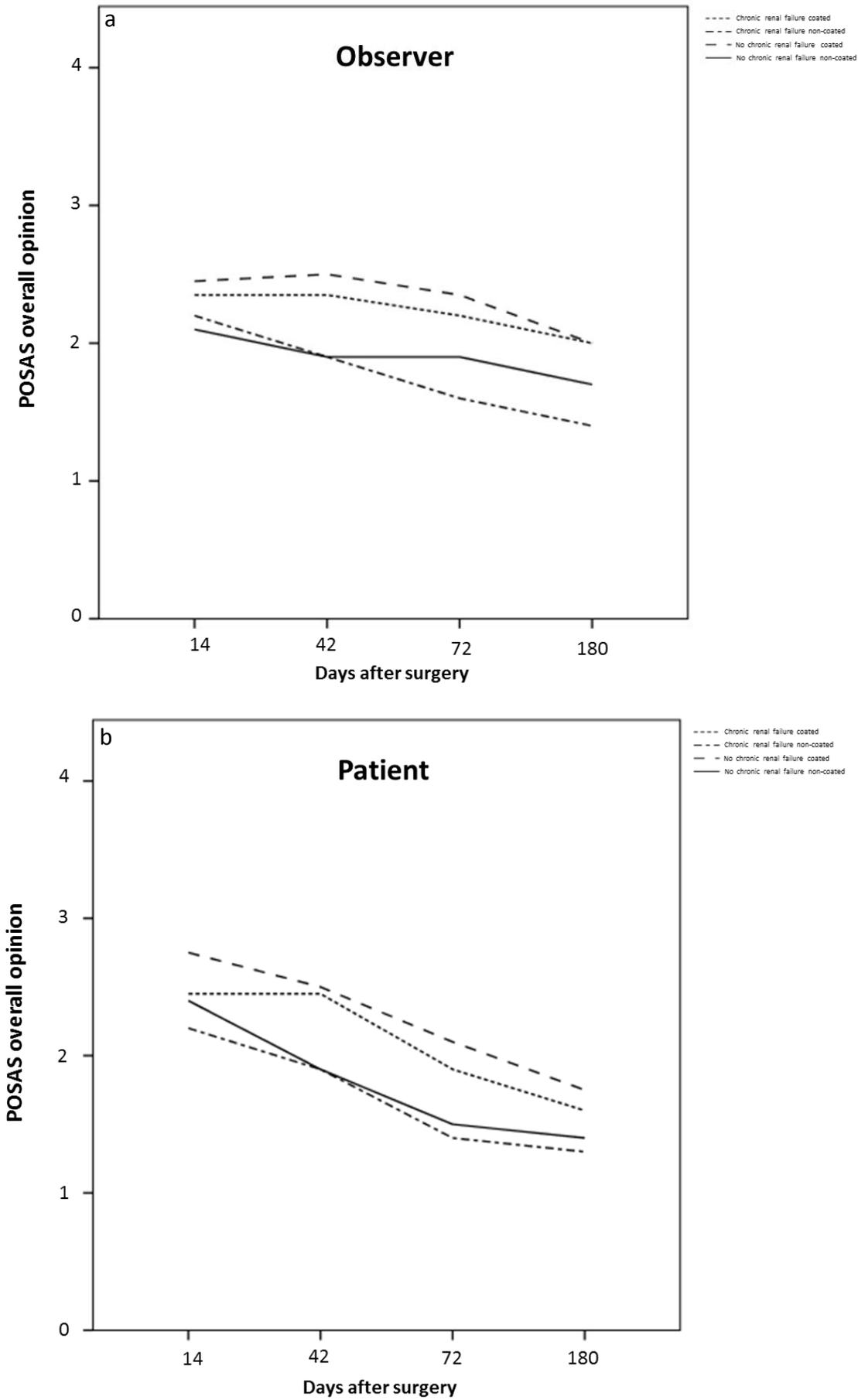


Figure 4

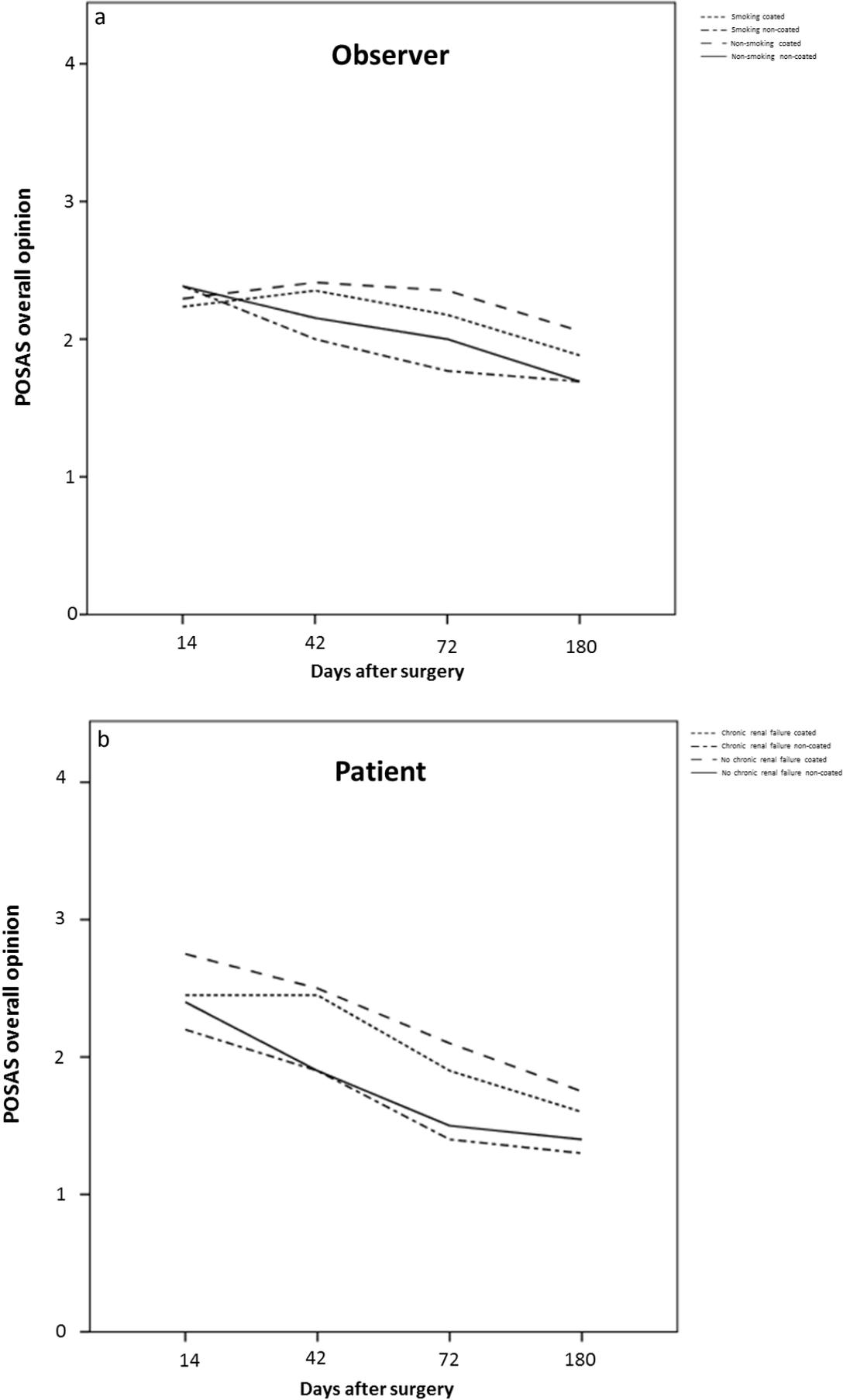
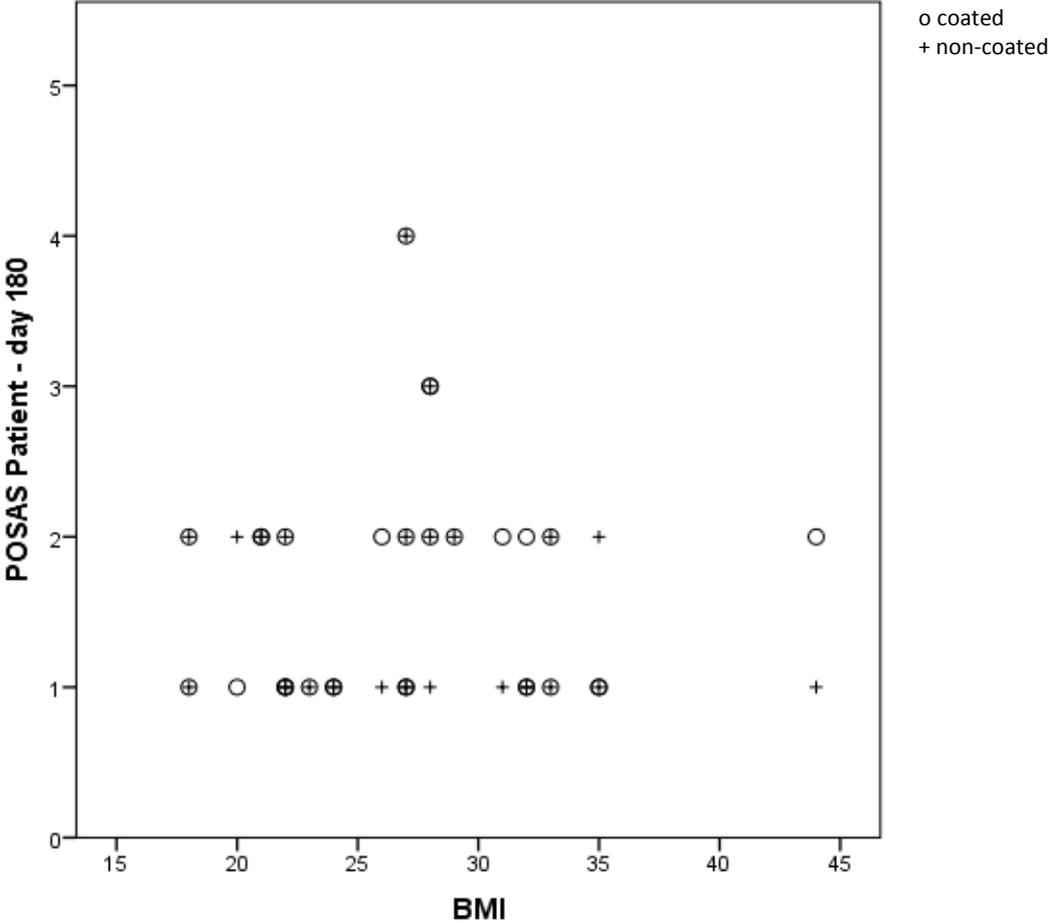


Figure 5



# Supplemental Material 1

## POSAS Observer scale

The Patient and Observer Scar Assessment Scale v2.0 / EN

Date of examination: \_\_\_\_\_

Observer: \_\_\_\_\_

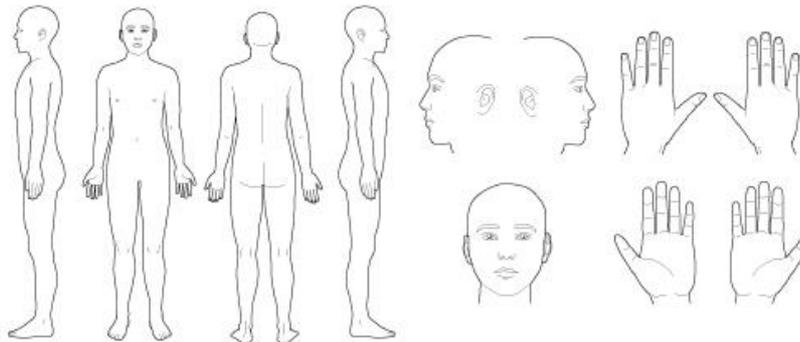
Location: \_\_\_\_\_

Research / study: \_\_\_\_\_

Name of patient: \_\_\_\_\_

Date of birth: \_\_\_\_\_

Identification number: \_\_\_\_\_



PARAMETER	1 = normal skin      worst scar imaginable = 10										CATEGORY
	1	2	3	4	5	6	7	8	9	10	
VASCULARITY	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	PALE   PINK   RED   PURPLE   MIX
PIGMENTATION	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	HYPO   HYPER   MIX
THICKNESS	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	THICKER   THINNER
RELIEF	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	MORE   LESS   MIX
PLIABILITY	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	SUPPLE   STIFF   MIX
SURFACE AREA	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	EXPANSION   CONTRACTION   MIX
OVERALL OPINION	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	

### Explanation

The observer scale of the POSAS consists of six items (vascularity, pigmentation, thickness, relief, pliability and surface area). All items are scored on a scale ranging from 1 ('like normal skin') to 10 ('worst scar imaginable'). The sum of the six items results in a total score of the POSAS observer scale. Categories boxes are added for each item. Furthermore, an overall opinion is scored on a scale ranging from 1 to 10. All parameters should preferably be compared to normal skin on a comparable anatomic location.

### Explanatory notes on the items:

- **VASCULARITY** Presence of vessels in scar tissue assessed by the amount of redness, tested by the amount of blood return after blanching with a piece of Plexiglas.
- **PIGMENTATION** Brownish coloration of the scar by pigment (melanin); apply Plexiglas to the skin with moderate pressure to eliminate the effect of vascularity.
- **THICKNESS** Average distance between the subcuticular-dermal border and the epidermal surface of the scar.
- **RELIEF** The extent to which surface irregularities are present (preferably compared with adjacent normal skin).
- **PLIABILITY** Suppleness of the scar tested by wrinkling the scar between the thumb and index finger.
- **SURFACE AREA** Surface area of the scar in relation to the original wound area.

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Supplemental Material 3



Supplemental Material 4



## Figure Legends

**Figure 1** POSAS Overall Opinion of Observers (a) and Patients (b) on follow-up days 14, 42, 72 and 180 for titanium-coated suture material (blue bar) and non-coated suture material (red bar).

**Figure 2** Correlation analysis between POSAS Overall Opinion for observers (a) and patients (b) and diabetes mellitus type II on follow-up days 14, 42, 72 and 180 for titanium-coated suture material and non-coated suture material.

**Figure 3** Correlation analysis between POSAS Overall Opinion for observers (a) and patients (b) and chronic renal failure on follow-up days 14, 42, 72 and 180 for titanium-coated suture material and non-coated suture material.

**Figure 4** Correlation analysis between POSAS Overall Opinion for observers (a) and patients (b) and smoking on follow-up days 14, 42, 72 and 180 for titanium-coated suture material and non-coated suture material.

**Figure 5** Correlation analysis between POSAS Overall Opinion and Body Mass Index (BMI) on follow-up day 180 for titanium-coated suture material and non-coated suture material.

**Supplemental Material 1** Patient Observer and Patient Scale Assessment Scale for Observers. The scale is designed for scar evaluating of professionals and contains six items that are scored numerically on a ten-step scale. The items should be compared to regular skin at a comparable anatomic area. To ensure quality of examination, more than one professional should evaluate the POSAS. The items for professionals include Vascularity, Pigmentation, Thickness, Relief, Pliability and Surface Area. Furthermore, it asks for an Overall Opinion. With kind permission of P.P.M. van Zuijlen, Beverwijk-NL.

**Supplemental Material 2** Patient Observer and Patient Scale Assessment Scale for patients. The scale is designed for scar evaluating of non-professionals/patients and contains six items that are scored numerically on a ten-step scale. Items include pain, itching, color difference, stiffness, thickness and irregularity in comparison with regular skin. Also, just like in the Observers Score, it asks for an Overall Opinion. With kind permission of P.P.M. van Zuijlen, Beverwijk-NL.

**Supplemental Material 3** Intraoperative photographic documentation of wound closure in ALT donor site. You can see the 50:50 fashion that was assessed using titanium coated suture material (Seratan<sup>®</sup>) for one half of the wound closure and non-titanium coated material (Seralon<sup>®</sup>) for the other half. Markings were only made for illustration reasons and removed immediately after taking the photograph to ensure single blinding of the patient.

**Supplemental Material 4** Photographic documentation of wound closure in ALT donor site on day 14.

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**Contributions**

LB, SL and LK contributed to the conception and design of the study; LB, GO and LK performed the experiments, collected and analyzed data; LB wrote the manuscript; All authors reviewed and approved the final version of the manuscript.

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**Ethics declarations****Ethics approval and consent to participate**

Study protocol was approved by The Ethics Committee of Leipzig University.

**Consent for publication**

Informed consent for publication was obtained from all the study subjects.

**Competing interests**

The authors declare that they have no competing interests.