Cohort Study

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Incidence of incisional hernias and cosmetic outcome after laparoscopic single-incision cholecystectomy: a long-term follow-up cohort study of 125 patients

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Background: Studies have evaluated long-term occurrence of incisional hernia, cosmesis, and postoperative pain after single-incision laparoscopic cholecystectomy (SILC). However, the follow-up periods were rarely defined longer than 12 months. The authors performed a cohort study to evaluate hernia rate and cosmesis in a prolonged follow-up period.

Methods: All patients that underwent SILC at the University Hospital Brandenburg an der Havel Hospital between December 2008 and November 2014 were evaluated in terms of postoperative complications, and a follow-up telephone interview including the existence of hernias and chronic pain was performed. Cosmesis and the overall satisfaction of the scar was measured by POSAS (Patient and Observer Scar Assessment Scale).

Results: In total 125 patients underwent SILC. The single-incision approach was completed in 94.4%, an additional trocar was necessary in 3.2% ($n=4$) and a conversion to 4 trocar cholecystectomy was required in 2.4% ($n=3$). Intraoperative complications occurred in 0.8% and postoperative complication in 12.8% of all patients. Follow-up telephone interview was performed in 49.6% of 125 patients. The mean follow-up period was 138.9 months (11.6 years). Overall, in 3.6%, an incisional hernia was diagnosed. A total of 3.6% reported pain in the region of the umbilicus with a mean VAS (visual analog scale) of 2/10. The mean POSAS score was 7.8. Overall, 82.3% of this cohort rate their satisfaction of the scar with a 1/7, resembling the best possible result of the scar.

Conclusion: The present study demonstrates that SILC is a safe alternative in terms of incisional hernia rate and complications with a high satisfaction of the scar even after one decade after surgery. In comparison to shorter follow-up period and multiport laparoscopic cholecystectomy, our result is comparable.

Keywords: cholecystectomy, chronic pain, cosmesis, incisional hernia, single incision

Introduction

For single-incision laparoscopic cholecystectomy (SILC), two working trocars are inserted through a single incision in the region of the umbilicus. The assumption of SILC is that less incisions and, therefore, also less trauma result in even less postoperative pain and higher cosmetic satisfaction[1]. A meta-analysis reported cosmetic superiority in the short-term, mid-term, and long-term outcomes of SILC compared to multiport laparoscopic cholecystectomy (MLC), but long-term outcome was defined as 6–12 months [37 randomized controlled trials (RCTs), $n=3051$][2].

The single incision used in the SILC comes at the cost of a larger incision at the umbilicus to accommodate all the surgical instruments. It is well known that the size of the scar is a critical risk

HIGHLIGHTS

- Cohort study to evaluate the SILC (single-incision laparoscopic cholecystectomy) in long-term hernia rate, chronic pain, and cosmesis after 138.9 months using Patient and Observer Scar Assessment Scale (POSAS) and telephone interview.
- In total, 125 patients underwent SILC; the follow-up telephone interview was performed in 62 patients.
- Single-incision approach was completed in 94.4%, an additional trocar was necessary in 3.2% ($n=4$), and a conversion to 4 trocar cholecystectomy was required in 2.4% ($n=3$) with intraoperative complications occurred in 0.8% and postoperative complication in 12.8%.
- Long-term hernia rate after 138.9 months is 3.6%, chronic pain is reported in 3.6%, and mean POSAS score is 7.8.
- 82.3% rate their satisfaction of the scar with the best possible result.

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Sponsorships or competing interests that may be relevant to content are disclosed at the end of this article.

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factor for the development of incisional hernia[3,4], therefore the question arises if the SILC is really a more suitable method than the MLC. This is supported by large meta-analysis that showed a significantly higher risk for the occurrence of incisional hernias of single-incision surgery in general compared to the multiport laparoscopic surgery, though less than half of the included studies only have a follow-up period of 12 months or less (22 RCTs, $n = 3340$; 23 RCTs, $n = 2471$)[5,6]. Based on the fact that only half of the hernias occur within the first 12 months and 27–35% of incisional hernias appear after more than 3 years, there is a need for a long-term survey with a longer follow-up period to estimate a more valid hernia rate[7,8].

The longest mean follow-up period we found in our literature research for incisional hernias after single-incision cholecystectomy was 70 months (5.7%)[9]. The incidence here is clearly higher than the incidence at 6 months or 1 year (4.5%), as reported in the meta-analysis of Jensen *et al.*[10] (40 studies, $n = 5618$). This raises the question whether the true incidence of incisional hernias after SILC is underreported because of the short follow-up period[11].

Therefore, the primary aim of this single-center cohort study was to investigate the long-term incidence of incisional hernias after SILC in a follow-up period of 8–14 years. In addition, the long-term cosmetic outcome and satisfaction are measured. The second aim of this study was to evaluate the long-term rate of complications including chronic pain.

Patients and methods

The study cohort is a part of the SILAP – study registered at the German Registry of Clinical Trials DRKS (DRKS00004594). The SILAP study was founded by KARL STORZ GmbH & Co. KG, Tuttlingen, Germany, Covidien AG, Neuhausen am Rheinfall, Switzerland, Richard und Annemarie Wolf-Stiftung, Knittlingen, Germany, and the Institute for Quality Assurance in Surgical Care gGmbH, Otto-von-Guericke-University, Magdeburg, Germany. Especially for this follow-up study, no funding was received. The study has been performed according to the STROCCS guidelines[12]. The study was approved by the ethics committee of Brandenburg Medical School (E-01-20210815, October 2021) and conducted in accordance with the ethical standards of the Helsinki Declaration of 1975.

Prior to the conception of the study, we conducted literature research using Pubmed from March 2020 to June 2020. We used the combination of the following Medical Subject Headings: single-incision OR single-port OR one wound AND laparoscopic AND cholecystectomy OR hernia OR cosmesis OR long-term.

Study population

We included all patients who underwent SILC at the University Hsopital Brandenburg an der Havel Hospital between December 2008 and November 2014 in this cohort study. This cohort was also included in the 'Prospective multicenter observational quality study of single-incision multi-port/single port abdominal surgery (SILAP-trail)'[13].

Inclusion criteria

Indications for SILC were symptomatic cholecystolithiasis, acute cholecystitis with or without cholecystolithiasis, uncomplicated chronic inflammation, conditions after biliary pancreatitis, and polyps of the gallbladder. Additional inclusion criteria for elective or emergency SILC were an age more than 18 years, patient consent, and an ASA (American Society of Anesthesiologists) score of I–III.

Exclusion criteria

Exclusion criteria were an age less than 18 years, pregnancy, preoperative findings of choledocholithiasis, or gallbladder carcinoma or a participation in other clinical trials that could affect the study. Cholecystectomy due to other surgeries is an additional exclusion criterion.

Study design

This study is a prospectively collected cohort study with retrospective analysis of long-term complications, incisional hernia rate, and scar satisfaction using a telephone interview.

Preoperative, intraoperative, and postoperative data were recorded using the Prospective multicenter observational quality study of single-incision multiport/single port abdominal surgery protocol of the Institute for Quality Assurance in Surgical Care GmbH of Otto von Guericke University Magdeburg (shown in the appendix, Supplemental Digital Content 1, http://links.lww.com/MS9/A308). Personal data included sex, age at the time of surgery, and body mass index (BMI). The ASA classification and previous operations were also documented[14].

For the follow-up survey, we performed a telephone interview, which has been successfully implemented in other studies with a similar design[15,16], using a non-validated questionnaire designed for this study consisting of three parts (shown in the appendix, Supplemental Digital Content 1, http://links.lww.com/MS9/A308). For the follow-up, we initially send all patients a consent form following the telephone interview in case of positive answer. If no response was received, patients were contacted by telephone up to three times. Patient with negative response or no response after three times were excluded.

The first part included questions about the existence of hernias, a protrusion at rest or under manipulation (abdominal press) with high sensitivity and specificity for the presence of hernia[2].

Patients with other abdominal operations at the umbilicus since the SILC, which was not a hernia repair, were excluded from the evaluation.

Chronic pain was measured using a visual analog scale (VAS), with 0 representing 'no pain' and 10 representing 'the most imaginable pain'.

Risk factors for the development of hernias like physical work, BMI, chronic lung disorders, diabetes mellitus, aortic aneurysm, immunosuppressive drugs, anticoagulants, or smoking were evaluated[17].

Furthermore, we performed the Patient Scar Assessment Scale (PSAS) questionnaire, part of the Patient and Observer Scar Assessment Scale (POSAS), to evaluate the cosmetic outcome of the scar[18], containing six questions regarding symptoms within the last 4 weeks, like pain, itching, color, stiffness, thickness, and irregularity of the scar. Ultimately, patients were asked about the overall cosmetic satisfaction.

Those questions were answered by the study participant on a numerical scale of 1–10 (1 stands for 'no change' or 'very high satisfaction' and 10 for 'very strong change' or 'very dissatisfied'). The score of the items answered resulted in a final numerical score, which was used as an indicator for cosmetic satisfaction[19].

Surgical procedures

Prophylactic antibiotic treatment with cefuroxime and metronidazole was administered to all patients before skin incision and continued in dependence of the intraoperative situation. The skin was incised for ~2 cm at the left of the umbilicus, and the abdominal approach was performed in open mini laparotomy. The trocars were placed directly through the fascia. After placing a 10 mm trocar in the center of the incision, the pneumoperitoneum (12 mmHg) was installed. We placed a flexible 5 mm trocar inferior and another normal 5 mm trocar superior. After diagnostic laparoscopy, the gallbladder was fixed by using 1–2 sutures at the anterior abdominal wall (Fig. 1). The cystic artery and the cystic duct were clipped by two lapro- or PDS- or titan clips. We closed the fascial defect by using an absorbable suture (Vicryl 2/0). The skin incision was sutured subcutaneous (Vicryl 3/0) and closed with a topical skin adhesive.

Statistical analysis

From the database, the following variables were extracted: age at the time of surgery, sex, BMI (in kg/m^2), ASA classification, and indication for surgery. Univariable distribution of quantitative variables were examined graphically by histograms to assess feature distribution. For roughly normally distributed variables, the mean and standard deviation (SD) and otherwise the median and interquartile range (IQR) were used. Categorical variables were generally reported as frequency and percentage. Categorical variables were compared using the Chi square test (χ^2) and Fisher's Exact Test, and numerical continuous variables were compared by the Wilcoxon–Mann–Whitney Test. Statistical significance was defined as a *P*-value of less than 0.05. Statistical analysis was performed with R (version 4.2.3, R Software Foundation, Vienna, Austria).

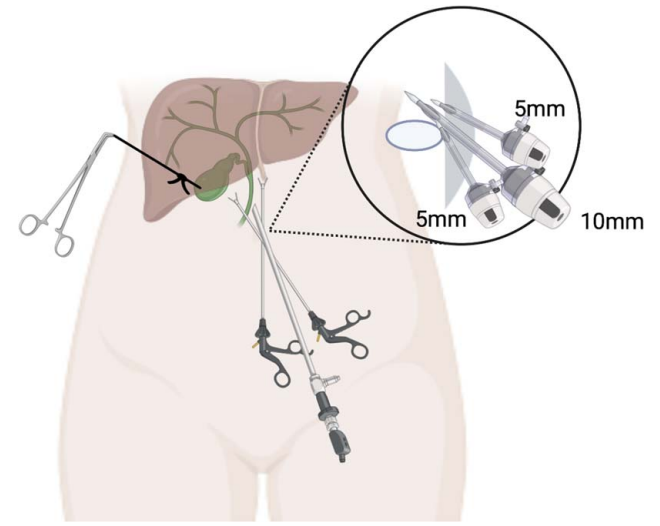

Figure 1. Single-incision cholecystectomy; 2 cm skin incision at the left of the umbilicus with the trocars (2× 5 mm and 10 mm) placed directly through the fascia. The gallbladder was fixed by suture at the anterior abdominal wall.

Results

In total, 125 patients underwent SILC during 2008 and 2014 at the University Hospital Brandenburg an der Havel Hospital in Germany, with a mean age of 46.9 years. Overall, 75.2% of the patients were female and 24.8% were male. The average BMI was 28.5 kg/m^2 (minimum: 17 kg/m^2, maximum: 46 kg/m^2).

Patients were classified in 21.6% as ASA I and in 3.2% as ASA III. ASA II represented the largest group with 94 patients (75.2%).

In 94.4% ($n=119$) the indication for surgery was due to symptomatic cholecystolithiasis. In 20% of patients ($n=25$), the SILC was performed due to acute cholecystitis, and in 20 patients (16.8%) due to choledocholithiasis or biliary pancreatitis. The indication for gallbladder removal due to a gallbladder polyp was present in 9 patients (7.2%). One patient had a cholecystolithiasis and an additional unclear liver cyst. Some patients had two or more of these indications. 32% ($n=40$) of the cohort had a prior surgery at the time of indication.

Three patients already had an umbilical hernia preoperatively, which was treated intraoperatively by suture (Table 1).

Perioperative data

The mean operation time was 59 min (minimum: 35 min, maximum: 128 min). Overall, SILC was completed in 94.4% ($n=118$); an additional trocar was necessary in 3.2% ($n=4$), and in 2.4% ($n=3$), a conversion to the classic 4 trocar cholecystectomy was required. There was no conversion to open surgery.

Intraoperative complications occurred in one case (0.8%). This patient required 48 h monitoring after surgery because of an intraoperative tachycardia.

Postoperative hospital stays averaged 3.3 days, with a maximum of 7 days. In 12.8% ($n=16$), postoperative complications were reported. Of these, postoperative rebleeding occurred in two cases (1.6%); one of them needed a laparoscopic revision with postoperative monitoring in the intensive care unit. A blood transfusion was not necessary. With 5.7% ($n=7$), the largest part suffered from single site infections. Severe postoperative pain occurred in three cases (2.4%). Allergic reaction due to thromboprophylaxis, postoperative tachycardia, and postoperative stone passage occurred in other individual cases. One patient had a significantly prolonged convalescence due to multimorbidity.

Follow-up

The telephone survey was performed with 62 patients (49.6%) of 125 patients; six of these patients were excluded because they underwent another operation at the umbilicus after SILC ($n=56$). Sixty patients did not give a consent or could not be reached, three patients died between surgery and follow-up. The mean follow-up period was 138.9 months, corresponding to 11.6 years. The mean BMI was 28.6 kg/m^2.

In total, an incisional hernia was diagnosed in 3.6% ($n=2$). In one of these cases, sublay mesh implantation was performed. This is consistent with the protrusion in the area of the scar, which was positively answered in one case. In one of these cases with incisional hernia, bronchial asthma was present as a risk factor, and in the other case, obesity was present as a risk factor.

With 7.1% ($n=4$), the consultation of a doctor because of the scar was higher (Table 2).

Table 1

Basic descriptive data (SILC).

Variables	All patients, $n=125$[a]
Age (years)	46.9.0 (17–80.0)
Men	31.0 (24.8%)
Women	94.0 (75.2%)
BMI (kg/m^2)	28.5 (17.0–46.0)
ASA	
1	27.0 (21.6%)
2	94.0 (75.2%)
3	4.0 (3.2%)
Indication for cholecystectomy	
History of biliary colic	118.0 (94.4%)
Acute biliary colic	1.0 (0.8%)
Acute cholecystitis	25.0 (20.0%)
Gallbladder polyp	9.0 (7.2%)
Conditions after choledocholithiasis/biliary pancreatitis	21.0 (16.8%)
Associated conditions	
Additional umbilical hernia (intraoperative treatment)	3.0 (2.4%)
Liver cyst	1.0 (0.8%)
Previous abdominal operations	40.0 (32.0%)
Operating time (minutes)	59.0 (49.0–69.0)
Intraoperative complication	
Intraoperative tachycardia	1.0 (0.8%)
Additional trocar	4.0 (3.2%)
Conversion to 4 trocar cholecystectomy	3.0 (2.4%)
Conversion to open cholecystectomy	0.0 (0.0%)
Postoperative complication	16.0 (12.8%)
Wound infection	7.0 (5.7%)
Unclear erythema	1.0 (0.8%)
Hemorrhage with revision	1.0 (0.8%)
Multimorbidity	1.0 (0.8%)
Skin bleeding	1.0 (0.8%)
Local intolerance of enoxaparin	1.0 (0.8%)
Severe postoperative pain	3.0 (2.4%)
Postoperative choledocholithiasis	1.0 (0.8%)
Postoperative hospitalization (days)	
1	1.0 (0.8%)
2	7.0 (5.6%)
3	96.0 (76.8%)
4	9.0 (7.2%)
5	6.0 (4.8%)
6	4.0 (3.2%)
7	2.0 (1.6%)

[a]Mean (minimum–maximum); *n* (%).

ASA, American Society of Anesthesiologists; BMI, body mass index; SILC, single-incision laparoscopic cholecystectomy.

Table 2

Follow-up data.

Variables	$n=125$[a]
Follow-up	62 (49.6%)
Lost in follow-up	63 (50.4%)
Another operation at the umbilicus (without hernia repair)	6
Follow-up analysis	**n = 56**[a]
Follow-up period (month)	138.9
BMI (kg/m^2)	28.6 (20.0–45.0)
Incisional hernia	2.0 (3.6%)
Incisional hernia repair (sublay mesh)	1.0 (1.8%)
VAS	
0	54.0 (96.4%)
1	0 (0%)
2	2.0 (3.6%)
Do you consult a doctor because of the scar?	4.0 (7.1%)
Do you have a protrusion at the scar?	1.0 (1.8%)
Does belly press results in a protrusion of the scar?	0.0 (0.0%)
Chronic pain	2.0 (3.6%)
Satisfaction of the scar	
1	48.0 (85.7%)
2	4.0 (7.1%)
3	3.0 (5.4%)
7	1.0 (1.8%)

[a]*n* (%); mean (minimum–maximum).

BMI, body mass index; VAS, visual analog scale.

A total of two patients (3.6%) reported pain in the region of the umbilicus, with a mean VAS of 2/10.

The mean POSAS was 7.8 (range: 6–22). The POSAS in the patients without scar hernia was 7.8 (SD = 2.8), and in the patients with incisional hernia, it was 8.5 (SD = 3.5) without statistical significance ($P=0.82$). Overall, 82.3% of this cohort rated their satisfaction with the scar with a 1/7, resembling the best possible result of the scar. The mean satisfaction was 1.28 (SD = 0.73) (Table 3).

Discussion

Previously, open cholecystectomies were considered the gold standard. Due to lower rates of hernia, postoperative wound infection, and shorter hospital stays, laparoscopic surgery became more important in the last decades[3], so today ~90% of cholecystectomies are performed using laparoscopic techniques[20].

A progression of the current MLC is the SILC, firstly published by Navarra *et al.*[21], who initially reported the first 'single-wound cholecystectomy'. According to the statement of the European association for endoscopic surgery (EAES), single-incision cholecystectomy is feasible and seems safe compared to four-port laparoscopic cholecystectomy[1]. The advantage of SILC is a better cosmesis and lower postoperative pain at the cost of a longer operation time and a higher need of an additional trocar compared to MLC without a difference in postoperative morbidity[22].

There is an inconsistency in the hernia rate, especially regarding the long-term follow-up. A nationwide prospective cohort study found no significant difference after a mean follow-up time of 48 months (4% after SILC, 6% after MLC) between these two surgical procedures[23]. The longest follow-up we found was 70 months after SILC in a RCT published by Klein *et al.*[9] with a hernia rate of 5.7%. If we compare our long-term follow-up hernia rate to these studies, we found a lesser rate of

Table 3

POSAS and cosmesis.

Variables	Follow-up $n=56$[a]	Incisional hernia, $n=2$[a]	No incision hernia, $n=54$[a]	P[b]
POSAS	7.8 (2.8)	8.5 (3.5)	7.8 (2.8)	0.819
Satisfaction	1.29 (0.93)	4.0 (4.2)	1.2 (0.5)	0.095

[a]Mean (standard deviation).

[b]Mann–Whitney test.

POSAS, Patient and Observer Scar Assessment Scale.

incisional hernia, but they added a clinical examination, so with 3.6% our result could be underrepresented. This study provides more data for the long time follow-up to find out the 'real rate of hernias' after SILC, but of course there is more evidence needed to answer this question. Compared to a large retrospective cohort study, which presented an incidence of 4.1% for incisional hernia after MLC with a mean follow-up of 89.8 months, the result of our study is not inferior[24].

The main reason for choosing an operation type is the recommendation of the surgeon and less postoperative pain. But especially for young women, the scar is a crucial reason[25]. SILC should be discussed critically in patients with risk factors. In our cohort study, obesity and asthma bronchiale were presented as risk factors for incisional hernia after SILC.

Meta-analyses have shown the superiority of SILC over MLC in terms of cosmesis in the first year after surgery (46 RCTs, $n = 5141$; 37 RCTs, $n = 3051$)[11,26]. However, the longest follow-up we found was a mean of 62.8 months by Raakow and colleagues[16]. The mean POSAS score for cosmetic satisfaction here was 8.7 to which our result 7.8 is superior. The reason is unclear, but they included SILC and single-incision appendectomy in their evaluation. The clinical relevance of the difference remains ambiguous. But both in our cohort and in the other cohort, the majority was satisfied with the cosmesis in long-term follow-up.

Overall, single-incision cholecystectomy is not established as the clinical standard. On the one hand, the triangulation of the instruments and, therefore, the preparation are more difficult following a significantly longer operation time for SILC[27]. Although the learning curve is short and the operating time could be reduced significantly from the first 10 patients (110 min ± 11.6) to the following 10 patients (73 min ± 5.9) in SILC, a meta-analysis showed that the significant mean difference of operating time between SILC and MLC is 16.90 min. This seems not that much, but the impact of the opportunity cost cannot be neglected. The average cost of the MLC according to the studies included was 2263.30€. So, the opportunity costs of using the SILC versus the MLC are on average 755.97€ higher, a strong argument for using MLC in today's era of increasing economic pressure in hospitals (3 studies, $n = 813$)[28].

Our presented study carries several limitations. Firstly, the retrospective design of this study without a control group carries the risk of selection bias. With 125 patients, this cohort is small, and the patients included in the cohort are a selected population, so there is a risk for selection bias and the hernia rate in the presenting study could be underestimated. Additionally, only 49.6% of the cohort participated in the telephone interview, which is certainly due to the long follow-up period, but the number of participants must be larger for a better power. It must be noted that those who did not accept to participate were more likely to be dissatisfied, so the satisfaction could be biased.

Additionally, we performed a telephone interview to evaluate the hernia rate and cosmesis. Although there is a high sensitivity and specificity for the questions we used, there was no clinical examination or imaging. Also, for the evaluation of the cosmesis, there was no clinical assessment, just a patient-administered score.

Conclusion

Summarizing, the present study demonstrates, taking into account the limitations, that SILC is a safe alternative in terms of incisional hernia rate and complications even after one decade after surgery. In comparison to shorter follow-up period and MLC, our result is comparable.

Especially, for patients with a high demand for cosmetic results, the SILC is a good alternative with a high satisfaction of the scar.

Ethical approval

In accordance with the ethical standards of the Helsinki Declaration of 1975, the trial has been ethically approved in October 2021 by the Ethics Committee of the Brandenburg Medical School (E-01-20210815, October 2021).

Consent

Written informed consent was obtained from the patients for publication and any accompanying images. A copy of the written consent is available for review by the Editor-in-Chief of this journal on request. If no written informed consent was possible because of the telephone interview, the patients were kindly asked for informed consent. In case of telephone interview consent was given verbally, the written informed consent was signed on behalf of the patient.

Sources of funding

The SILAP study was founded by KARL STORZ GmbH & Co. KG, Tuttlingen, Germany, Covidien AG, Neuhausen am Rheinfall, Switzerland, Richard und Annemarie Wolf-Stiftung, Knittlingen, Germany, and the Institute for Quality Assurance in Surgical Care gGmbH, Otto-von-Guericke-University, Magdeburg, Germany. Especially for this follow-up study, no funding was received.

Author contribution

All authors contributed to the study conception and design. Study design, study concept, and data collection: R.M. and N.K.; investigation and literature research, development of the follow-up questionnaire, contacting the patient and follow-up telephone interview, interpretation of the data, Tables 1–3, and first draft of the manuscript: N.K.; data analysis: R.H. and N.K.; review and editing: R.M., C.P., and R.H. All authors commented on previous versions of the manuscript and read and approved the final manuscript.

Conflicts of interest disclosure

All authors declare that they have no conflicts of interest.

Research registration unique identifying number (UIN)

1. Name of the registry: German Registry of Clinical Trails DRKS (as a part of the SILAP study).
2. Unique identifying number or registration ID: DRKS 00004594.

3. Hyperlink to your specific registration (must be publicly accessible and will be checked): https://drks.de/search/de/trial/DRKS00004594.

Guarantor

Niklas Krollmann.

Data availability statement

All datasets generated during and/or analyzed during the current study are available upon reasonable request.

Provenance and peer review

Not commissioned, externally peer-reviewed.

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