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Research Article

Prospective Single-Arm Observational Study to Assess a Braided Silk Suture for Mucosal Closure in Oral Surgery in Clinical Practice (SILKOS Study)

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Abstract

Objectives: This study aims to evaluate the safety, effectiveness, and performance of a non-absorbable braided silk suture for mucosal closure in oral surgery in routine clinical practice.

Methods: The SILKOS study is a prospective, monocentric, single-arm, observational study involving adult patients undergoing mucosal wound closure with a non-absorbable braided silk suture in oral surgery. The primary endpoint was the evaluation of the safety parameters (incidence of postoperative wound dehiscence and complications). Secondary endpoints included wound healing assessment, assessment of pain and satisfaction of the patient, microorganism contamination of the used thread, and intraoperative performance and handling characteristics of the suture material.

Results: A total of 105 patients were enrolled. No postoperative wound dehiscence and complications of any grade, either during surgery or postoperatively, were reported. The mean wound healing assessment score was 80.27 ± 14.89 (in a scale from 0-100). Sutures were removed, on average, after 8.58 ± 5.42 days. At suture removal, the mean pain VAS score assessed by patients was 43.96 ± 32.00 and the mean satisfaction VAS score reported by patients was 80.71 ± 13.23. Abnormal microbiological results were found in 37/79 patients. All assessed bacteria were found. Prevotella intermedia, Fusobacterium nucleatum/periodonticum, Peptostreptococcus micros, and Capnocytophaga spp exhibited the highest levels. Intraoperative performance and handling characteristics were predominantly rated as good to excellent.

Conclusions: This study demonstrated the absence of complications or wound dehiscence and the favorable properties of non-adsorbable silk sutures for mucosal closure in oral surgery within routine clinical practice.

Clinical trial registration: NCT05296902

Keywords

Oral surgery; Non-absorbable sutures; Mucosa closure; Complications; Dentistry; Microbial adherence.

Introduction

Sutures have historically been fundamental for wound closure in surgical management [1]. The primary purpose of sutures is to maintain wound edge apposition until healing has progressed sufficiently and enough tensile strength is regained, enabling undisturbed wound healing [1-4].

Wound healing in oral surgery adheres to general physiological principles but encounters unique challenges due to the distinctive environment of the oral cavity [5,6]. These include a heightened risk of infection due to bacterial colonization from oral mucosa and food detritus, the constant presence of saliva, high vascularization, and continuous movement of oral tissues during speaking and eating. In addition, contact with avascular structures such as enamel, ceramic restorations, and metal implants hinders active metabolic exchange during healing [4,5,7,8]. Oral surgical procedures are frequently associated with various complications, including pain, moderate bleeding, and swelling [9]. These interventions typically conclude with the suturing of the surgical wound. The selection of the most suitable suture material depends on several factors, including the location, the number of tissue layers to be sutured, wound tension, suture depth, edema presence, and expected removal time [1,4].

The ideal suture material should possess several key characteristics, including optimal handling, flexibility, low memory, good sliding properties, high knot stability, sufficient strength, capillarity, good traction resistance, minimal traumaticity, and inert behavior (including no or minimal tissue and inflammatory reactivity and bacterial colonization) [1,3]. Suture materials are classified based on several structural and physical characteristics, including size, surface texture, filament structure (monofilament or multifilament), origin (natural or synthetic), and degradation properties (absorbable or non-absorbable) [1,10]

In recent years, there has been significant progress in the development of surgical sutures, primarily attributed to technological advancements in materials science [1]. Despite the availability of a diverse range of suture materials, no single suture material is suitable for all surgical and medical needs [1]. While advancements in suture technology have introduced various alternatives, silk sutures remain highly valued for their cost-effectiveness and exceptional handling properties, especially in specialized fields such as ophthalmic, neural, and cardiovascular surgery [10-12]. Silk sutures are characterized by their strength, pliability, and secure knotting [10]. Adverse reactions to silk sutures are commonly associated with virgin silk, which retains a sericin coating and may also contain additional waxes or silicones [10,11]. According to the US Pharmacopeia's definition, silk is classified as non-biodegradable due to its prolonged retention of tensile strength for more than 60 days [13]. However, degradation does occur over time, influenced by physical, chemical, and biological factors such as enzymatic activity, mechanical environment, material quantity, gross morphology, secondary structure, treatment history, and implantation site [10,14]. Since mucosal sutures in oral surgical procedures often involve suturing overlying tissue, non-absorbable suture materials are commonly used due to their durability and precise wound stabilization. These sutures are typically removed within 7 days postoperatively, a timeframe that balances adequate wound healing with minimizing infection risk and tissue irritation [4,15].

There is limited research on the use of silk sutures in oral surgery, particularly Silkam® (B. Braun Aesculap, Tuttlingen, Germany) sutures. Previous studies have focused on clinical, histological, and patient-report outcomes, including healing, inflammatory reactions, postoperative complications, bacterial accumulation, and patient satisfaction and discomfort. Several studies have emphasized the advantages of monofilament sutures such as polyamide, nylon, Expanded Polytetrafluoroethylene (ePTFE), polyglecaprone 25, and Dafilon 4/0. These sutures have been shown to promote superior wound healing, minimize bacterial colonization, reduce inflammation risks, and/or improve patient satisfaction compared to braided alternatives such as silk [3,12,16-20]. Nevertheless, no significant differences were found in wound bleeding and patient discomfort between silk and monofilament polyglecaprone 25 [19]. Among multifilament sutures, the inflammatory reaction of oral tissues after surgery was lower for absorbable polyglycolic acid than silk sutures, although the postoperative histological, clinical, and patient-reported outcomes were statistically similar [12,21,22]. In addition, the multifilament absorbable catgut sutures demonstrate a shorter average wound healing time after third molar impaction surgery compared to silk sutures, although suturing with catgut typically requires more time to perform due to its handling characteristics [23]. Other studies found that silk sutures exhibited the smallest affinity toward the adhesion of bacteria compared to other non-absorbable multifilament sutures [18]. Furthermore, the application of cyanoacrylate glue has been associated with reduced postoperative inflammation and favorable clinical and histological healing outcomes compared to silk sutures for closing surgical incisions [24]. These findings highlight the need to tailor suture material selection to the specific surgical context and tissue characteristics, as no single material is universally ideal for all scenarios.

This study aims to evaluate the safety, effectiveness, and performance of a non-absorbable braided silk suture for mucosal closure in oral surgery in routine clinical practice, with a focus on the postoperative wound dehiscence and complications, wound healing assessments, bacterial contamination, pain and satisfaction of patients, and intraoperative performance and handling characteristics.

Materials and Methods

Study design

The SILKOS study is a prospective, monocentric, single-arm, observational study conducted by oral surgeons in the Facultat d'Odontologia, Universitat Internacional de Catalunya, in accordance with the World Medical Association Declaration of Helsinki, all its amendments, national regulations, and regulations relevant to the research of medical devices. The study was approved by the Independent Ethic Committee of Clínica Universitaria de Odontología (Spain), with the registration number NCT05296902, and all patients gave their written informed consent before enrolling in the study.

Patients received standard care without study-related interventions, ensuring routine clinical practice and treatment decisions remain at the investigator's discretion.

The expected study duration per patient was 7 days postoperatively, consisting of a preoperative visit, a surgery visit, and a suture removal visit (7-14 days postoperatively).

This study evaluated a silk non-absorbable suture (Silkam®) for oral surgery in adult patients. Silkam®, a braided suture material made from silk fibrils (polypeptide chains), is available in both undyed (white) and black-dyed versions (colored with hematein) and spans a USP size range from USP 8/0 (0.4 metric) to USP 6 (8 metric). Coated with refined paraffin wax or beeswax, Silkam® is designed for soft tissue approximation in various procedures, including general surgery, skin closure, oral surgery, and ophthalmic surgery.

Patient population

Eligible patients for the study were adult patients undergoing mucosal wound closure with Silkam® as the suture material in oral surgery, provided they had given written informed consent. Exclusion criteria included: use of medication affecting wound healing, having a condition impairing wound healing, having hypersensitivity or allergy to the suture material, participating in another clinical trial or study, or inability to comply with study requirements (e.g., due to dementia).

Assessments

The primary endpoint was the evaluation of the safety parameters, including the incidence of postoperative wound dehiscence and complications of Grade 1 and Grade 2, defined by Askar, et al. [9]. until the last follow-up visit available. Grade 1 complications were defined as localized complication(s) accompanied by no adverse effects on the success of the surgery, and grade 2, localized complication(s) accompanied by adverse effects on the success of the surgery. Secondary endpoints included other safety, effectiveness, and performance parameters. Briefly, rate of postoperative complications of Grade 3 to 6 according to Askar et al. [9] until the last follow-up visit available (Grade 3: localized or systemic complication(s) that impairs the patient's daily routine but does not require hospitalization; Grade 4: localized or systemic complication(s) that impairs the patient's daily routine and requires hospitalization; Grade 5: localized or systemic complication(s) that inflicts irreversible damage to ≥ 1 anatomical structures; Grade 6: localized or systemic complication(s) that lead to death), wound healing assessment by the physician at the suture removal visit using the Patient and Observer Scar Assessment Scale (POSAS) [25] a valid and reliable instrument with good internal consistency to evaluate scars (on a scale from 0 to 100, where 0 represents very poor wound healing and 100 excellent); assessment of pain and satisfaction of the patient using the Visual Analogue Scale (VAS; on a scale from 0 to 100, where 0 represents no pain/very poor satisfaction and 100 extreme pain/excellent satisfaction) at the suture removal visit. Contamination of the used thread was also evaluated for the following microorganisms: Aggregatibacter actinomycetemcomitans, Porphyromonas gingivalis, Tannerella forsythia, Treponema denticola, Prevotella intermedia, Peptostreptococcus micros, Fusobacterium nucleatum/periodonticum, Campylobacter rectus, Eubacterium nodatum, Eikenella corrodens, Capnocytophaga spp. Microorganism levels were defined as "Bacterial load below the detection limit", "Bacterial load at the detection limit", "Increased bacterial load", "High bacterial load", and "Extremely high bacterial load". "Extremely high bacterial load" was considered abnormal microbiological results. The intraoperative performance and handling characteristics of the suture material used in oral surgery were evaluated by the physicians using a questionnaire including five dimensions (knot security, knot run-down, knot pull tensile strength, tissue drag, and pliability) and a five-point scale ranging from "Excellent" to "Poor".

Exploratory analysis included examining the correlations between the assessed variables (including number of teeth treated, incision length, pain and satisfaction VAS scores, and variables related to the microbiological evaluation) using both parametric (Pearson) and non-parametric (Spearman) methods.

Statistical considerations

The sample size was calculated based on an expected composite incidence of 14.4% for Grade 1 and Grade 2 complications associated with Silkam® suture use. Using a two-sided 95% Agresti-Coull confidence interval for a binomial proportion with a true value of 0.144, a sample size of 99 participants was determined to yield a half-width of at most 0.075, with a conditional probability of 0.80. A 5% drop-out rate was expected. Consequently, 105 patients were planned for enrollment in the study.

A descriptive statistical analysis was conducted to summarize the study variables. For quantitative variables, central tendency and dispersion measures were calculated, including the mean and Standard Deviation (SD). Qualitative variables were described using counts and percentages.

For statistical comparisons of binary data, the *Chi-Square test* was applied. Non-parametric data were analyzed using the Wilcoxon-Mann-Whitney U test or the Kruskal-Wallis test. For parametric data, the t-test and one-way ANOVA were used. A significance level of 0.05 was used for statistical testing. All available data were analyzed; thus, missing data were not replaced by estimates. All statistical analyses were performed using the statistical software package SAS VIYA software version V.04.00 (SAS Institute Inc., Cary, NC, USA).

Results

Participant flow

A total of 105 patients were enrolled in the study from May 2022 to October 2023. One hundred patients completed the study as scheduled, while 5 patients terminated prematurely or were lost to follow-up.

Patient characteristics

Baseline characteristics of patients are described in Table 1. Briefly, the mean age of patients was 44.33 ± 18.43 years, and 56.19% were female.

Patient characteristics	Value
Demographic data	
Mean age, years (SD)	44.33 (18.43)
Female, n (%)	59.00 (56.19)
Anthropometric data	
Mean weight, kg (SD)	71.68 (15.04)
Mean height, cm (SD)	168.41 (8.99)
Mean body mass index, kg/cm² (SD)	25.15 (4.17)
Medical history/Risk factors	
Current smoker, n (%)	21 (20.00)
Diabetes, n (%)	3 (2.86)
Insulin-dependent diabetes, n (%)	0 (0.00)
Use of antibiotics, n (%)	3 (2.86)
Use of chlorhexidine, n (%)	4 (3.81)
Immunosuppression, n (%)	0 (0.00)
Surgery data	
Indication for surgery	
Place implants, n (%)	19 (18.10)
Remove impacted teeth, n (%)	14 (13.33)
Other*	
Exodontia, n (%)	55 (52.38)
Number of teeth treated	
One tooth treated, n (%)	77 (73.33)
Two teeth treated, n (%)	22 (20.95
Three teeth treated, n (%)	2 (1.90)
Four teeth treated, n (%)	4 (3.81)
Mean incision length, mm (SD)	10.89 (2.47)
Suture technique	
Interrupted, n (%)	53 (50.48)
Continuous, n (%)	39 (37.14)
Other	
Cross, n (%)	8 (7.62)
Simple, n (%)	4 (3.81)
Horizontal mattress, n (%)	1 (0.95)

*Most frequent indications for surgery, performed in more than 10 patients. IQR: interquartile range; SD: standard deviation.

Table 1: Baseline patient characteristics (N=105).

Surgery characteristics

Surgery parameters are described in Table 1, Table 2, and Table 3. The indications for surgery included exodontia in 55 (52.38%) patients, implant placement in 19 (18.10%), and removal of impacted teeth in 14 (13.33%). The mean incision length was 10.89 ± 2.47 mm. A total of 143 affected teeth were recorded, with 86 (60.14%) located in the maxilla and 57 (39.86%) in the mandible. An interrupted suture technique was used in 53 (50.48%) patients, while a continuous suture technique was used in 39 (37.14%) patients. The most commonly used suture material was black 4/0, applied in 73 (69.52%) patients, while the most frequent needle type was DS 19 mm, used in 69 (65.71%) patients.

Variable, n (%)	Surgery type		
	All (N=143)	Implant placement (N=22)	Removal of impacted teeth (N=27)
Tooth name			
Central incisor	5 (3.50)		
Lateral incisor	4 (2.80)		
Canine tooth	7 (4.90)	2 (7.41)	1 (4.55)
First premolar	7 (4.90)	3 (11.11)	
Second premolar	10 (6.99)	5 (18.52)	1 (4.55)
First molar	21 (14.69)	13 (48.15)	2 (9.09)
Second molar	17 (11.89)	4 (14.81)	3 (13.64)
Wisdom tooth	72 (50.35)		15 (68.18)
Anatomic location			
Maxillary	86 (60.14)	10 (37.04)	12 (54.55)
Mandibular	57 (39.86)	17 (62.96)	10 (45.45)
Side			
Left	81 (56.64)	16 (59.26)	12 (54.55)
Right	62 (43.36)	11 (40.74)	10 (45.45)

Table 2: Teeth and location (N=143).

Materials, n (%)	Surgery type		
	All (N=105)	Implant placement (N=19)	Removal of impacted teeth (N=14)
Thread color			
Black	105 (100.00)	19 (100)	14 (100)
USP size			
4/0	73 (69.52)	10 (52.63)	12 (85.71)
5/0	32 (30.48)	9 (47.37)	2 (14.29)
Needle type			
DS	101 (96.19)	18 (94.74)	12 (85.71)
DGMP	3 (2.86)	1 (5.26)	2 (14.29)
DSMP	1 (0.95)		
Needle size			
19 mm	73 (69.52)	10 (52.63)	12 (85.71)
16 mm	32 (30.48)	9 (47.37)	2 (14.29)
Suture combination			
Black 4/0	73 (69.52)	10 (52.63)	12 (85.71)
Black 5/0	32 (30.48)	9 (47.37)	2 (14.29)
Needle combination			
DS 19 mm	69 (65.71)	9 (47.37)	10 (71.43)
DS 16 mm	32 (30.48)	9 (47.37)	2 (14.29)
DGMP 19 mm	3 (2.86)	1 (5.26)	2 (14.29)
DSMP 16 mm	1 (0.95)		

Table 3: Use of threads and needles (N=105).

DS: 3/8 circle cutting needle; DGMP: 3/8 circle trapezoidal micro engraved body needles with microtips; DSMP: 3/8 circle cutting needles with microtips; USP: United States Pharmacopeia.

Safety

Incidence of postoperative wound dehiscence and complications

No postoperative wound dehiscence and complications of any grade, either during surgery or postoperatively, as defined by Askar et al. [9] were reported, resulting in a complication rate of 0%.

Efficacy

Wound healing assessment

The mean wound healing assessment score was 80.27 ± 14.89 on a scale from 0 to 100, where 0 represents very poor wound healing and 100 excellent. Sutures were removed, on average, after 8.58 ± 5.42 days.

Pain assessment and medication

The mean pain VAS score assessed by patients at suture removal was 43.96 ± 32.00 (Figure 1). A total of 32 patients (30.48%) reported no pain after surgery. Of them, 14 (13.33%) did not require any pain medication, while 18 (17.14%) used pain medication but discontinued it before suture removal (Table 4). Seventy-one (67.62%) patients experienced pain after surgery, which lasted on average 3.76 ± 1.72 days. Among these, 61 (58.10%) patients used pain medication but stopped before suture removal, while 8 (7.62%) patients continued taking pain medication. Two (1.90%) patients reported ongoing pain since surgery, both of whom were still using pain medication at suture removal.

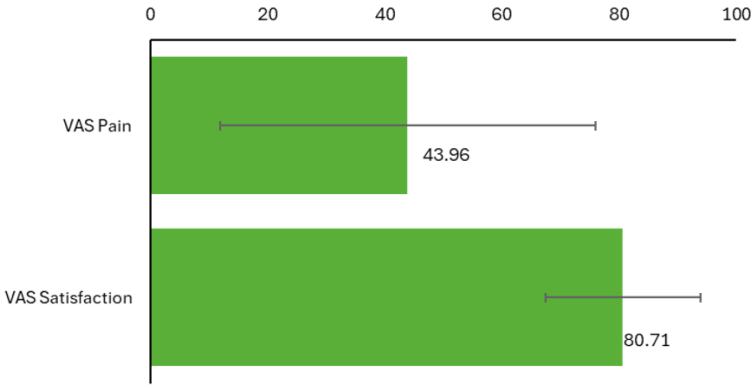

Figure 1: Pain and satisfaction reported by the patients (N=105).

Mean and standard deviation are shown. (0=no pain, 100=heavy pain). Satisfaction: (0=very poor, 100=excellent).

Variable, n (%)	Pain after surgery		
	No pain	Pain present after surgery	Ongoing pain since surgery
Pain medication since surgery			
No	14 (13.33)	1 (0.95)	
Yes, stopped	18 (17.14)	61 (58.10)	
Yes, ongoing		8 (7.62)	2 (1.90)
Unknown		1 (0.95)	

Table 4: Pain medication (N=105).

Satisfaction of the patient

The mean satisfaction VAS score reported by patients at the time of suture removal was 80.71 ± 13.23 (Figure 1).

Notably, correlation analysis revealed a significant negative correlation between the pain and satisfaction VAS scores reported by patients ($p<0.0001$; $r=-0.48845$).

Microbiological analysis of the thread

The microbiological analyses of the removed suture thread were performed in samples from 79 (75.24%) patients. Overall, abnormal results were found in 37 (35.24%) patients. The detailed results of the microbiological analyses are shown in Figure 2. Briefly, all assessed bacteria were found, although at varying levels. In several of them, including Aggregatibacter actinomycetemcomitans, Porphyromonas gingivalis, Tannerella forsythia, Treponema denticola, Campylobacter rectus, and Eubacterium nodatum, most of the samples had a bacterial load below the detection limit or at the detection limit. A significant proportion of samples showed an increased load of Fusobacterium nucleatum/periodonticum, Eikenella corrodens, and Tannerella forsythia. Several samples exhibited high accumulation of Fusobacterium nucleatum/periodonticum, *Peptostreptococcus micros*, and *Capnocytophaga spp*. Additionally, *Capnocytophaga spp* and Prevotella intermedia were presented at extremely high levels in a significant amount of patients. Overall, Prevotella intermedia, Fusobacterium nucleatum/periodonticum, *Peptostreptococcus micros*, and *Capnocytophaga spp* exhibited the highest levels.

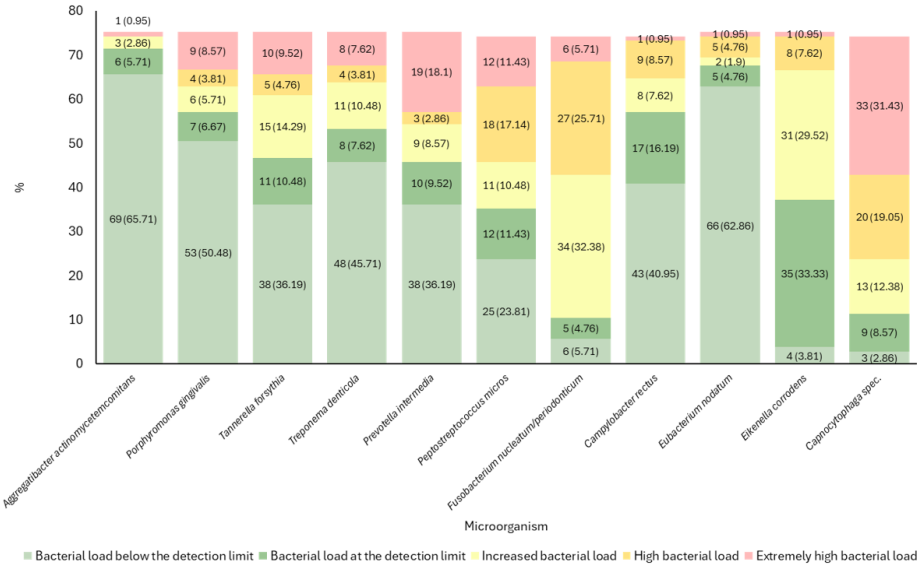

Figure 2: Microbiological analysis of the threads (N=105).

N of patients (percentage of total patients) is shown. The analyses were performed in samples from 79 patients. One data point was not available for *Peptostreptococcus micros*, *Fusobacterium nucleatum*/*periodonticum*, *Campylobacter rectus*, and *Capnocytophaga spp*. "Bacterial load below the detection limit" corresponds to <10^4 pathogens, "Bacterial load at the detection limit" to 10^4, "Increased bacterial load" to<10^5, "High bacterial load" to <10^6, and "Extremely high bacterial load" to ≥10^6. For Aggregatibacter actinomycetemcomitans, "Bacterial load below the detection limit" corresponds to <10^3 pathogens, "Bacterial load at the detection limit" to 10^3, "Increased bacterial load" to<10^4, "High bacterial load" to <10^5, "Extremely high bacterial load" to ≥10^5.

Performance

Intraoperative performance and handling of the suture material

Intraoperative performance and handling of the suture material were evaluated across five key qualities: knot security, knot run-down, knot pull tensile strength, tissue drag, and pliability, as shown in Figure 3. All qualities scored highest in the "excellent", "very good", and "good" categories. Only a small number of responses rated aspects as "poor": 5 (4.76%) physicians regarding knot run-down, 4 (3.81%) about tensile strength, 5 (4.76%) about tissue drag, and 2 (1.9) about pliability.

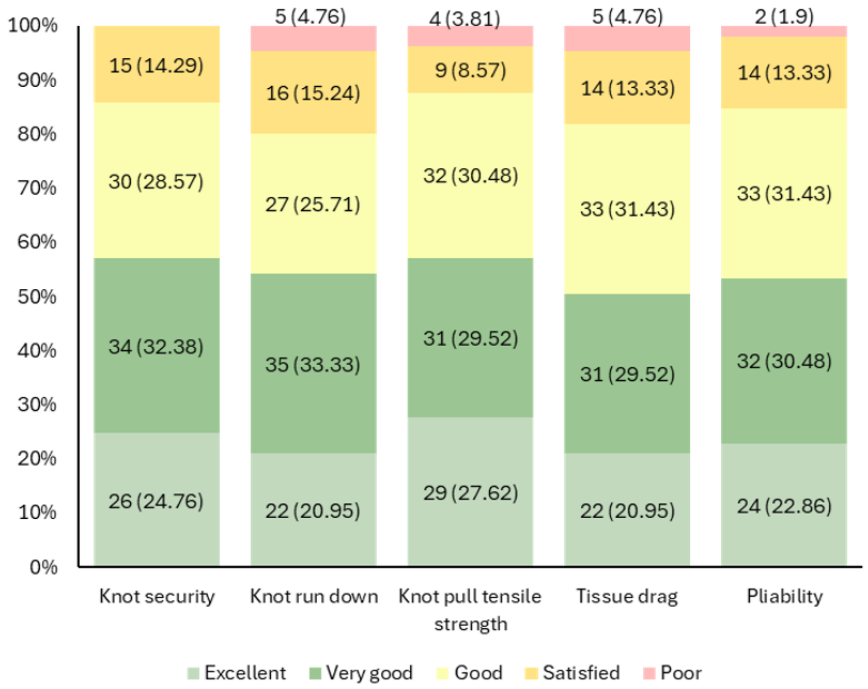

Figure 3: Intraoperative performance of the suture material (N=105).

N of patients (percentage of total patients) is shown.

Suture loss

Among the 100 patients who completed the study as planned, 9 (8.57%) lost their suture before the scheduled suture removal visit, and one (0.95%) required suture removal in the Emergency Room (ER). Out of the 5 patients who terminated prematurely, 3 (2.86%) lost the suture before the suture removal visit.

Discussion

This prospective single-arm observational study assessed the safety, effectiveness, and performance of a non-absorbable braided silk suture for mucosal closure in oral surgery in routine clinical practice.

In this study, no complications of any grade nor wound dehiscence were observed. Only one patient required suture removal in the ER for unknown reasons. Several studies report minimal complications with silk sutures in oral surgery. For instance, Quaglia, et al. [16] reported the complete absence of any postsurgery complications when comparing polyamide and silk sutures in the healing of post-extraction sockets. Balamurugan, et al. [22] reported no complications 7 days after oral surgery when comparing polyglycolic acid suture and silk. Banche, et al. [18] showed no signs of local infection at the time of suture removal nor complications of wound healing after 3 weeks. Parrini, et al. [26] reported an absence of dehiscence in oral surgical sites when using either PTFE or silk sutures. In the same study, all procedures were uneventful, with no major complications observed. Sala-Pérez et al. [19]. reported one case of surgical site infection with silk suture 72 hours postoperatively. Nevertheless, studies comparing suture materials in oral surgery reveal that silk sutures elicit a higher inflammatory response compared to other materials, such as polyglycolic acid, cyanoacrylate glue, and non-absorbable synthetic monofilament polypropylene [7,21,24]. Overall, the absence of complications in the current study suggests that the braided silk suture has a reduced risk of infection.

Wound healing is influenced by various factors, including the patient's overall health and habits, oral hygiene practices, the specific surgical procedure performed, and the suture material used [5]. In this study, the wound healing assessment by the dentist during the suture removal visit was very positive (with a score around 80, where 100 is excellent). In a previous study, Sortino et al. [21] also observed acceptable wound conditions 8 days after oral surgery with black silk and polyglycolic acid sutures. Quaglia et al. [16] found that the traditional silk suture resulted in a favorable wound healing index after 7 days of tooth extraction with a mean score around 7 on a scale ranging from 4, representing an excellent score, to 12, corresponding to severely impaired healing. However, they found better and faster healing with polyamide sutures. Syaflida et al. [23] evaluated the healing status following third molar impaction surgery using a grading

of good (0-1), moderate (2), and poor (>3). The mean healing score after 7 days of surgery was 1.4 for silk suture, indicating a healing status ranging from good to moderate. In the same study, the multifilament absorbable catgut sutures showed a shorter average wound healing time than silk sutures [23]. Dragovic, et al. [7] found a soft tissue healing score when using silk sutures of around 4.1 on a scale ranging from 1 (very poor healing) to 5 (excellent healing) 7 days after oral surgery. Nevertheless, better healing was observed with synthetic materials (non-absorbable monofilament polypropylene, absorbable monofilament copolymer of E-caprolactone, glycolide, trimethylene carbonate, lactide, and absorbable multifilament copolymer of glycolide and lactide) compared to natural silk suture, as well as with monofilament compared to multifilament sutures [7]. Sala-Pérez, et al. [19] observed no significant differences in wound bleeding between silk sutures and monofilament antibacterial polyglecaprone 25 sutures 3 and 7 days after the surgical removal of impacted lower third molars. Overall, the absence of complications observed in our study, combined with the positive assessment of wound healing, suggests that the use of silk suture may contribute to favorable wound healing outcomes. However, further investigations comparing different suture materials would be of interest.

While individual factors such as pain tolerance, anticipated pain, and expectations play a role in how pain is perceived during oral surgery, the complexity of the oral surgery procedure and the quality of the postoperative care are critical determinants in managing and minimizing discomfort [27]. The mean pain VAS score of 43.96 ± 32.00 at suture removal reported in the current study indicates moderate pain levels experienced by patients. Two-thirds of the patients experienced pain following surgery, which resolved before suture removal and lasted, on average, less than 4 days. In addition, only 2% reported persistent pain at the time of suture removal. Dilan, et al. [28] reported very low pain, with a mean score of 0.8 on a VAS scale (where 0 indicates no pain and 10 the worst pain imaginable) in patients 7 days after impacted lower third molar surgery using silk suture. In the same study, patients with Polyethylene Terephthalate (PET) sutures experienced less pain 12 and 24 hours postsurgery than those with silk sutures, although no significant differences were observed 7 days after surgery [28]. Sala-Pérez, et al. [19] reported a similar level of patient discomfort with both monofilament antibacterial polyglecaprone 25 and silk sutures for 7 days after oral surgery. Other studies comparing suture materials regarding postoperative pain or discomfort after oral surgery showed that polyamide, polyester material coated with Teflon, and barbed sutures were more favorable than silk sutures [16,29,30]. Altogether, these findings suggest that silk sutures are associated with moderate postoperative pain, with only a small proportion of patients experiencing persistent pain until the suture removal.

Interestingly, a significant negative correlation was observed between pain and satisfaction scores reported by patients in the SILKOS study. The high mean satisfaction VAS score of 80.71 reported by patients at suture removal indicates a generally positive postoperative experience with silk sutures. Nevertheless, previous studies have shown higher satisfaction of patients with polyamide sutures than silk sutures [16]. Overall, the level of satisfaction is encouraging and suggests that the suture material meets the expectations of patients in terms of comfort and overall experience.

The oral cavity harbors more than 700 species of microbes [31]. Diminished plaque retention and subsequent bacterial load are essential for limiting postoperative surgical site infection, attenuating the inflammatory response, and promoting optimal tissue healing [3,33]. This study found abnormal microbiological results in 37 out of 79 assessed patients, which is a significant proportion. Capnocytophaga spp., *Fusobacterium nucleatum*/*periodonticum*, *Prevotella intermedia*, and *Peptostreptococcus micros* exhibited the highest levels, although all tested microorganisms (Aggregatibacter actinomycetemcomitans, *Porphyromonas gingivalis*, *Tannerella forsythia*, *Treponema denticola*, *Campylobacter rectus*, *Eubacterium nodatum*, *Eikenella corrodens*) were found. Of particular interest were *Fusobacterium spp*, *Prevotella spp*., and *Peptostreptococcus spp*., which, together with *Streptococcus spp*., *Staphylococcus epidermidis*, *Staphylococcus aureus*, coagulase-negative *Staphylococci*, *Bacteroides fragilis*, *Escherichia coli*, *Enterococcus spp*., *Pseudomonas aeruginosa*, and *Serratia spp*. have been previously recovered from sutures associated with postoperative surgical site infections [33-35]. Sala-Pérez, et al. [19] identified several bacterial species found postsurgery in silk sutures, such as the *Streptococcus viridans* group, coagulase-negative *Staphylococcus*, *Veillonella spp*., and *Lactobacillus spp*., as well as pathogenic microorganisms Citrobacter freundii complex, *Prevotella spp*., *Prevotella disiens*, *Fusobacterium spp*., and *Peptostreptococcus spp*. Sortino, et al. [21] also found potentially pathogenic microorganisms, such as *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Staphylococcus aureus*, *Streptococcus pyogenes*, and *Enterobacterium*, and the fungi Candida albicans, in silk sutures. Banche, et al. [18] showed that the predominant bacterial strains identified 8 days after surgery on a variety of sutures (silk, polyamide, PET coated with polyethylene vinyl acetate, PET coated with polybutylate, PET coated with silicone, and polyglecaprone 25 sutures) included Streptococcus spp. (*S. mitis*, *S. sanguis*, *S. oralis*, *S. mutans*, *Gemella morbillorum*), *Staphylococcus warneri*, *Neisseria spp*., *Actinomyces spp*., *Pasteurella spp*., *Veillonella parvula*, *Peptostreptococcus spp*., *Actinobacillus spp*., *Prevotella spp*., and *Fusobacterium spp*. Despite detecting several of these microorganisms in the sutures of patients of the present study, the absence of complications suggests that silk sutures offer a reduced risk of infection.

Several studies have compared the microorganism accumulation in silk sutures to other suture materials after oral surgery. Banche, et al. [18] reported that silk sutures had the lowest bacterial adhesion compared to other non-absorbable multifilament sutures

(polyamide, PET coated with polyethylene vinyl acetate, PET coated with polybutylate, and PET coated with silicone). However, absorbable monofilament polyglecaprone 25 sutures exhibited the lowest overall microbial load [18]. Asher, et al. [17] compared the bacterial accumulation of different suture materials (silk, coated polyglactin, nylon, and polyester) 10 days after surgery in patients who underwent oral surgery. They found aerobic and anaerobic bacteria in the sutures of all patients. Nylon sutures, which are monofilamentous, exhibited significantly reduced bacterial levels compared to braided sutures (silk, coated polyglactin, and polyester sutures), which had similar levels [17]. Dragovic, et al. [7]. found significantly lower levels of microorganisms in monofilament sutures compared to multifilament sutures. Silk sutures and the absorbable multifilament copolymer of glycolide and lactide sutures exhibited the highest microbial load [7]. Sala-Pérez, et al. [19] found that silk sutures harbored significantly higher levels of both aerobic and anaerobic microorganisms at days 3 and 7 postsurgery compared to monofilament antibacterial polyglecaprone 25 sutures. Leknes, et al. [20] demonstrated that the monofilament ePTFE suture reduced bacterial plaque formation within the suture canal compared to silk suture 7 days postsurgery. Similarly, Parrini, et al. [26] showed that aerobic and anaerobic bacteria retention increased in silk sutures compared to monofilament PTFE sutures 7 days after third molar surgery. Bucci, et al. [3] also observed that the bacterial levels were higher in the silk sutures than in monofilament polyamide and multifilament polyglycolide sutures. Pons-Vicente, et al. [30] observed that silk sutures removed 7 days after oral surgery had higher levels of aerobic and anaerobic organisms compared to multifilament braided polyester coated with Teflon, although the differences were not statistically significant. Dilan, et al. [28] visually evaluated plaque accumulation following impacted lower third molar surgery and observed that the non-absorbable multifilament PET sutures exhibited less plaque accumulation than silk sutures 2 days after surgery. However, this difference was not observed after 7 days [28]. Sortino, et al. [21] showed that the presence of anaerobic and aerobic bacteria was similar in silk sutures and multifilament polyglycolic acid sutures 8 days after surgery, but potentially pathogenic microorganisms were only present in silk sutures. Finally, Uysal, et al. [29] reported that the use of barbed sutures significantly reduced plaque formation and bacterial colonization at 3 and 7 days post-oral surgery compared to silk sutures. Despite prior evidence suggesting that silk sutures accumulate more microorganisms than other materials, the clinical outcomes reported in the present study evaluating silk sutures were very positive.

Although the ideal suture material does not exist, intraoperative performance and handling characteristics are crucial factors in suture material selection as they directly impact the effectiveness and efficiency of the suturing process [1]. The positive scores for knot security, knot run-down, knot pull tensile strength, tissue drag, and pliability found in the present study demonstrate the good handling characteristics of the silk fibril suture in oral surgery. Although some comparative studies suggest better intraoperative handling properties of silk compared to other natural sutures, such as catgut sutures, other studies have shown that synthetic suture materials, such as Teflon-coated polyester, polypropylene, and other copolymers, exhibit superior properties [7,23,30]. The favorable intraoperative performance and handling characteristics reported in our study may have contributed to the observed positive wound healing outcomes and might be related to the relatively low rate of suture loss. Suture loss can occur due to a combination of surgical knotting techniques, suture materials, mechanical stress during and after surgery, patient-related factors such as tongue movement, high chewing activity, and oral hygiene, and the natural degradation process of sutures [32]. Our study exhibited suture loss in 8.57% of patients before the scheduled removal, with an additional 0.95% requiring early removal in the ER. Balamurugan, et al. [22] reported a similar rate of suture loss with silk sutures, with 8% being lost 7 days postsurgery, while all sutures were retained when using polyglycolic acid sutures. While Leknes, et al. [20] reported the loss of 2 sutures after 10 days of surgery, both with silk and ePTFE sutures, among 10 evaluated patients, Parrini, et al. [26] observed no suture loss 7 after surgery with either PTFE or silk sutures in their study of 10 patients. Overall, these results highlighted the good intraoperative performance and handling characteristics of silk sutures in oral surgery.

This study has limitations that should be considered. The absence of a parallel control group constrains our ability to compare outcomes to alternative interventions. The retrospective nature of the study implies data generation according to routine clinical practice and limits the standardization of data collection. In this study, different surgical interventions (extractions, impacted 3D molar extractions, and dental implant placement) have been performed, with different degrees of invasiveness and associated morbidity, which may influence the final results. Additionally, the monocentric nature of the study restricts the generalizability of findings to broader healthcare contexts and diverse patient populations. These limitations underscore the need for future research to expand our knowledge upon the current study's observations.

Conclusion

The SILKOS study demonstrated the absence of complications or wound dehiscence when non-adsorbable silk sutures were used for mucosal closure in oral surgery under routine clinical practice. Wound healing at the time of suture removal was assessed as highly positive. Patients reported moderate postoperative pain and close to excellent satisfaction, suggesting an overall positive experience with silk sutures. In addition, physicians highlighted the good handling characteristics of the silk sutures for mucosal closure in oral surgery. The study also characterized microbial accumulation in the sutures, identifying *Capnocytophaga spp*., Fusobacterium nucleatum/periodonticum, Prevotella intermedia, and *Peptostreptococcus* micros as the most prevalent species.

Overall, the findings underscore the favorable properties of silk sutures for mucosal closure in oral surgery within routine clinical practice.

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Ethical Considerations

The SILKOS study was conducted in accordance with the World Medical Association Declaration of Helsinki, all its amendments, national regulations, and regulations relevant to the research of medical devices. The study was approved by the Independent Ethic Committee of Clínica Universitaria de Odontología (Spain), with the registration number NCT05296902, and all patients gave their written informed consent before enrolling in the study.

Conflicts of interests

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Author contributions

CRS and PA contributed to the conception or design of the work; CRS, PA, MQP, OOP, FHA, and JGL to the acquisition, analysis, or interpretation of data for the work. CRS and PA wrote the original draft with support. All authors critically reviewed the manuscript and approved the published version of the manuscript.

Declaration of generative AI in scientific writing

During the preparation of this work, the authors used a large language model to verify grammar and improve the clarity of the text. After using this tool, the authors carefully reviewed, edited, and approved the content as needed and take full responsibility for the content of the published article.

Data statement

The datasets analyzed during the current study are available from the corresponding author upon reasonable request. The data includes sensitive information, such as patient data.

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