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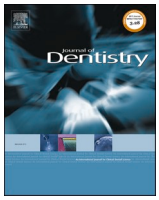

Prospective, multi-centric, international, single-arm, cohort study to assess a synthetic polyamide suture material in oral surgery to close the mucosa - MUCODA study.

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ABSTRACT

Objectives: The aim was to collect different clinical parameters systematically and proactively regarding safety, effectiveness, and performance of a nylon monofilament suture under routine clinical practice for oral surgery.
Methods: The study design was prospective, bicentric, international, single-armed, and observational. A non-absorbable suture was applied to close the mucosa after different dental surgical interventions. Main objective was the incidence of combined postoperative complications until suture removal. The 95 % Confidence Interval (Agresti-Coull method) was used to prove the non-inferiority with a pre-specified upper margin of 21.9 %. Secondary variables were intraoperative suture handling, patient pain and satisfaction, wound healing, aesthetic appearance, and bacterial contamination.
Results: 105 patients were enrolled. Complication rate was low (1.9 %), 2 swellings occurred. Pain was present for 1.61 days ± 1.42 after various dental interventions with an average pain level of 20.98 ± 22.60 (VAS). Patients with impacted third molar extraction showed the longest pain duration (6 days) combined with the highest mean pain level of 35.33 ± 30.45 (VAS). Intraoperative suture handling was very good to excellent. Suture removal was done after an average duration of 7.56 ± 2.09 days. Patient's satisfaction was high, and an excellent wound healing was reported by the dentists. Aesthetic appearance only performed in implant patients was rated by oral surgeons with an average of 96.19 ± 3.79 points [min. 80 – max. 100] at 5 months post-operatively. Thread bacterial analysis showed that *F. nucleatum* was the most present species.
Conclusions: Our findings indicate that the non-absorbable, nylon-based monofilament suture used is safe and quite suitable for oral mucosal closure after various dental surgical interventions such as tooth extraction, implant placement and impacted third molar extraction.
Clinical significance: This study showed the safe use of a non-absorbable, nylon-based monofilament suture for different oral surgical interventions under daily routine clinical practice.

1. Introduction

Currently, there are many different suture materials and needles on the market that surgeons can choose from to obtain an accurate approximation of the wound edges to enable undisturbed wound healing. The ideal suture material should have the following characteristics: good handling, low memory, good sliding, high knot stability, good traction resistance, minimal tissue trauma, inert behaviour, less bacterial colonization, great flexibility, low tissue reactivity and low inflammatory response as well as non-allergenic properties [1]. Also, the choice of suture material in wound management largely depends on factors such as the number of tissue layers involved in wound closure, tension across the wound, depth of suture placement, presence of oedema and expected time of suture removal. The suture material

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should also be sufficiently strong and elicit minimal or no inflammatory reactions [2].

Suture materials are classified according to their origin (natural and synthetic), structure (monofilament and multifilament), and biological properties by means of a degradation profile over a certain period (absorbable and non-absorbable) [3,4]. Important features of absorbable suture materials are their way of absorption and loss of tensile strength over time. Both are very important factors for ascertaining whether the used absorbable suture material will stay intact long enough and ensure sufficient strength to facilitate and promote wound healing. However, as absorbable suture materials are dissolved under the influence of proteolytic enzymes or hydrolysis, it would be preferable not to have them remain in the tissue longer than necessary [5,6].

Non-absorbable sutures can be classified according to their origin, either as natural (i.e., silk) or synthetic (i.e., polyamides or polyesters) [3,4]. Non-absorbable sutures must maintain their tensile strength and are indicated whenever continuous support of the wound is indicated (i.e., tendons). Almost all suture materials are subject to a certain loss of tensile strength but are still considered non-absorbable sutures if their tensile strength is maintained for more than 60 days [7]. The non-absorbable monofilament sutures tend to accumulate the least amount of plaque, thus leading to less bacterial contamination over the suture thread and therefore, improving tissue healing by lowering the inflammatory process [1]. Comparing these properties of the monofilament suture to silk, it was traditionally the material of choice for dental and several surgical procedures because of the low cost and easy handling. The inflammatory process of the suture material on the tissues tends to be more prominent with silk and cotton than with other materials such as nylon, polyester, PTFE, poliglecaprone 25 and PGA. Concerning this inflammatory process, delayed wound healing and severe tissue reaction could occur with silk [8,9].

Although there are different suture materials on the market for surgical procedures, the surgeon should be aware of the nature of the material, the biological healing processes, and the way they interact with tissues. These factors are considered critical and must be taken into consideration to ensure that the suture will retain the gathered flap edges with sufficient strength [8]. Usually, the superficial wound needs five to ten days to heal, although some surgical procedures will need the suture to remain in place 14 to 28 days and for this reason, the absorbable suture is dissolved by the action of certain enzymes or hydrolysis. Therefore, it would be preferable to remove it when its presence is no longer necessary. Thus, in oral surgeries, the right suture material can be evaluated depending on the depth of the tissues that need to be repositioned. Non-absorbable sutures are routinely used and usually removed between 5 and 7 days postoperatively [5].

Another important factor influencing tissue reaction is the bacterial adhesion to the suture; silk tends to have a higher number of bacteria compared to nylon, which has the least amount of bacterial adhesion, like poliglecaprone, and for this reason, bacterial colonization plays a major role in tissue reaction. The clinical studies that have been carried out to date have reported that the attribution of any systematic disease/condition might influence the tissue reaction, affecting the authentic response of the soft tissue to the suture such as poorly controlled diabetes mellitus and cardiovascular disease. Another factor that may influence the reaction is tobacco use, although its influence remains unclear due to the lack of data [9].

The non-absorbable suture that we used in this study was made of nylon, a synthetic polyamide suture. This material has the property of high tensile strength, and there is a minimal tissue reaction when comparing it to polyesters and polypropylene [6]. The nylon sutures are characterised by high pliability to allow good healing and easier handling of the suture compared to polypropylene, but the latter has lower tissue drag compared to nylon [7].

The main objective of the present study was the assessment of a nylon suture material regarding post-operative complications occurring after different oral surgical interventions performed in clinical routine.

2. Materials and methods

This study is reported according to the STROCSS Guideline, a standard guideline for published observational studies [10].

2.1. Registration and ethical approval

In accordance with the Declaration of Helsinki, the trial was registered on 15 May 2020 before the start of recruitment in ClinicalTrials.gov (NCT04390620). https://clinicaltrials.gov/study/NCT04390620?term=dafilon%20and%20mucosal%20closure&rank=1. The final study protocol was approved by the responsible Ethics Committees for the participating clinics (CIR-ECL-2020–04; F-2020–044-z). The ethics approval was needed to meet national requirements. A study protocol was developed *a priori* but not published in a peer-reviewed journal.

All enrolled patients gave their written informed consent to the scientific analysis of their pseudonymized data set in accordance with Regulation (EU) 2016/679 (General Data Protection Regulation).

2.2. Study design

The study was designed as an international, multi-centric, prospective, single-arm cohort study. In this study, a polyamide non-absorbable suture (Dafilon®, B. Braun Surgical SAU, Rubí, Spain) was evaluated for oral surgery in adult patients. It is a sterile, monofilament, non-absorbable surgical material produced from polyamide. The suture material is available blue or black coloured to make it more readily recognizable, but it is also available undyed in the natural beige colour. It fulfils all requirements of the European Pharm. and the United States Pharm. for sterile, non-absorbable sutures. USP sizes from 5 to 6/0 are intended to be used for soft tissue approximation in skin closure and oral surgery. Two centres participated in the study. All enrolled patients were prospectively followed up until suture removal, which took place 10 ± 5 days post-operatively. In addition, those patients who received an implant placement were prospectively followed up 1 month post-operatively in Spain (centre 001) and 5 months post-operatively in Germany (centre 002) depending on the routine clinical practice of each centre. Regular monitoring visits were performed to ensure data quality and validity.

2.3. Inclusion and exclusion criteria

Inclusion criteria

- Adult patients undergoing different oral surgical interventions (tooth extraction, removal of impacted tooth, implant surgery).

Exclusion criteria

- Oral surgery procedures requiring bone regeneration.
- Emergency surgeries.
- Pregnancy.
- Patients taking medications like antibiotics, anticonvulsants, angiogenesis inhibitors, steroids, and non-steroidal anti-inflammatory drugs, that might affect wound healing.
- Patients with hypersensitivity or allergy to suture material.

2.4. Population and interventions

A total of 105 patients were planned to be enrolled in this study including a drop-out rate of 5 %, further information can be found under sample size calculation. Both the surgical intervention and the suture technique used for mucosal closure were performed according to the clinic's standard or the surgeon's preference. The suture material was applied by oral surgeons who had been trained in, and were familiar with, the use of a polyamide non-absorbable suture (PNA suture). The

surgeons selected on their own the USP size of the thread used. The patients were treated under routine clinical conditions.

2.5. Outcomes

In their retrospective analysis, Askar et al. assessed for the first time the rate of postoperative complications after different oral surgical interventions [9]. In addition, they categorized the postoperative complications in various grades, ranging from I-V, depending on their severity (Table 1). Their retrospective analysis also included mandibular and maxillary impacted tooth extraction as well as implant surgeries, which were the selected indications to be performed in our study. Askar et al. observed the highest incidence and severity of complications after surgical removal of impacted third molar teeth.

In patients undergoing impacted mandibular third molar extraction, the incidence of Grade I was 22.6 %, of Grade II 3 % and of Grade III 31 %. For impacted maxillary third molar tooth extraction, the following incidences were reported: Grade I: 13.3 %, Grade II: 4 % and Grade III: 19.7 %. Lower rates for Grade I to Grade III were observed in implant patients compared to impacted third molar extraction patients.

The main outcome of the present study was the combined incidence of Grade I and Grade II until suture removal in patients undergoing either tooth extraction, impacted third molar tooth extraction or implant surgery. As mentioned above, the highest rates were found by Askar et al. in patients with impacted third molar tooth extraction. The highest incidence of Grade I and II in this patient population was 23.6 % and 4 % leading to a combined incidence of 27.6 %. For comparison of our main outcome parameter, we chose a more conservative setting because we used the incidences of Grade I and Grade II reported for all type of surgeries in the Askar study, which showed 11.1 % for Grade I and 3.3 % for Grade II, leading to a combined incidence of 14.4%. This combined rate was used for the comparison of our main outcome parameter as well as for sample size calculation.

As secondary variables, we analysed various safety, effectiveness, and performance parameters.

Safety parameters:

- Intraoperative complications and device deficiencies.
- Individual postoperative complications of Grade I, II, III, IV and V at suture removal (10 ± 5 days post-operatively) and at the optional follow-up visit depending on the routine clinical practice [9].

Table 1
Classification of postoperative complications as defined by Askar et al. [9].

Grade I	Exaggerated swelling
	Mild postoperative bleeding
	Delayed wound healing
	Oral candidiasis
	Postoperative dentinal hypersensitivity
	Angular cheilitis
Grade II	Flap dehiscence
	Membrane exposure
	Localized infection of the surgical site
	Graft necrosis
Grade III	Fever
	Skin rash
	Neuropraxia/paraesthesia
	Trimus
	Osteomyelitis
	Septicaemia
	Sinusitis
	Alveolar osteitis
	Chymosis
	Excessive and severe bleeding
	Prolonged exaggerated swelling
Grade IV	Major complications that require immediate hospitalisation i.e. drug induced anaphylaxis, septicaemia.
Grade V	Major complications that lead to irreversible damage i.e., neurotmesis, axonotmesis.

Effectiveness parameters:

- Pain assessment using the visual analogue scale (VAS 1–100) at 10 ± 5 days follow-up visits and at optional follow-up visit depending on the routine clinical practice [11].
- Wound healing assessment at 10 ± 5 days after surgery and at the optional follow-up visit depending on the routine clinical practice using a Likert scale ranging from 1 (poor) to 100 (best) [12].
- Aesthetic appearance in the implant patients was assessed by the physician using a Likert-scale ranging from 1 (worst) to 100 (excellent) only at the optional follow-up visit depending on the routine clinical practice [12].
- Patient satisfaction was assessed using a Likert scale ranging from 1 (maximally dissatisfied) to 100 (maximally satisfied) at 10 ± 5 days after surgery and at the optional follow-up visit depending on the routine clinical practice [12].
- The parameter of bacterial contamination of the thread at 10 ± 5 days after surgery was only evaluated in the Spanish clinic because this was done in a clinical routine setting [13,14].

The method used for the bacterial assessment:

On the day of suture removal, the whole thread was removed and taken for bacterial assessment. Sampling was performed in the deepest bags using ISO blotting paper tips No. 40 [15]. The samples collected with blotting paper were placed in a 1.5 ml test tube (Eppendorf AG, Hamburg, Germany) and kept at 4 °C until DNA extraction at the Echevarne Laboratory. DNA extraction was performed with High Pure PCR Template Preparation Kit (Roche, Mannheim, Germany) according to the manufacturer's recommendations. DNA was split into aliquots for the microIDent@ PCR test (Hain Lifescience, Nehren, Germany), using the primers reported by Ashimoto et al. for *P. gingivalis, T. forsythia, T. denticola* and *Prevotella intermedia (P. intermedia*) and those reported by Tran and Rudney for *A. actinomycetemcomitans* [13,14].

PCR amplification was carried out in a reaction volume of 25 μl consisting of 2.5 μl of DNA and 22.5 μl of reaction mix containing 17.5 μl primer mix, 2.5 μl of 10x PCR buffer, 2.5 μl of 25 mmol l^{-1} $MgCl_2$ and 1 U taq polymerase (Fermentas, Thermo Fisher Scientific, Waltham, MA, USA). The PCR amplification reaction was performed in a thermal cycler (Mastercycler, Eppendorf AG, Hamburg, Germany). The amplification conditions were as follows: initial denaturation step at 95 °C for 5 min; 10 cycles at 95 °C for 30 s and at 60 °C for 2 min; 20 cycles at 95 °C for 10 s, at 55 °C for 30 s and at 72 °C for 30 s; and a final extension step at 72 °C for 10 min.

The amplification product was hybridized to the probes on the strips by reverse hybridization using the microIDent@ kit (Hain Lifescience, Nehren, Germany) according to the manufacturer's instructions. Briefly, biotinylated amplicons were denatured and incubated, at 45 °C with hybridization buffer, together with hybridization strips containing 2 control lines and 5 species-specific probes. Once the PCR products bond to their respective complementary probes, a highly specific washing step followed, removing any non-specifically bound DNA. This was followed by the addition of streptavidin-conjugated alkaline phosphatase. A wash was performed, and the hybridization products were visualized by adding an alkaline phosphatase substrate. Each strip was scanned using Adobe Photoshop Elements image processing software (Adobe Systems, San Jose, CA, USA). After adjusting the contrast (automatic contrast), the luminescence of the strips was measured. The range of the white background of the strips and the conjugated control were set to 100 %, and the value of each band was expressed as the percentage of control staining. Two controls were used, one for amplification (PCR inhibition detection) and the other for hybridization.

The semi-quantitative methodology was adjusted (sensitivity) using the following species at concentrations of 10 -10^8 bacteria: *A. actinomycetemcomitans* ATCC 33,384, *P. gingivalis* ATCC 33,277, *T. forsythia* ATCC 43,037, *T. denticola* ATCC 35,405, *P. intermedia* ATCC 25,611. The sensitivities of the microIDent results were 10^3 - 10^4

bacteria. No cross-reactivity was found between these species. The specificity of microIDent was previously established by database analysis [13–16].

The following species could be detected with the chosen method: *Fusobacterium nucleatum, Capnocytophaga, Eikenella corrodens, Peptostreptococcus, Prevotella intermedia, Campylobacter rectus, Prophyromonas gingivalis, Tannerella forsythia, Treponema denticola, Eubacterium nodotum* and *Aggregatibacter actinomycetemcomitans, Parvimonas micra* colonization of the thread was reported in the following concentrations: < 10,000, <100,000, < 1000,000 and >1000,000.

Performance parameters:

- Intraoperative handling assessment of the suture material. The surgeons completed a questionnaire after each oral surgical intervention. The categories were knot security, tensile strength, knot run down, as well as the tissue drag and pliability of the suture. Each category was rated on a five-point Likert-type scale as follows: 'excellent', 'very good', 'good', 'satisfactory' and 'poor' [12].

2.6. Sample size

As described under "outcomes" our main outcome parameter was the combined incidence of postoperative complications of Grade I and Grade II. For comparison and sample size calculation, the complications rates of Grade I and Grade II reported by Askar et al. in 3900 patients after different oral surgeries were used [9]. The published rates were 11.1 % for Grade I and 3.3 % for Grade II leading to a combined incidence of 14.4 % which was used to calculate the sample size. In addition, we used a non-inferiority margin, which was set to 7.5 %, because in the Askar study, the highest rate reported for Grade I after impacted mandibular third molar extraction was 22.4 %.

In the present study, a composite Grade I and Grade II complication rate of p(test) = 14.4 % was expected, when the nylon suture material was used. With the non-inferiority margin of 7.5 %, rates of $M = 21.9$ % (14.4 %+7.5 %) or more were considered unacceptable. The margin was based on clinically and statistically important differences. The study hypothesis was proven when the upper limit of the 95 % confidence interval for the test proportion did not exceed the margin M.

For a two-sided 95 % Agresti-Coull confidence interval for a binomial proportion whose true value was 0.144, a sample size of $n = 99$ yields a half-width of at most 0.075 with a conditional probability of 0.80. When the expected drop-out rate is 5 %, the number to be recruited increases to $n = 105$. A total of 105 patients were therefore enrolled in the current study, including a drop-out rate of 5 %.

2.7. Statistical methods

All patients who had a surgical intervention using the polyamide suture material were included in the analysis. Deviations from the study plan were assessed as plan violations. If at least one of the inclusion or exclusion criteria was not fulfilled, the patient was removed from the study. As an inclusion criterion, the term 'if more than one incision is performed in the same patient, only one incision will be included' was mentioned. Therefore, the multiple teeth treated with only one incision in a single patient was not declared as having violated the study protocol and stayed in the full-study analysis. The missing data were analysed as such and not replaced by estimates.

For comparing our study results with the corresponding ranges from the literature, 95 % confidence intervals (Agresti-Coull method) were applied. All statistical tests were performed two-tailed with a prespecified significance level of α=5 %. A confirmatory statistical test was performed for the main outcome parameter (combined complication rate of Grade I and Grade II); exploratory statistical tests were performed for evaluating the effects of interest. The p-values of explanatory tests were interpreted as measures of difference in the current sample rather than a significant difference in the basic population. SAS software version 9.4, SAS Institute Inc., Cary, NC, USA was used for the sample size calculation.

3. Results

3.1. Participant flow

Recruitment took place between July 2020 and April 2021 and the post-operative follow-up examination was completed in April 2021. The first patient was enrolled on 2 July 2020, the last patient was recruited on 7 April 2021 and the last follow-up visit was performed on 14 April 2021. The study was regularly completed.

The study population consisted of 105 patients, 45 were enrolled in Spain and 60 in Germany. The disposition of patients over the study period can be found in Fig. 1. Patients undergoing tooth extraction or impacted third molar tooth extraction completed the study after suture removal. Implant patients received an additional follow-up visit in Spain after 1 month and after 5 months in Germany, because this was the clinical routine standard in the respective countries. No patient was lost to follow-up or withdrawal.

3.2. Demographics and baseline characteristics

An equal gender distribution was observed in the study population (54 females and 51 males). Patients averaged 55.6 ± 18.84 years of age [range 18–89 years]. The mean BMI was 25.12 ± 3.57 kg/m^2 [range: 19.57–39.18 kg/m^2]. The study population included 10 smokers (9.5 %). Other risk factors were not reported in the study population. A detailed collection of preoperative data is presented in Table 2.

3.3. Intraoperative details

In total, 119 teeth were treated in 105 patients (tooth extraction $N =$ 18 patients; removal of impacted teeth $N = 30$ patients; implant placement $N = 57$ patients). In total, 66 teeth (55.46 %) were mandibular, and 53 maxillary (44.54 %). Most extracted teeth were placed on the first molar position ($N = 43$, 36 %), followed by wisdom teeth ($N = 33$, 27 %), second premolar ($N = 15$, 12 %) and second molar teeth ($N = 14$, 11 %). The implant placement was predominantly performed on the first molar position mandibular ($N = 19/32$, 59 %) as well as maxillary ($N =$ 17/32, 53 %).

A mean length incision of 12.33 ± 2.70 mm was recorded for the study population. The mean length incision was comparable between different intervention types. Most patients received one suture thread to close the mucosal incision. In all cases, dental extraction forceps were used for tooth extraction. After tooth removal, adaptive sutures were used. When suturing the extraction socket of single-rooted teeth, only one suture was performed. In extraction sockets of multi-rooted teeth, a double suture was applied. In none of the extraction cases, mucosal flaps were carried out. Regarding implant site preparation, horizontal incisions were usually made in the median position of the ridge to create a one-sided flap design. In all implant patients, all implants were inserted post extractive. The suture material was applied in all patients exclusively in an interrupted single suture technique. The preferred USP thread sizes were 4/0 and 5/0 (40 % and 60 %, respectively) coloured blue combined with a cutting DS 19 mm needle. In all patients who had teeth extraction, no pharmacological medication was administered beside pain killers. A total of two oral surgeons performed the interventions, one in Germany and one in Spain.

3.4. Safety

Main outcome parameter

No adverse events or adverse device effects occurred intraoperatively. All sutures were left in place until the planned suture removal. Until the day of suture removal, 2 adverse events ($N = 2$

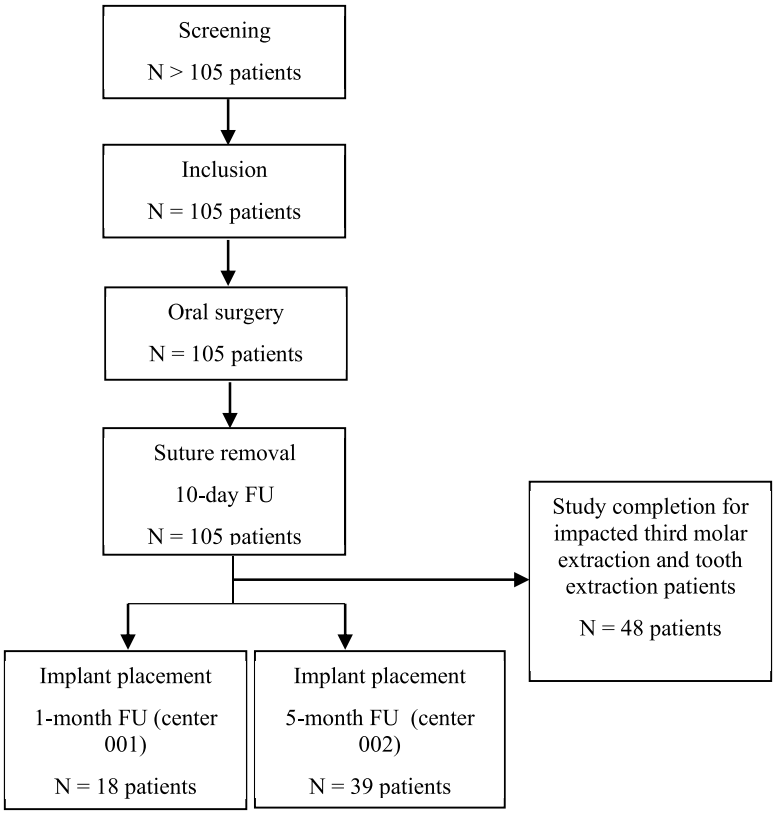

Fig. 1. Patient flow chart of the study.

Table 2
Demographics, baseline characteristics and indication for surgery.

Demographics	Number of patients	105
	Gender (females/males)	54/51
	Age[1] (years)	55.60 ± 18.84 (18–89)
	Weight (kg)	72.71 ± 13.70 (46–112)
	Height (cm)	169.71 ± 8.90 (149–194)
	BMI[2] (kg/m^2)	25.12 ± 3.57 (19.54–39.18)
Baseline characteristics	Smoker (No)	95 (90.48)
	Diabetes (No)	0 (0)
	Diabetes insulin dependent (No)	0 (0)
	Use of antibiotics (No)	0 (0)
	Use of chlorhexidine (No)	0 (0)
	Immunosuppression (No)	0 (0)
Indication for surgery	Implant placement	57/105 (54.29)
	Impacted teeth	30/105 (28.57)
	Tooth extraction	18/105 (17.14)

[1] Data are frequency counts (percentage of total) or the mean ± SD plus range in parentheses.
[2] BMI: body mass index.

Table 3
Main outcome parameter: Combined Grade I and Grade II complication rate in the total study population and per indication group.

Indication	No. of patients	No. of events	Rate	Lower CL	Upper CL
All	105	2 (swelling)	3.33 %	0.00 %	18.1 %
Subgroups:					
Impacted teeth	30	1	1.75 %	0.00 %	10.2 %
Tooth extraction	18	0	0.00 %	0.00 %	0.00 %
Implant	57	1	1.75 %	0.00 %	10.2 %

CL: confidence level, No.: number.

swelling) were recorded in 105 patients, leading to a total Grade I and Grade II complication rate of 1.90 %, (CI 95 % [0.1 % – 7.1 %]) (Table 3). No serious adverse event was reported.

A swelling was observed in one implant patient (1/57=1.75 %) and in one patient with an impacted third molar extraction (1/30 = 3.33 %) for 3–4 days after surgery, but swelling was resolved when the patients came for a check-up. The intensity of both events was assessed as mild, both were resolved with no sequelae and reported as an expected common event in oral surgical procedures. No causal relationship with the suture material was mentioned.

The main objective of the present study was the clinical assessment of the polyamide suture material regarding the combined postoperative complication rate of Grade I and Grade II rate after different oral surgical interventions. According to Askar et al., the postoperative complication "swelling" falls into the category of Grade I. The combined complication rate of Grade I and Grade II was 1.9 % in the current study compared to 14.4 % reported by Askar et al. after various oral surgeries. Furthermore, only swelling was observed in two patients in the present study (one implant patient and one impacted third molar extraction) leading to 1.9 % compared to 3.4 % shown for swelling in the Askar study after different oral surgical interventions. The effect was even more obvious, when only the rate was used for Grade I reported for mandibular impaction patients (22.6 %), for maxillary impaction patients (13.3 %) and implant patients (6.7 %) by Askar et al. Furthermore, regarding only swelling our rate was 4.16 % for impacted mandibular third molar extraction compared to 11 % in the Askar study; and 1.75 % swelling in

implant patients versus 1.7 % in the Askar study. Our findings indicate that using a synthetic polyamide suture material for different oral surgical interventions a low complication rate can be obtained.

Other safety parameters

No adverse events were detected in the follow-up visits performed either 1 month or 5 months after surgery. In our study, no event occurred which falls under the Grade III, IV or V category.

3.5. Performance

Time to suture removal

The suture material was removed in all patients after an average duration of 7.56 ± 2.09 days, range [min. 6 – max. 14 days] after initial oral surgery (Table 4). One outlier was observed having the suture removal at 23 days postoperatively in the Spanish clinic because this patient was not able to come earlier due to the corona pandemic situation. No difference was observed depending on oral interventions (impacted third molar extraction 7.9 ± 2.12 days, implant placement 7.56 ± 2.32 days, tooth extraction 7.00 ± 0.84 days).

Handling of suture material

Intraoperative handling was assessed by the dentists/oral surgeons using a 5 point Likert-Scale (1 excellent – 5 poor) All dimensions (knot security, knot run down, knot pull strength, pliability, and tissue drag) were mostly rated with 2 points (very good; 3–12 % of all surgeries) or 1 point (excellent; 88–100 % of all surgeries) indicating that the suture material is quite suitable for oral surgery (Fig. 2).

Pain

Average pain level was 20.98 ± 22.60 using the VAS scale (Table 4). Pain was present for 1.61 ± 1.42 days after surgery and lasted for up to 6 days after the surgical procedure. The patients with an impacted third molar tooth extraction showed the longest pain duration of 6 days combined with the highest mean pain levels 35.33 ± 30.45. Contrary to that, the implant placement or tooth extraction patients reported pain for up to 5 and 4 days with an average pain level of 14.96 ± 16.42 and 16.11 ± 12.0, respectively.

Pain medication was stopped by 69 patients before suture removal. No analgesic use was recorded for the residual patients between oral surgical intervention and suture removal.

Wound healing assessment

Average wound healing assessment by oral surgeons was 88.95 ± 7.26 using a scale ranging from 1 (poor) to 100 (best) at day of suture removal in all patients independent of the type of oral surgery performed (Table 4). In implant patients, wound healing was additionally rated at the follow up visit performed until 5 months postoperatively. In these patients, an improvement of wound healing was observed showing 90.32 ± 5.86 at day of suture removal and 96.79 ± 3.95 at the follow-up visit. The outcome indicates that wound healing was excellent when the mucosal closure was performed using a polyamide non-absorbable suture material.

Patient satisfaction

At suture removal, the mean satisfaction level was 92.75 ± 8.37 points in the total study population (Table 4). No difference could be observed depending on the type of oral surgical intervention. In the follow-up visits, implant patients reported an average satisfaction level of 98.13 ± 4.82 points until 5 months after oral mucosal closure. A statistically significant increase of satisfaction was observed in the German centre in patients undergoing an implant placement from suture removal to 5 months post-operative (90.13 ± 8.39 vs. 98.82 ± 2.45; $p < 0.0001$). In the Spanish centre, however, the level of satisfaction was comparable upon suture removal and 1-month postoperative (97.22 ± 5.75 vs. 96.47 ± 7.86; $p = 0.74$).

Aesthetic appearance

Aesthetic result was only judged by the oral surgeons/dentists in patients with an implant placement. Aesthetic assessment was obtained for all implant patients in the German centre ($N = 40$), whereas only 2 patients were evaluated in the Spanish centre, in total 42/57 (74 %) implant patients. An excellent aesthetic appearance was reported by oral surgeons at 1 and 5 months after surgery for these patients [mean 96.19 ± 3.79; [min. 80 – max. 100] (Table 4).

Bacterial contamination of the thread

Bacterial assessment of the removed threads was only performed in the Spanish clinic. Sutures were removed after a mean duration of 8.16 ± 3.04 days postoperatively in the Spanish clinic and all removed threads were analysed for bacterial colonization. In 36/45 patients (80.0 %), bacterial contamination was found on the threads removed after oral mucosal closure. Bacterial colonization was seen on threads extracted from impacted teeth patients as well as from implant patients. The identified types of bacteria belong to the prevalent bacterial species present in healthy people's oral cavity. *Fusobacterium nucleatum, Capnocytophaga* and *Eikenella corrodens* were the most predominate detected bacteria and found in 35, 30 and 25 patients, respectively. *Peptostreptococcus* could be found in 6 cases, *Prevotella intermedia* in 5 cases, *Campylobacter rectus* in 4 cases, and *Prophyromonas gingivalis, Tannerella forsythia* and *Treponema denticola* were observed in 3 patients each. *Eubacterium nodotum* and *Aggregatibacter actinomycetemcomitans* were not attached to any of the removed sutures. Depending on the microbiological analysis, 20/36 patients (55.5 %) received a 7-day antibiotic treatment.

Subgroup analysis

Using multiple linear regression models for continuous outcomes, different variables were analysed including age, type of surgery, BMI, smoking status, USP size of the thread, centre, and gender. The analysis showed that age was an influencer regarding duration of pain upon suture removal ($p = 0.0255$); the older the patient, the shorter was the duration of pain. The pain level upon suture removal was mainly affected by the type of indication such as impacted third molar extraction ($p = 0.0007$). Finally, the USP size could be identified as a factor affecting patient's satisfaction upon suture removal ($p = 0.0004$). Regardless of the performed oral intervention, a better patient satisfaction was seen when USP 4/0 was used for oral mucosal closure.

Smoking could be identified as a potential risk factor in tooth extraction patients. Smokers of this population had pain for a longer period combined with higher pain levels. In addition, regarding the wound healing assessment, lower rating levels by dentists were seen for smokers compared to non-smokers (rating level: 80.00 vs. 90.50, respectively), and non-smoker satisfaction was higher compared to that of smokers (rating level: 92.19 vs. 80.00, respectively). No influence of the smoking status on the secondary outcome parameter was found in

Table 4
Secondary outcome parameter of the study.

Parameter	Number of patients	Min	Max	Mean	SD
Days to suture removal	105	6.00	14.00	7.56	2.09
Pain (VAS)	105	0.00	95.00	20.98	22.60
Duration of pain (days)	105	0.00	6.00	1.61	1.42
Wound healing assessment by the dentist at suture removal (Likert scale (1–100))	105	65.00	100.00	88.95	7.26
Wound healing assessment by the dentist 5 months postop (Likert scale (1–100))	42	80.00	100.00	96.79	3.95
Aesthetic assessment by the dentist 5 months postop (Likert scale (1–100))	42	80.00	100.00	96.19	3.79
Patient satisfaction at suture removal (Likert scale (1–100))	105	60.00	100.00	92.75	8.57
Patient satisfaction postoperatively (Likert scale (1–100))	56	70.00	100.00	98.13	4.82

Max.: maximum, Min.: minimum, postop.: post-operatively, SD: standard deviation, VAS: visual analogue scale.

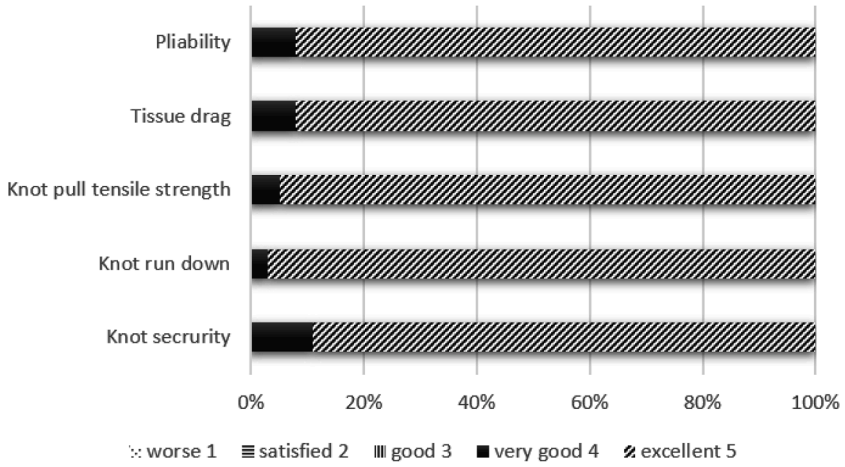

Fig. 2. Intra-operative handling assessment of nylon suture for oral surgery.

patients with a third molar extraction or an implant placement.

4. Discussion

The current study is a post-market surveillance study evaluating the safety and effectiveness of a non-absorbable monofilament polyamide-based suture material applied in various oral surgical interventions for the oral mucosa closure. A typical population was treated in daily clinical routine in two European countries. Clinics in Germany and Spain were chosen because they used this kind of suture on a routine basis.

Askar and colleagues were the first to analyse the postoperative complication rate after various oral surgical interventions in 2019. In addition, they grouped the postoperative complications depending on their severity into different Grades ranging from Grade I to Grade V. Their retrospective analysis enrolled a population undergoing mandibular and maxillary impacted tooth extraction as well as implant surgeries, in addition to these kind of interventions, more complicated ones such as trans-crestal sinus lift, guided bone regeneration, guided tissue regeneration, open flap debridement, osseous surgery, connective tissue grafts, free gingival grafts, gingivectomy, and crown lengthening were included as well as. Their study population consisted of a total of 3900 patients equally distributed into 13 intervention groups, 300 cases per group.

As mentioned above our aim was to investigate the clinical outcome of a polyamide-based suture material in oral surgery and we have chosen tooth extraction, impacted third molar extractions as well as implant surgeries as indications to be included. More complex surgeries were omitted in our study. Our main interest was the postoperative complication rate occurring until suture removal which was done approximately 7–14 days after surgery. Therefore, we used the complication rates of the Askar study reported for Grade I (11.1 %) and Grade II (3.3 %) in the total population, and for comparison of our safety outcome, we combined both Grades leading to 14.4 % in total. We made this decision even though other types of oral surgeries, which were not performed in our study, were also covered by this rate. The reason was that it was a more conservative approach as taking only the rates of Grade I and Grade II reported in the Askar study for impacted mandibular third molar extractions (22.6 % Grade I and 3 % for Grade II), impacted maxillary third molar extractions (13.3 % Grade I and 4 % for Grade II), and implant surgeries (6.7 %% Grade I and 2 % Grade II), which would lead to a much higher combined complication rate. Furthermore, according to Askar et al., the highest rate of Grade I was observed after mandibular and maxillary impaction, as shown in Fig. 2 of their publication.

The population enrolled in our study was comparable regarding demographic data with the cohort of the retrospective study published by Askar et al.; gender (51.4 % females and 48.6 % males vs. 51.3 % females and 48.7 % males), age 55.6 ± 18.84 years (range 18–89 years] vs. 54.8 ± 16.0 [range 17–91 years] and smoking status 9.5 vs. 9.4 %, respectively.

In the Askar study, surgery distribution by anatomic location showed that 65.2 % was in the maxilla and 34.8 % in the mandible, whereas in our study most of the treated teeth were mandibular (55.5 %) vs. 44.5 % maxillary. In total, 69.9 % of patients in the Askar study received antibiotics, a higher percentage compared to our group (55.5 %) [9].

Incidence and severity of postoperative complications are key elements in determining the risk-benefit ratio of any surgical procedure. In our study, we observed a combined complication rate (Grade I and Grade II) of 1.9 %. We found only a swelling in two patients (1.9 %) whereas the other complication types could not be observed. Our results indicated a lower combined complication rate compared to the one Askar et al. used for comparison (14.4 %). Furthermore, a comparison of the individual complication rate for swelling showed 3.4 % in the Askar study and 1.9 % in ours. The surgical removal of impacted teeth had the highest incidence and severity of complications according to Askar et al. The individual incidence of Grade I was 23.3 % for mandibular impacted teeth removal and 13.3 % for maxillary impacted teeth removal which was obviously much higher compared to our rate (1.9 %). We found one swelling in a patient with a third molar extraction and the other in a patient with an implant placement [9].

Regarding implant placement, 9 % of the implant patients developed a complication and moderate bleeding was the most frequent event (3.7 %) according to Askar et al. [9]. Our study included 54 % of patients receiving an implant placement but no bleeding was seen. Only one patient (1/57, 1.75 %) showed a mild swelling which resolved 4 days after surgery with no sequelae. This swelling rate agreed with the Askar study, which found a swelling rate of 1.7 % in the implant group.

According to Askar et al., the Grade I, Grade II and Grade III complication rate was higher in patients with impacted mandibular third molar extraction compared to impacted maxillary third molar extraction. In total, 22.6 % of patients with a mandible third molar extraction had a Grade I complication compared to 13.3 % of patients with maxillary third molar extraction [9]. In contrast, a lower occurrence rate of a Grade I complication was observed in our study because only one patient with an impacted mandible third molar extraction showed a Grade I complication (swelling total impacted third molar extraction 1/30, 3.33 %, regarding mandible location 1/24, 4.16 % versus an 11 % swelling for mandibular location in the Askar trial). No causal relationship with the applied suture material was mentioned. Both events were recorded as an expected common event in clinical routine for these kinds of dental surgeries.

Askar and colleagues also identify age as a risk factor for prolonged,

exaggerated swelling in patients with impacted mandible third molar extractions, whereas age significantly reduces the likelihood of excessive pain in patients with impacted maxilla third molar extractions [9]. In our study, we could show that age influenced pain duration, whereas pain level was mainly affected by the type of surgery, meaning that the highest pain levels were seen in patients with impacted third molar extractions ($p = 0.0007$). This finding agrees with the literature because excessive pain was mostly reported due to extracting impacted mandibular (12.3 %) and maxillary (5.3 %) molars.

Since no diabetic patients were included in our study, no association can be made regarding this risk factor. Smoking had a significant influence in our study regarding pain level and pain duration in patients with tooth extractions. Furthermore, smoking had a negative effect on patient satisfaction and wound healing assessment done by the dentists in tooth extraction patients.

The bacterial contamination assessment of the removed suture was only performed in the Spanish centre. The use of a synthetic monofilament suture gave us the opportunity to reduce the amount of bacterial adhesion compared to multifilament sutures according to the literature. The bacterial analysis of the removed sutures performed in the Spanish clinic showed that the anaerobic gram-negative pathogens (*Fusobactrum nucleatum, Eikenella corrodens* and *Capnocytophaga* species) were the most common bacterial species that contaminated the suture. On the contrary, a study conducted by Mahesh et al. observed fewer anaerobic bacteria among all different types of suture material used in their study [17]. Nadafpour et al. investigated the bacterial contamination of, nylon, PGA, and silk sutures, whereby PGA demonstrated the highest value of accumulation of gram-positive aerobic and anaerobic bacteria. Comparing these results to ours, we found the correlation of anaerobic but disagreed with the gram-negative bacteria [18].

Asher et al. evaluated the accumulation of aerobic and anaerobic bacteria on silk, Triclosan coated PGA, nylon, and polyester sutures in 50 patients who had undergone different types of oral surgical procedures such as implant surgery and flap surgery. All four types of sutures were applied in the oral cavity of all patients. The results showed equal accumulation of bacteria on triclosan coated PGA, silk and polyester sutures; however, the nylon suture showed significantly lower accumulation of aerobic and anaerobic bacteria [19]. This study had results like ours. Regarding the removed nylon suture material investigated, we could also find some anaerobic bacteria such as *Fusobacterium nucleatum*, which was the most observed bacteria on the removed suture material, followed by *Capnocytophaga* and *Eikenella corrodens. Campylobacter rectus* was found on 4 removed sutures, *Peptostreptococcus* was detected on 6 removed sutures, *Prevotella intermedia* was observed on 5 removed sutures, *Porphyromonas gingivalis, Tannerella forsythia* and *Treponema denticola* contaminated 3 removed sutures. On the other hand, *Eubacterium nodatum* and *Aggregatibacter actinomycetemcomitans* were not attached to any of the removed sutures. In our study, we could observe that 20 % of patients showed the presence of at least one pathogen of the red complex. Moreover, 90 % of patients showed the presence of at least one pathogen of the 11 individuals analysed.

Also, Sala Perez et al. showed a significantly lower accumulation of aerobic and anaerobic bacteria on triclosan coated poliglecaprone suture compared with the silk sutures on day 3 after implantation; however, this difference was no longer significant on day 7. Thus, it was concluded that the antibacterial properties of triclosan lasted for up to 3 days postoperatively and decreased significantly thereafter [20].

Faris and colleagues obtained a similar result with nylon. The aim of their systematic review was to evaluate the most heavily used suture materials with regards to their inflammatory response, their bacterial adhesion, and their physical properties when used to close oral wounds. The study showed that almost all suture materials (catgut, PGA sutures, nylon, expanded polytetrafluoroethylene, and silk sutures) caused bacterial adherence and tissue reaction. In nylon and chromic catgut, the number of bacteria accumulated was lowest. Also, they mentioned that silk and nylon were found to be more impacted than catgut and PGA in terms of physical characteristics such as tensile strength. They summarized that all sutures revealed varied degrees of irritation and microbial accumulation. Due to the greater surface area of multifilament sutures to which microorganisms can adhere, a higher bacteria contamination can be observed compared to monofilament sutures. Non-resorbable monofilament synthetic sutures such as nylon, however, exhibited less tissue response and less microbial accumulation and should therefore be the first choice [21].

Dragovic et al. found significantly lower quantity of microorganisms on monofilament sutures compared to multifilament ones, with the least bacterial amount observed on polypropylene suture material. They analysed a total of 4 different suture materials (non-absorbable multifilament, non-absorbable monofilament, absorbable multifilament, and absorbable monofilament) applied in oral surgery regarding biocompatibility, bacterial colonization, inflammatory reaction, and influence on wound healing. Their findings agreed with studies showing a lower microbial amount on nylon and PTFE sutures compared to silk. The authors conclude that, whenever possible, monofilament synthetic sutures should be used to obtain the best soft tissue healing and to reduce the risk of postoperative infection [22].

Also, Bucci and colleagues performed a microbiological analysis of bacterial plaque on three different threads removed 7 days postoperative after third molar extraction. In total, 30 patients were equally distributed to randomly receive either a silk based non-absorbable, multifilament, or a non-absorbable polyamide-based monofilament or an absorbable multifilament PGA suture material to close the wound. A significantly lower number of bacteria was found on polyamide sutures compared to silk sutures. In addition, the polyamide suture was less retentive than PGA, but the result was not significant. The authors stated that the use of monofilament polyamide surgical threads can help to reduce bacterial colonization and therefore promote faster and better healing [1].

In sum, several researchers demonstrated that nylon/polyamide is better to use than silk when minimization of the plaque retention is needed, even if different technical characteristics can make the use more difficult in some cases [1].

The ideal suture material should have the following properties: good handling, low memory effect, good sliding, high knot stability, absence of capillary and wicking effect, good traction resistance, low tissue trauma, inert behaviour, and less bacterial colonization [1]. Silk sutures elicit a mild tissue reaction and deliver good traction resistance and knot stability. Nylon threads are described as having good traction resistance and their elasticity lends them excellent handling even with thinner USP sizes, thus leading to minimal tissue reaction. PGA suture materials have excellent knot resistance and fluidity, high traction resistance, good handling and are described as leading to no tissue reaction [1]. Abellan et al. compared the mechanical properties of 5 different suture materials on various knot configurations. They analysed the failure load, elongation knot slippage and breakage. The following types were tested: silk, polyamide, PGA, glycolide-e-caprolactone copolymer (GCC), and PTFE. The authors found that PGA followed by the (GCC) had the most knot failure load, whilst PTFE showed the lowest [23]. In another study, Kim and colleagues assessed different surgical threads regarding the following characteristics: maximal tensile load, elongation rate, stiffness and energy absorbed before breakage. It was found that in non-absorbable sutures, the type of suture material significantly influenced tensile properties. Knot security was mainly influenced by the type of non-absorbable suture, and synthetic monofilament materials showed a tendency to be easily untied [24]. The clinical usefulness of a suture material is mainly defined by its intraoperative handling from the surgeon's perspective. Dragovic et al. found minimal tissue drag and ease during knot tying for a non-absorbable monofilament, which was better compared to the other tested suture materials. Furthermore, it was mentioned by Dragovic et al. that tensile strength loss is the second most important factor that influences the clinical convenience of the suture thread. In their study, multifilament sutures showed significantly

greater postoperative slacking, whereby the slacking effect was highest for silk suture and lowest for polypropylene suture. Another important factor is the postoperative ease of suture removal from the tissue. Multifilament silk sutures were the most difficult to remove, whereas the monofilament sutures were the easiest. The force needed to remove a polypropylene suture from the tissue was 50 % lower compared to silk sutures and about one third lower compared to a nylon suture. In addition, during removal of the suture material, the authors detected significantly greater pain in the multifilament patient group compared to the monofilament counterparts. Furthermore, the monofilament absorbable suture was the most acceptable one from the patient́s point of view, because it leads to less discomfort compared to the other used sutures [22].

The handling characteristics (knot security, tensile strength, knot run down, etc.) of our nylon-based suture material were rated as very good to excellent by the oral surgeons/dentists in all categories. The dentists judged the aesthetic appearance of the implant patients as excellent combined with high patient satisfaction regardless of the oral surgical intervention type that was performed. In addition, overall wound healing assessment by the oral surgeons/dentists yielded a very good rating. Average pain level was low in the present cohort and the mean duration of pain was 2 days with small differences depending on the type of dental intervention. Additionally other variables can have a significant influence on wound healing such as Ozone, photo-biomodulation and probiotics [25–27]. Therefore, future studies are needed to test these adjunctive treatments in combination with different suture materials to test their mutual effects.

The limitations of our study are the absence of a parallel control group, a retrospective comparison, the lack of clinical studies and a limited number of different oral intervention types. Despite the advantages of nylon sutures in decreasing the accumulation of microorganisms, studies on nylon sutures are limited. Thus, further studies are warranted in this respect. Also, future studies should focus on nylon sutures and daily use of chlorhexidine on the accumulation of oral microorganisms, especially of anaerobic bacteria and peri-pathogenic microorganisms.

5. Conclusion

The present study was a single-arm, prospective, observational study conducted in Germany and Spain involving patients treated under daily clinical practice using nylon sutures for oral mucosal closure after various dental surgical interventions. Intraoperative handling of the suture material appearance was excellent. The application of the nylon suture material led to a low postoperative complication rate combined with high patient satisfaction, an outstanding wound healing assessment by the oral surgeon and a low retention of microbiota. Our findings indicate that a nylon/polyamide-based suture material is safe and optimal for different dental surgeries to close the mucosa.

CRediT authorship contribution statement

S. García-González: Writing – original draft. **S. Aboul-Hosn Centenero:** Conceptualization, Writing – review & editing. **P. Baumann:** Conceptualization, Methodology, Project administration, Formal analysis, Writing – original draft, Writing – review & editing, Validation. **I. Fita-Esteban:** Writing – original draft. **F. Hernández-Alfaro:** Writing – review & editing. **N. Weyer:** Conceptualization, Investigation, Writing – review & editing.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests.

PB is employed by Aesculap AG. IFE is employed by B. Braun Surgical, S.A.U. The other authors declare no conflicts of interest.

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