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Research paper



Real-World Evaluation of Dual-Axis Barbed PDO Knotless Sutures in Elective Soft Tissue Closure: A Multicenter Observational Study

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Abstract

Background: The knotless barbed sutures are designed to overcome the problems of traditional knotted sutures through their ability to prevent knot slippage and maintain uniform tension. The absorbable polydioxanone knotless suture PINION™ PDO with dual-axis barbs provides both secure and efficient wound closure.
Aim: The study design aims to assess the clinical performance and safety aspects of PINION™ PDO sutures during soft tissue approximation
Methodology: The retrospective, multicenter observational research included 114 patients who maintained complete follow-up data throughout 12 months. The study documented demographic details along with wound characteristics, suture usage, closure time, and complications at three different time points: discharge, 2 months, and 12 months.
Results: Most procedures were elective (91.23%), primarily involving the abdominal and groin regions. The average time required for wound closure was 7.77 ± 2.13 minutes. The postoperative complications remained low throughout the study period, with 8.77% at discharge, 1.75% at 2 months, and no complications at 12 months. Surgical site infections, together with serious adverse events, did not occur throughout the study.
Conclusion: The results showed that PINION™ PDO knotless sutures provided high safety levels, easy handling, and efficient procedural performance. The study findings demonstrate that this material may function as a suitable replacement for traditional sutures in typical surgical procedures.

Keywords: *Barbed Sutures; Knotless Sutures; Polydioxanone; Surgical Wound Closure; Tissue Approximation.*

1. Introduction

Surgical sutures play a pivotal role in wound closure and tissue approximation across different surgical domains. Over the past few years, the development of absorbable synthetic sutures has remarkably enhanced the postoperative outcomes by lessening the necessity of suture removal, reducing the foreign body reactions, and improving patient comfort [1] [2]. Polydioxanone (PDO) monofilament sutures have shown promising outcomes and have been extensively utilized in surgical field due to their greater tensile strength retention and steady absorption profile [3]. However, conventional knotted sutures, including those made of PDO, are associated with several notable drawbacks such as knot slippage, increased foreign body mass at the wound site, prolonged operative time, and uneven tension distribution [4].
To overcome these limitations, the knotless suture technologies were developed, which eliminate the need for knot. Thereby, reducing the operative time, minimize foreign contamination, enhance tension uniformity, and potentially lower the risk of bacterial colonization often associated with knot sites [4] [5]. With the advanced mechanisms, such as barbed or self-anchoring in these sutures, the requirement for knot tying is removed, which results in shorter closure times and better load distribution and potentially better cosmetic and functional outcomes [4] [6].

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Dual-axis barbed sutures have been designed to enhance tissue engagement through their two opposing vector anchoring system which provides stability without needing knots [7] [8]. The suture design enables even tension distribution between wound edges which prevents tissue gapping and cut-through [7] [8]. The PDO monofilament maintains its tensile strength during the first healing phase and undergo hydrolysis, which extends wound support without leaving permanent foreign substances [3] [9]. Together with these mechanical and material properties, the dual-axis PDO barbed sutures achieve secure wound approximation which need minimal surgical handling. The PINION™ PDO knotless suture combines this advantage with biocompatibility feature.

Early preclinical and clinical studies indicated that knotless sutures may use less the operative time and streamline the surgical procedure without compromising wound integrity; however, real-world data across diverse surgical areas and patient populations remains limited [10] [11]. To address this evidence gap, this multicentre retrospective observational study evaluates the real-world safety and clinical performance of PINION™ PDO knotless sutures.

2. Methodology

2.1. Study design

The present study was a retrospective, multicenter, observational analysis involving the review of pre-existing patient records from three tertiary care hospitals. Medical records of 114 adult patients who underwent soft tissue approximation using the PINION™ PDO Knotless Suture between April 2022 and May 2024. The study included all adult patients who received the study device and had complete documentation and a minimum of 12-month follow-up. The patients were excluded if they had incomplete medical data, known hypersensitivity to polydioxanone, or active infection at the surgical site during the procedure. No interventions were made as part of this study, and all data were obtained from standard medical records. All data related to the study were collected retrospectively using a pre-designed form, which included baseline demographics, procedural details, wound characteristics, postoperative events, and follow-up outcomes (Figure 1).

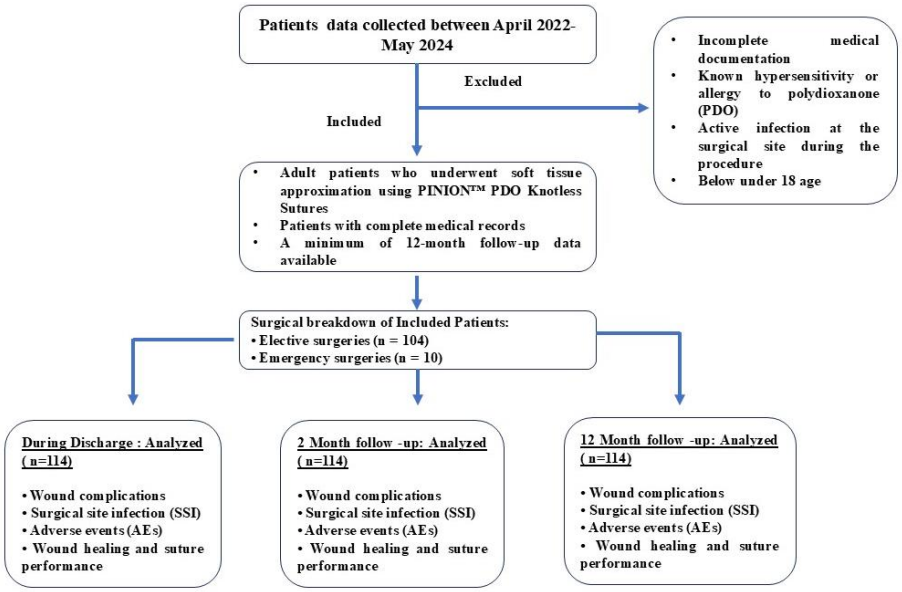


Fig. 1: Flowchart Illustrating the Retrospective Study Design and Patient Follow-Up Pathway for Evaluating PINION™ PDO Knotless Sutures.

2.2. Study endpoints

The primary endpoint of the study measured the total number of complications that occurred during the first two months after procedure completion. This included the assessment of infection, erythema, wound separation, necrosis, seroma, hematoma, and delayed wound healing following PINION™ PDO Knotless Suture use. The secondary endpoints of the study were the total time needed to close the wound during surgery and the number of adverse events related to sutures throughout the 12-month follow-up period. The postoperative complications evaluated were cellulitis, marked tenderness, erythema, wound separation, full fascial dehiscence, necrosis, seroma, hematoma, and delayed wound healing.

2.3. Device description

The PINION™ PDO Knotless Suture consists of sterile, synthetic, absorbable monofilament poly(p-dioxanone) material, which functions for knotless soft tissue approximation. The sutures contain dual-axis cut cog-shaped barbs, which are spaced 13–17 per centimeter for secure tissue anchorage without needing surgical knots. The sutures used in this study are of a bidirectional barbed design, featuring surgical needles mounted at both ends, with barbs oriented in opposite directions from the midpoint of the strand. This configuration enables efficient closure by allowing symmetrical tissue approximation from the centre outward, ensuring uniform tension distribution across the wound edges (Figure 2).

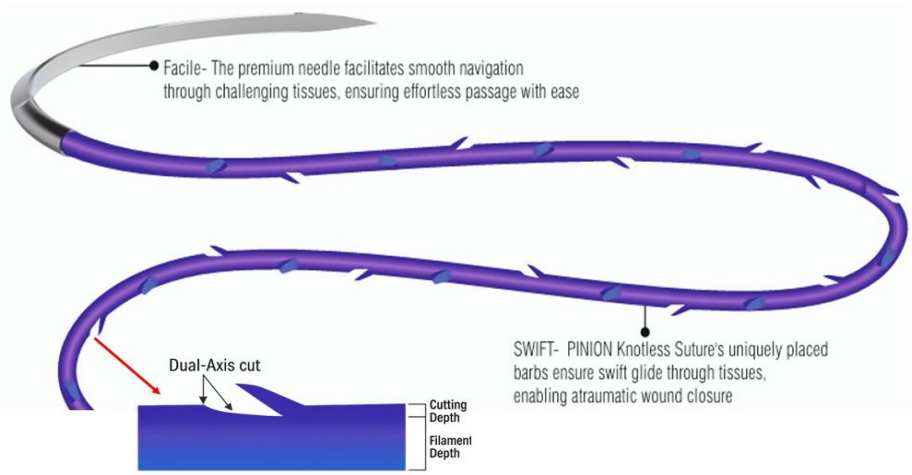


Fig. 2: A Visual Representative Image of the Structure of PINION^{TM} PDO Knotless Suture Showing Dual-Axis Barbs for Secure, Knotless Closure and A Facile Needle for Smooth Tissue Passage. (Figure Adopted and Modified from Original Company Image, Meril Life Sciences Pvt. Ltd., India).

The knotless nature of the suture reduces the overall suture bulk and may help decrease the risk of surgical site infections (SSIs) by eliminating knots, which are known to serve as potential sites for bacterial colonization. The sutures come in five different length options, including 15 cm, 30 cm, 45 cm, 60 cm, and specialised 30×30 cm double-armed variants. They are available in USP sizes 1-0 to 2-0,3-0, and 4-0. The sutures come with ½ circle round bodies, reverse cutting and taper point needles that have dimensions ranging between 17 mm and 37 mm. The sutures are sterilized using ethylene oxide and are intended for single-use in procedures requiring reliable, absorbable, knotless closure.

2.4. Statistical analysis

The data analysis was performed using Microsoft Excel and IBM SPSS Statistics version 27.0. Patient demographics and clinical parameters are presented using descriptive statistics. Continuous variables were assessed for distribution using the Kolmogorov–Smirnov test and are expressed as mean ± standard deviation (SD). Categorical variables are summarized as frequencies and percentages. The analysis was primarily descriptive, reflecting real-world clinical patterns without inferential or comparative statistical testing.

2.5. Ethics declarations

Ethical approval and consent to participate. The research followed the Declaration of Helsinki and the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH) - Good Clinical Practice (GCP) and ISO 14155:2020 GCP standards. The Institutional Ethics Committee approved the study before carrying it out (IEC approval letter; IEC/AUG/2024). Due to the study's observational and retrospective design, which required no direct patient treatment modifications, the ethics committee granted an exemption from obtaining informed consent.

3. Results

A total of 114 patients were enrolled across three tertiary care centres. All patients underwent soft tissue approximation procedures using the PINION^{TM} PDO Knotless Suture and completed follow-up assessments up to 12 months.

3.1. Demographics and baseline characteristics

The research included 114 participants, with a mean age of 53.06 ± 11.83 years. The cohort consists primarily of 80 male patients (70.18%). The study population included 35 patients with hypertension (30.79%), 25 patients with hernia disorder (21.93%), 18 patients with diabetes (18.42%), and other illnesses (14.91%). The study revealed one patient (0.88%) with a bleeding disorder and two patients (1.75%) with documented hypersensitivity (Table 1).

Table 1: Demographic and Clinical Characteristics of the Study Population

Category	Subcategory	n (%)
Gender, n=114		
	Male	80 (70.18)
	Female	34 (29.82)
Age, Mean ± SD		53.06±11.83
Age Bifurcation, n=114		
	25-39	15 (13.16)
	40-54	42 (36.84)
	55-69	45 (39.47)
	70-80	12 (10.53)
Medical History, n=114		
	Bleeding Disorder	01 (00.88)
	Hypertension	35 (30.70)
	Diabetes	21 (18.42)
	Anemia	00 (00.00)
	Hernia Disorder	25 (21.93)
	Hypersensitivity	02 (01.75)

	other illness	17 (14.91)
Social Habits		
	Smoking	09 (07.89)
	Alcohol	06 (05.26)

n (%) = number of patients (percentage).

3.2. Preoperative characteristics

The 114 patients presented with deep lacerations, as shown in Table 2. The most common type of wound was incisional wounds, which were 72.81%, followed by debridement, which were reported 9.65%, and infection-related wounds were 8.77%. The remaining wound types included irrigation-related, gangrenous, and decubitus-origin wounds. The skin edges were well defined in 72.81% of cases, while the remaining wounds had diffused margins.

Table 2: Patient Demographics, Wound Characteristics, Diagnoses, and Surgical Profiles Prior to and During PINION™ PDO Knotless Suture Procedures

Category	Subcategory	n (%)
Laceration Depth, n= 114		
	Superficial	0 (0)
	Deep	114 (100.00)
Wound Edge Type, n= 114		
	Diffused	31 (27.19)
	Well defined	83 (72.81)
Wound Type, n= 114		
	Incision	83 (72.81)
	Irrigate	04 (03.51)
	Debride	11 (09.65)
	Infection	10 (08.77)
	Gangrene	03 (02.63)
	Decubitus Aetiology	03 (02.63)
Diagnosis, n= 114		
	Bilateral Inguinal Hernia	31 (27.19)
	Right Inguinal Hernia	06 (05.26)
	Left Inguinal Hernia	11 (09.65)
	Umbilical Hernia	13 (11.40)
	Supraumbilical Hernia	17 (14.91)
	Epigastric Hernia	01 (00.88)
	Ventral Hernia	05 (04.39)
	Adenomyotic Uterus	03 (02.63)
	Calculus Cholecystitis	01 (00.88)
	Uterine Fibroid	02 (01.75)
	Symptomatic Fibroid Uterus	01 (00.88)
	Severe Arthritis	01 (00.88)
	Swelling and Pain in Abdomen	22 (19.30)
Number of Wounds Treated per Patient, n= 114		
	1	75 (65.79)
	2	36 (31.58)
	3	03 (02.63)
Type of Surgical Procedure, n= 114		
	Elective	104 (91.23)
	Emergency	10 (08.77)
Wound Location (Wound 1), n= 114		
	Abdomen	34 (29.82)
	Umbilical Region	14 (12.28)
	Inguinal Region	22 (19.30)
	Other	52 (45.61)
Incision Length, n= 114		
	Wound 1 (n=114)	6–43 cm
	Wound 2 (n=39)	12–42 cm
	Wound 3 (n=3)	12–42 cm

cm = Centimeter.

The most common underlying diagnosis were bilateral inguinal hernia (27.19%), followed by supraumbilical hernia (14.91%), and umbilical hernia (11.40%). A limited case of ventral and epigastric hernias, adenomyotic uterus, and abdominal swelling was also reported. Most patients had a single wound (65.79%), and most procedures were elective (91.23%). The most common wound locations were found in the abdomen (29.82%), groin (19.30%) and umbilical region (12.28%). The most common incision length was 42 cm and the shortest was 6 cm.

3.3. Intraoperative characteristics

Supplementary table 3 illustrates that deep sutures were used in 55.32% of cases, followed by continuous suturing, which was used in 41.84% of cases. All patients received the PINION™ PDO Knotless Suture. The majority of patients needed either one (63.16%) or two (32.46%) sutures, while other patients needed additional sutures. The mean wound closure time was 7.77 ± 2.13 minutes, which demonstrates that the procedure was efficient and easy to perform regardless of the anatomical location.

Table 3: Intraoperative Characteristics, Including Suturing Techniques, Suture Usage, and Wound Closure Time

Category	Subcategory	n (%)
Suturing Technique, n= 114		
	Interrupted	02 (01.42)
	Continuous	59 (41.84)
	Deep	78 (55.32)
	Subcutaneous	02 (01.42)
Number of PINION™ PDO Sutures Used, n= 114		
	1	72 (63.16)
	2	37 (32.46)
	3	03 (02.63)
	4	02 (01.75)
Average Wound Closure Time, Mean ± SD (minutes)		7.77 ± 2.13

4. Application of PINION™ PDO Sutures in Diverse Surgical Settings

Figure 3A–C depicts the intraoperative application of PINION™ PDO Knotless Sutures across distinct surgical modalities. The suture demonstrated usefulness for tissue approximation in laparoscopic and minimally invasive procedures (Figure 3A–B) by providing consistent barb engagement without the requirement for knot tying. The suture showed both smooth handling and secure soft tissue layer closure in open surgery (Figure 3C), which strengthens its ability to work well in different operative settings.

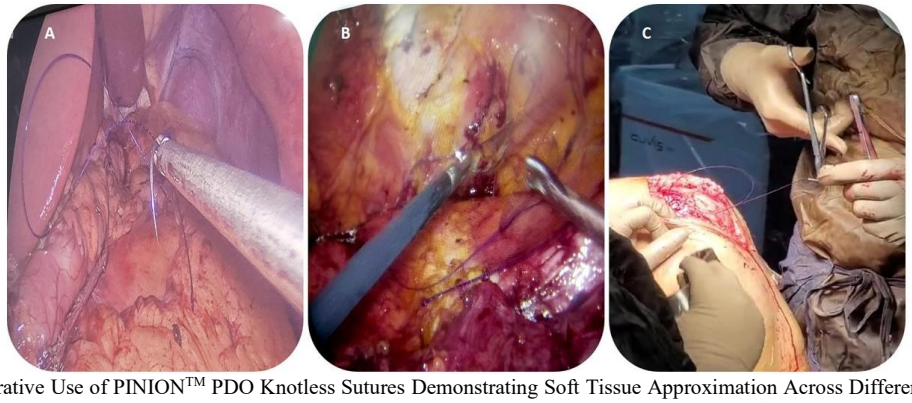


Fig. 3: (A–C). Intraoperative Use of PINION™ PDO Knotless Sutures Demonstrating Soft Tissue Approximation Across Different Surgical Approaches. (A) Laparoscopic Tissue Closure with Visible Barbed Suture Engagement. (B) Fascial Closure During Minimally Invasive Surgery. (C) Open Procedure Showing Knotless Suturing Technique in Soft Tissue Layers.

5. Clinical Outcomes and Safety

No cases of wound infection, edema, or hematoma were reported throughout the 12-month follow-up. At the time of discharge, 3 patients (2.63%) experienced serosanguineous discharge, 1 patient (0.88%) had erythema. Swelling, itching, and redness near the wound site were each reported in 4 patients (3.51%); notably, all three symptoms co-occurred in the same subset of patients. Cellulitis was noted in 2 patients (1.75%) (Table 4). At the 2-month follow-up, 1 patient (0.88%) developed seroma and another patient (0.88%) reported haemorrhage. Importantly, no patients experienced adverse events at the 12-month assessment. Throughout the study period, there were no serious adverse events reported.

Table 4: Postoperative Adverse Events Observed at Discharge, 2-Month, and 12-Month Follow-Up

Events, n =114	During Discharge n (%)	2-month FU n (%)	12-month FU n (%)
Wound infection	0	0	0
Edema	0	0	0
Serosanguineous discharge	3 (2.63 %)	0	0
Erythema	1 (0.88%)	0	0
Hematoma	0	0	0
Seroma	0	1 (0.88%)	0
Hemorrhage	0	1 (0.88%)	0
Swelling	4* (3.51%)	0	0
Itching	4* (3.51%)	0	0
Redness near wound	4* (3.51%)	0	0
Cellulitis near wound region	2	0	0

*Same patient(s); FU: Follow up.

6. Discussion

The present research is a multicentre retrospective observational study that assessed the clinical performance and safety of the PINION™ PDO Knotless Suture when used in standard soft tissue approximation procedures. The study results showed minimal postoperative complications (8.77% at discharge, 1.75% at 2 months, and 0% at 12 months) and no adverse events or surgical site infections (SSIs) reported. Barred sutures have steadily demonstrated a reduction in operative and wound closure times among various surgical disciplines, without compromising safety features. A meta-analysis study consisting of 2111 participants demonstrated that the use of barbed sutures led to a significant reduction in operation time, with an average difference of -12.04 minutes (95% CI: -16.94 to -7.14; $p < .001$) compared to conventional sutures [12]. In gynaecologic laparoscopic surgeries, the inclusion of barbed sutures has been related to enhanced efficiency.

A study by Greenberg and Einarsson has highlighted that barbed suture eases the tissue approximation without the need for knot tying, thereby reducing closure times and maintaining tissue integrity [14]. Similarly, in colorectal surgery, the use of barbed sutures for the abdominal wall has markedly reduced the colorectal closure time and reduced superficial surgical site infections (SSIs) [14]. Our study reported a mean wound closure time of 7.17 minutes, aligning with these findings and underscoring the efficiency of barbed sutures in standard surgical procedures. Furthermore, a systematic review and meta-analysis study by Li et al. reported a reduced closure time in total knee arthroplasty without increasing the incidence related to wound-related complications such as infection and dehiscence [15].This is further supported by a randomized controlled trial study carried out by Sundaram et al, which demonstrated a significant reduction in arthrotomy closure time (3 ± 2 min vs 13 ± 5 min; $p < 0.001$), when barbed sutures were used with no significant difference in post-operative complications rates [16]. Additionally, A randomized controlled trial by Lopez et al. found that barbed PDO sutures (V-Loc 90) provided comparable surgical outcomes to conventional sutures in laparoscopic hysterectomy, with no increase in complications, supporting their safe and efficient use for fascial closure [17]. It is plausible that elective surgeries, comprising 91.23% of cases in our cohort, contributed to the reduced complication rates observed in our study.

Although several studies have mentioned support the safety and efficiency of barbed sutures, however literatures have also highlighted the studies which reports the higher complication rates in certain surgical interventions. For example, Sarhan et al. (2024) in their study has mentioned elevated complication rates in spine surgery [4] and similar findings have been reported in unicompartmental knee arthroplasty and abdominal wall closure studies [18] [19]. The complication rates found in these studies were often allied with high-tension tissues closure planes, deeper soft-tissue dissection, and regions with lesser vascular supply. Reporting such findings in the studies suggest that barbed suture performance is highly reliant on the biomechanical and biological characteristics of the operative field.

In contrast, most of the surgical interventions in our cohort consists of elective abdominal and groin surgeries, which typically require low-tension closure planes and have well-perfused tissue beds. Prior studies have highlighted that barbed sutures perform more steadily in low-tension closures focused on uniform tissue approximation, rather than high-load environments [13]. Hence, the changes in surgical approach, tissue properties, and operative field biomechanics more likely to have contributed in lowering the complication rates observed in our study relative to findings from higher-risk surgical domains.

Device design characteristics may further contribute to the variation observed across published studies. The dual-axis barbs in PINION™ PDO distribute tension proportionally, which reduces the localized stress concentration. Biomechanical evaluations studies consist of comparison between bidirectional to unidirectional barbed configurations have revealed that dual-axis systems perform more uniform load sharing, which reduces the focal tissue trauma [20]. These mechanical design advantages may support improved wound stability and help explain the absence of wound separation in our cohort.

The research about barbed sutures shows that operator technique stands as the essential factor which determines successful results. Research on arthroplasty and spine surgery shows that poor suture technique through shallow tissue penetration, incorrect tension application and irregular tissue movement leads to wound complications including seroma and erythema [19]. While in our study the closures of wounds were carried out by surgeons who were familiar with barbed suture, which helped in mitigating the technique related complications and helped in achieving a favourable clinical outcome.

The material composition also plays a critical role. Polydioxanone (PDO), the core polymer in PINION, is known for its favourable biocompatibility, extended strength retention, and predictable hydrolytic degradation profile, retaining tensile strength for up to 6 weeks and fully absorbing within 180–210 days. These mechanical properties support durable wound closure, particularly in deep-layer approximation, which was employed in over half the cases (55.32%) in our cohort.

The absence of surgical site infections in our cohort demonstrates how suture materials and designs can impact postoperative results. The previous studies have confirmed that bacterial adherence and biofilm formation occur on suture surfaces, especially when knots are present, because they introduce more foreign material into the wound. The study by Ercan et al. showed that untreated suture surfaces allowed bacterial colonisation, which supports the significance of surface properties for infection prevention [21]. Similarly, the meta-analysis study by Depuydt et al. on abdominal surgeries demonstrated that triclosan-coated sutures produced better SSI prevention results than uncoated sutures, which confirms the impact of suture composition and antimicrobial design [18]. However, the benefits of barbed or knotless sutures are closely associated with proper material selection and surgical technique. Chawla et al. in their study reported increased SSI rates with barbed sutures in uni-compartmental knee arthroplasty, primarily associated with inappropriate application or material mismatch [19].

7. Limitations

The research study contains limitations which need to be acknowledged. Firstly, the study uses an observational non-comparative design which prevents researchers from making direct comparisons between different suturing techniques. Secondly, the research investigates elective procedures which do not represent the actual complication rates occur during emergency situations or when tissues experience high stress or contamination. Finally, the study's retrospective data collection approach through 12-month follow-up periods leads to selection and information bias as unreported confounding variables could affect the analysis of actual treatment results.

8. Strengths

The study shows notable strengths despite a limitations. The inclusion of various types of wounds and anatomical locations provides a detailed view of the device's versatility and performance. Importantly, the consistent absence of wound dehiscence, suture-related complications, and surgical site infections strongly supports the clinical safety and reliability of the PINION™ suture material. Furthermore, the real-world setting also increases the external validity and demonstrates typical clinical conditions under which the device may be used.

9. Conclusion

The results of this multicenter observational study suggest that PINION™ PDO Knotless Sutures could be a safe and effective option for soft tissue approximation across a range of surgical procedures. The device reported excellent wound integrity, low complication rates, and an absence of surgical site infections, findings that align with the proposed benefits of barbed, knotless suture designs. The current study's evidence supports the incorporation of PINION™ PDO into routine surgical practice might act as a reliable alternative to traditional suturing methods. Future prospective, randomized studies with larger cohorts and long-term follow-up are warranted to confirm and expand upon these findings.

Acknowledgements

None

Conflicts of Interest

KKS is employed at Meril Life Sciences, the manufacturer of the evaluated device, their role in this study was limited strictly to technical clarification regarding device characteristics and editorial support. KKS not been involved in patient management, study design, data collection, data access, statistical analysis, or outcome interpretation. All clinical data were obtained, verified, and analyzed independently by the participating investigators. All other authors declare no conflicts of interest.

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