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Post-Market Clinical Follow-up of Six Absorbable Surgical Sutures: A Prospective Multi-Center Observational Study

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Abstract

Introduction: Surgical sutures are critical for tissue approximation following surgery or injury. Absorbable sutures eliminate the need for post-operative removal and reduce patient burden. This paper reports primary clinical data from a prospective observational Post-Market Clinical Follow-up (PMCF) study examining the clinical performance and observed safety outcomes of six absorbable surgical suture products.

Aims and Objectives: To evaluate the clinical performance, safety, and acceptability of six absorbable surgical sutures in routine elective surgical use; to assess user-reported handling quality, wound closure effectiveness (absence of wound reopening at Day 7), incidence of adverse events, and overall user satisfaction.

Materials and Methods: This prospective multi-center observational PMCF study was conducted across two surgical sites in India (January 2022 – October 2022) in accordance with MDR 2017/745 ANNEX XIV Part B, MDCG 2020-7, and ISO 14155:2020. Six absorbable suture products (n = 60 per product; total = 360) manufactured by Futura Surgicare Pvt Ltd and marketed under the Dolphin Sutures brand were evaluated. Of 360 enrolled subjects, 304 (84.2%) were per-protocol; 4 (1.1%) underwent dental procedures with sutures contraindicated in dental use (PDO, PGCL25 — true protocol deviations), and 52 (14.4%) underwent neurosurgical procedures with sutures contraindicated in neurological use (PGLA910, PGLA910 Fast, PDO Barbed — true protocol deviations). PGA, PGLA910, and PGLA910 Fast are approved for dental use; PGCL25 is approved for neurosurgical use; their subjects in these settings are per-protocol. Surgeon-reported ratings (eight attributes; 1–5 Likert scale) were analysed descriptively.

Results: Mean performance scores ranged from 4.00 (PGCL25; SD 0.279; 95% CI 3.937–3.988) to 4.93 (PDO Barbed; SD 0.255; 95% CI 4.904–4.957). All products rated "Good" or "Excellent". Packaging-removal difficulty was reported by 100% of PGA users and 50% of PGLA910 users, requiring CAPA action. No wound dehiscence or superficial infection was recorded. Four non-serious adverse events (transitory local irritation and delayed absorption) occurred exclusively in the 4 subjects who received

PDO or PGCL25 sutures during dental procedures (true protocol deviations); no AEs occurred in 304 per-protocol subjects.

Conclusion: This PMCF study supports acceptable clinical performance and user-reported safety of all six absorbable sutures within their per-protocol indications. No safety concerns were identified among 304 per-protocol subjects. Packaging usability requires corrective action for PGA and PGLA910. Only 56 of 360 subjects (15.8%) constituted true protocol deviations. Dental use of PDO and PGCL25, and neurosurgical use of PGLA910, PGLA910 Fast, and PDO Barbed, represent off-label deviations; findings from these subjects should not be used to support extended indications.

Keywords: Absorbable Sutures, Post-Market Clinical Follow-Up, Wound Healing, Clinical Safety

1. Introduction

In the evolving landscape of surgical interventions, absorbable sutures represent a significant advancement in wound management and patient care. These sutures, designed to be metabolized by the body, obviate the need for post-operative removal, reducing patient discomfort and complications associated with non-absorbable sutures [1, 2]. Their development has been guided by the need to maintain mechanical strength during critical wound-healing phases while minimizing tissue reactivity [3].

The advent of synthetic absorbable sutures has broadened their applicability across surgical specialties. Polyglycolic acid, polylactic acid, and polydioxanone sutures offer predictable absorption rates and tensile strength profiles tailored to specific tissue requirements [4]. Coatings and surface modifications have further improved handling characteristics and biocompatibility [5].

Regulatory requirements under MDR 2017/745 mandate ongoing Post-Market Clinical Follow-up (PMCF) for marketed medical devices. This prospective observational PMCF study was conducted to evaluate the clinical performance and observed safety outcomes of six specific absorbable suture products manufactured by Futura Surgicare Pvt Ltd across multiple surgical specialties. This manuscript reports primary prospective clinical data and is not a literature review. Primary endpoints included user-assessed handling performance, wound closure effectiveness, and adverse event recording.

2. Methodology

2.1 Study Design and Setting

This was a prospective multi-center observational PMCF study at two surgical sites in India (January 2022 – October 2022). Site 1: multi-specialty hospital with general, plastic, and vascular surgical capacity. Site 2: specialist centre with maxillofacial and dental surgical facilities. Study design complied with MDR 2017/745 ANNEX XIV Part B, MDCG 2020-7, and ISO 14155:2020. Reported per the STROBE statement for observational studies.

2.2 Investigational Products

Six products manufactured by Futura Surgicare Pvt Ltd (Bengaluru, Karnataka, India): Coated & Braided Polyglycolic Acid Suture (PGA) (Petcryl), Coated & Braided Polyglactin 910 Suture (PGLA910) (Petcryl 910), Coated & Braided Polyglactin 910 Fast Suture (PGLA910 Fast) (Petcryl 910 Fast), Monofilament, Polydioxanone Absorbable Surgical Suture (PDO) (Duracryl), Monofilament Poliglecaprone 25 Absorbable Surgical Suture (PGCL25) (Petcryl Mono), Monofilament Polydioxanone Surgical Barbed Suture (PDO Barbed) (Durabarb). Target: 60 subjects per product (n = 360 total).

2.3 Study Population and Eligibility Criteria

Adult subjects (≥18 years) undergoing elective procedures for which an absorbable suture was the indicated choice were eligible. Inclusion criteria:

- Written informed consent obtained prior to enrolment.
- Subject undergoing a procedure requiring soft tissue approximation or ligation with an absorbable suture as the clinically indicated choice.

Exclusion criteria:

- Subjects unable or unwilling to provide written informed consent.
- Subjects requiring extended tissue approximation under stress.
- Known sensitivities or allergies to suture material components.
- Suturing in paediatric patients, infected tissues, geriatric patients, lactating mothers, or pregnant women.
- Dental procedures using PDO, PGCL25, or PDO Barbed sutures (contraindicated in dental use per PMCF protocol).
- Neurosurgical procedures using PDO, PDO Barbed, PGLA910, or PGLA910 Fast sutures (contraindicated in neurological use per PMCF protocol).

Clarification of protocol scope: PGA, PGLA910, and PGLA910 Fast are approved for dental use under this protocol; subjects receiving these sutures in dental procedures are per-protocol. PGCL25 is approved for neurosurgical use; subjects receiving PGCL25 in neurosurgical procedures are per-protocol. Despite this, 4 subjects received PDO or PGCL25 in dental settings (true dental deviations), and 52 subjects received PGLA910, PGLA910 Fast, or PDO Barbed in neurosurgical settings (true neurosurgical deviations). These deviations are retained for regulatory transparency and reported separately.

2.4 Sample Size

A total of 360 subjects (60 per product) were enrolled on the basis of a descriptive design; no formal power calculation was required. This allocation was sufficient for reliable estimation of descriptive statistics. Post-market data (sales volume >10,000 units/year, low complaint rate) supported this sample size.

2.5 Endpoints and Predefined Success Criteria

Primary performance endpoint: User-assessed handling quality across eight attributes (pliability, tensile strength, knot security, needle penetration efficiency, sterility, suture visibility, ease of handling, knot placement) on a 1–5 Likert scale. Predefined success criterion: mean score ≥4.0 per product (corresponding to “Good” or better).

Primary safety endpoint: Wound closure effectiveness, defined as absence of wound reopening, re-rupturing, or superficial wound infection at Day 7 post-operative visit. Predefined safety success criterion: wound-complication-free rate ≥90% at Day 7 in per-protocol subjects. Secondary safety endpoints: wound dehiscence, superficial infection, transitory local irritation, and delayed absorption at long-term follow-up (4–8 months).

2.6 Data Collection and Rating Scale

Surgeons completed a standardized PMCF checklist post-procedure, rating attributes on a 5-point Likert scale (1 = Poor to 5 = Excellent). Mean scores were computed per product and categorized as Good (4.00–4.89) or Excellent (4.90–5.00). Descriptive statistics including SD, median, and 95% CI were computed to characterize variability (Table 5).

2.7 Protocol Deviation Classification

Following reconciliation of the enrolled dataset against the approved protocol, two categories of true pro-

tocol deviation were identified:

- True dental protocol deviations (n = 4): Subjects who received PDO (n = 2) or PGCL25 (n = 2) during dental procedures. These sutures are contraindicated for dental use per the PMCF protocol.
- True neurosurgical protocol deviations (n = 52): Subjects who received PGLA910 (n = 18), PGLA910 Fast (n = 13), or PDO Barbed (n = 21) during neurosurgical procedures. These sutures are contraindicated for neurosurgical use per the PMCF protocol.

Per-protocol subjects (n = 304): PGA — 60 (dental: per-protocol); PGLA910 — 42 (12 general + 30 dental: both per-protocol); PGLA910 Fast — 47 (15 general + 32 dental: both per-protocol); PDO — 58 (general: per-protocol); PGCL25 — 58 (17 general + 41 neurosurgery: both per-protocol); PDO Barbed — 39 (general: per-protocol). No formal sensitivity analysis was performed for the 56 deviation subjects; this is an acknowledged limitation.

2.8 Follow-Up Schedule

All 360 enrolled subjects completed Day 7 assessment. Long-term follow-up (4–8 months) was completed per the schedule for all product groups except PGA. Since all PGA subjects underwent dental procedures (per-protocol for PGA), long-term follow-up was not included in the study design for this group, as routine dental wound monitoring does not require extended post-operative review. Long-term FU completion: PGA — N/A; PGLA910 — 30; PGLA910 Fast — 30; PDO — 58; PGCL25 — 58; PDO Barbed — 60.

2.9 Statistical Analysis

Descriptive statistics were applied throughout. Mean and SD are reported for continuous Likert data; median and range are provided; 95% confidence intervals are presented. Frequencies and percentages are used for categorical variables. No inferential comparisons were performed. Analysis performed using Microsoft Excel 2021, Version 17.0.

2.10 Ethics and Registration

Ethics approval: ACE Independent Ethics Committee (DCGI Reg. No. ECR/141/Indt/KA/2013/RR-19; NABH Certificate No. EC-CT-2018-0029). CTRI registration: CTRI/2022/01/039498. Conducted per GCP guidelines. Written informed consent obtained from all participants prior to enrolment. Sponsor: Futura Surgicare Pvt Ltd (see Declarations).

3. Results

3.1 Enrolment and Protocol Deviation Summary

A total of 360 subjects were enrolled across six product groups (60 per group). Table 1 presents the per-protocol and true protocol deviation counts for each product. Of 360 enrolled subjects, 304 (84.4%) were per-protocol. True dental deviations totalled 4 subjects (1.1%): PDO — 2, PGCL25 — 2. True neurosurgical deviations totalled 52 subjects (14.4%): PGLA910 — 18, PGLA910 Fast — 13, PDO Barbed — 21. PGA subjects (n = 60) were all enrolled for dental procedures, which is a per-protocol application for this product. PGCL25 neurosurgical subjects (n = 41) are per-protocol as PGCL25 is approved for neurosurgical use under this protocol.

Table 1: Enrolment Summary — Per-Protocol and True Protocol Deviation Subjects by Suture Product

Suture Product (Abbreviation) (Brand Name)	Approved Procedure Categories	Per-Protocol, n	True Dental Deviation, n †	True Neuro Deviation, n ‡	Total Enrolled, n
Coated & Braided Polyglycolic Acid Suture (PGA) (Petcryl)	General Soft Tissue Approximation & Dental Surgery	60	0	0	60
Coated & Braided Polyglactin 910 Suture (PGLA910) (Petcryl 910)	General Surgery, Plastic Surgery & Dental Surgery	42	0	18	60
Coated & Braided Polyglactin 910 Fast Suture (PGLA910 Fast) (Petcryl 910 Fast)	General Surgery, Plastic Surgery & Dental Surgery	47	0	13	60
Monofilament Polydioxanone Absorbable Surgical Suture (PDO) (Duracryl)	General Surgery	58	2	0	60
Monofilament Poliglecaprone 25 Absorbable Surgical Suture (PGCL25) (Petcryl Mono)	General Surgery, Plastic Surgery, Vascular Surgery & Neurosurgery	58	2	0	60
Monofilament Polydioxanone Surgical Barbed Suture (PDO Barbed) (Durabarb)	General Surgery	39	0	21	60
TOTAL		**304(84.4%)**	**4 (1.1%)**	**52 (14.4%)**	**360 (100%)**

† True dental protocol deviations: Only PDO and PGCL25 are contraindicated for dental use. PGA, PGLA910, and PGLA910 Fast are approved for dental use and their dental subjects are per-protocol.
‡ True neurosurgical protocol deviations: PGLA910, PGLA910 Fast, PDO Barbed, and PDO are contraindicated for neurosurgical use. PGCL25 is approved for neurosurgical use and its 41 neurosurgical subjects are per-protocol. PDO had zero neurosurgical subjects.

3.2 Demographic Characteristics

Age distribution (Table 2) and gender distribution (Table 3) are presented across all enrolled subjects. The 21–40 and 41–60 age brackets were most prevalent across all groups. Gender distribution was broadly balanced.

Table 2: Age Distribution of All Enrolled Subjects by Suture Product

Suture *	Age 1–20, n (%)	Age 21–40, n (%)	Age 41–60, n (%)	Age 61–80, n (%)	Age 81–100, n (%)
PGA	3 (5%)	28 (47%)	13 (22%)	16 (26%)	0 (0%)
PGLA910	1 (2%)	9 (15%)	26 (43%)	24 (40%)	0 (0%)
PGLA910 Fast	5 (8%)	12 (20%)	29 (48%)	13 (22%)	1 (2%)
PDO	2 (3%)	4 (7%)	29 (48%)	21 (35%)	4 (7%)
PGCL25	3 (5%)	15 (25%)	15 (25%)	27 (45%)	0 (0%)
PDO Barbed	0 (0%)	17 (28%)	32 (53%)	9 (15%)	2 (3%)

* Abbreviations: PGA = Polyglycolic Acid; PGLA910 = Polyglactin 910; PGLA910 Fast = Polyglactin 910 Fast; PDO = Polydioxanone; PGCL25 = Poliglecaprone 25; PDO Barbed = Polydioxanone Surgical Barbed.

Table 3: Gender Distribution of All Enrolled Subjects by Suture Product

Suture Product (Abbreviation) (Brand Name)	Subjects, n	Male, n (%)	Female, n (%)
Coated & Braided Polyglycolic Acid Suture (PGA) (Petcryl)	60	28 (47%)	32 (53%)
Coated & Braided Polyglactin 910 Suture (PGLA910) (Petcryl 910)	60	31 (52%)	29 (48%)
Coated & Braided Polyglactin 910 Fast Suture (PGLA910 Fast) (Petcryl 910 Fast)	60	34 (57%)	26 (43%)
Monofilament Polydioxanone Absorbable Surgical Suture (PDO) (Duracryl)	60	33 (55%)	27 (45%)
Monofilament Poliglecaprone 25 Absorbable Surgical Suture (PGCL25) (Petcryl Mono)	60	28 (47%)	32 (53%)
Monofilament Polydioxanone Surgical Barbed Suture (PDO Barbed) (Durabarb)	60	37 (62%)	23 (38%)
Total (all groups)	**360**	**191 (53%)**	**169 (47%)**

All product groups included 60 subjects each (total N = 360). Data include per-protocol and deviation subjects combined.

3.3 Usability and Handling Performance

Packaging-removal difficulty was reported by 100% of PGA users (n = 60) and 50% of PGLA910 users (n = 30) (Table 4A). No crushing or crimping damage was quantified in this dataset. Overall performance ratings ranged from Good (PGA, PGLA910, PGLA910 Fast, PDO, PGCL25) to Excellent (PDO Barbed; mean 4.93). All products met the predefined performance success criterion of mean ≥4.0.

Table 4A: Usability Observations — Packaging Removal Difficulty by Suture Product

Suture *	Difficulty Removing from Pouch, n (%)
PGA	60 (100%) ♦
PGLA910	30 (50%) ♦
PGLA910 Fast	0 (0%)
PDO	0 (0%)
PGCL25	0 (0%)
PDO Barbed	0 (0%)

* Abbreviations: PGA = Polyglycolic Acid; PGLA910 = Polyglactin 910; PGLA910 Fast = Polyglactin 910 Fast; PDO = Polydioxanone; PGCL25 = Poliglecaprone 25; PDO Barbed = Polydioxanone Surgical Barbed.

♦ 100% packaging-removal difficulty for PGA and 50% for PGLA910 represents a systematic usability signal requiring CAPA action; see Section 4.4.

3.4 Clinical Safety Observations

Four adverse events were recorded in the study, all occurring in the 5 subjects who received PDO or PGCL25 sutures during dental procedures (true protocol deviations). No adverse events were recorded among any of the 304 per-protocol subjects, nor among the 52 neurosurgical deviation subjects (Table 4B).

Table 4B: Clinical Safety Observations by Suture Product

Suture *	Clinical Safety Observations	Severity / Outcome
PGA	None	None
PGLA910	None	None
PGLA910 Fast	None	None
PDO	Transitory local irritation; delayed absorption in 2 subjects (dental protocol deviation) †	Minor; non-serious; resolved without intervention
PGCL25	Transitory local irritation; delayed absorption in 2 subjects (dental protocol deviation) †	Minor; non-serious; resolved without intervention

PDO Barbed	None	None

* Abbreviations: PGA = Polyglycolic Acid; PGLA910 = Polyglactin 910; PGLA910 Fast = Polyglactin 910 Fast; PDO = Polydioxanone; PGCL25 = Poliglecaprone 25; PDO Barbed = Polydioxanone Surgical Barbed.

† All 4 AEs occurred exclusively in true dental protocol-deviation subjects (PDO: n=2; PGCL25: n=2 enrolled, 2 AEs each). These events are not attributable to per-protocol use. See Table 7 for AE details.

3.5 Overall Performance Ratings

Table 5 presents mean performance scores, SD, median, range, and 95% CI for each product. All six products met or exceeded the predefined success criterion (mean ≥4.0). PDO Barbed achieved the highest mean (4.93; SD 0.255; 95% CI 4.904–4.957), classified as Excellent. PGCL25 had the lowest mean (4.00; SD 0.279) but met the success criterion. The narrow SD values across all products indicate high consistency in surgeon ratings.

Table 5: Overall Performance Ratings with Descriptive Statistics by Suture Product

Suture *	Mean Score **	SD	Median (Range)	95% CI (Lower, Upper)	Category
PGA	4.12	0.331	4 (3–5)	(4.095, 4.155)	Good
PGLA910	4.12	0.331	4 (3–5)	(4.083, 4.167)	Good
PGLA910 Fast	4.50	0.665	5 (3–5)	(4.440, 4.560)	Good
PDO	4.51	0.592	4 (3–5)	(4.461, 4.568)	Good
PGCL25	4.00	0.279	4 (3–5)	(3.937, 3.988)	Good
PDO Barbed	4.93	0.255	5 (4–5)	(4.904, 4.957)	Excellent

* Abbreviations: PGA = Polyglycolic Acid; PGLA910 = Polyglactin 910; PGLA910 Fast = Polyglactin 910 Fast; PDO = Polydioxanone; PGCL25 = Poliglecaprone 25; PDO Barbed = Polydioxanone Surgical Barbed.

** Rating thresholds: 4.00–4.89 = Good; 4.90–5.00 = Excellent (scale: 1 = Poor to 5 = Excellent). SD = Standard Deviation; CI = Confidence Interval.

3.6 Follow-Up and Adverse Event Summary

All 360 subjects completed Day 7 follow-up. No wound dehiscence, re-rupturing, or superficial wound infection was recorded at Day 7 in any subject. Long-term follow-up was completed for all product groups except PGA (not applicable for this product's use case). All per-protocol subjects remained free of adverse events throughout the follow-up period (Table 6).

Table 6: Follow-Up Visits and Adverse Event Summary by Suture Product

Suture *	Day 7 FU, n	Long-term FU, n	Wound Dehiscence, n (%)	Superficial Infection, n (%)	Other AE, n (%)	Device-Related Assessment
PGA	60	N/A †	0 (0%)	0 (0%)	0 (0%)	Dental use per-protocol for PGA; no long-term FU conducted †
PGLA910	60	30	0 (0%)	0 (0%)	0 (0%)	No AEs; long-term FU completed for 30 per-protocol subjects
PGLA910 Fast	60	30	0 (0%)	0 (0%)	0 (0%)	No AEs; long-term FU completed for 30 per-protocol subjects
PDO	60	58	0 (0%)	0 (0%)	2 (3.3%) ‡	AEs in 2 dental deviation subjects only; resolved without intervention
PGCL25	60	58	0 (0%)	0 (0%)	2 (3.3%) ‡	AEs in 2 dental deviation subjects only; resolved without intervention
PDO Barbed	60	60	0 (0%)	0 (0%)	0 (0%)	No AEs

* Abbreviations: PGA = Polyglycolic Acid; PGLA910 = Polyglactin 910; PGLA910 Fast = Polyglactin 910 Fast; PDO = Polydioxanone; PGCL25 = Poliglecaprone 25; PDO Barbed = Polydioxanone Surgical Barbed.

FU = Follow-Up. AE = Adverse Event. N/A = Not applicable.

† PGA was used exclusively in dental procedures (per-protocol for PGA). Dental wound healing does not require extended post-operative follow-up; long-term FU was therefore not conducted for this group.

‡ AEs occurred in 2 PDO and 2 PGCL25 true dental deviation subjects respectively. All 304 per-protocol subjects and all 52 neurosurgical deviation subjects were AE-free.

3.7 Adverse Event Detail

Table 7 details all four recorded adverse events. All were non-serious, device-related to off-label dental use, and resolved without intervention. No AE onset or duration data were available from site records.

Table 7: Adverse Event Detail Report

AE No.	Product	Procedure / Protocol Status	AE Description	Seriousness	Causality & Resolution
AE 1	PDO	Dental procedure (true protocol	Transitory local irritation at suture site	Non-serious	Possibly related to off-label dental use; resolved without intervention

		deviation — PDO contraindicated in dental)			
AE 2	PDO	Dental procedure (true protocol deviation — PDO contraindicated in dental)	Delayed suture absorption	Non-serious	Possibly related to off-label dental use; suboptimal absorption for oral mucosa; resolved
AE 3	PGCL25	Dental procedure (true protocol deviation — PGCL25 contraindicated in dental)	Transitory local irritation at suture site	Non-serious	Possibly related to off-label dental use; resolved without intervention
AE 4	PGCL25	Dental procedure (true protocol deviation — PGCL25 contraindicated in dental)	Delayed suture absorption	Non-serious	Possibly related to off-label dental use; resolved

Note: AE onset (post-operative day) and duration data were not available in site records and are therefore not reported. All AEs were non-serious and resolved without intervention or re-hospitalization.

3.8 Per-Protocol Subgroup Summary

Among the 304 per-protocol subjects: no adverse events, wound dehiscence, or wound infections were recorded at any time point. All products met the predefined safety success criterion of ≥90% wound-complication-free rate at Day 7. All six products met the predefined performance success criterion (mean ≥4.0). The predefined success criteria were fully met for all products in the per-protocol population.

4. Discussion

4.1 Clinical Performance

All six absorbable sutures met the predefined performance success criterion across the per-protocol population, supporting their acceptability for approved surgical applications. These findings align with prior evidence documenting the wound healing and biocompatibility advantages of absorbable materials [6, 7]. High performance ratings across pliability, tensile strength, and knot security reflect surgeon satisfaction with handling properties consistently identified as key determinants of clinical utility [8].

4.2 Protocol Deviation — Dental Use

The true dental protocol deviations number only 4 subjects (1.1% of the total cohort): 2 subjects who received PDO and 2 who received PGCL25 during dental procedures. These two products are explicitly contraindicated for dental use in the approved PMCF protocol. All four adverse events in the study occurred in this small subgroup, consistent with the known unsuitability of PDO and PGCL25 for the oral mucosal environment [12]. PGA (n = 60), PGLA910 (n = 30), and PGLA910 Fast (n = 32) were used in dental settings and are approved for dental application; these subjects are per-protocol and AE-free. The dental deviation finding should be disclosed in the PMCF report and the contraindications for PDO and PGCL25 in dental surgery must be clearly stated in the products' instructions for use.

4.3 Protocol Deviation — Neurosurgical Use

True neurosurgical protocol deviations involve 52 subjects (14.4%): PGLA910 (n = 18), PGLA910 Fast (n = 13), and PDO Barbed (n = 21) used in neurosurgical procedures, for which these products are contraindicated per the PMCF protocol. PGCL25 is approved for neurosurgical use and its 41 neurosurgical subjects (per-protocol) reported no adverse events. No AEs were recorded among the 52 neurosurgical deviation subjects either; however, these data cannot support safety or performance claims for neurological applications given the study was not designed or powered for this purpose. The PMCF findings support use of PGLA910, PGLA910 Fast, and PDO Barbed only within approved non-neurological indications. Use in neurological procedures constitutes off-label use and must not be incorporated into regulatory performance or safety claims for these products.

4.4 Usability — Packaging CAPA

Packaging-removal difficulty reported by 100% of PGA users and 50% of PGLA910 users represents a systematic, not incidental, usability failure. Under MDR 2017/745 and ISO 14971, this mandates a Corrective and Preventive Action (CAPA). The CAPA has been confirmed as acceptable per regulatory standards [Comment confirmed by study team]. Recommended corrective actions: (1) engineering review of the pouch opening mechanism for PGA and PGLA910 sutures; (2) formalized usability testing per IEC 62366-1; (3) updated instructions for use or product labelling as an interim measure; (4) risk assessment update to address potential suture damage during difficult pouch removal. This finding must be formally reported in the post-market surveillance report and PMCF evaluation report for both products [9].

4.5 Statistical Findings

Complete descriptive statistics (mean, SD, median, range, and 95% CI) have been obtained for all performance scores and are presented in Table 5. The narrow SD values (0.255–0.665) across all products indicate high consistency in surgeon assessments. PGCL25 showed the lowest mean (4.00) and narrowest SD (0.279), suggesting consistently moderate ratings at the lower boundary of acceptability. PDO Barbed showed the highest mean (4.93) with a narrow CI (4.904–4.957), confirming superior and consistent performance. These data fully satisfy the statistical reporting requirements for PMCF studies under MDR 2017/745 and MDCG 2020-7.

4.6 Comparison with Existing Literature

The safety and performance profile observed in this study is broadly consistent with published evidence on absorbable sutures in general and plastic surgery [3, 5, 13]. The complete absence of AEs in 304 per-protocol subjects is consistent with prior data on polyglycolic acid and polyglactin sutures [6]. The packaging usability concern aligns with documented importance of suture packaging design in clinical environments [9]. The superior performance of PDO Barbed (mean 4.93) is consistent with published

evaluations of barbed suture technology [10]. The dental AEs in PDO and PGCL25 deviation cases are consistent with the known tissue reactivity of these materials in oral mucosal environments [12].

4.7 Conflict of Interest and Funding

The study was sponsored by Futura Surgicare Pvt Ltd, manufacturer of the investigational products. Data collection was conducted by Dr. Klinisch Research Private Limited as an independent CRO. Statistical analysis and manuscript preparation were conducted independently of the device manufacturer. Full declarations are in the Declarations section.

4.8 Limitations

(1) Observational non-comparative design precludes causal inference or between-product comparisons. (2) Surgeon-reported outcomes are not independently verified. (3) Protocol deviations (n = 56; 15.5%) affect interpretation of certain product-specific findings. (4) No formal sensitivity analysis for deviation subgroups. (5) Long-term follow-up not conducted for PGA group (dental use). (6) AE onset and duration data were unavailable from site records. (7) Two-site study limits generalizability. These limitations are inherent to the PMCF design and should be disclosed in the regulatory PMCF evaluation report.

This study contributes to the evidence supporting the clinical performance and user-reported safety of absorbable sutures within approved indications. Future PMCF cycles should enforce stricter protocol adherence, contemporaneous AE documentation, and continuation of statistical variability reporting.

5. Conclusion

This prospective observational PMCF study supports acceptable clinical performance and user-reported handling characteristics of all six evaluated absorbable sutures within their per-protocol approved indications. Among 304 per-protocol subjects, no adverse events, wound complications, or safety concerns were identified throughout the follow-up period. All products met the predefined performance success criterion (mean score ≥4.0), with PDO Barbed achieving Excellent ratings (mean 4.93). Packaging usability concerns for PGA (100%) and PGLA910 (50%) represent actionable findings requiring CAPA, confirmed acceptable per regulatory standards.

True protocol deviations affected only 56 of 360 subjects (15.5%): 4 in dental applications (PDO and PGCL25, which are contraindicated in dental use) and 52 in neurosurgical applications (PGLA910, PGLA910 Fast, and PDO Barbed, which are contraindicated in neurological use). Four non-serious adverse events occurring exclusively in the dental deviation group underscore the importance of adhering to approved indications. Neurosurgical deviation subjects reported no AEs; however, these data are insufficient to establish neurological safety or performance and should not be used to support extended indications. Continued post-market surveillance and strict protocol adherence in future PMCF cycles are recommended.

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