

A Retrospective, Multicenter, Observational Real World Post Market Clinical Follow Up Study to Evaluate Acute Safety and Device Procedural Success of ADVACRYL (Polyglactin 910) Surgical Suture. (ADVACRYL PMCF Study)

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Abstract

In this real-world experience Post-marketing Clinical Follow-up study conducted in accordance with EU MDR 2017/745 in 109 subjects from >90 surgical centers across various surgical specialties, ADVACRYL (Polyglactin 910) braided, synthetic absorbable sterile surgical sutures demonstrated excellent suture, needle, and overall performance. No wound complications or adverse events were reported in this study during the follow-up period of 3 months, and there were no reports of prolonged or repeat hospitalization. ADVACRYL (Polyglactin 910) sutures are a safe and effective option for a very wide variety of surgical procedures in a diverse population.

Keywords: Polyglactin 910, Braided, Synthetic absorbable suture, Ophthalmic surgery.

INTRODUCTION

Sutures are sterile surgical threads used to approximate and/or ligate tissues. They are essential for wound closure in a variety of surgical procedures, including general surgery, gynecology, ophthalmology, and cardiovascular surgery. Sutures are available in a wide range of materials, including natural (e.g., catgut, silk) and synthetic (e.g., nylon, polyester, polyglactin 910).[1]

Braided, synthetic absorbable sterile surgical sutures are a type of suture that is composed of multiple strands woven together. This braiding process results in a suture that is strong, flexible, and easy to handle. Synthetic absorbable sutures are made from a variety of materials. Advanced MedTech Solutions (AMS) (<https://www.amsltd.com/products/ADVACRYL/>) a braided coated synthetic absorbable suture called

ADVACRYL that is composed of a copolymer made from 90% glycolide and 10% L-lactide, coated with a mixture composed of Poly (glycolide-co-lactide) and calcium stearate. This coating reduces tissue drag and improves knot security.

ADVACRYL suture is available in both dyed and undyed form. ADVACRYL suture complies with United States Pharmacopeia requirement for “Absorbable Surgical Suture” and the European Pharmacopoeia for “Sterile Synthetic Absorbable Braided Sutures”.

Polyglactin 910 sutures are indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery, peripheral nerve anastomosis, and microsurgery for vessels less than 2 mm diameter. They are not indicated for use in cardiovascular tissues.

The absorption process begins at the suture surface and progresses inward. The progressive loss of tensile strength and eventual absorption of ADVACRYL occurs by means of hydrolysis where the copolymer degrades to glycolic and lactic acids which are subsequently absorbed and metabolized in the body. Absorption begins as a loss of tensile strength followed by a loss of mass. The suture is designed to maintain 70% of its tensile strength for 14 days, 50% for 21 days, 20% for 28 days, and is completely absorbed in the body within approximately 80 days. The rate of absorption depends on several factors, including the suture diameter, the type of tissue, and the patient's individual metabolism. ADVACRYL (Polyglactin 910) sutures are completely absorbed within 80 days.[2]

ADVACRYL (Polyglactin 910) sutures are a safe and effective option for a variety of surgical procedures. They offer several advantages over other types of sutures, including:

- Excellent tensile strength and knot security
- Smooth passage through tissue
- Minimal tissue reaction
- Predictable absorption

Some disadvantages of Braided, Synthetic Absorbable Sterile Surgical Sutures include:

- Cost: These sutures can be more expensive than other types of sutures.
- Potential for infection: There is a small risk of infection associated with the use of any type of suture, but the risk is slightly higher with synthetic sutures.
- Potential for suture extrusion: In some cases, the suture may extrude through the skin, which can be unsightly and uncomfortable.

ADVACRYL sutures have been used widely in various types of surgical procedures. We are not aware of any systematic study done till date in an Indian population to determine safety and performance of the Polyglactin 910 suture in real world scenario.

MATERIALS AND METHODS

Study Design and Conduct

A real-world experience study was designed as ‘A Multicenter, Real World Retrospective Post Market Clinical Follow-up Study to Evaluate Acute Safety and Device Procedural Success of Polyglactin 910 (ADVACRYL) Surgical Suture.’(ADVACRYL PMCF STUDY)

A combination of heterogeneous data from different centers was collected to reinforce analyses and strengthen clinical outcomes.

ETHICS COMMITTEE APPROVAL

Institutional Ethics Committee approval was obtained from the ACEAS Independent Ethics Committee,

Ahmedabad -380015 after submitting the clinical study documents (Product Information, PMCF protocol (AMS/ADVACRYL/2021 Ver. 02), CRF, etc.). The informed consent was waived on account of this being a retrospective study. Since ADVACRYL is a CE-certified device, the study was conducted as per the regulatory guidelines of EU MDR 2017/745. The study done as per the ICH – GCP, ICMR guidelines and New Drugs & Clinical Trials Rules 2019 (India).

ELIGIBILITY AND INCLUSION

The study initiated in total 156 patients, PMCF data of 120 Subjects was collected from January 2023 to September 2023. 109 Subjects data was analyzed.

All the subjects enrolled met the inclusion criteria in the study and were included in this retrospective study.

Inclusion criteria

- Patients ≥ 18 years of age.
- Patients who have been treated with ADVACRYL (Polyglactin 910) suture.

Exclusion criteria

- As this is retrospective review of the data, there are no formal exclusion criteria for the study.

Outcome measures/ endpoints

Primary Endpoint

- Number of Subjects presenting with wound complications [Time Frame: 03 months].
- Any wound disruption, wound dehiscence, fluid accumulation, and separation (Surgical Site Infection (SSI), Hematoma, Separation, Seroma, etc.).

Secondary Endpoint

- Mean Operation Time in minutes [Time Frame: Intraoperative]
- Total procedure time [Time Frame: Intraoperative]
- Any Device Malfunction or Device Failure [Time Frame: Intra and Postoperative]
- Any Device Malfunction or Device Failure related to the use of ADVACRYL (based on the Investigator's Investigation for events not limited to Failure to perform or any other Malfunction when used in compliance with the Instructions for Use.)
- Length of Hospital Stay in days [Time Frame: From Postoperative through 03 month]
- Number of patients requiring Reoperation or Additional Surgical procedure [Time Frame: From Postoperative through 03 months]
- Number of patients presenting with Adverse Events related to the use of ADVACRYL surgical suture [Time Frame: From Postoperative through 03 months] (Any Adverse Events related to the use of ADVACRYL were based on the Investigator's Investigation.)
- Number of patients requiring Additional Surgical procedure resulting from Device malfunction, Device failure or any Adverse events [Time Frame: From Postoperative through 03 months]
- All comer Subjects with ADVACRYL of any size or length were included in study and follow up for 3 months as per PMCF plan.

RESULTS AND DISCUSSION

Study Report

Data of 120 subjects was collected from different Surgeons and Hospitals collected from January 2023 till September 2023. 109 PMCF forms out of 120 were analysed. 11 forms were rejected due to incomplete data.

STUDY POPULATION: AGE, GENDER, MEDICAL AND TREATMENT HISTORY BASELINE CHARACTERISTICS

For Baseline Characteristics, the following attributes were studied.

1. Subjects' Age
2. Subjects' Gender
3. Medical History

Mean age of the study population age was 43.8 years with lowest age of 24 and highest age of 67, Describe categories with 56 % of males and 44% of females. Four subjects had medical history of diabetes mellitus, and hypertension and out of four, two subjects had both.

Table 1: Gender distribution of the subjects

Gender	109 Subjects
Female	44%
Male	56%

Figure 1: Gender distribution of the subjects

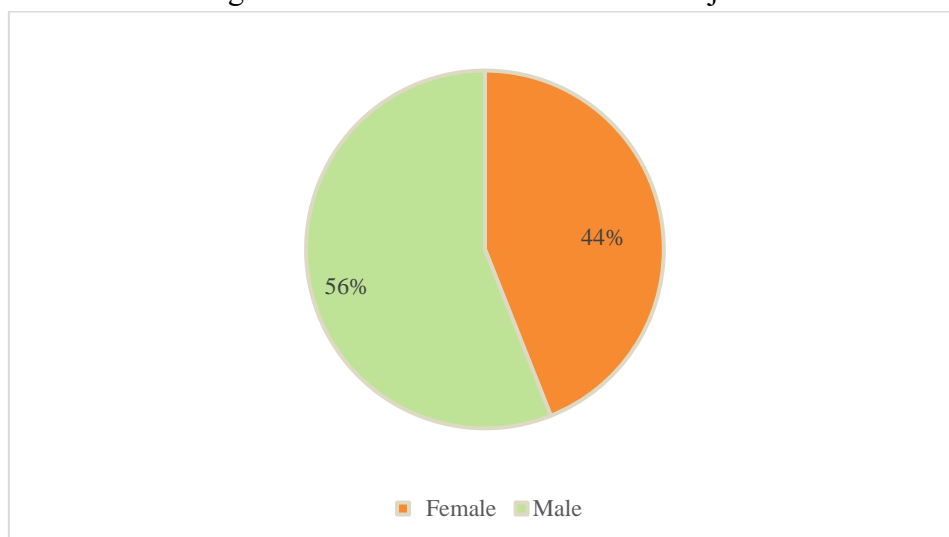


Table 2: Age categories

Age Categories	109 Subjects
Between 18 and 65 years	99%
≥65 years	1%

Figure 2: Age Categories

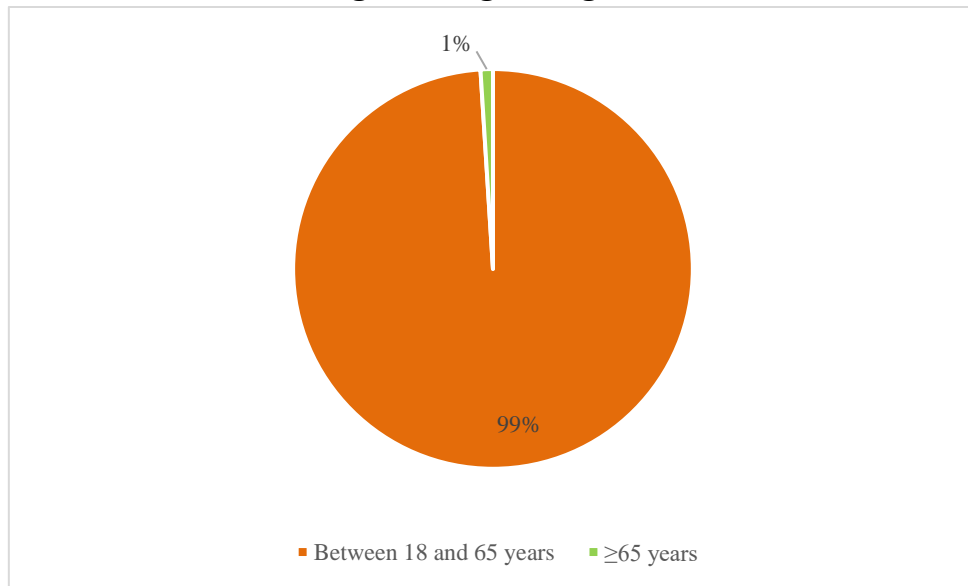
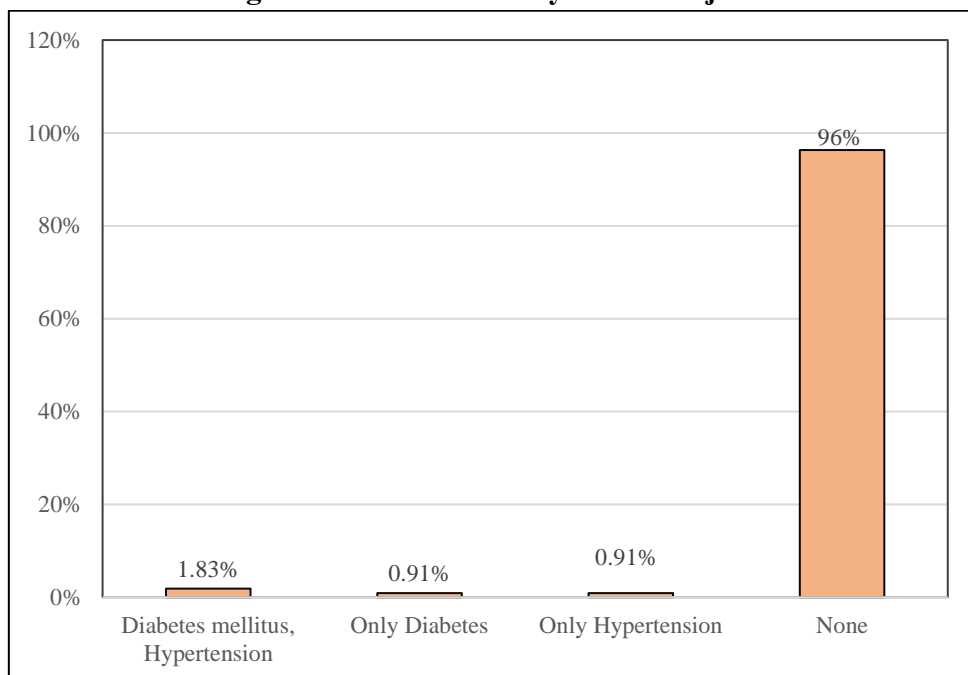


Table 3: Medical history of the subjects

Medical History	109 Subjects	Percentage
Diabetes mellitus, Hypertension	2	1.83%
Only Diabetes Mellitus	1	0.91%
Only Hypertension	1	0.91%
None	105	96.33%

Figure 3: Medical history of the subjects



OPERATIVE DATA ANALYSIS

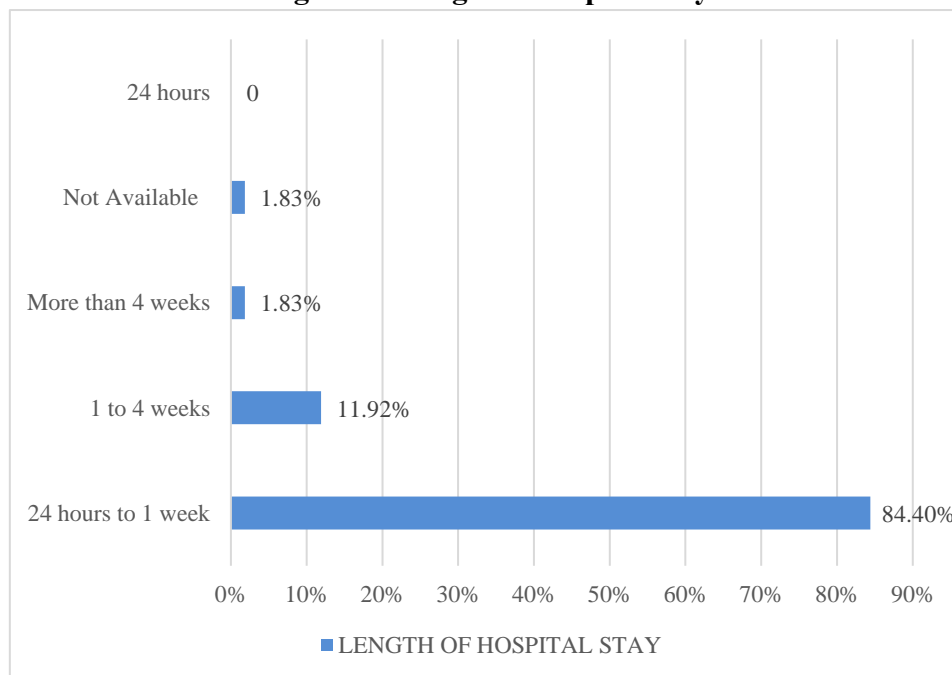
LENGTH OF HOSPITAL STAY

In total, the length of hospital stays of 84.40% of the subjects was 24 hours to 1 week, 11.92% of 1 to 4 weeks, 1.83% of more than 4 weeks; however, 1.83% of the data was not available.

Table 4: Length of hospital stay

Length of Hospital Stay	109 Subjects	Percentage
24 hours to 1 week	92	84.40%
1 to 4 weeks	13	11.92%
More than 4 weeks	2	1.83%
Not Available	2	1.83%
24 hours	0	0%

Figure 4: Length of hospital stay



PATIENT BASELINE INFORMATION

CLINICAL PRESENTATION ON THE DAY 0

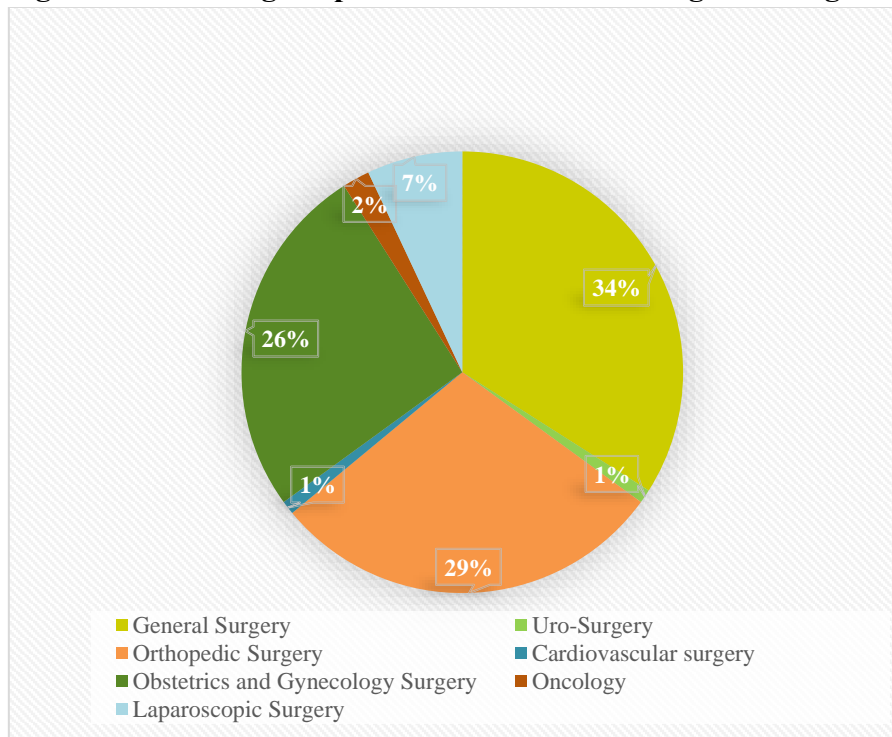
Of the 109 subjects, 34% of the Subjects underwent procedures in General Surgery, 29% in Orthopedic Surgery, 26% in Ob and Gyn Surgery, 7% in laparoscopic surgery, 2% Oncology, 1% in Cardiovascular and 1% in Uro-surgery categories.

STATICAL ANALYSIS: SURGERY

Table 5: List of surgical procedure where ADVACRYL was used

Surgery name	Number of subjects (109 subjects)	Percentage
General Surgery	37	34%
Orthopedic Surgery	32	29%
Obstetrics and Gynecology Surgery	28	26%
Laparoscopic Surgery	8	7%
Oncology	2	2%
Cardiovascular Surgery	1	1%
Uro-Surgery	1	1%

Figure 5: Percentage of procedures in various Surgical Categories



STATISTICAL ANALYSIS: STATE

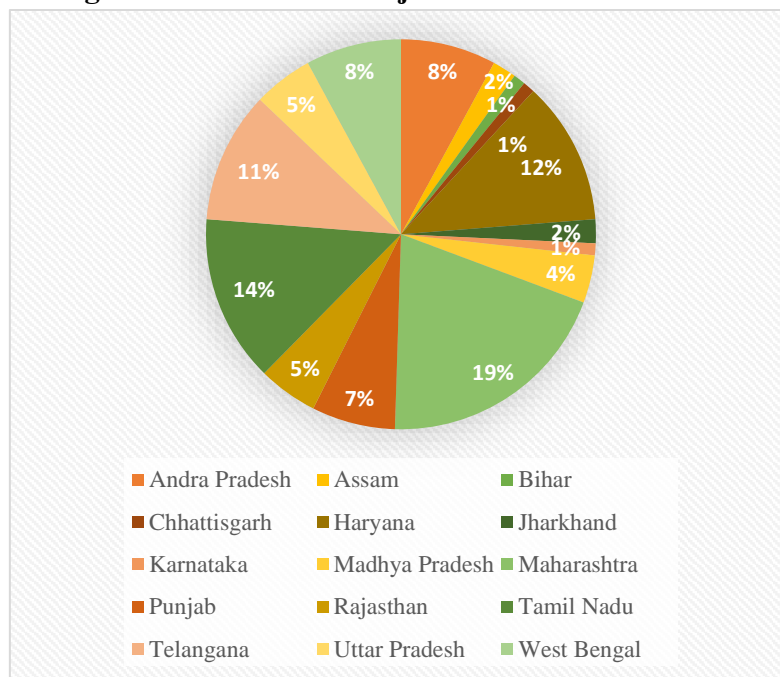
In total, 20% of the Subjects from Maharashtra, 14% from Tamil Nadu, 12% from Haryana, 11% from Telangana, 8% from Andra Pradesh, 8% from West Bengal, 7% from Punjab, 5% from Rajasthan, 5% from Uttar Pradesh, 4% from Madhya Pradesh, 2% from Assam, 2% from Jharkhand, 1% from Bihar, 1% from Chhattisgarh, 1% from Karnataka.

Table 6: Number of subjects from different states

State	Number of Subjects (109 Subjects)	Percentage
Maharashtra	21	20%

Tamil Nadu	15	14%
Haryana	12	12%
Telangana	11	11%
Andra Pradesh	8	8%
West Bengal	8	8%
Punjab	7	7%
Rajasthan	5	5%
Uttar Pradesh	5	5%
Madhya Pradesh	4	4%
Assam	2	2%
Jharkhand	2	2%
Bihar	1	1%
Chhattisgarh	1	1%
Karnataka	1	1%

Figure 6: Number of Subjects from different states



ADVACRYL HANDLING CHARACTERISTICS

SUTURE PERFORMANCE

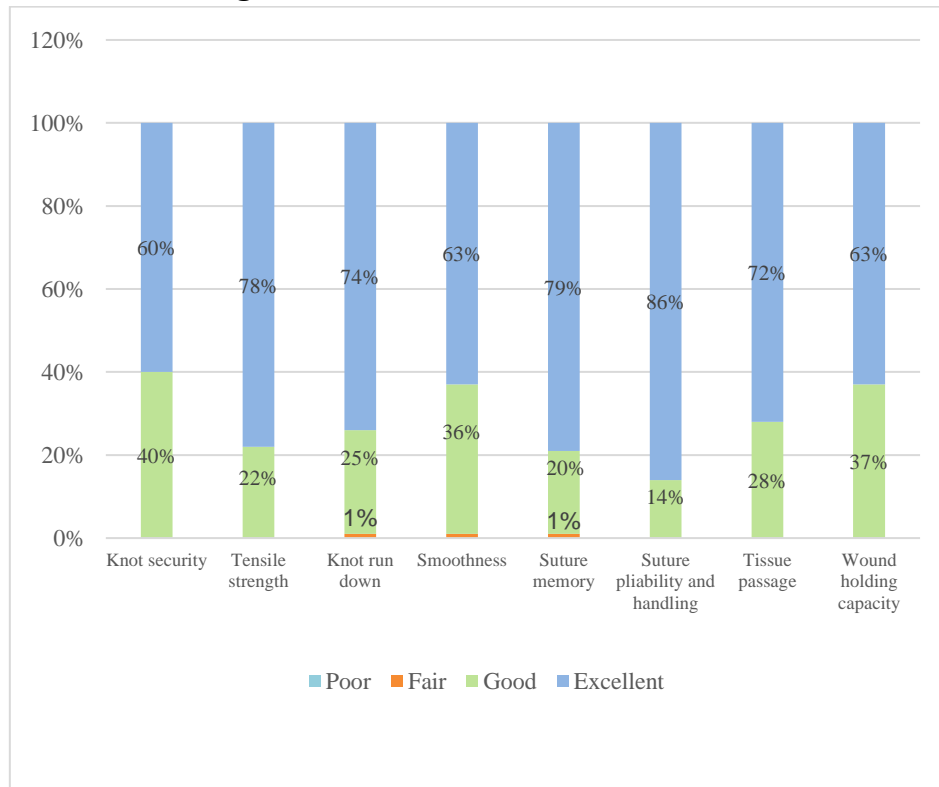
For Suture Performance, Knot Security, Tensile Strength, Knot Run Down, Smoothness, Suture Memory, Suture Pliability and Handling, Tissue Passage, and Wound Holding Capacity attributes were studied.

Table 7: Rating of Suture Performance attributes

109 Number of Subjects analyzed				
Rating Category	Poor	Fair	Good	Excellent
Knot security	0%	0%	40%	60%

109 Number of Subjects analyzed				
Rating Category	Poor	Fair	Good	Excellent
Tensile strength	0%	0%	22%	78%
Knot run down	0%	1%	25%	74%
Smoothness	0%	1%	36%	63%
Suture memory	0%	1%	20%	79%
Suture pliability and handling	0%	0%	14%	86%
Tissue passage	0%	0%	28%	72%
Wound holding capacity	0%	0%	37%	63%

Figure 7:Suture Performance attributes



NEEDLE PERFORMANCE

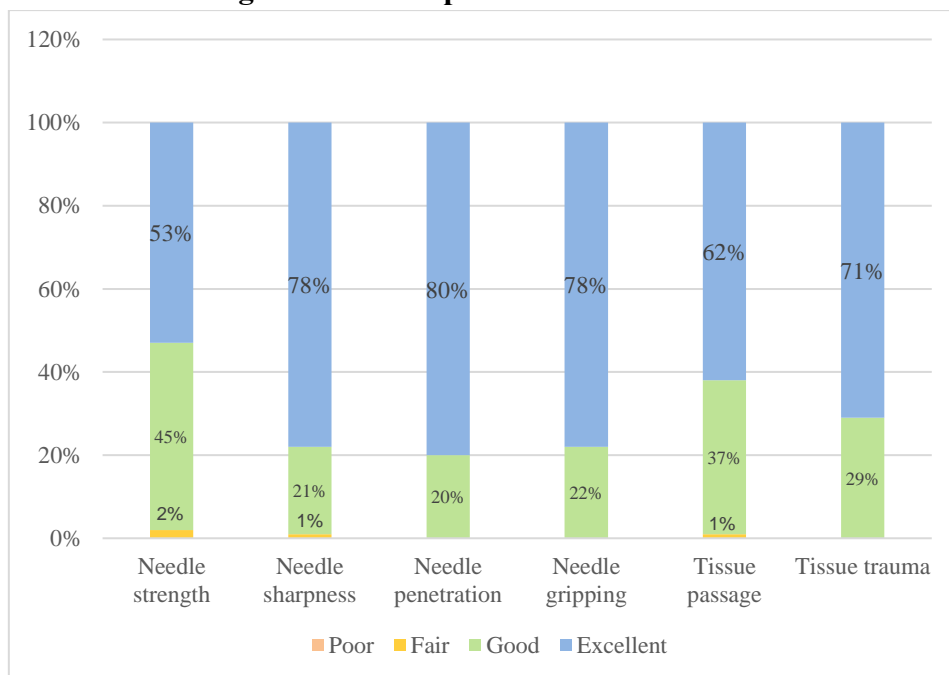
For needle performance like Needle strength, Needle sharpness, Needle penetration, Needle gripping, Tissue passage, and Tissue trauma were studied.

Table 8: Rating of Needle Performance attributes

109 Number of Subjects analyzed				
Rating Category	Poor	Fair	Good	Excellent
Needle strength	0%	2%	45%	53%
Needle sharpness	0%	1%	21%	78%

Needle penetration	0%	0%	20%	80%
Needle gripping	0%	0%	22%	78%
Tissue passage	0%	1%	37%	62%
Tissue trauma	0%	0%	29%	71%

Figure 8: Needle performance attributes



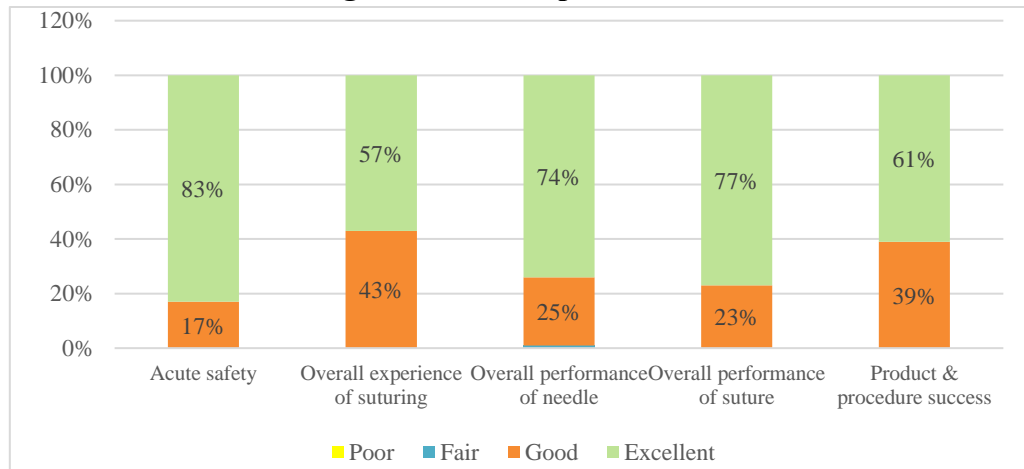
OVERALL PERFORMANCE

For Overall Performance of The Product, Acute Safety, Overall Experience of Suturing, Overall Performance of Needle, Overall Performance of Suture, Product & Procedure Success attributes were studied.

Table 9: Rating of Overall performance of the product

109 Number of Subjects analyzed				
Rating Category	Poor	Fair	Good	Excellent
Acute safety	0%	0%	17%	83%
Overall experience of suturing	0%	0%	43%	57%
Overall performance of needle	0%	1%	25%	74%
Overall performance of suture	0%	0%	23%	77%
Product & procedure success	0%	0%	39%	61%

Figure 9: Overall performance



CLINICAL PRESENTATION FOR THREE MONTHS FOLLOW UP DATA

At 3 months follow up, the following attributes were studied.

- Tissue approximation
- Wound complications like wound disruption, wound dehiscence, fluid accumulation, separation.
- Suture Absorption time.
- Details of adverse events/ serious adverse events

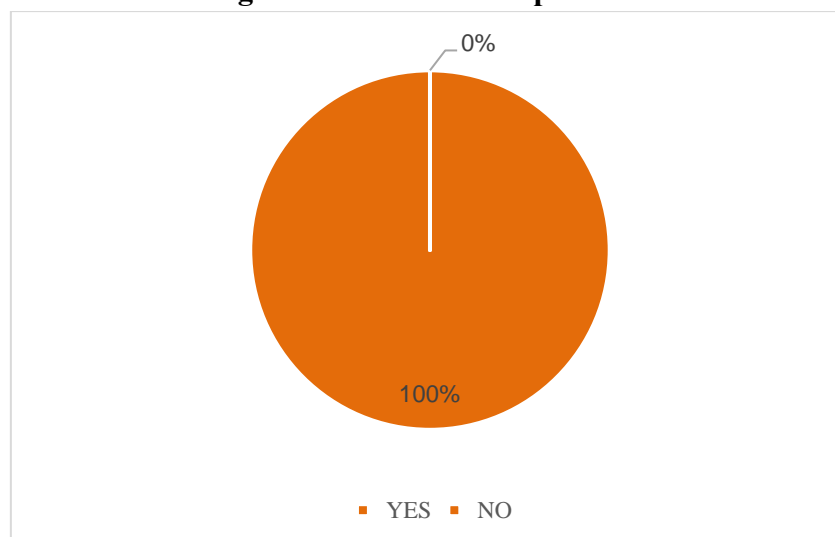
WOUND COMPLICATION

No wound complication was seen in any of the subjects at the end of 3 months follow up.

Table 10: Wound complication

Wound complication	109 Subjects
Yes	0%
No	100%

Figure 10: Wound Complication



ADVERSE EVENTS (AE) OR SEVERE ADVERSE EVENTS (SAE):

In all the cases of clinical application in different surgical sites, there were no adverse events or severe adverse events reported on the day of operation or surgery and at 3 months follow up.

Table 11: Adverse reaction

Adverse reaction	109 Subjects
Yes	0%
No	98%
Not Available	2%

Figure 11: Adverse reaction

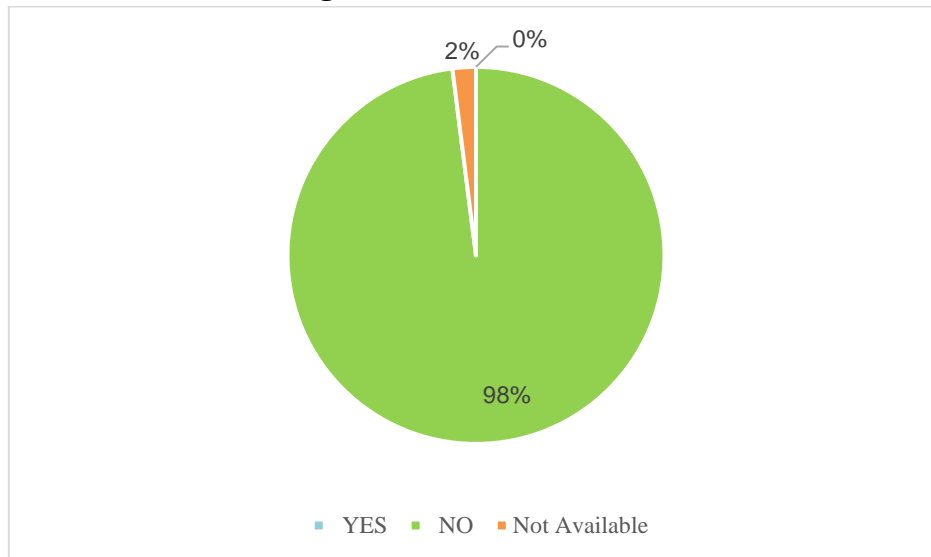


Table 12: Tensile strength of Polyglactin 910 suture

Day of Implantation	Approximate % original strength remaining
14 days	70%
21 days	50%
28 days	20%

LIMITATIONS

PMCF studies can suffer from limitations like limited data and subject selection bias. Best efforts to overcome these limitations were made by collecting sufficient data from an extremely high number of surgical centres across a wide geography and surgical specialties, by maintaining a high rate of follow-up data collection and analysing data with a very high standard of accuracy.

CONCLUSION

In this real-world experience study in 109 subjects, ADVACRYL (Polyglactin 910) braided, synthetic absorbable sterile surgical sutures are used in a variety of surgical procedures. Follow-up data was

obtained with a high rate of completion and high degree of accuracy.

The study included subjects' data from >90 surgical centers across 15 different states of India, and included usage across 7 different surgical specialties, which demonstrates the wide diversity of clinical use of ADVACRYL (polyglactin 910) sutures.

The study successfully achieved its primary and secondary safety and performance objectives, over a significantly long 3-month follow-up period.

ADVACRYL demonstrated excellent suture, needle and overall performance and were consistently rated excellent in surgeon's feedback across surgical specialties.

No wound complications or adverse events were reported in this study during the follow-up period of 3 months, and there were no reports of prolonged or repeat hospitalization.

ADVACRYL (Polyglactin 910) sutures are a safe and effective option for a very wide variety of surgical procedures in a diverse population.

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The study was sponsored by Advanced MedTech Solutions Pvt Ltd., Gujarat, India. No Financial remuneration or other benefits were paid to the hospitals or doctors contributing the subjects' data. The authors are full-time employees of Advanced MedTech Solutions Pvt. Ltd.

Conflict of Interest

None

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