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A Retrospective, Multicenter, Observational Real World Post Market Clinical Follow up Study to Evaluate Acute Safety and Device Procedural Success of ADVACRYL RAPID (Braided Coated Polyglactin 910) Surgical Suture. (ADVACRYL RAPID 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 70 subjects from >50 surgical centers across various surgical specialties, ADVACRYL RAPID (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 RAPID (Braided coated 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, Absorbable Suture, Ophthalmic Surgery, Obstetrics and Gynecology 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]

Advanced MedTech Solutions (AMS) (https://www.amsltd.com/products/ADVACRYL-RAPID/) ADVACRYL RAPID is a braided synthetic absorbable sterile surgical suture composed of a copolymer made from 90% glycolide and 10% L-lactide.

ADVACRYL RAPID (Braided Coated Polyglactin 910) in comparison to ADVACRYL has a rapid loss of strength and absorption rate. The characteristic rapid loss of strength is achieved by use of a polymer

material with a lower molecular weight than regular ADVACRYL (polyglactin 910) suture.

Braided synthetic absorbable sterile surgical sutures such as ADVACRYL RAPID, are widely used in various surgical applications due to their predictable absorption and handling properties.

The evidence supporting the use of these sutures is robust, with multiple studies demonstrating their efficacy and safety. For instance, a study by Dunlap et al. showed that glycolactide sutures have superior initial strength and more predictable absorption times compared to chromic collagen sutures, making them suitable for ophthalmic surgery.[2] Additionally, Yaman et al. found that multifilament sutures, including those made from glycolide and lactide copolymers, are prone to higher bacterial colonization compared to monofilament sutures, which can impact wound healing.[3]

The primary complications associated with these sutures include tissue drag and potential for infection due to the interstices of the braid structure.[4] The study by Yaman et al. highlighted that multifilament sutures have a higher tendency for microbial colonization, which can adversely affect wound healing.[3] However, these sutures generally exhibit minimal tissue reaction and predictable absorption, with complete absorption occurring within 7-9 weeks.[2]

Applications

ADVACRYL RAPID (Braided Coated Polyglactin 910) is intended for use in general soft tissue approximation where only short-term wound support is required and where the rapid absorption of the suture would be beneficial.

These sutures are commonly used in various surgical fields, including ophthalmic surgery, general surgery, and dentoalveolar surgery. Their rapid loss of strength and absorption rate makes them particularly suitable for tissues that heal quickly and do not require prolonged support. It is also successfully used in ophthalmic surgery for conjunctival sutures. They provide adequate initial strength and predictable absorption, which is crucial for delicate tissues.[2] In dentoalveolar surgery, despite their higher bacterial colonization, they are still used due to their handling properties and predictable absorption.[3]

Due to its absorption profile ADVACRYL RAPID suture is useful for skin closure, particularly in Paediatric surgery, episiotomies, circumcision and closure of oral mucosa.

In summary, braided synthetic absorbable sutures composed of 90% glycolide and 10% L-lactide are well-supported by clinical evidence for their efficacy and safety, though they do have some complications related to bacterial colonization and tissue drag. Their applications are broad, particularly in surgeries requiring rapid absorption and minimal tissue reaction.

The common side effects associated with these types of sutures are as follows:

1. **Acute Allergic Reactions:** Although rare, acute allergic reactions can occur. In a study by Helveston and Callahan, only 1.5% of cases experienced an acute allergic reaction when using Polyglactin 910 (Vicryl) sutures.[5]
2. **Tissue Irritation:** These sutures can cause irritation, particularly when left partially exposed. This is especially relevant in ophthalmic surgeries where sutures at the conjunctival limbus can cause excessive tissue reaction.[5]
3. **Infection Risk:** Multifilament sutures, including those made from glycolide and lactide copolymers, have a higher propensity for bacterial colonization compared to monofilament sutures. This can increase the risk of infection, particularly in contaminated or high-risk surgical fields.

4. **Tissue Drag:** The braided structure of these sutures can lead to increased tissue drag during placement, which may cause additional tissue trauma.

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

ADVACRYL RAPID 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.

ADVACRYL RAPID suture gets bio-absorbed and bio-degraded over the period. The progressive loss of tensile strength and eventual absorption of ADVACRYL RAPID suture occurs by means of hydrolysis where the co-polymer 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 mass. Post implantation approximately 42% of the original tensile strength remains at 5 days. All the original tensile strength is lost by approximately 10 to 14 days post-implantation. The rate of absorption depends on several factors, including the suture diameter, the type of tissue, and the patient's individual metabolism. ADVACRYL RAPID (Braided Coated Polyglactin 910) sutures are completely absorbed within 42 days. ADVACRYL RAPID 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 Braided coated 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 Braided Coated Polyglactin 910 (ADVACRYL RAPID) Surgical Suture.' (ADVACRYL RAPID 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 RAPID /2021 Ver. 02), CRF, etc.). The informed consent was waived on account of this being a retrospective study. Since ADVACRYL RAPID 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 was planned to include 156 subjects, we could not reach these numbers due to various reasons like less than expected sales, instability in our organization, etc. PMCF data of 70 Subjects was collected from January 2023 to December 2023 for which analysis has been done.

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

Inclusion criteria

Patients who have been treated with ADVACRYL RAPID (Braided Coated 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 RAPID (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 RAPID surgical suture [Time Frame: From Postoperative through 03 months] (Any Adverse Events related to the use of ADVACRYL RAPID 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 RAPID 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 70 subjects was collected from different Surgeons and Hospitals collected from January 2023 till December 2023.

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 35.3years with lowest age of 10 and highest age of 68, Describe categories with 34 % of males and 66% of Females. One Subject had medical history of diabetes mellitus.

Table 1: Gender distribution of the subjects

Gender	70 Subjects
Female	66%
Male	34%

Figure 1: Gender distribution of the subjects

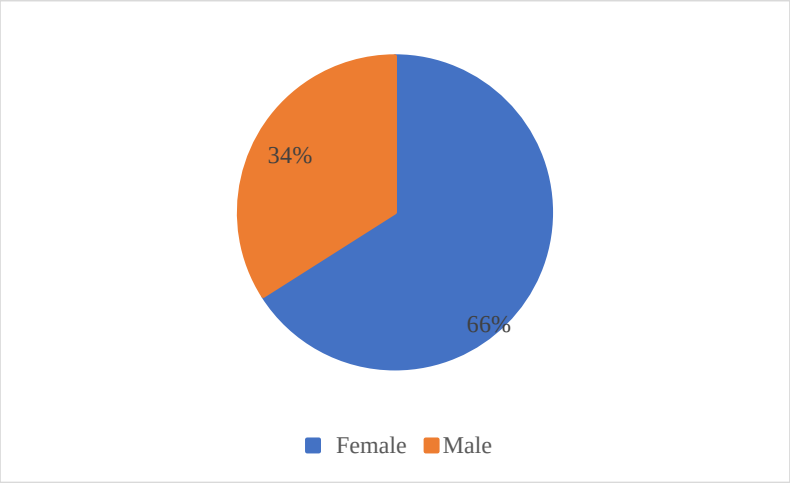


Table 2: Age categories

Age Categories	70 Subjects
≤ 18years	4%
Between 18 and 65 years	93%
≥65 years	3%

Figure 2: Age Categories

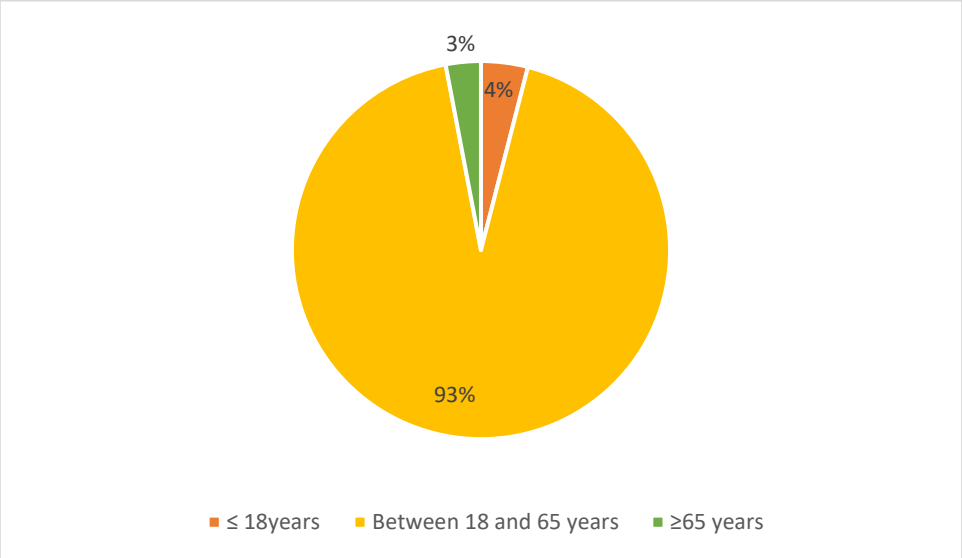
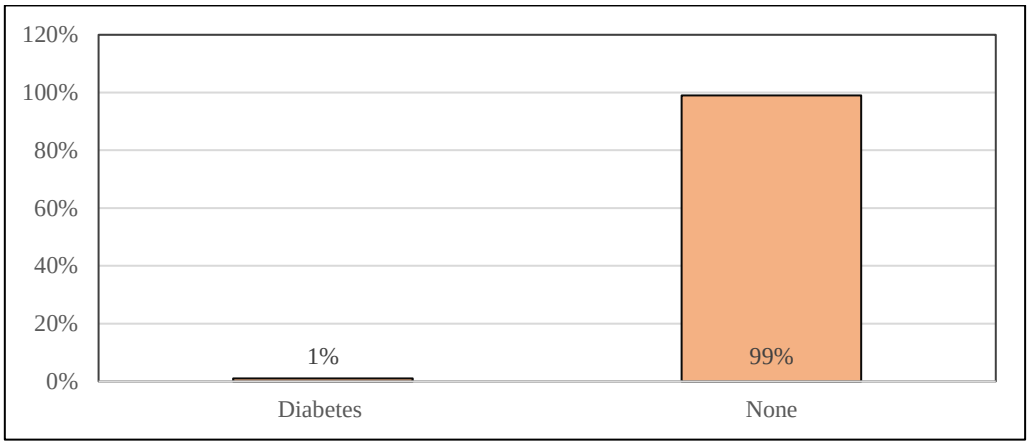


Table 3: Medical history of the subjects

Medical history	70 Subjects	Percentage
Diabetes mellitus	1	1%
None	69	99%

Figure 3: Medical history of the subjects



Operative Data Analysis

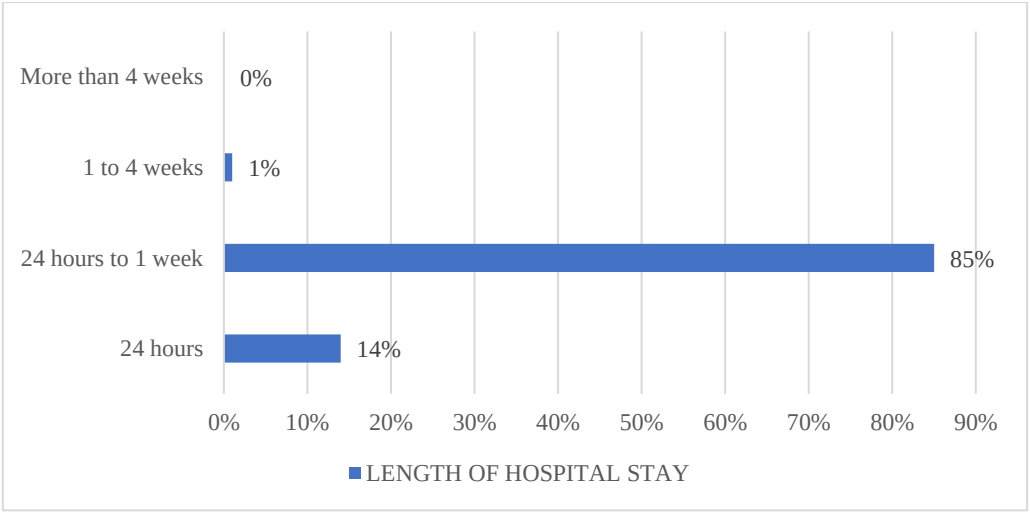
Length Of Hospital Stay

In total, the length of hospital stays of 85% of the subjects was 24 hours to 1 week, 14 % was 24 hours, 1% of 1 to 4 weeks.

Table 4: Length of hospital stay

Length of Hospital Stay	70 Subjects	Percentage
24 hours	10	14%
24 hours to 1 week	59	85%
1 to 4 weeks	1	1%
More than 4 weeks	0	0%

Figure 4: Length of hospital stay



Patient Baseline Information

Clinical Presentation On The Day 0

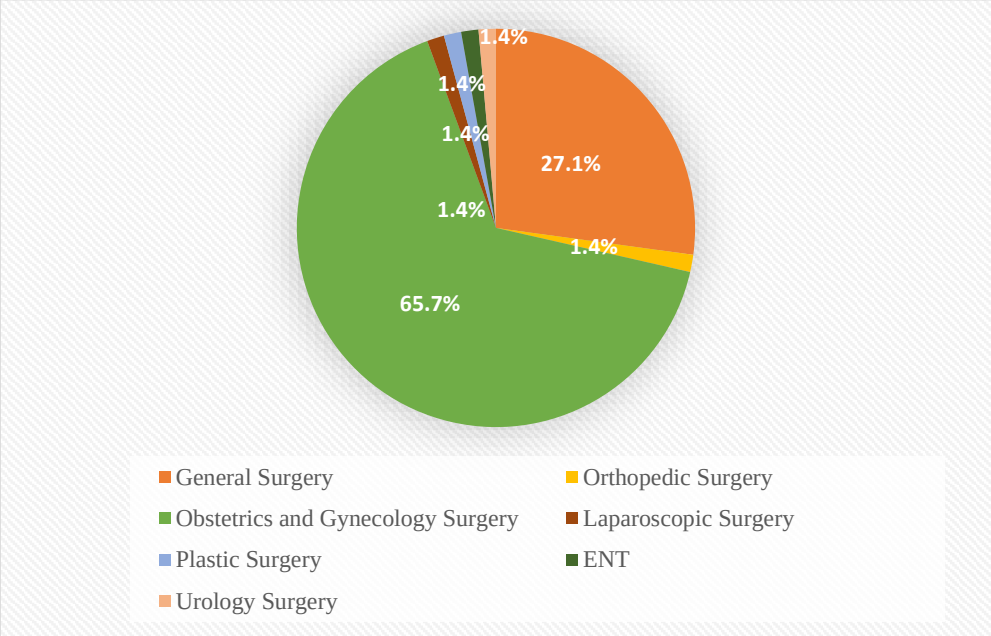
Of the 70 subjects, 65.7% of the Subjects underwent procedures in Obstetrics and Gynecology Surgery, 27.1% in General Surgery, 1.4% in Orthopedic Surgery, 1.4% in laparoscopic surgery, 1.4% in Plastic surgery, 1.4% in ENT and 1.4% in Urology surgery categories.

Statical Analysis: Surgery

Table 5: List of surgical procedure where ADVACRYL RAPID was used

Surgery name	Number of subjects (70 subjects)	Percentage
General Surgery	19	27.1%
Orthopedic Surgery	1	1.4%
Obstetrics and Gynaecology Surgery	46	65.7%
Laparoscopic Surgery	1	1.4%
Plastic Surgery	1	1.4%
ENT	1	1.4%
Urology Surgery	1	1.4%

Figure 5: Percentage of procedures in various Surgical Categories



Statistical Analysis: State

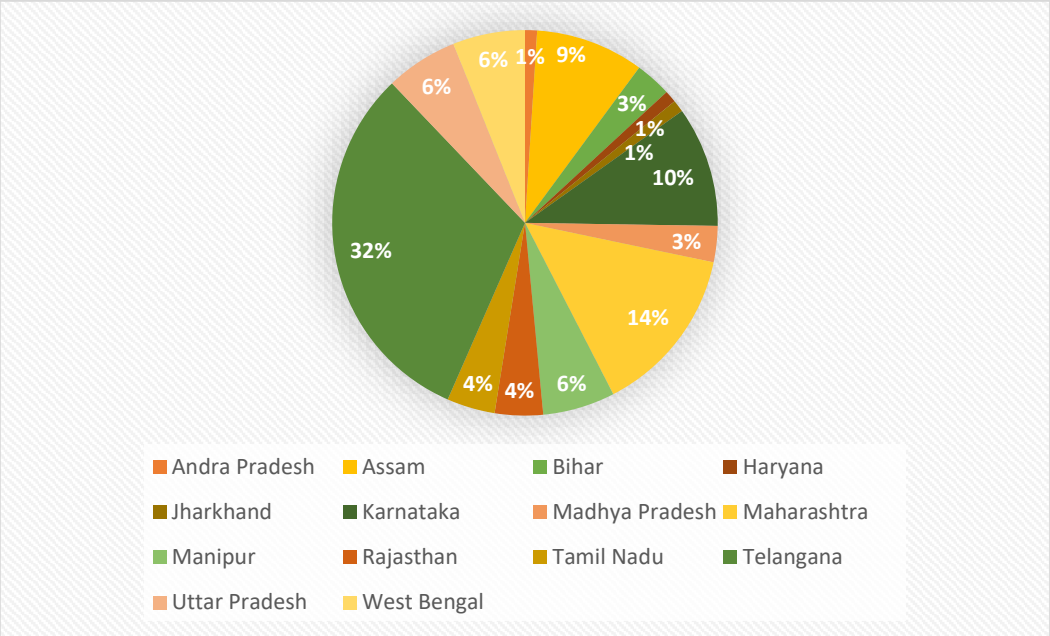
In total, 32% of the Subjects from Telangana, 14% from Maharashtra, 10% from Karnataka, 9% from Assam, 6% from West Bengal, 6% from Uttar Pradesh, 6% from Manipur, 4% from Tamil Nadu, 4% from Rajasthan, 3% from Madhya Pradesh, 3% from Bihar, 1% from Haryana, 1% from Andra Pradesh, 1% from Jharkhand.

Table 6: Number of subjects from different states

State	Number of Subjects (70 Subjects)	Percentage
Andra Pradesh	1	1%
Assam	6	9%
Bihar	2	3%
Haryana	1	1%

Jharkhand	1	1%
Karnataka	7	10%
Madhya Pradesh	2	3%
Maharashtra	10	14%
Manipur	4	6%
Rajasthan	3	4%
Tamil Nadu	3	4%
Telangana	22	32%
Uttar Pradesh	4	6%
West Bengal	4	6%

Figure 6: Number of Subjects from different states



Advacryl Rapid Handling Characteristics

Suture Performance

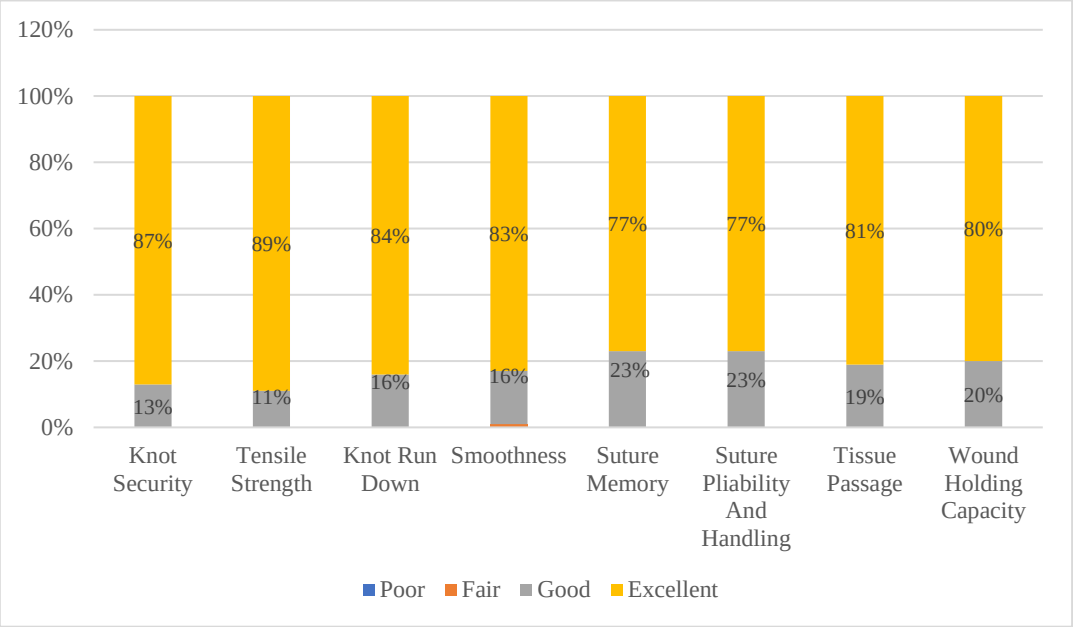
For Suture Performance, Knot Security, Tensile Strength, Knot Run Down, Smoothness, Suture Memory, Suture Pliability and Handling, Tissue Passage, and Wound Holding Capacity attributes were studied.

Table 7: Rating of Suture Performance attributes

70 Subjects analyzed				
Rating Category	**Poor**	**Fair**	**Good**	**Excellent**
Knot Security	0%	0%	13%	87%
Tensile Strength	0%	0%	11%	89%
Knot Run Down	0%	0%	16%	84%
Smoothness	0%	1%	16%	83%
Suture Memory	0%	0%	23%	77%
Suture Pliability And Handling	0%	0%	23%	77%

70 Subjects analyzed				
Rating Category	**Poor**	**Fair**	**Good**	**Excellent**
Tissue Passage	0%	0%	19%	81%
Wound Holding Capacity	0%	0%	20%	80%

Figure 7:Suture Performance attributes



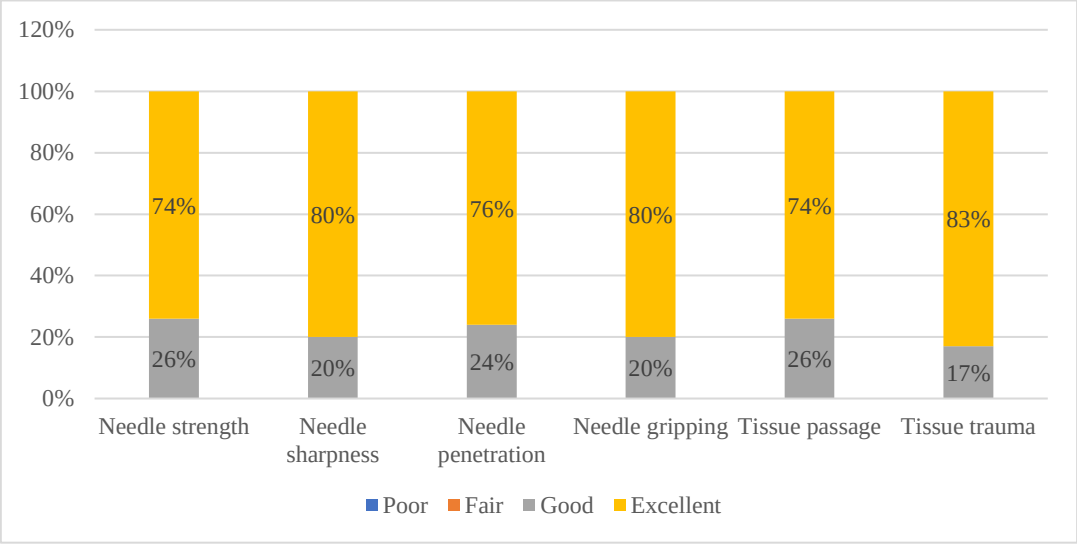
Needle Performance

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

70 Number of Subjects analyzed				
Rating Category	**Poor**	**Fair**	**Good**	**Excellent**
Needle strength	0%	0%	26%	74%
Needle sharpness	0%	0%	20%	80%
Needle penetration	0%	0%	24%	76%
Needle gripping	0%	0%	20%	80%
Tissue passage	0%	0%	26%	74%
Tissue trauma	0%	0%	17%	83%

Figure 8: Needle performance attributes



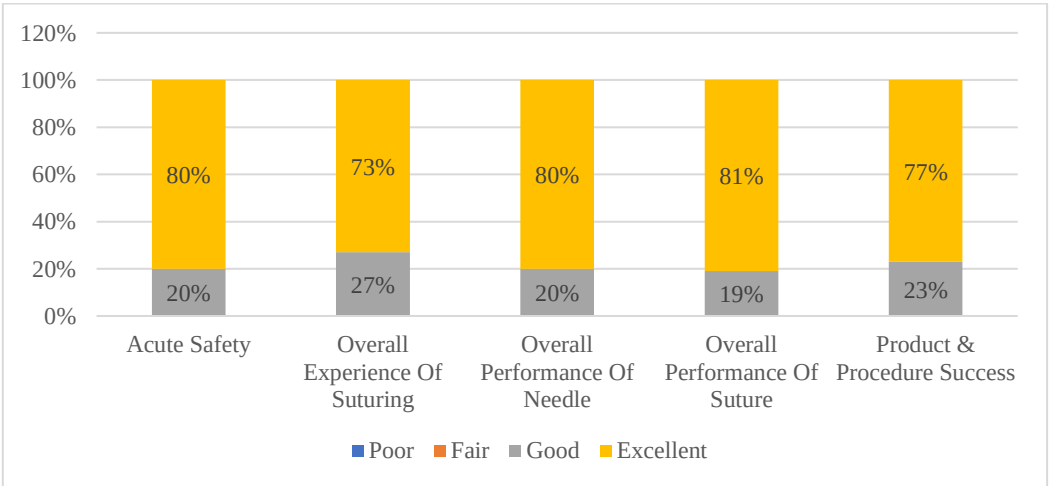
Overall Performance

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

70 Number of Subjects analyzed				
Rating Category	**Poor**	**Fair**	**Good**	**Excellent**
Acute Safety	0%	0%	20%	80%
Overall Experience Of Suturing	0%	0%	27%	73%
Overall Performance Of Needle	0%	0%	20%	80%
Overall Performance Of Suture	0%	0%	19%	81%
Product & Procedure Success	0%	0%	23%	77%

Figure 9: Overall performance



Clinical Presentation For Three Months Follow Up Data

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

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

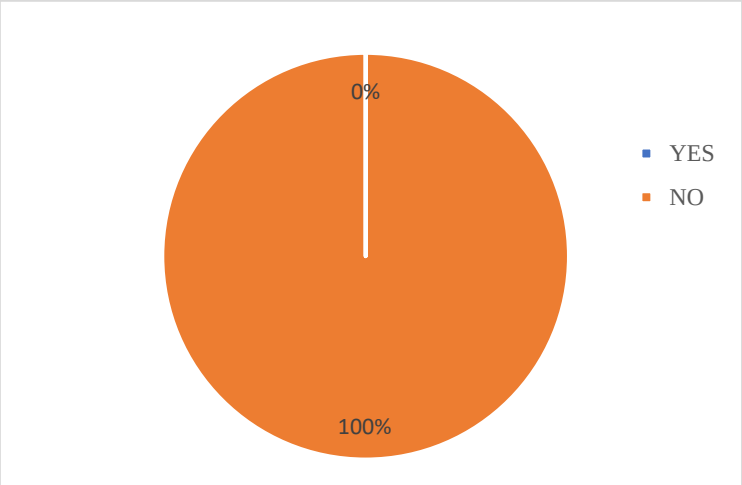
Wound Complication

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

Table 10: Wound complication

Wound Complication	70 Subjects
Yes	0%
No	100%

Figure 10: Wound Complication



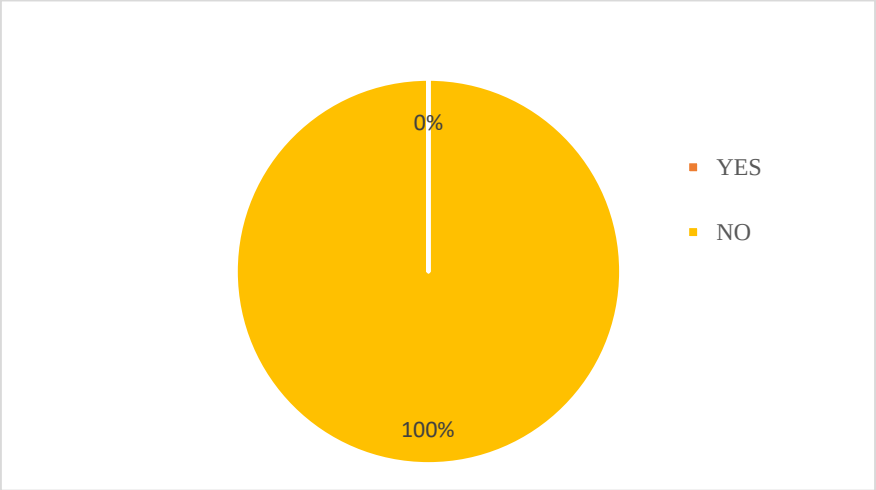
Adverse Events (AE) Or Severe Adverse Events (SAE):

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	70 Subjects
Yes	0%
No	100%

Figure 11:Adverse reaction



All the original tensile strength is lost by approximately 10 to 14 days post-implantation. ADVACRYL RAPID is essentially absorbed completely up to 42 days.

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 70 subjects, ADVACRYL RAPID (Braided Coated 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 >50 surgical centers across 14 different states of India, and included usage across 7 different surgical specialties, which demonstrates the wide diversity of clinical use of ADVACRYL RAPID (Braided Coated 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 RAPID 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 RAPID (Braided Coated 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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Financial Disclosure statement
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
No conflict of interest of any of the parties. Source documents can be made available on request.

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