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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 ADVALENE (Polypropylene) Surgical Suture. (ADVALENE 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 80 subjects from >65 surgical centers across various surgical specialties, ADVALENE (Polypropylene) monofilament, synthetic, non-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. ADVALENE (Polypropylene) sutures are a safe and effective option for a very wide variety of surgical procedures in a diverse population.

Keywords: Polypropylene, Monofilament, Non absorbable, Synthetic suture, Cardiovascular 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]

Monofilament, non- absorbable sterile surgical sutures are a type of suture that is composed of single strand. As this consists of single filament, cause minimum tissue trauma, less infection risk and minimal tissue reaction. Synthetic non-absorbable sutures are made from a variety of materials. Advanced MedTech Solutions (AMS) https://www.amsltd.com/products/advalene/ a monofilament synthetic non-absorbable suture called ADVALENE suture is a non-absorbable sterile surgical suture composed of an isotactic crystalline stereoisomer of polypropylene, a synthetic linear polyolefin.

ADVALENE suture is dyed with Phthalocyanine Blue to enhance visibility in tissue. ADVALENE suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic surgery, peripheral nerve anastomosis, cardiovascular and neurological procedures.
ADVALENE suture is contraindicated in patients with known sensitivities or allergies to Polypropylene. ADVALENE suture is not absorbed nor is subjected to degradation or weakening by the action of tissue enzymes. Due to its relative biological inertness, it is recommended for use where the least possible suture reaction is desired. As a monofilament it has been successfully employed in surgical wound which subsequently become infected or contaminated where it can minimize later sinus formation and suture extrusion due to its lack of adherence to tissue, ADVALENE suture is effective as a pull-out suture.
ADVALENE suture complies with United States Pharmacopeia requirement for "non-absorbable surgical suture" and the European Pharmacopoeia for "Sutures, Sterile Non-Absorbable".

Suture construction	Suture Color	Tensile strength Retention (%)	Mass Absorption* (days)
Monofilament	Undyed / Blue	Permanent	Non- absorbable

*Mass Absorption: Time in days required for suture to be totally absorbed in the body.

ADVALENE suture is designed to offer the following advantages.

Features	Benefits
Monofilament Construction	Smooth passage through the tissue with minimal tissue drag and minimal trauma
lsotactic strength for permanent wound support	Absolute regular & longitudinal structure for minimal suture breakage & fraying, optimal elasticity & elongation assuring knot stability & security and enhanced pliability & handling for easy knot tying & smooth knot run-down
Exceptionally smooth surface	For minimal tissue drag & minimal trauma
Excellent elasticity	Knot deforms and flattens to provide excellent knot security with excellent elasticity & elongation guaranteeing a stable knot

The current level of evidence for synthetic non-absorbable, sterile surgical sutures composed of an isotactic crystalline stereoisomer of polypropylene, such as ADVALENE, is supported by several studies focusing on their mechanical properties, biocompatibility, and clinical performance.
Polypropylene sutures are known for their high tensile strength and minimal tissue reactivity. Naleway et al. demonstrated that polypropylene sutures have a significant failure load, making them suitable for applications requiring durable wound support.[2] Additionally, Saxena et al. highlighted the development of antimicrobial polypropylene sutures, which showed promising in vitro and in vivo results, including the absence of adverse tissue reactions and effective antimicrobial properties.[3]
Clinical studies have also shown that polypropylene sutures perform well in various surgical contexts. Dragovic et al. found that non-resorbable polypropylene sutures provided superior soft tissue healing and elicited the least inflammatory reaction compared to other suture materials in oral surgery.[4] Furthermore, Moledina et al. reported that polypropylene sutures had lower complication rates, such as suture infection and granuloma formation, compared to absorbable sutures in the Lateral Tarsal Strip procedure.[5]

In summary, the evidence supports the use of ADVALENE polypropylene sutures for their mechanical strength, biocompatibility, and favorable clinical outcomes in various surgical applications.

Common complications associated with the use of polypropylene sutures include:

1. **Foreign Body Reactions:** Polypropylene sutures can act as foreign bodies, leading to complications such as abscesses, fistula formation, and secondary infections. A case study reported cutaneous symptoms and complications related to retained polypropylene sutures.[6]
2. **Stone Formation:** In urologic surgeries, polypropylene sutures have been implicated in the formation of urinary calculi, with associated fibrosis around the sutured urothelium.[7]
3. **Suture Extrusion and Foreign Body Attachment:** Polypropylene sutures used in enteric closures have been reported to extrude into the intestinal lumen, serving as sites for foreign body attachment and causing recurrent intestinal disease.[8]
4. **Granuloma Formation and Suture Infection:** In procedures such as the Lateral Tarsal Strip, polypropylene sutures have been associated with granuloma formation and suture infections, although at lower rates compared to absorbable sutures.[4]
5. **Erosions and Urinary Retention:** In the context of synthetic slings for urinary incontinence, polypropylene sutures have been associated with vaginal and urethral erosions and urinary retention, necessitating surgical intervention in some cases.[9]

These complications highlight the importance of careful patient selection, surgical technique, and postoperative monitoring when using ADVALENE polypropylene sutures.

ADVALENE Polypropylene sutures, known for their high tensile strength and minimal tissue reactivity, are particularly beneficial in several patient populations:

1. **Oral Surgery Patients:** Polypropylene sutures have demonstrated superior soft tissue healing and minimal inflammatory reaction in oral surgical procedures. Dragovic et al. found that these sutures provided the best healing outcomes and the least microbial adherence compared to other suture materials.[10]
2. **Patients Undergoing Abdominal Wall Repair:** Polypropylene meshes used in the repair of abdominal wall defects show complete integration and increased resistance to traction over time, making them suitable for patients requiring durable and strong wound support.[11]
3. **Patients with Penile Deviation:** In the context of Essed-Schroeder plication for penile deviation, polypropylene sutures were associated with lower rates of postoperative discomfort and pain compared to other nonabsorbable sutures, making them a preferable choice for these patients.[12]
4. **Gynecological Surgery Patients:** In vaginal uterosacral ligament suspension (USLS) procedures, polypropylene sutures were associated with lower suture-related complication rates, such as granulation tissue and suture erosion, compared to multifilament polyester sutures, without increasing surgical failure rates.[13]
5. **Patients at Risk of Postoperative Infection:** The development of antimicrobial polypropylene sutures has shown promising results in reducing microbial colonization and infection rates, which is particularly beneficial for patients at higher risk of postoperative infections.[3]

In summary, polypropylene sutures are advantageous for patients undergoing oral surgery, abdominal wall repair, penile deviation correction, gynecological procedures, and those at risk of postoperative infections due to their high tensile strength, minimal tissue reactivity, and favorable clinical outcomes.

ADVALENE 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 pol-

ypropylene 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 Polypropylene (ADVALENE) Surgical Suture.' (ADVALENE 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/ADVALENE/2021 Ver. 02), CRF, etc.). The informed consent was waived on account of this being a retrospective study. Since ADVALENE 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 80 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 ADVALENE (Polypropylene) 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 ADVALENE (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 ADVALENE surgical suture [Time Frame: From Postoperative through 03 months] (Any Adverse Events related to the use of ADVALENE 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 ADVALENE 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 80 subjects was collected and analysed from different Surgeons and Hospitals from January 2023 till December 2023.

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

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 43.4 years with lowest age of 28 and highest age of 70, describe categories with 82 % of males and 18% of Females. Five Subject had medical history of diabetes mellitus, 9 subjects had hypertension and one subject had both diabetes and hypertension.

Table 1: Gender distribution of the subjects

Gender	80 Subjects
Female	18%
Male	82%

Figure 1: Gender distribution of the subjects

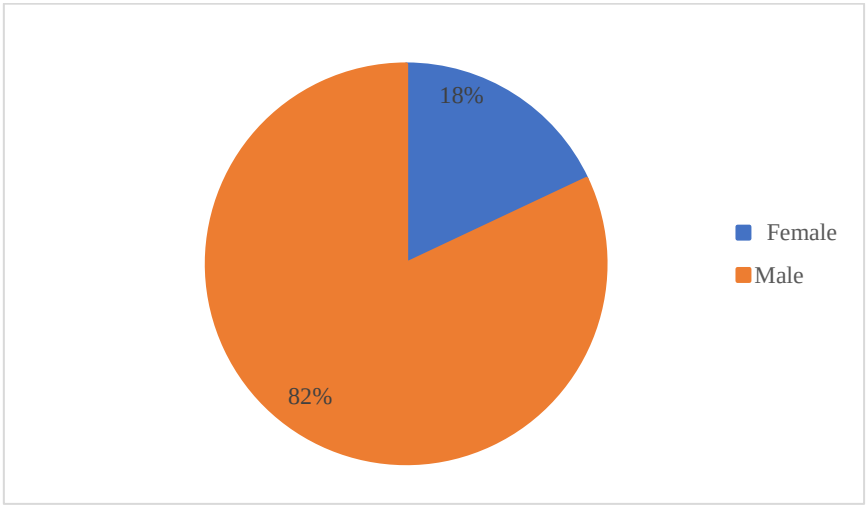


Table 2: Age categories

Age categories	80 Subjects
≤ 18 years	0%
Between 18 and 65 years	90%
≥ 65 years	10%

Figure 2: Age Categories

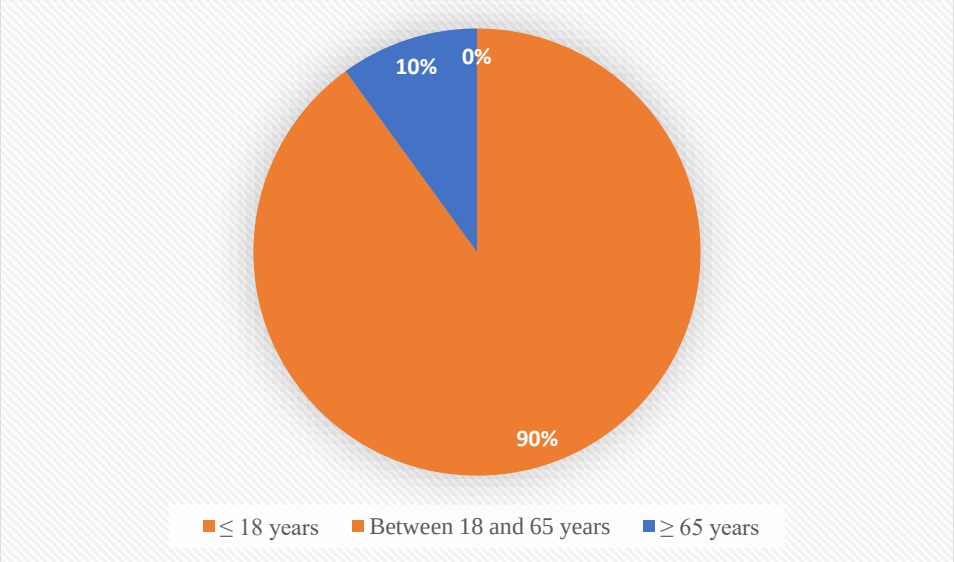
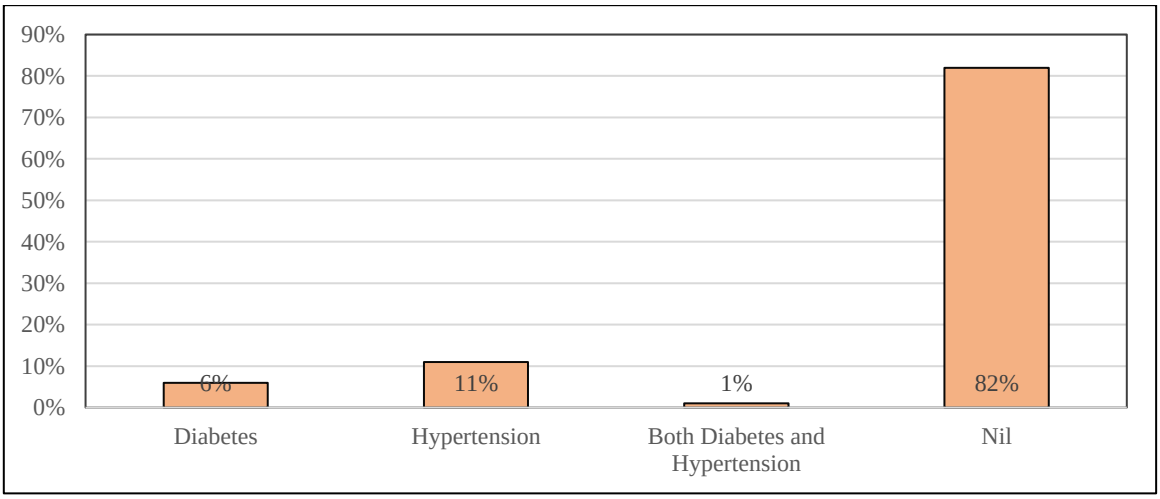


Table 3: Medical history of the subjects

Medical history	80 Subjects	Percentage
Diabetes	5	6%
Hypertension	9	11%
Both Diabetes and Hypertension	1	1%
Nil	65	82%

Figure 3:Medical history of the subjects



OPERATIVE DATA ANALYSIS

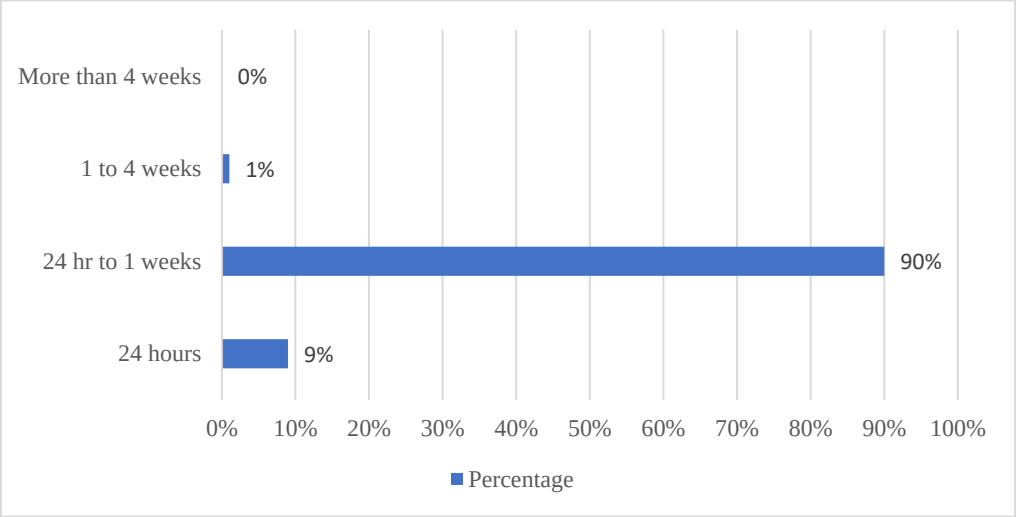
LENGTH OF HOSPITAL STAY

In total, the length of hospital stays of 90% of the subjects was 24 hours to 1 week, 9% of 24 hours, 1% of 1-4 weeks.

Table 4: Length of hospital stay.

Length of Hospital Stay	80 Subjects	Percentage
24 hours	7	9%
24 hr to 1 weeks	72	90%
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 80 subjects, 56% of the Subjects underwent procedures in General Surgery, 35% in Cardiovascular surgery, 3% in laparoscopic surgery,3% in Plastic surgery, 1% in Urology, 1% in Ob and Gyn Surgery and 1% in Onco Surgery.

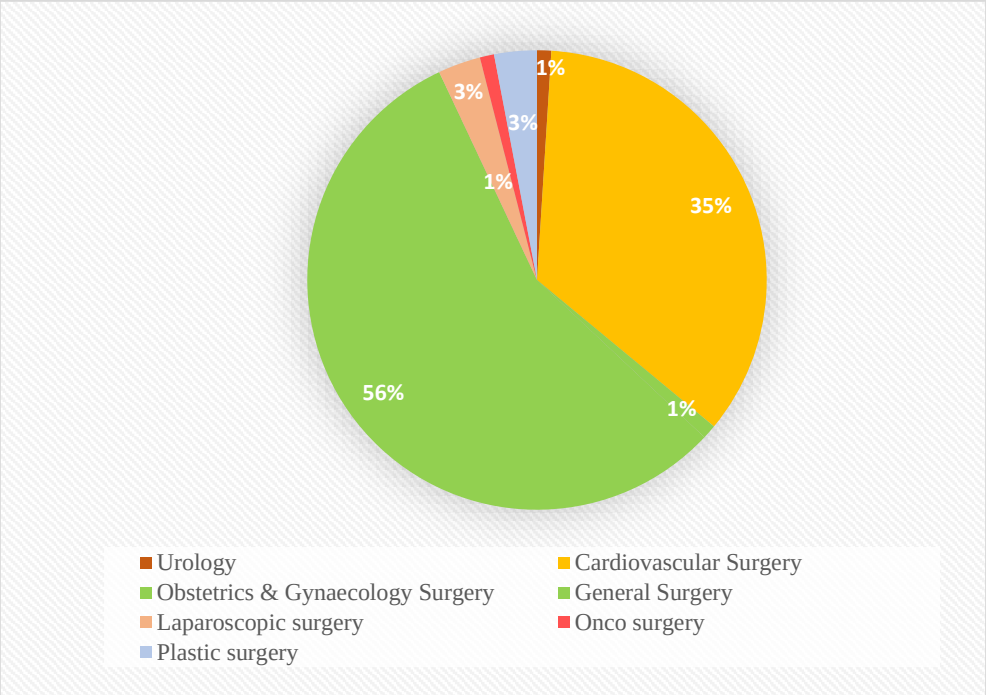
STATICAL ANALYSIS: SURGERY

Table 5: List of surgical procedure where ADVALENE was used.

Surgery name	Number of subjects (80 subjects)	Percentage
Cardiovascular Surgery	28	35%
General Surgery	45	56%
Laparoscopic surgery	2	3%
Onco surgery	1	1%
Plastic surgery	2	3%
Obstetrics & Gynaecology Surgery	1	1%

Urology	1	1%

Figure 5: Percentage of procedures in various Surgical Categories



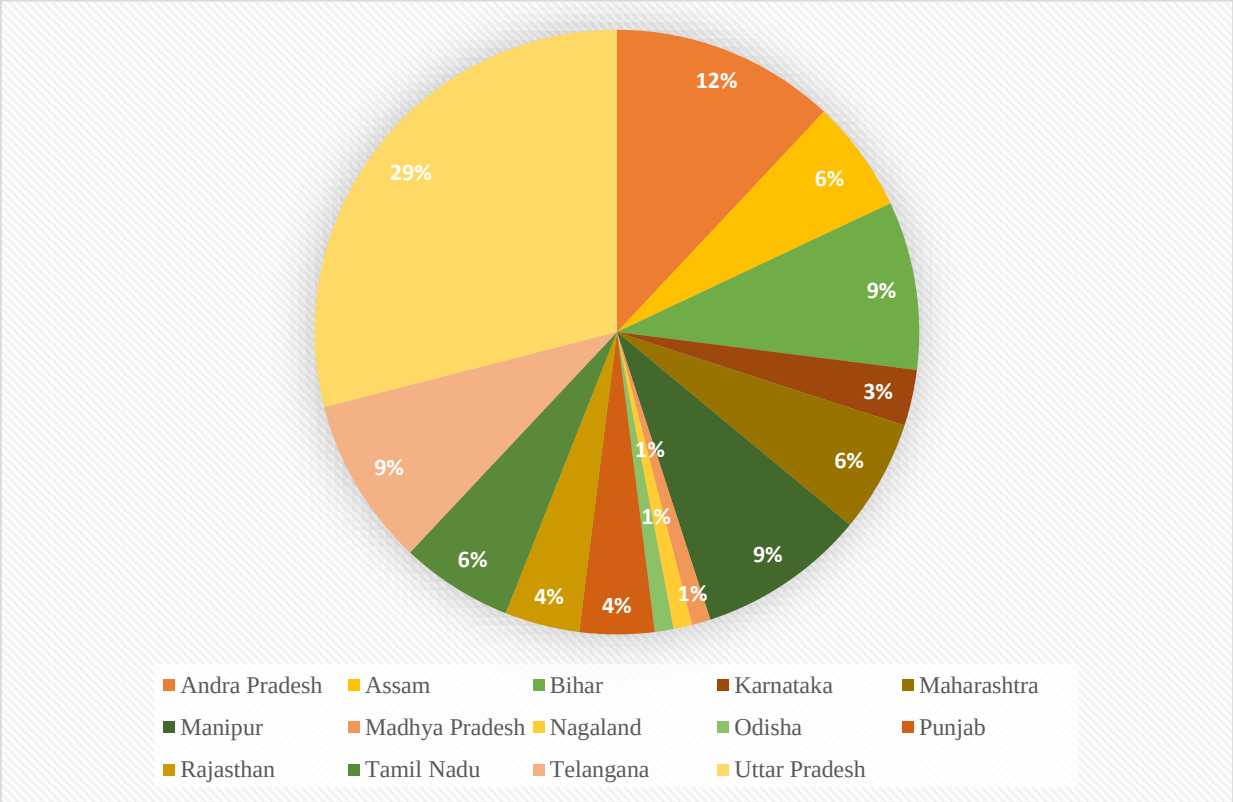
STATISTICAL ANALYSIS: STATE

In total, 29% of the Subjects from Uttar Pradesh, 12% from Andra Pradesh, 9% from Manipur, 9% from Telangana, 9% from Bihar, 6% from Tamil Nadu, 6% from Assam, 4% from Punjab, 4% from Rajasthan, 3% from Karnataka, 2% from Jharkhand, 1% from Madhya Pradesh, 1% from Nagaland, 1% from Odisha.

Table 6: Number of subjects from different states

State	Number of Subjects (80 Subjects)	Percentage
Andra Pradesh	8	12%
Assam	4	6%
Bihar	6	9%
Karnataka	2	3%
Maharashtra	4	6%
Manipur	6	9%
Madhya Pradesh	1	1%
Nagaland	1	1%
Odisha	1	1%
Punjab	3	4%
Rajasthan	3	4%
Tamil Nadu	4	6%
Telangana	6	9%
Uttar Pradesh	20	29%

Figure 6: Number of Subjects from different states



ADVALENE HANDLING CHARACTERISTICS

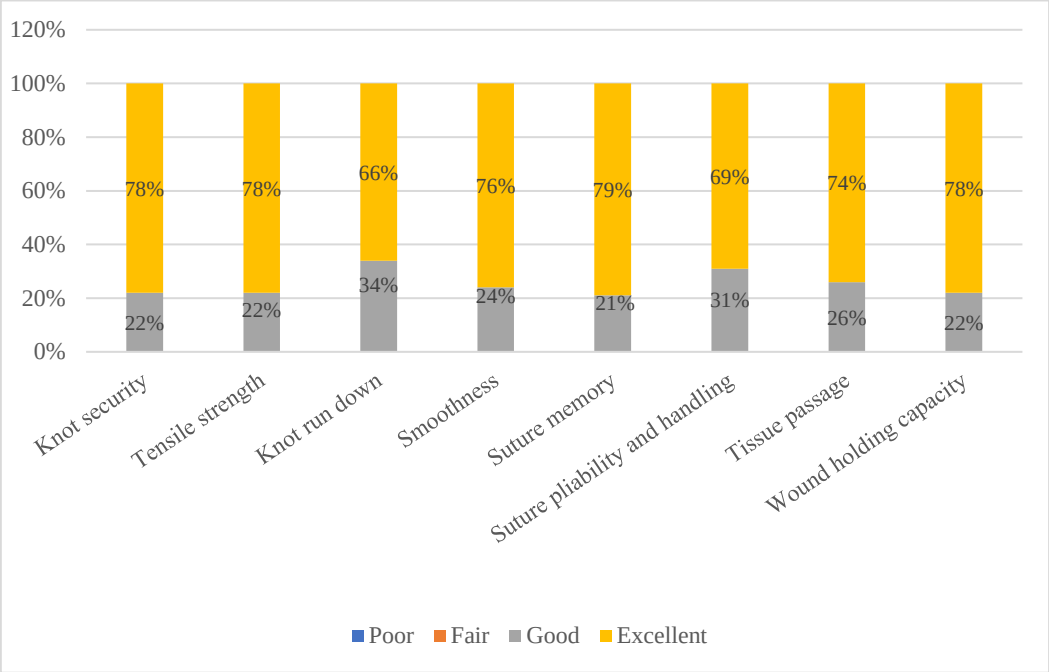
SUTURE PERFORMANCE

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

80 Number of Subjects analyzed				
Rating Category	**Poor**	**Fair**	**Good**	**Excellent**
Knot security	0%	0%	22%	78%
Tensile strength	0%	0%	22%	78%
Knot run down	0%	0%	34%	66%
Smoothness	0%	0%	24%	76%
Suture memory	0%	0%	21%	79%
Suture pliability and handling	0%	0%	31%	69%
Tissue passage	0%	0%	26%	74%
Wound holding capacity	0%	0%	22%	78%

Figure 7:Suture Performance attributes



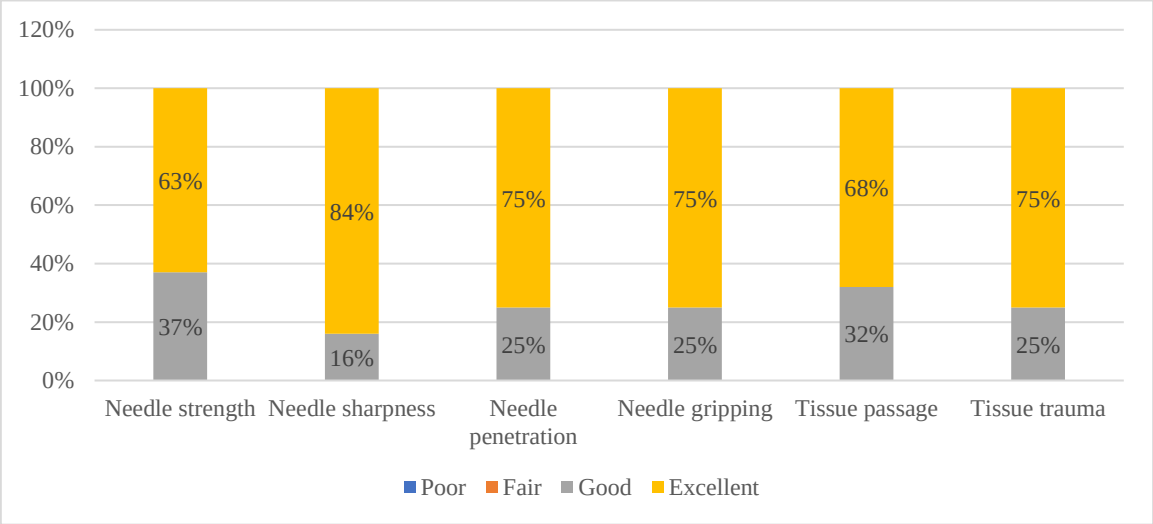
NEEDLE PERFORMANCE

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

80 Number of Subjects analyzed				
Rating Category	**Poor**	**Fair**	**Good**	**Excellent**
Needle strength	0%	0%	37%	63%
Needle sharpness	0%	0%	16%	84%
Needle penetration	0%	0%	25%	75%
Needle gripping	0%	0%	25%	75%
Tissue passage	0%	0%	32%	68%
Tissue trauma	0%	0%	25%	75%

Figure 8: Needle performance attributes



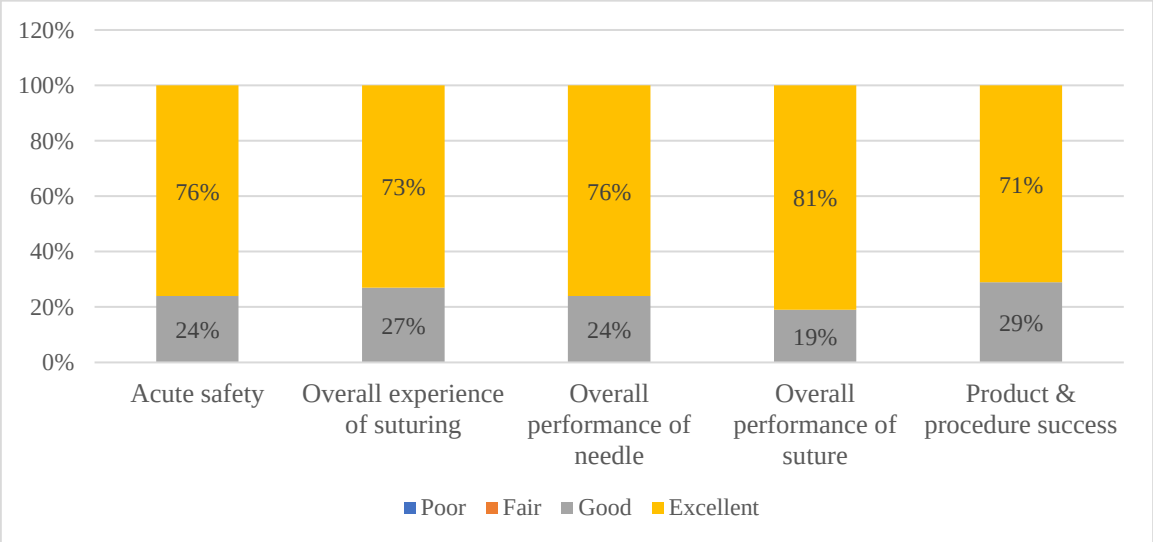
OVERALL PERFORMANCE

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

80 Number of Subjects analyzed				
Rating Category	**Poor**	**Fair**	**Good**	**Excellent**
Acute safety	0%	0%	24%	76%
Overall experience of suturing	0%	0%	27%	73%
Overall performance of needle	0%	0%	24%	76%
Overall performance of suture	0%	0%	19%	81%
Product & procedure success	0%	0%	29%	71%

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. Details of adverse events/ serious adverse events

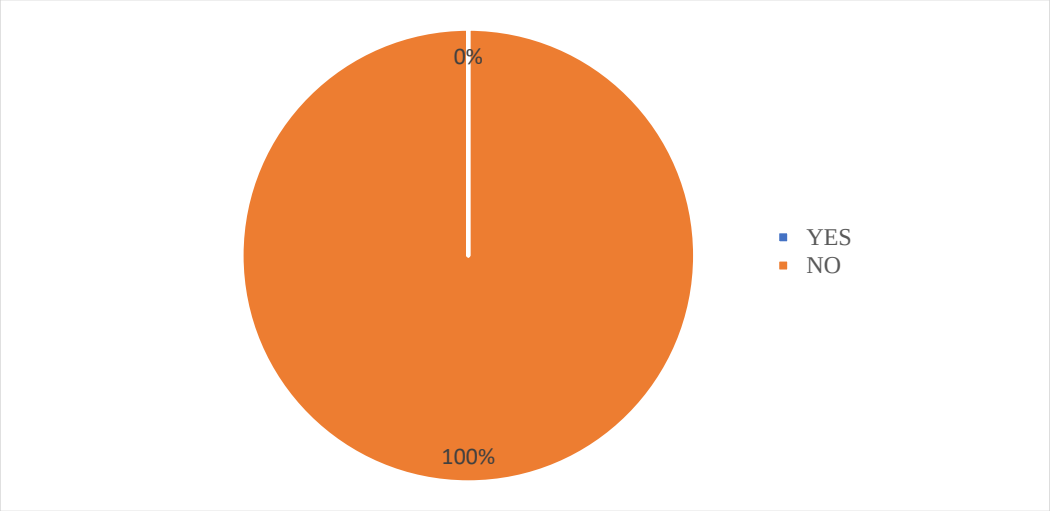
WOUND COMPLICATION

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

Table 10: Wound complication

Wound complication	80 Subjects
Yes	0%
No	100%

Figure 10: Wound Complication



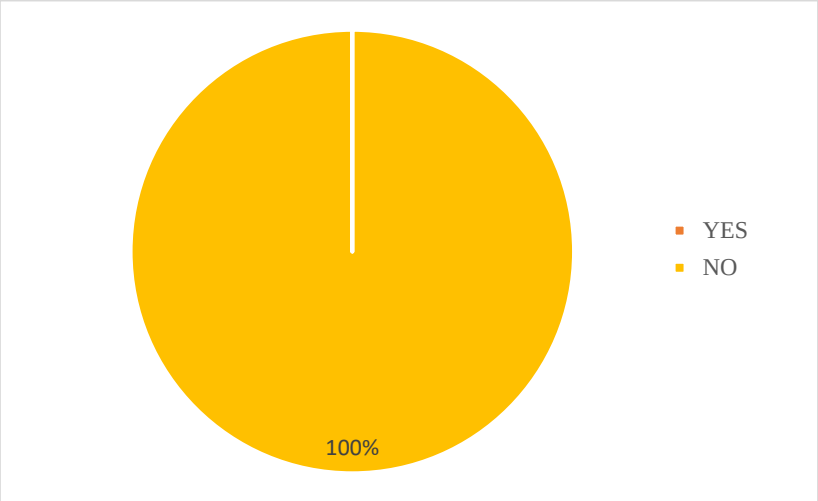
ADVERSE EVENTS (AE) OR SEVERE ADVERSE EVENTS (SAE):

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	80 Subjects
Yes	0%
No	100%

Figure 11:Adverse Reaction



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 80 subjects, ADVALENE (Polypropylene) monofilament, synthetic non- 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 >65 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 ADVALENE (Polypropylene) sutures.
- The study successfully achieved its primary and secondary safety and performance objectives, over a significantly long 3-month follow-up period.
- ADVALENE 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.
- ADVALENE (Polypropylene) 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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