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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 ADVALON (Polyamide) Surgical Suture. (ADVALON 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 >70 surgical centers across various surgical specialties, ADVALON (Polyamide) 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. ADVALON (Polyamide) sutures are a safe and effective option for a very wide variety of surgical procedures in a diverse population.

Keywords: Polyamide, Monofilament, Non - 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]

Advanced MedTech Solutions (AMS) https://www.amsltd.com/products/advalon ADVALON suture is a non-absorbable sterile surgical suture composed of the long chain aliphatic polymers Nylon 6-6.6. ADVALON suture is indicated for use in general soft tissue approximation and/or ligation and ophthalmic procedure.

Due to the gradual loss of tensile strength which may occur over prolonged periods in-vivo, ADVALON suture should not be used where permanent retention of tensile strength is required. ADVALON suture is contraindicated in patients with known sensitivities or allergies to Polyamide. ADVALON suture elicits a minimal initial inflammatory reaction in tissues which is followed by gradual encapsulation of the suture

by fibrous connective tissues. Although polyamide is not absorbed, progressive hydrolysis of the polyamide, In-vivo may result in gradual loss over time of tensile strength. ADVALON suture is effective as a pull-out suture due to its lack of adherence to tissue.

ADVALON sutures are dyed black with Logwood dye Hematin - Black CI 75290. ADVALON 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	Effective Tensile strength Retention (%)	Mass Absorption* (days)
Monofilament	Black	Gradual Loss of Tensile Strength over a period of time. Gradual encapsulation of the suture by fibrous connective tissue	Non- absorbable

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

ADVALON suture is designed to offer the following advantages

Features	Benefits
Monofilament Construction	Smooth passage through the tissue with minimal tissue drag and minimal trauma
Acapillarity	Lesser chance of bacterial transmission, lesser chance of infection
Excellent pliability	Excellent pliability provides exceptional handling and knot tying properties
Excellent elasticity	Superior tactile feedback to the surgeon, minimal suture breakage
Inert polymer	Minimal tissue reaction proving ideal for infected wound closure with suture of choice for desired cosmetic outcomes

A prospective, multi-centric, international cohort study assessed the safety, effectiveness, and performance of a nylon monofilament suture in oral surgery. The study found a low complication rate (1.9%) and high patient satisfaction, with excellent wound healing reported by dentists.[2] This indicates that nylon-based monofilament sutures are suitable for oral mucosal closure after various dental surgical interventions.

Another study compared bacterial accumulation on different suture materials following oral surgery. It found that nylon sutures had significantly lower colony-forming unit (CFU) levels compared to silk, coated polyglactin, and polyester sutures, suggesting that nylon sutures may reduce the risk of postoperative infection due to their lower microbial accumulation.[3]

A systematic review evaluating suture materials in oral surgery concluded that non-resorbable monofilament synthetic sutures, including nylon, exhibited less tissue response and microbial accumulation compared to other materials.[4] This supports the use of nylon sutures for minimizing tissue reaction and infection risk.

In ophthalmic surgery, the load-bearing and deformation characteristics of monofilament nylon 66 were

found to be beneficial, although the performance can be influenced by the manner in which the suture is stressed.[5]

Overall, the clinical evidence suggests that non-absorbable, sterile surgical monofilament sutures composed of Nylon 6 and Nylon 6.6 are effective and safe for use in various surgical contexts, particularly in oral and ophthalmic surgeries, due to their favorable handling characteristics, low complication rates, and reduced microbial accumulation.

ADVALON sutures are particularly recommended for oral surgery patients, those at risk of infection, patients requiring minimal tissue reaction, and certain ophthalmic surgery patients. These recommendations are based on their demonstrated safety, effectiveness, and favorable clinical outcomes in these specific populations.

1. **Oral Surgery Patients:** The MUCODA study demonstrated that these sutures are highly effective and safe for oral mucosal closure after various dental surgical interventions, such as tooth extraction, implant placement, and impacted third molar extraction. The study reported a low complication rate (1.9%) and high patient satisfaction, with excellent wound healing outcomes.[2]
2. **Patients at Risk of Infection:** Nylon sutures have been shown to have lower bacterial adherence compared to other suture materials like silk and polyglactin. This makes them particularly suitable for patients who are at higher risk of postoperative infections, as they minimize microbial accumulation and tissue reaction.[4]
3. **Patients Requiring Minimal Tissue Reaction:** Nylon sutures exhibit less tissue response compared to other materials, which is beneficial for patients who may have heightened inflammatory responses or are undergoing procedures where minimal tissue reaction is crucial for optimal healing.[4]
4. **Ophthalmic Surgery Patients:** In pediatric cataract surgery, although absorbable sutures like Advacryl are preferred to avoid repeated anesthesia, nylon sutures are still used due to their favorable handling characteristics and lower rates of complications like suture loosening and vascularization.[6]

While non-absorbable Nylon 6 and Nylon 6.6 sutures are generally safe and effective, they can cause pain, swelling, bacterial contamination, tissue reaction, and specific complications related to suture protrusion and breakage in oral and ophthalmic surgeries.[2,4,7,8]

ADVALON 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 Polyamide 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 Polyamide (ADVALON) Surgical Suture.’ (ADVALON 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/ADVALON/2021 Ver. 02), CRF, etc.). The informed consent was waived on account of this being

a retrospective study. Since ADVALON 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 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 ADVALON (Polyamide) 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 ADVALON (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 ADVALON surgical suture [Time Frame: From Postoperative through 03 months] (Any Adverse Events related to the use of ADVALON 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 ADVALON 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 44.35 years with lowest age of 25 and highest age of 69, describe categories with 66 % of males and 34% of Females. No Subject had medical history of diabetes mellitus and Hypertension.

Table 1: Gender distribution of the subjects

Gender	80 Subjects
Female	66%
Male	34%

Figure 1: Gender distribution of the subjects

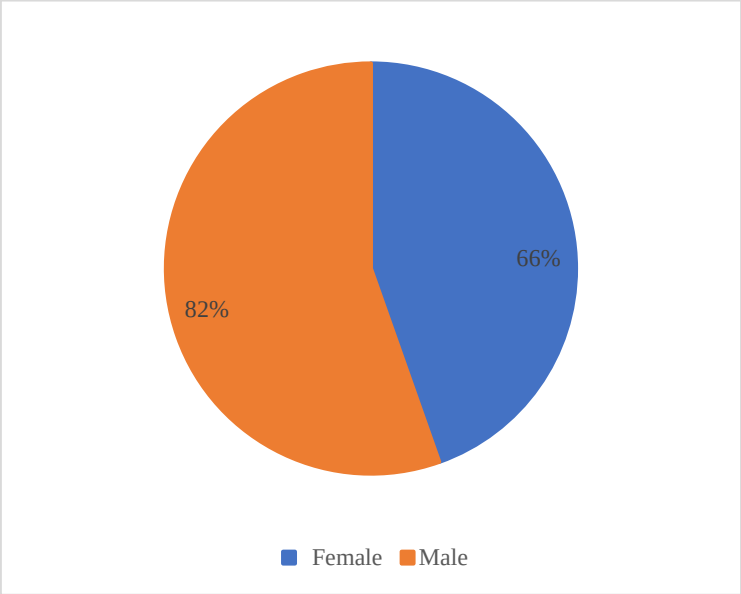
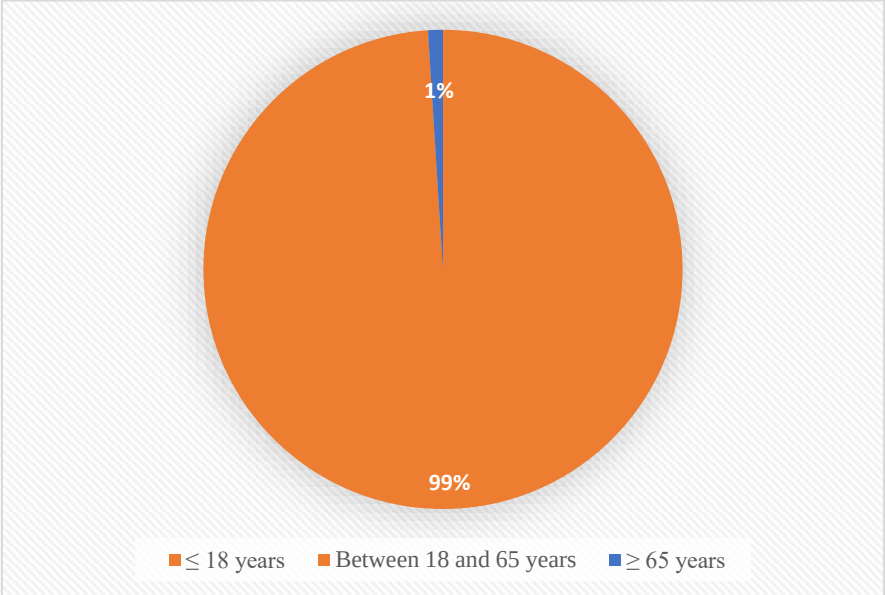


Table 2: Age categories

Age categories	80 Subjects
≤ 18 years	0%
Between 18 and 65 years	99%
≥ 65 years	1%

Figure 2: Age Categories



OPERATIVE DATA ANALYSIS

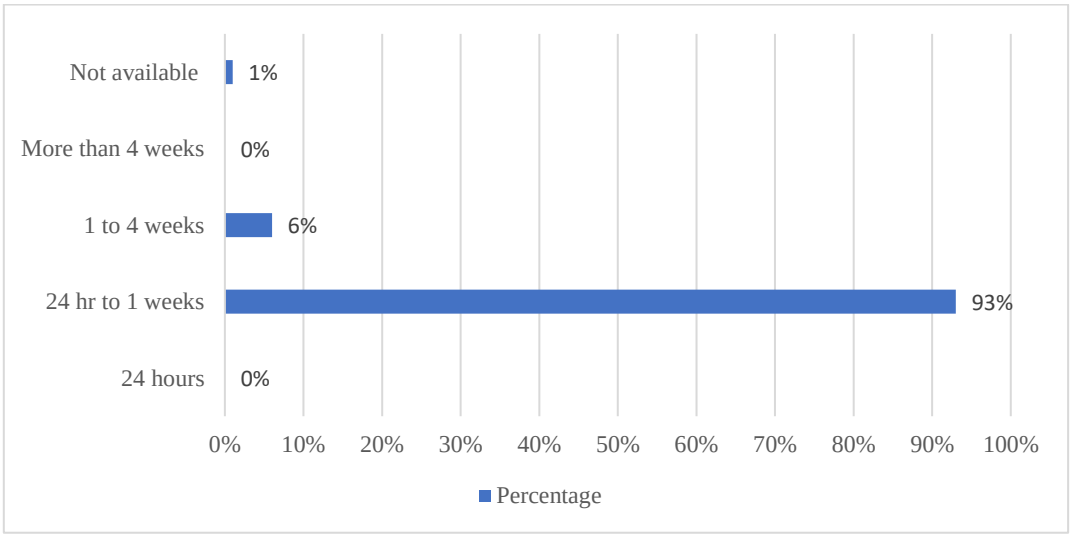
LENGTH OF HOSPITAL STAY

In total, the length of hospital stays of 93% of the subjects was 24 hours to 1 week, 6% of 1-4 weeks. However, 1% subjects' data was not available.

Table 3: Length of hospital stay.

Length of Hospital Stay	80 Subjects	Percentage
24 hours	0	0%
24 hr to 1 weeks	74	93%
1 to 4 weeks	5	6%
More than 4 weeks	0	0%
Not available	1	1%

Figure 3: Length of hospital stay



PATIENT BASELINE INFORMATION

CLINICAL PRESENTATION ON THE DAY 0

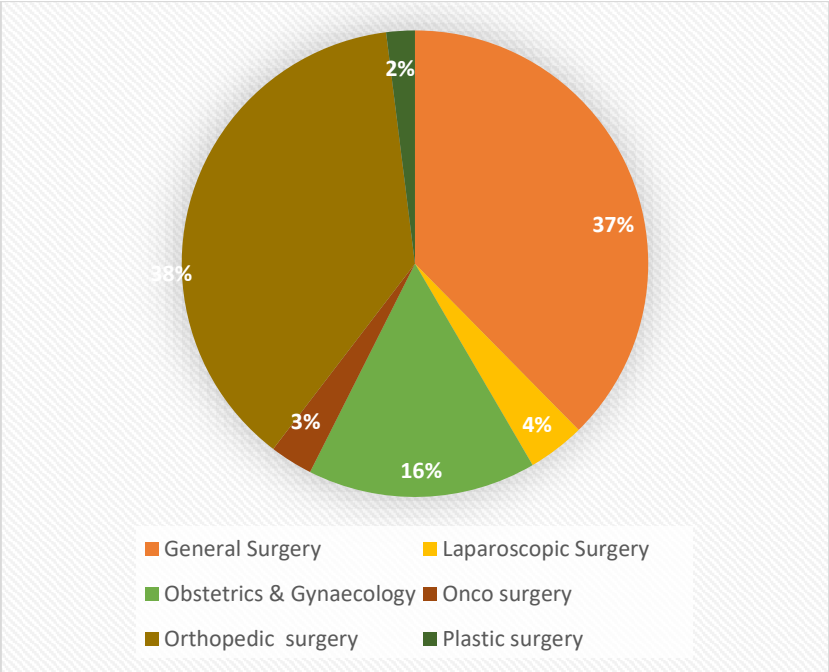
Of the 80 subjects, 38% of the Subjects underwent procedures in General Surgery, 38% in Orthopaedic surgery, 16% in Obstetrics and Gynaecology Surgery, 4% in laparoscopic surgery,3% in Plastic surgery, and 3% in Onco Surgery.

STATICAL ANALYSIS: SURGERY

Table 4: List of surgical procedure where ADVALON was used.

Surgery name	Number of subjects (80 subjects)	Percentage
General surgery	30	38%
Laparoscopic Surgery	3	4%
Obstetrics & Gynaecology	13	16%
Onco surgery	2	3%
Orthopaedic surgery	30	38%
Plastic surgery	2	3%

Figure 4: Percentage of procedures in various Surgical Categories



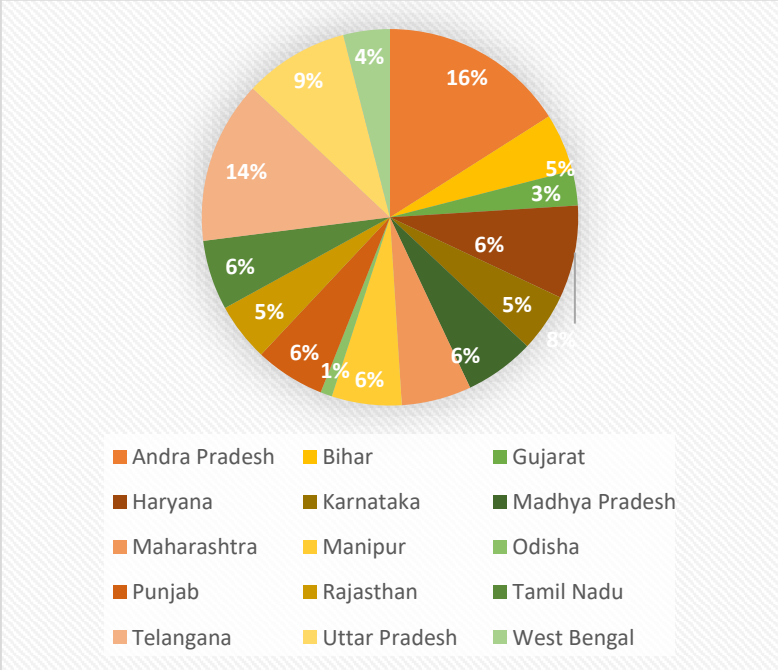
STATISTICAL ANALYSIS: STATE

In total, 16% of the Subjects from Andra Pradesh, 14% from Telangana, 9% from Uttar Pradesh, 8% from Haryana, 6% from Madhya Pradesh, 6% from Maharashtra, 6% from Manipur, 6% from Punjab, 6% from Tamil Nadu, 5% from Rajasthan, 5% from Bihar, 5% from Karnataka, 3% from Gujarat, and 1% from Odisha

Table 5: Number of subjects from different states

State	Number of Subjects (80 Subjects)	Percentage
Andra Pradesh	13	16%
Bihar	4	5%
Gujarat	2	3%
Haryana	6	8%
Karnataka	4	5%
Madhya Pradesh	3	6%
Maharashtra	5	6%
Manipur	5	6%
Odisha	1	1%
Punjab	5	6%
Rajasthan	4	5%
Tamil Nadu	5	6%
Telangana	11	14%
Uttar Pradesh	7	9%
West Bengal	3	4%

Figure 5: Number of Subjects from different states



ADVALON HANDLING CHARACTERISTICS

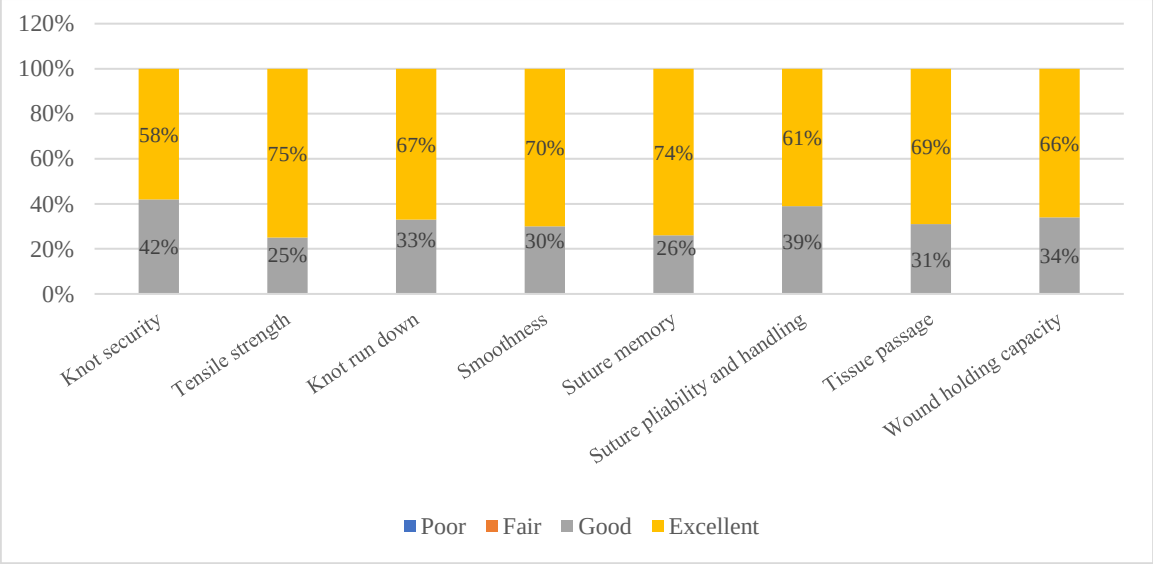
SUTURE PERFORMANCE

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 6: Rating of Suture Performance attributes

80 Number of Subjects analysed				
Rating Category	**Poor**	**Fair**	**Good**	**Excellent**
Knot security	0%	0%	42%	58%
Tensile strength	0%	0%	25%	75%
Knot run down	0%	0%	33%	67%
Smoothness	0%	0%	30%	70%
Suture memory	0%	0%	26%	74%
Suture pliability and handling	0%	0%	39%	61%
Tissue passage	0%	0%	31%	69%
Wound holding capacity	0%	0%	34%	66%

Figure 6:Suture Performance attributes



NEEDLE PERFORMANCE

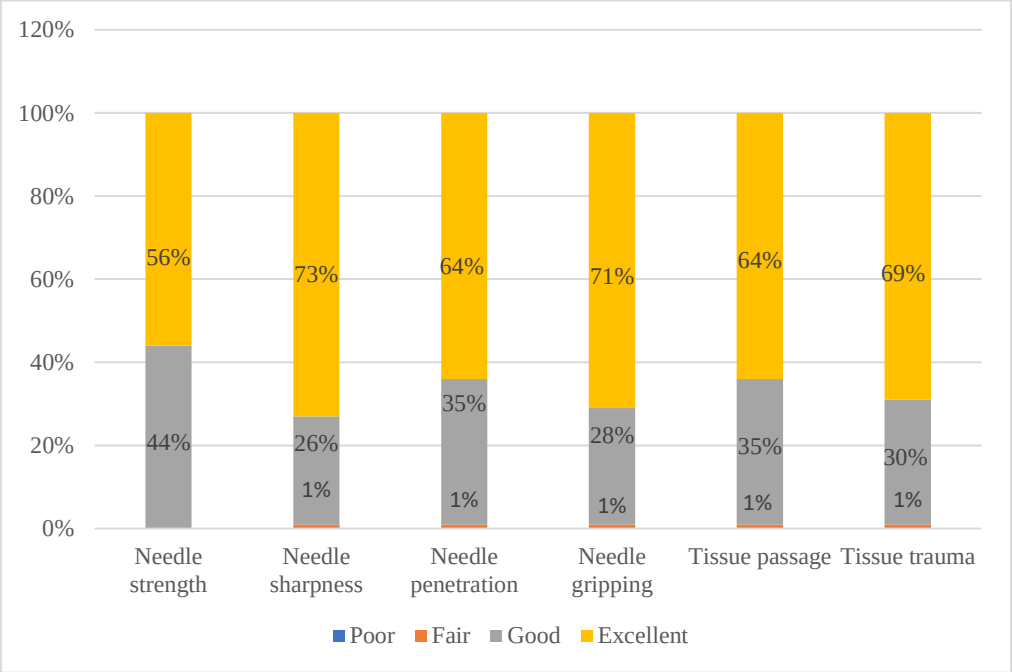
For needle performance like Needle strength, Needle sharpness, Needle penetration, Needle gripping, Tissue passage, and Tissue trauma were studied.

Table 7: Rating of Needle Performance attributes

80 Number of Subjects analyzed				
Rating Category	**Poor**	**Fair**	**Good**	**Excellent**
Needle strength	0%	0%	44%	56%
Needle sharpness	0%	1%	26%	73%

Needle penetration	0%	1%	35%	64%
Needle gripping	0%	1%	28%	71%
Tissue passage	0%	1%	35%	64%
Tissue trauma	0%	1%	30%	69%

Figure 7: Needle performance attributes



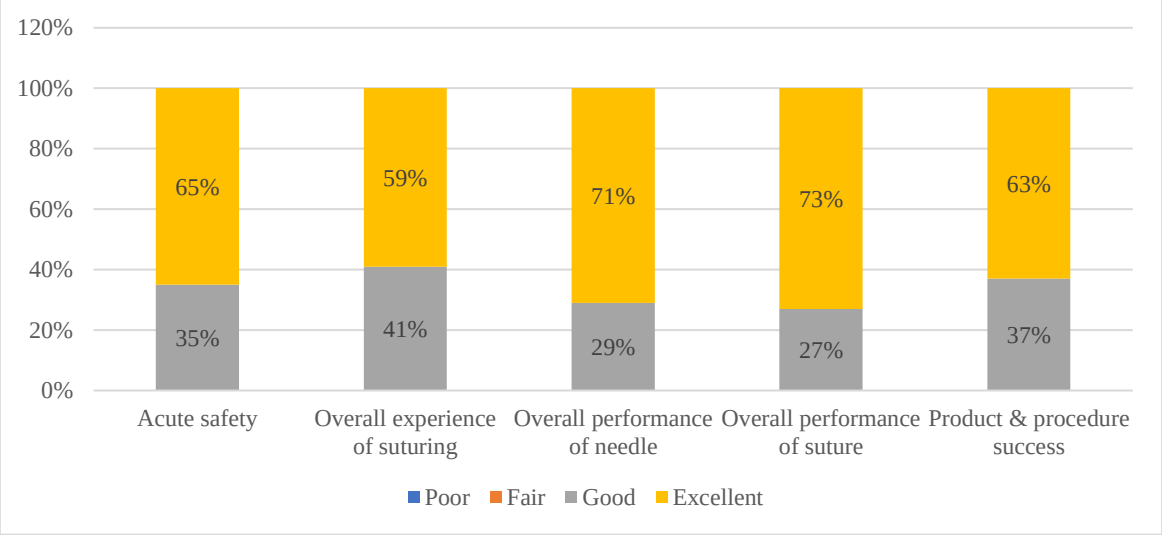
OVERALL PERFORMANCE

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 8: Rating of Overall performance of the product

80 Number of Subjects analyzed				
Rating Category	**Poor**	**Fair**	**Good**	**Excellent**
Acute safety	0%	0%	35%	65%
Overall experience of suturing	0%	0%	41%	59%
Overall performance of needle	0%	0%	29%	71%
Overall performance of suture	0%	0%	27%	73%
Product & procedure success	0%	0%	37%	63%

Figure 8: 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

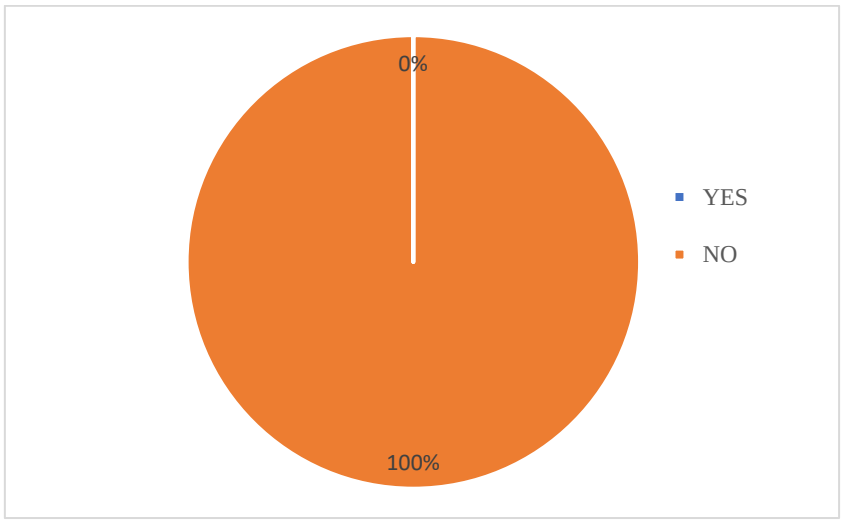
WOUND COMPLICATION

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

Table 9: Wound complication

Wound complication	80 Subjects
Yes	0%
No	100%

Figure 9: Wound Complication



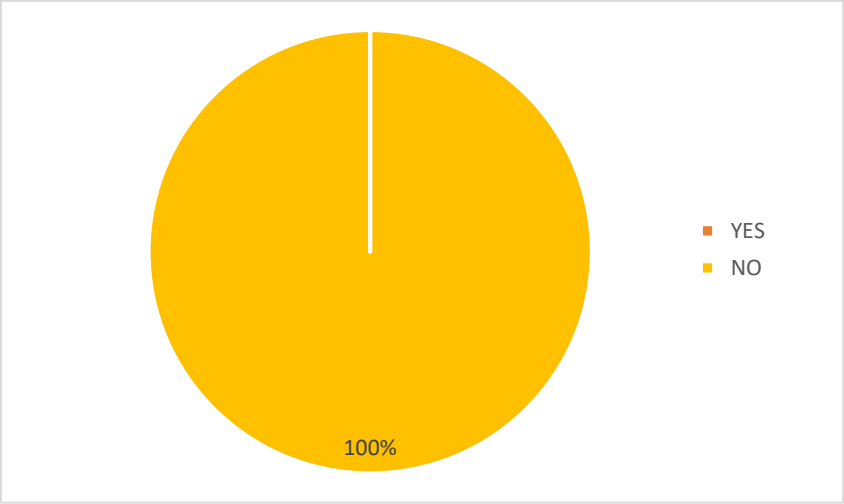
ADVERSE EVENTS (AE) OR SEVERE ADVERSE EVENTS (SAE):

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 10: ADVERSE REACTION

Adverse reaction	80 Subjects
Yes	0%
No	100%

Figure 10: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, ADVALON (Polyamide) 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 >70 surgical centers across 15 different states of India, and included usage across 6 different surgical specialties, which demonstrates the wide diversity of clinical use of ADVALON (Polyamide) sutures.
- The study successfully achieved its primary and secondary safety and performance objectives, over a significantly long 3-month follow-up period.
- ADVALON 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.

- ADVALON (Polyamide) 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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