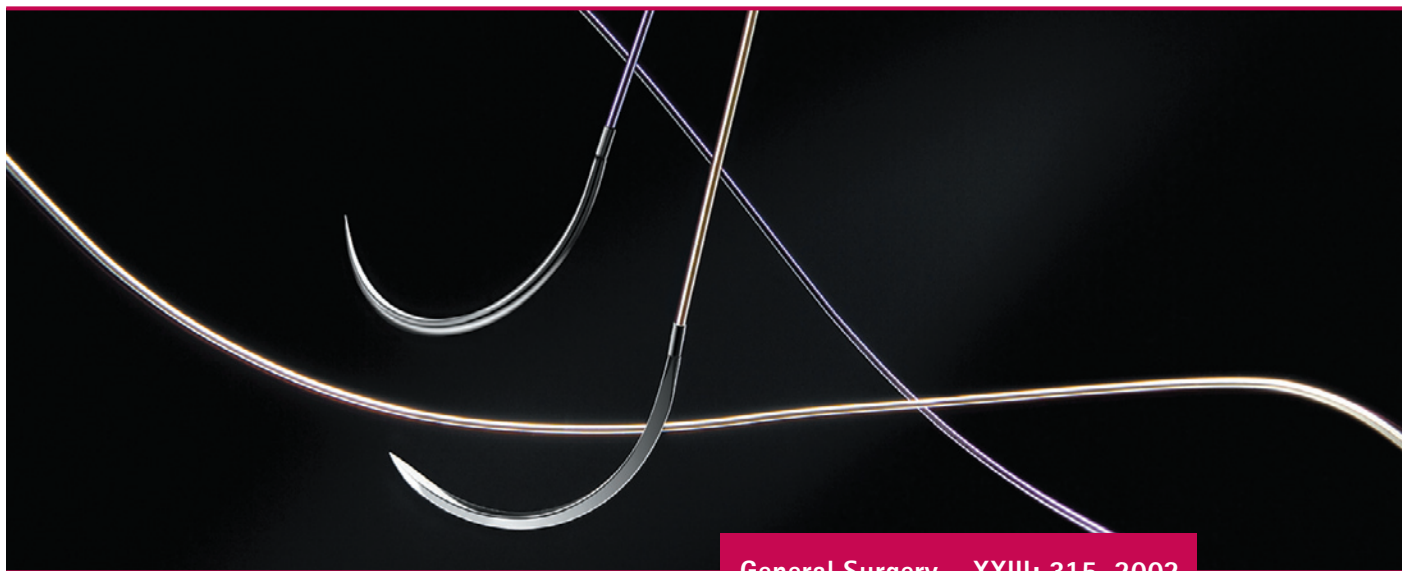


B. Braun Sutures

Monosyn®

Multi-centric A.C.O.I. study of a new
mid-term absorbable monofilament suture



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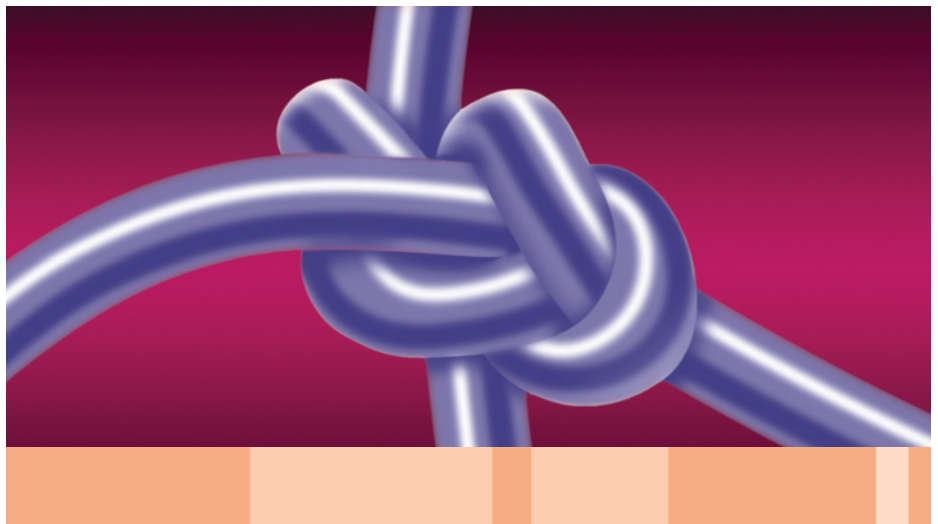
Introduction

The purpose of the study was to verify the possibility of use and safety of Monosyn®, a new mid-term absorbable monofilament suture in general surgery, as well as demonstrating how a mid-term absorbable monofilament suture can be a valid alternative to a polyfilament suture since the former has less potential for bacterial infection compared to the last one.

The study was carried out using consolidated suturing and knotting techniques. The evaluation was made based on the characteristics of ease of handling, the healing process and the frequency of complications post-operatively and upon routine checks.

The selection of the patients was done according to the order of admittance to hospital, taking into consideration the inclusion and exclusion criteria.

The checks were carried out upon discharge and as routine between the 10th day and the 3rd month post-operatively.



Inclusion criteria

1. *Patients of both sexes to undergo surgical intervention where sutures with the characteristics of Monosyn® may be used.*
2. *Age $\geq 13 \leq 80$ years old*
3. *ASA I - III, life expectancy > 6 months*

Exclusion criteria

1. *Neurological and cardiovascular tissue*
2. *Patients who are to undergo successive radiotherapy on the area operated on.*
3. *Patients suffering from local or general pathologies which may have consequences for the healing process (e.g. uraemia, massive hypoproteinemia, severe avitaminosis, etc.)*
4. *The use of other suture materials in the area designated for the use of Monosyn®.*
5. *Patients with ASA III or more or with a life expectancy of less than 6 months.*



Materials and Methods

150 patients were operated with the suture subject to the study.

Of these 49% were male and 51% female: the average age was 49 years for the men and 55 for the women.

■ *Table 1 identifies the pathologies for which the patients underwent surgical intervention*

■ *Table 2 shows the methods of use of Monosyn®*

Following surgical intervention, the surgeons were asked to complete a questionnaire in which they were asked for their first impressions following the use of Monosyn®.

Table 1

Pathology

N

Neoplasias	27
– Colon - Sigma	17
– Stomach	10
Thyroid	31
Appendix	5
Cholecyst calculus	13
Haemorrhoids	1
Hernias and laparoceli	32
Breast	15
Hydrocele	1
Uterine fibromatosis	7
Prostatic hyperplasia	2
Neoformations	4
Other	12

Table 2

Method of use

N

Intestine	15
– Gastroenteric anastomosis	2
– Jejunum-jejunal anastomosis	1
– Ileocolic anastomosis	4
– Colocolic anastomosis	5
– Suture	3
Bladder	3
– Wall	2
– Urethral anastomosis	1
Cholecyst	7
Breast	8
Peritoneal fascia	67
Vascular ligatures	31
Subcutaneous	51
Other	4

Results

Table 3

Evaluation

N

Easy to handle	15%
Good	9%
Excellent	8%
Excellent knot security	23%
Good elasticity	9%
Good ductility	10%
High tensile strength	15%
Good flexibility	11%

There were no complications relating to the use of the suture, none at early post-operative checks and only one subcutaneous serum collection at late post-operative checks, which were however, not due to the use of Monosyn®.

■ *Table 3 summarizes the evaluation of the surgeons*

Conclusion

The impressions referred by the users indicate above the excellent security of the knot and easy handling, 2 characteristics traditionally known as typical for polyfilament sutures.

From the careful evaluation of the results it can easily be affirmed that Monosyn® is a valid alternative to mid-term absorbable polyfilament sutures. Indeed the benefit of monofilament structure (compared to polyfilament sutures: less bacterial potential and less tissue trauma) knot security good handling and short mass absorption (in 90 days maximum) comparable to polyfilament sutures, can only be associated with Monosyn®.



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