PROSPECTIVE STUDY ON THE SAFETY AND PERFORMANCE IN REAL CONDITIONS OF THE SUSPENSION THREAD NAMED INFINITE-THREAD®
(THREAD & LIFT LABORATORY)

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Investigation site: Medical practice for aesthetic and anti-aging medicine
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I. INTRODUCTION

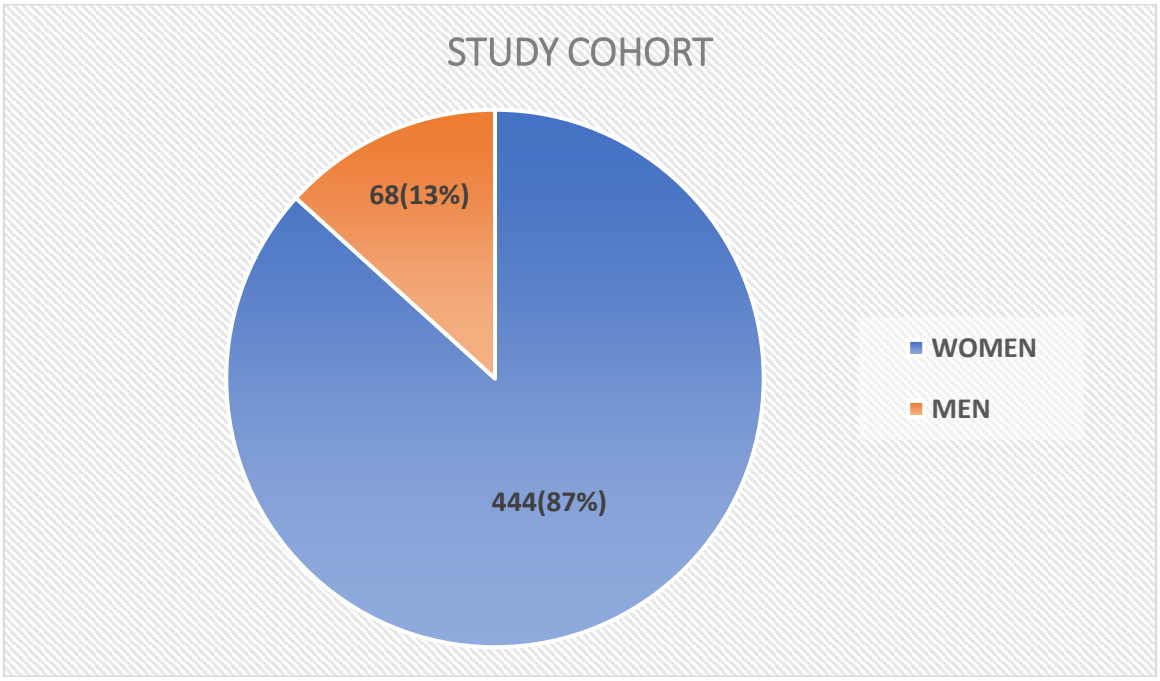
This prospective study aims to measure the safety and performance of the non-absorbable suspension thread of the brand “Infinite-Thread®”, manufactured by the Thread & Lift laboratory, in real life over a period ranging from 1 to 5 years (2018-2023) and implanted on the face and neck areas.

This is a prospective, single-center, observational clinical investigation, carried out by and on the initiative of Dr. ZAMMIT Pierre-Jean (promoter, investigator and author)**.**
Dr. ZAMMIT Pierre-Jean has been practicing aesthetic medicine since 2000, graduated from the DIU of Morphological and Anti-Aging Medicine in 2007 and teaches this discipline.

As of December 20, 2023, Dr. ZAMMIT Pierre-Jean has more than 3,000 thread lift procedures carried out for a total of 18,000 suspension threads implanted.

There was no training planned as part of this study. The investigator is accustomed to using this device and has received the same certified training from the Thread & Lift laboratory before its first use as all other user practitioners.

This study was carried out on a cohort of **512 patients** including 68 men and 444 women.



Graph 1: Distribution by gender of the cohort of 512 patients followed

The youngest patient in the study was 32 years old and the oldest was 92 years old.

II. PRESENTATION – PROTOCOL

1. Presentation of the medical device: non-absorbable suspension thread of the brand "Infinite-Thread®" manufactured by the Thread & Lift laboratory

Image 1: Picture of "Infinite-Thread®"

Infinite-Thread® suspension thread is composed of the following two non-absorbable biomaterials:

- A smooth green central part of the thread made of polyethylene terephthalate (PET / Polyester family)
- A purple cover part with cogs made of solid medical grade silicone

Infinite-Thread® suspension thread specifications:

- Thread composed of 800 cogs (series of 4 cogs every 1.5 millimeters over 30 centimeters)
- Anti-rollover cog technology (conical shape) and 8-axis hooking (45° rotation)
- Soft, non-aggressive cover, made of solid medical grade silicone
- Purple coloring of silicone useful for installation and removal
- Black coloring of the silicone in its center in order to delimit the middle of the thread and change in direction of the cogs

Image 2: Picture of the cogs technology of "Infinite-Thread®"

This medical device - Infinite-Thread® suspension thread – is CE marked since February 2018 (CE Certificate - No. 33932-2 issued by the notified body LNE/ Gmed).

2. Objectives and judgment criteria

a. Main objective

The main objective of this study is to evaluate the safety of the device up to 5 years after the intervention.

i. Main assessment criteria

The main assessment criteria are the complication rates related to the device or procedure up to 5 years after the intervention.

b. Secondary objectives

The secondary objectives of this study are:

- Evaluation of subjects' satisfaction with the performance of the medical device between 1 and 5 years after the intervention.
- Evaluation of practitioner satisfaction with the performance of the medical device between 1 and 5 years after the intervention.

i. Secondary assessment criteria

The secondary assessment criteria are:

- Subject satisfaction score (Likert scale – GAIS[1]) between 1 and 5 years after the intervention.
- Practitioner satisfaction score (Likert scale - GAIS) between 1 and 5 years after the intervention.

3. Clinical investigation population

a. Indication & Inclusion

The Infinite-Thread® suspension thread is indicated for the treatment of ptosis of the face and neck, in order to permanently reposition sagging subcutaneous tissues.

The inclusion criteria for this study are:

- Subject aged 18 or over
- Subject informed and not opposed to participating in the study
- Subject having been implanted with at least one Infinite-Thread® suspension thread

b. Non-inclusion

The non-inclusion criteria for this study are:

- Pregnant or breastfeeding women

[1]Global Aesthetic Improvement Scale

- Contraindications indicated by the laboratory (Allergy to components, infection, systemic diseases)

c. Criteria and procedures for exiting subjects participating in the clinical investigation

Subjects may terminate their participation at any time during the study, for whatever reason, without prejudice to subsequent care.

A subject who ends his participation may obtain, if he or she so requires, the withdrawal of his data and in any case any further processing of his data (non-use for statistical or scientific purposes).

A subject will be considered lost to follow-up if no direct contact has been established (including telephone) at the time of the end of the subject's theoretical participation (end-of-study visit) or if he or she has expressed his or her refusal to continue to participate in the study.

In the event of premature withdrawal of a subject from the study, no visit is required of the subject within the framework of the study.

Subjects who leave the study prematurely are not replaced.

d. Duration of the clinical investigation

Inclusion period: 5 years
Monitoring period: 1 year minimum (subject treated in 2022) to 5 years maximum (subject treated in 2018)
Duration of study: 6 years

Start of inclusions: 05/02/2018
End of inclusions: 31/12/2022
End of monitoring period: 31/12/2023
End of clinical investigation: 31/12/2023

4. Clinical investigation procedures

a. Clinical procedures and diagnostic methods

The management of the subjects and the intervention are the same as in usual practice in order to monitor the evolution of the patient and possible consequences/complications (main objective).

The date of the follow-up visit giving rise to the collection of the results of the secondary objectives of this study, for all subjects, is determined by the 5th year post-intervention of the 1st subject of this study, i.e. 2023.

All subjects who received the medical device between 2018 and 2022 are thus reviewed in 2023 in order to collect the results of the judgment criteria for the secondary objectives. During this visit, the satisfaction of the subject and the doctor are therefore evaluated. The primary objective also continues to be evaluated.

b. End of clinical investigation

The clinical investigation is considered to have ended at the last visit of the last subject and when the follow-up of the clinical investigation is completed.

c. Data collected

Pre-operative :

- Subject characteristics (weight, height, age, gender, smoker or not)
- Medical and surgical history
- Aesthetic history of the face and neck, and their location
- Taking photos (front, ¾ right, ¾ left) on the day of the procedure

Operative:

- Number of threads used
- Thread Location
- Immediate consequences/complications
- Taking photos of the thread drawings
- Taking post-operative photos (front, ¾ right, ¾ left)

Follow-up at 15 days:

- Complications and possible consequences
- Taking photos (front, ¾ right, ¾ left)

Follow-up at 2 months:

- Complications and possible consequences
- Taking photos (front, ¾ right, ¾ left)

Follow-up at 6 months:

- Complications and possible consequences
- Taking photos (front, ¾ right, ¾ left)

Follow-up at 1 year:

- Complications and possible consequences
- Taking photos (front, ¾ right, ¾ left)

Follow-up every year (if applicable):

- Complications and possible consequences
- Taking photos (front, ¾ right, ¾ left)

Final follow-up in 2023:

- Patient satisfaction with the result (LIKERT score - GAIS)
- Practitioner satisfaction with the result (LIKERT Score - GAIS)
- Complications and possible consequences
- Taking photos (front, ¾ right, ¾ left)

5. Installation techniques used

Installation technique used in the treatment of the "face" area: *"Deep J technique with partial implantation in the SMAS (Superficial MusculoAponeurotic System)"*

This technique consists of implanting the medical device according to the following protocol:

- 3 Infinite-Thread® suspension threads per side of the face, regardless of the patient's age, with an anchoring point at the temporal level 5 cm, on average, above the ear
- The first thread is implanted from the starting point of the platysmal bands towards the temple
- The second thread is implanted from the bitterness fold at the chin level towards the temple
- The third thread is implanted from the nasolabial fold towards the temple

It is also possible to choose a technique with the installation of 4 suspension threads per hemiface. This study will not make it possible to rule on this technique.

Installation technique used in the treatment of the "neck" area: *"2 threads per side of the neck"* technique.

This technique consists of implanting the medical device according to the following protocol:

- Starting point under the chin and platysmal bands connected by a knot at the occipital level

Specificities of these two installation techniques:

- Medical technique without surgery
- No incision and therefore no risk of scarring
- Implantation under local anesthesia by infiltration
- Operative time approximately 2 hours
- Mild pain and very well treated by taking analgesics
- No systematic post-operative treatment prescribed

III. BENEFITS

The device concerned in the context of this study is a non-absorbable suspension thread (also called permanent) with cogs (Infinite-Thread®) used for the enhancement (lifting) of sagging tissues of the face and neck. The effect is long-lasting.

Expected benefits:

- Reshape the oval of the face and correct sagging
- Reduce/Remove nasolabial folds
- Reduce/Remove bitterness folds
- Raise the cheekbones – Restore their original volume to the cheekbones
- Reduce/Make the visibility of the platysmal bands disappear

IV. RISKS

The expected risks can be categorized according to whether they are normal, non-serious "post-operative effects" and do not require any reintervention by the practitioner; or "post-operative complications" whose level of severity may vary, and which may require reintervention by the practitioner.

1. Post-operative effects

- Edema
- Discomfort felt when opening the mouth
- Sensitivity of the skin along the path of one or more threads
- Bruise
- Hematoma

2. Post-operative complications

- Infection
- Nerve or vascular injury
- Skin folds and/or depressions

3. Residual risks associated with the device

Following the risk analysis linked to the permanent suspension thread with cogs (Infinite-Thread®) from the Thread & Lift laboratory, their manufacturing process and their use according to the intended use, no residual risk has been identified.

4. Risks associated with study participation

The permanent suspension thread with cogs (Infinite-Thread®) from the Thread & Lift laboratory is a class IIb medical device and as such bears the CE marking.

The study being observational, the benefits and risks are those encountered in the usual practice of this type of intervention. There are therefore no additional risks added by this study.

5. Possible interactions with concomitant medical treatments

There are no known interactions with medical treatments.

6. Justification of the benefit/risk ratio

The risks are those of aesthetic medicine in general (inflammatory reactions, bruises, hematomas, infection, nerve or vascular lesions of the subcutaneous and cutaneous tissues)

These risks remain under control, the devices being used in their usual practice, by a doctor trained by the Thread & Lift laboratory and within the framework of CE marking.

The identified risks are therefore acceptable compared to the expected benefits for the subjects.

V. RESULTS OF THE MAIN OBJECTIVE – SAFETY

I. Post-operative effects

	Edema	Discomfort felt when opening the mouth	Thread path sensitivity	Bruise	Hematoma
Subjects	236	190	512	20	0
% Total cohort	46.09%	37.11%	100.00%	3.91%	0%

Table 1: Distribution of post-operative effects in 512 patients followed

a. Edema

Definition: Edema is swelling due to excess fluid. This swelling is due to an imbalance in the interstitial fluid. This interstitial fluid fills the space between cells. It is notably composed of water and mineral salts. It is evacuated through the lymphatic vessels. The most common symptom is swelling.

Etiology: This edema is the consequence of an inflammatory reaction caused by the passage of the needle for implantation of the suspension threads.

236 subjects were noted to have presented an inflammatory reaction leading to the appearance of edema, i.e. 46.09% of the total cohort.

The duration of resorption observed varies from 14 to 21 days on average after the intervention and does not require any reintervention.

b. Discomfort felt when opening the mouth

Etiology: This temporary discomfort is produced due to the implantation technique which involves protruding the mandibular edge near the mouth.

190 subjects were noted to have reported discomfort when opening their mouth, i.e. 37.11% of the total cohort.

The duration of the discomfort observed is 7 days on average after the operation and does not require any reoperation.

c. Sensitivity of the skin along the path of one or more threads

Etiology: This sensitivity is the consequence of the passage of the needle for implantation of the suspension threads.

512 subjects were noted to have demonstrated skin sensitivity, i.e. 100% of the total cohort.

The duration of sensitivity observed varies from 1 to 7 days on average after the intervention and does not require any reintervention.

d. Bruise

Definition: Infiltration of blood under the skin or into the tissues, following more or less significant localized bleeding, most often caused by trauma.

Etiology: The appearance of this bruise is due to the small pre-hole incision or the passage of the needle for implantation of the suspension threads.

There were 20 subjects with bruises, i.e. 3.91% of the total cohort.
Each time bleeding appeared during the procedure, a compression point was applied lasting from several seconds to several minutes.
The duration of resorption varies from 7 to 15 days on average after the intervention and does not require any reoperation.

e. Hematoma

No appearance of hematoma was noted.

II. Post-operative complications

	Skin folds and/or depressions	Infection	Nerve or vascular injury
Subjects	61	6	0
% Total cohort	11.91%	1.17%	0.00%

Table 2: Distribution of post-operative complications in 512 patients followed

a. Skin folds and/or depressions

Etiology: Skin folds and/or depressions are caused following the appearance of edema or bruising, or over tension of the thread.

61 subjects were noted to have presented skin folds and/or depressions, i.e. 11.91% of the total cohort.

- Small skin folds and/or depressions were noted in 51 subjects (among 61), i.e. 9.96% of the total cohort.

  The duration of this observed complication varies from 7 to 15 days on average after the operation, for small folds and/or depressions in the skin and does not require any reoperation.

- Larger skin folds and/or depressions were noted in 10 subjects (among 61), i.e. 1.95% of the total cohort.

  Larger skin folds and/or depressions require re-intervention by massaging the area in the days following the procedure, ideally on day +2 or day +3. All reoperations completely stopped the complication within the following 7 to 15 days.

b. Infection

The infection cases all occurred at the entry or exit point of the concerned thread.

The cases of infection were all treated by removal of the infected thread.

The time limit recommended by the laboratory for withdrawal is 15 days after the first signs of infection appear.

CASE 1: Infection of the temporal area – February 2019

Number of infected thread(s): 3

Diagnosis of infection: Less than 30 days after the procedure (February 2019).

Date of removal: Less than 30 days after the procedure (February 2019).

Removal of three threads by Dr. ZAMMIT.

Cause of infection: Non-compliance with the installation protocol resulting in a hair remaining half inside the thread entry point.

Follow-up: Patient seen again 6 months after removal for a new installation of 3 new threads (Infinite-Thread®). No further complications to report.

CASE 2: Infection of the temporal area – September 2019

Number of infected thread(s): 1

Diagnosis of infection: 60 days after the procedure (September 2019).

Date of removal: 60 days after the intervention (September 2019).

Removal of a thread by Dr. FOUMENTEZE in his medical practice in Nice.

Cause of infection: Non-compliance with the installation protocol resulting in a hair remaining half inside the entry point of a thread.

Follow-up: Patient seen again 6 months after removal for new placement of a new thread (Infinite-Thread®). No further complications to report.

CASE 3: Infection of the temporal area – March 2020

Number of infected thread(s): 1

Diagnosis of infection: 120 days after the procedure (March 2020).

Date of removal: 135 days after the intervention (March 2020).

Partial removal of a thread by Dr. FOUMENTEZE in his medical practice in Nice.
Final removal, by surgical approach, by Dr FAVOLI in his medical practice in Toulon.

Cause of infection: Non-compliance with the installation protocol resulting in a hair remaining half inside the entry point of a thread.

Follow-up: Patient did not return to consult.

CASE 4: Neck area infection – May 2020

Number of infected thread(s): 1

Diagnosis of infection: 120 days after the procedure (March 2020).

Date of removal: 180 days after the intervention (May 2020).

Removal of a thread by Dr. FOUMENTEZE in his medical practice in Nice.

Cause of infection: Hair found during extraction on the lower path of the thread.

Follow-up: Patient did not return to consult.

CASE 5: Infection of the temporal area – June 2020

Number of infected thread(s): 1

Diagnosis of infection: Less than 30 days after the procedure (June 2020).

Date of removal: Less than 30 days after the procedure (June 2020).

Removal of the thread by Dr. ZAMMIT.

Cause of infection: Non-compliance with the installation protocol resulting in a hair remaining half inside the entry point of a thread.

Follow-up: Patient did not return to consult.

CASE 6: Infection of the temporal area – February 2022

Number of infected thread(s): 1

Diagnosis of infection: 20 days after the procedure (January 2022).

Date of removal: 30 days after the intervention (February 2022).

Removal of the thread by Dr FOUMENTEZE in his medical practice in Nice.

Cause of infection: Non-compliance with the installation protocol leading to the absence of section of one end of a thread. The patient cut the thread herself.

Follow-up: Patient did not return to consult.

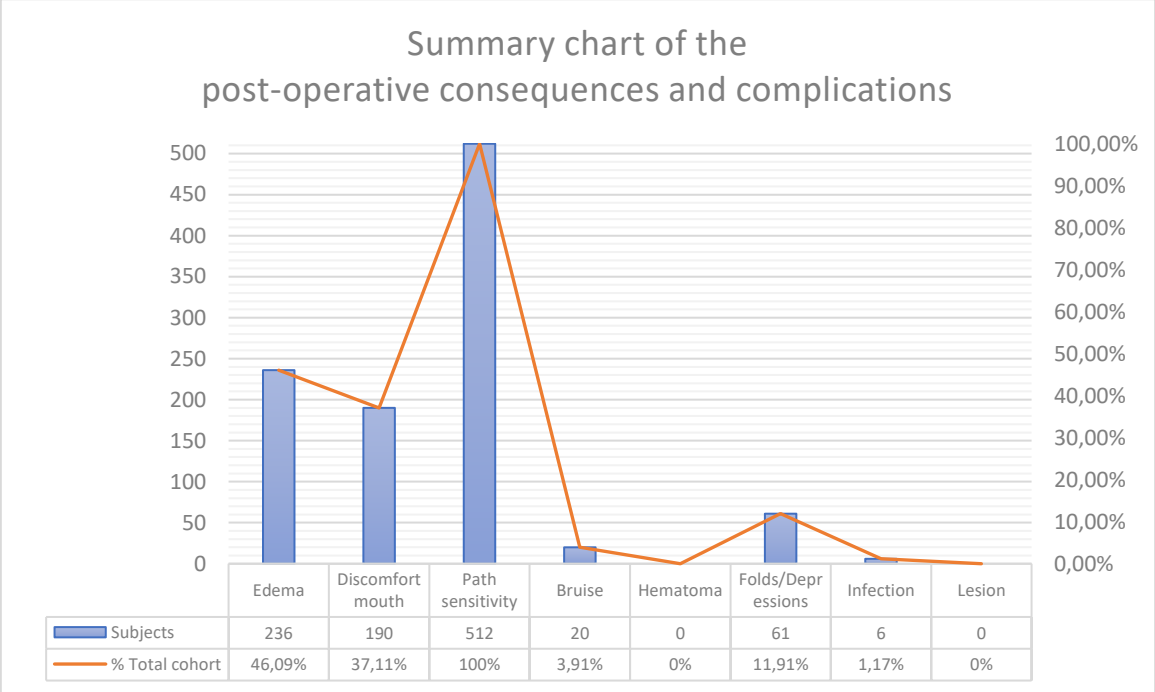
c. Nerve or vascular injury

No nerve or vascular damage was noted.

III. Summary of post-operative effects and complications

	Post-operative effects					Post-operative complications		
	Edema	Discomfort felt when opening the mouth	Thread path sensitivity	Bruise	Hematoma	Skin folds and/or depressions	Infection	Nerve or vascular injury
Subjects	236	190	512	20	0	61	6	0
% Total cohort	46.09%	37.11%	100.00%	3.91%	0.00%	11.91%	1.17%	0.00%

Table 3: Distribution of post-operative effects and complications in 512 patients followed



Graph 2: Summary graph of post-operative consequences and complications on 512 patients followed

IV. RESULTS OF SECONDARY OBJECTIVES – PERFORMANCE

1. Subject follow-up

A cohort of 512 patients, including 68 men and 444 women, was treated between 2018 and 2022.

Of these 512 patients, 430 patients (84%) participated in the follow-up visit in 2023 to assess the performance of Infinite-Thread®.

The overall rate of subjects lost to follow-up is 16%.

Year of the thread lift	Number of patients treated	Number of patients controlled in 2023	Percentage of patients controlled in 2023
2018	89	70	79%
2019	115	79	69%
2020	105	92	88%
2021	102	91	89%
2022	101	98	97%
2018-2022	**512**	**430**	**84%**

Table 4: Rate of patients controlled in 2023 out of 512 patients followed

2. Subject satisfaction

Of the 430 patients who participated in the follow-up visit in 2023, 70 had benefited from the placement of Infinite-Thread® 5 years previously (2018), 79 had benefited from the placement of Infinite-Thread® 4 years previously (2019), 92 had benefited from the placement of Infinite-Thread® 3 years previously (2020), 91 had benefited from the placement of Infinite-Thread® 2 years previously (2021) and 98 had benefited from the placement of Infinite-Thread® 1 year previously (2022).

The patient satisfaction scores are comparable for each year, with a level of satisfaction (very satisfied patients and satisfied patients) always higher than 80% of the patients surveyed.

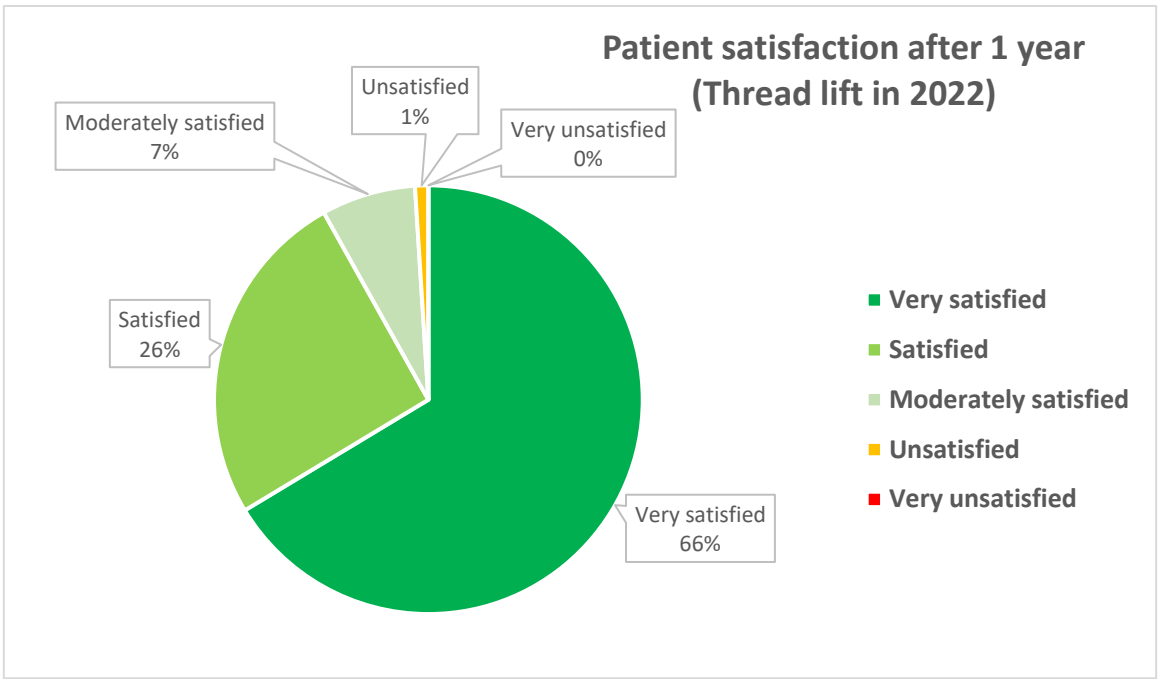
The level of unsatisfaction (unsatisfied patients and very unsatisfied patients) varies between 1% and 8.5% of the patients surveyed.

We cannot discern any obvious correlation in the evolution of this satisfaction over the years.

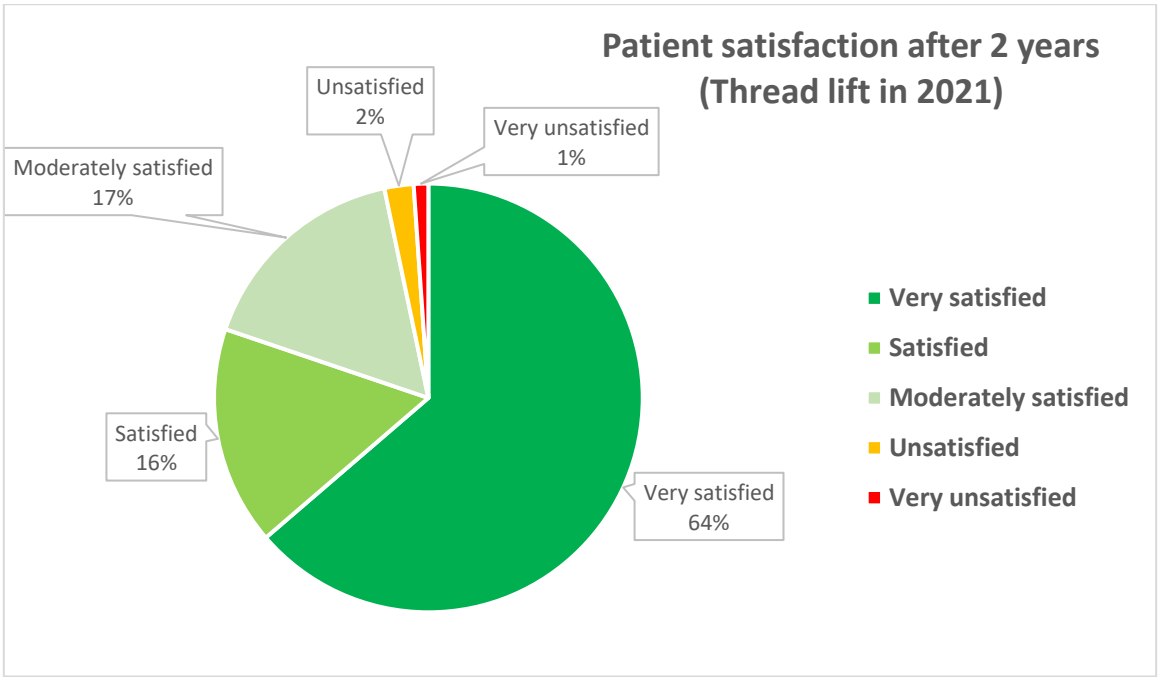
The average level of satisfaction (very satisfied patients and satisfied patients) is 83.9%.
The average level of dissatisfaction (dissatisfied patients and very dissatisfied patients) is 4.2%.

Year of the thread lift	Number of patients controlled in 2023	Very satisfied patients in 2023	Satisfied patients in 2023	Moderately satisfied patients in 2023	Unsatisfied patients in 2023	Very unsatisfied patients in 2023
2018	70	61.4% (43)	20.0% (14)	10.0% (7)	2.9% (2)	5.7% (4)
2019	79	64.6% (51)	16.4% (13)	16.4% (13)	2.5% (2)	0.0% (0)
2020	92	72.8% (67)	10.9% (10)	9.8% (9)	3.3% (3)	3.3% (3)
2021	91	63.7% (58)	16.5% (15)	16.5% (15)	2.2% (2)	1.1% (1)
2022	98	66.3% (65)	25.5% (25)	7.1% (7)	1.0% (1)	0.0% (0)
2018-2022	**430**	**66.0% (284)**	**17.9% (77)**	**11.9% (51)**	**2.8% (12)**	**1.4% (6)**

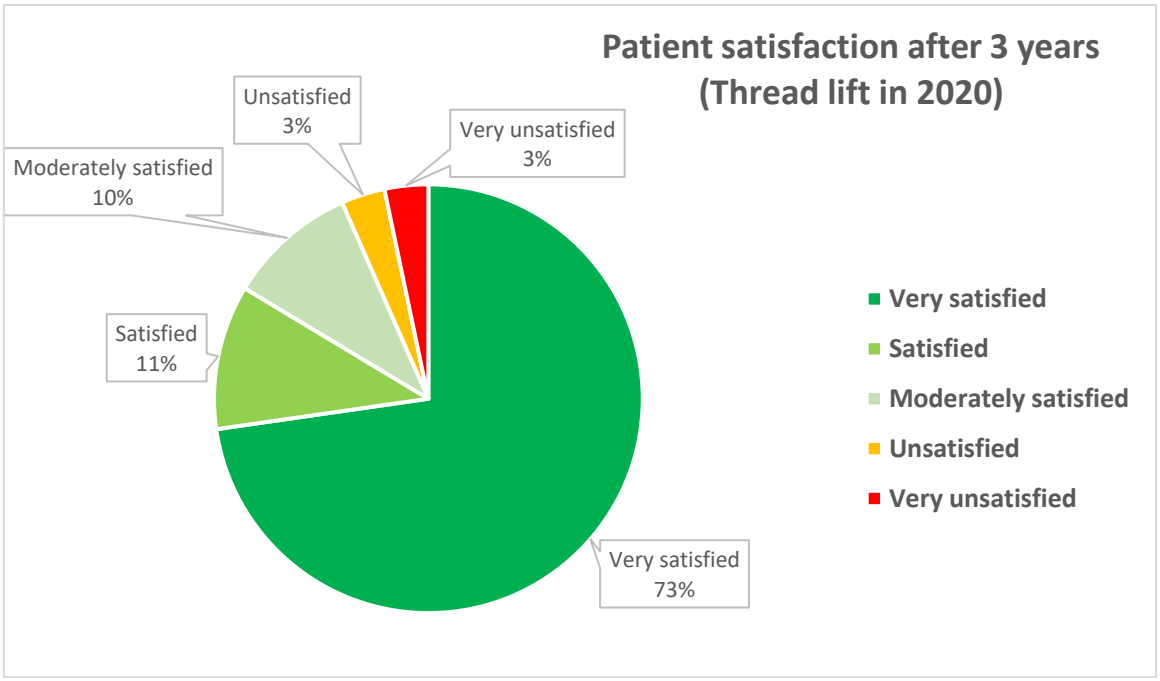
Table 5: Patient satisfaction rate controlled in 2023 on 430 patients



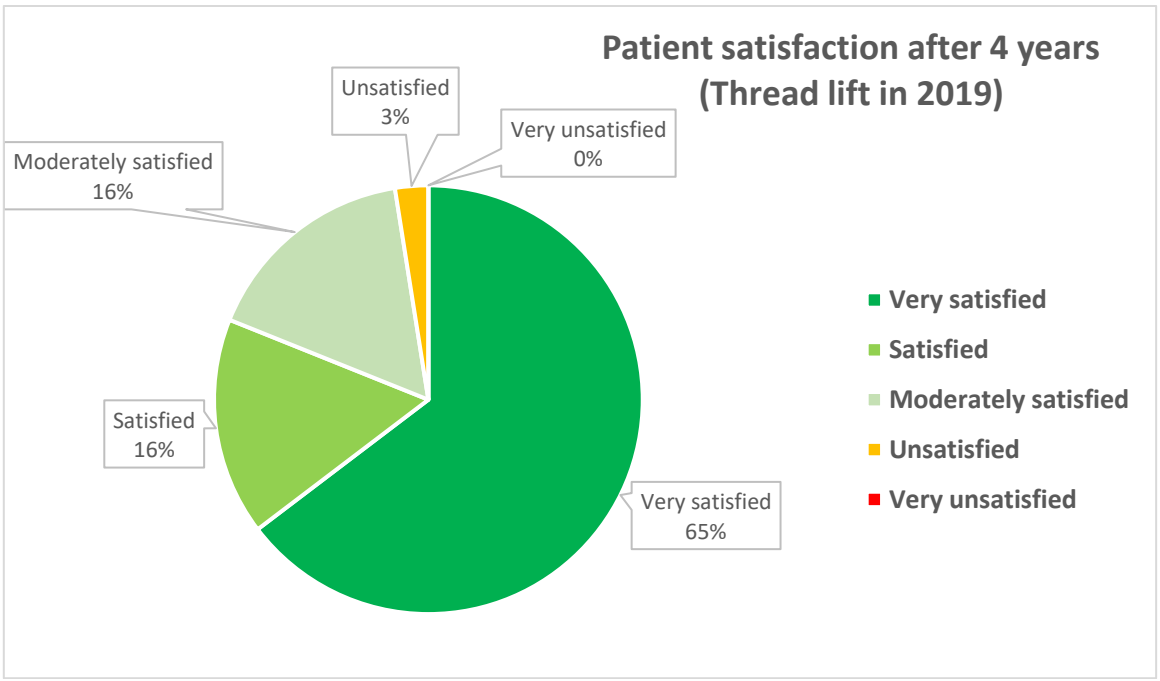
Graph 3: Patient satisfaction after 1 year in 2023 on 98 patients



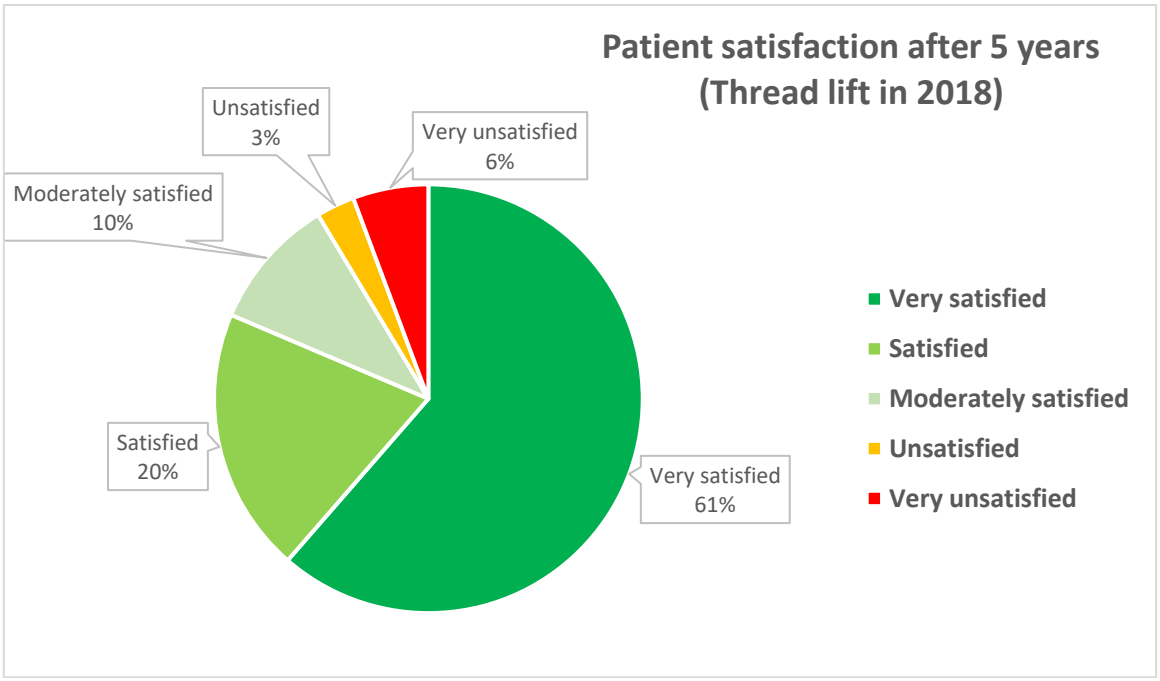
Graph 4: Patient satisfaction after 2 years in 2023 on 91 patients



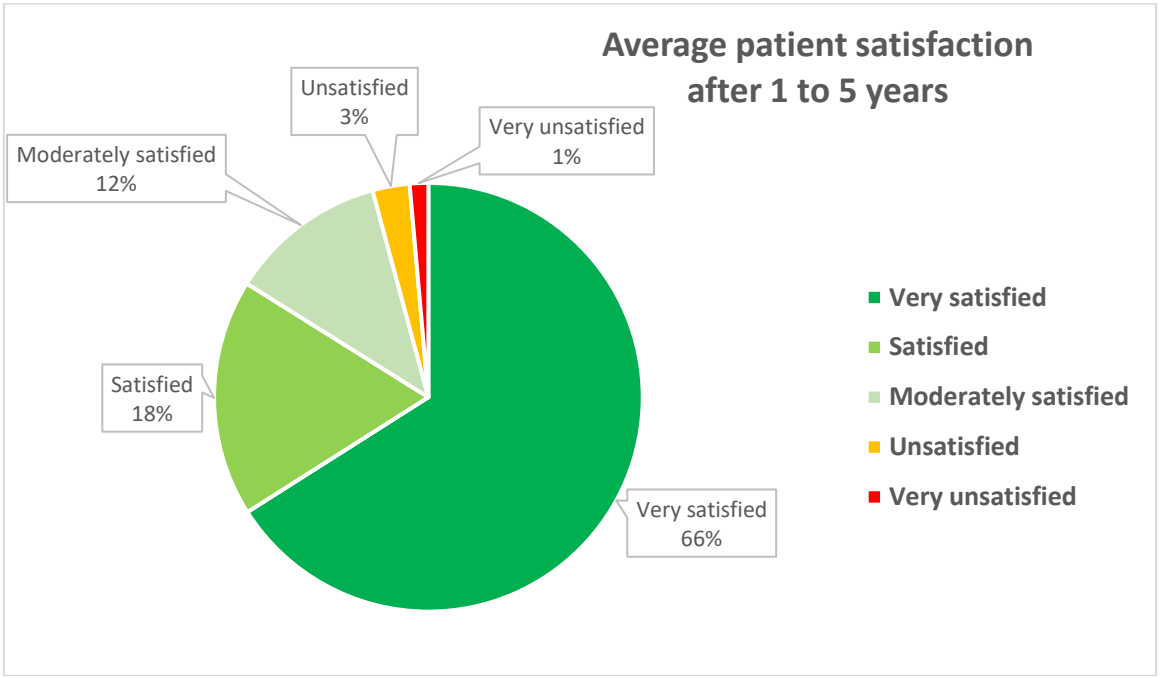
Graph 5: Patient satisfaction after 3 years in 2023 on 92 patients



Graph 6: Patient satisfaction after 4 years in 2023 on 79 patients



Graph 7: Patient satisfaction after 5 years in 2023 on 70 patients



Graph 8: Average patient satisfaction after 1 to 5 years on 430 patients controlled in 2023

3. Practitioner satisfaction

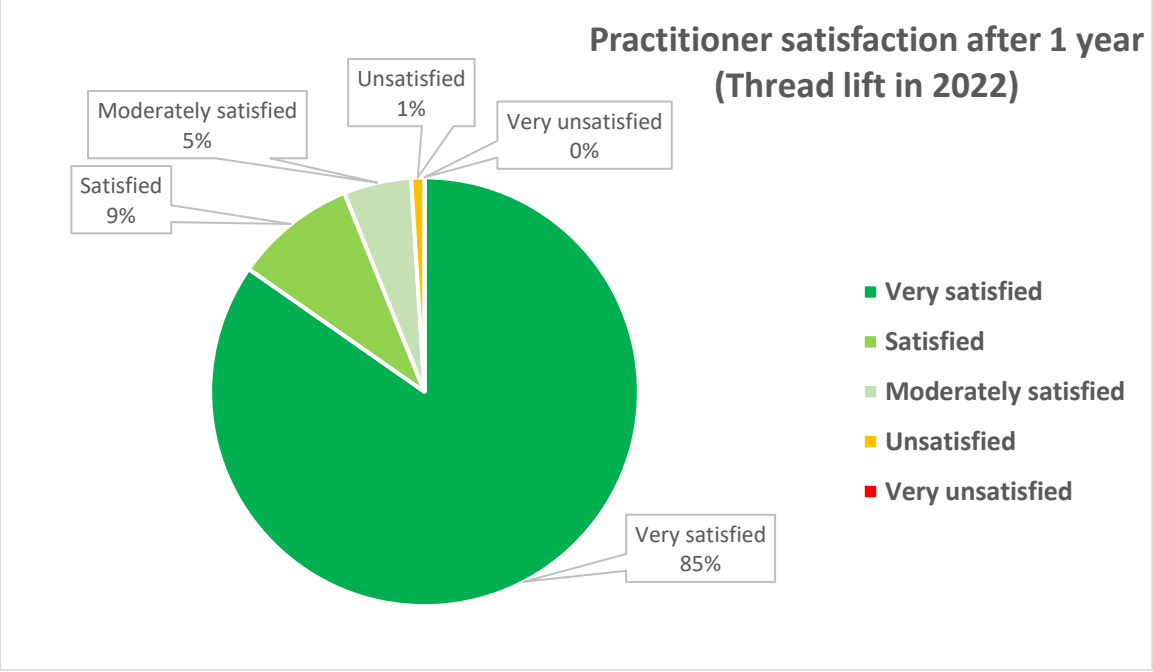
The practitioner satisfaction scores are comparable for each year, with a level of satisfaction (very satisfied and satisfied practitioner) always above 89.9%.
The level of dissatisfaction (unsatisfied and very unsatisfied practitioner) varies between 1% and 8.6%.

We cannot discern any obvious correlation in the evolution of this satisfaction over the years. However, it should be noted that practitioner unsatisfaction is higher among patients operated in 2018 with 8.6% compared to 3.8% in 2019, 4.4% in 2020, 3.3% in 2021 and 1% in 2022.

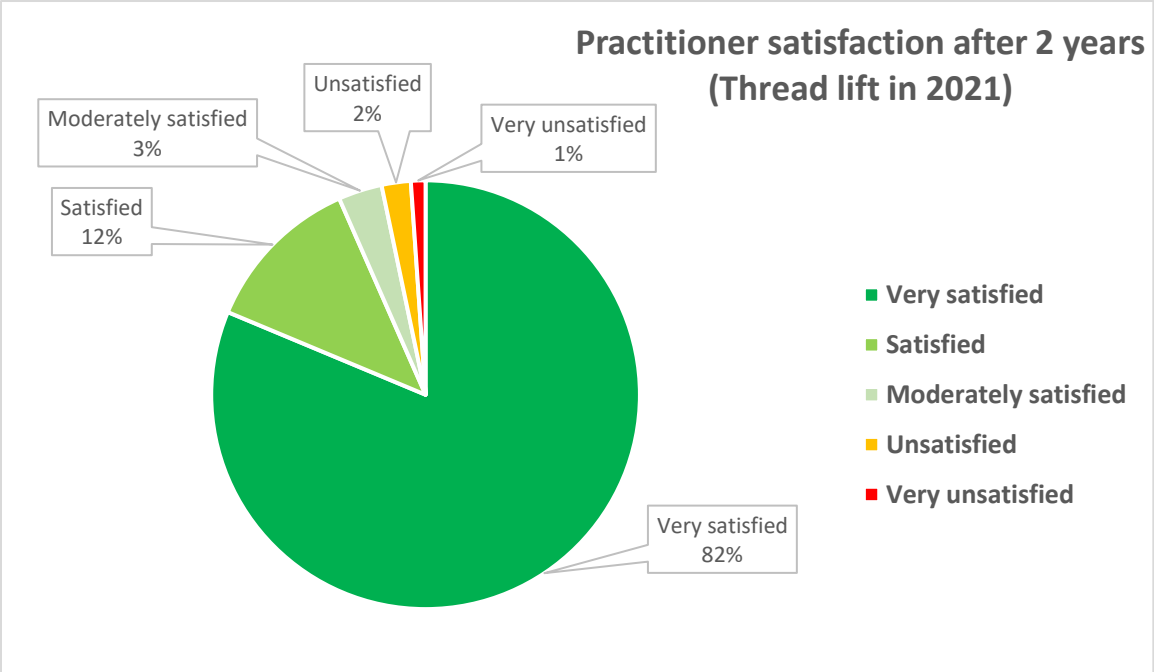
The average level of satisfaction (very satisfied and satisfied practitioner) is 91.6%.
The average unsatisfaction level (unsatisfied and very unsatisfied practitioner) is 3.9%.

Year of the thread lift	Number of patients controlled in 2023	Very satisfied practitioner in 2023	Satisfied practitioner in 2023	Moderately satisfied practitioner in 2023	Unsatisfied practitioner in 2023	Very unsatisfied practitioner in 2023
2018	70	80.0% (56)	10.0% (7)	1.4% (1)	2.9% (2)	5.7% (4)
2019	79	82.3% (65)	7.6% (6)	6.3% (5)	2.5% (2)	1.3% (1)
2020	92	84.8% (78)	5.4% (5)	5.4% (5)	3.3% (3)	1.1% (1)
2021	91	81.3% (74)	12.1% (11)	3.3% (3)	2.2% (2)	1.1% (1)
2022	98	84.7% (83)	9.2% (9)	5.1% (5)	1.0% (1)	0.0% (0)
2018-2022	**430**	**82.8% (356)**	**8.8% (38)**	**4.4% (19)**	**2.3% (10)**	**1.6% (7)**

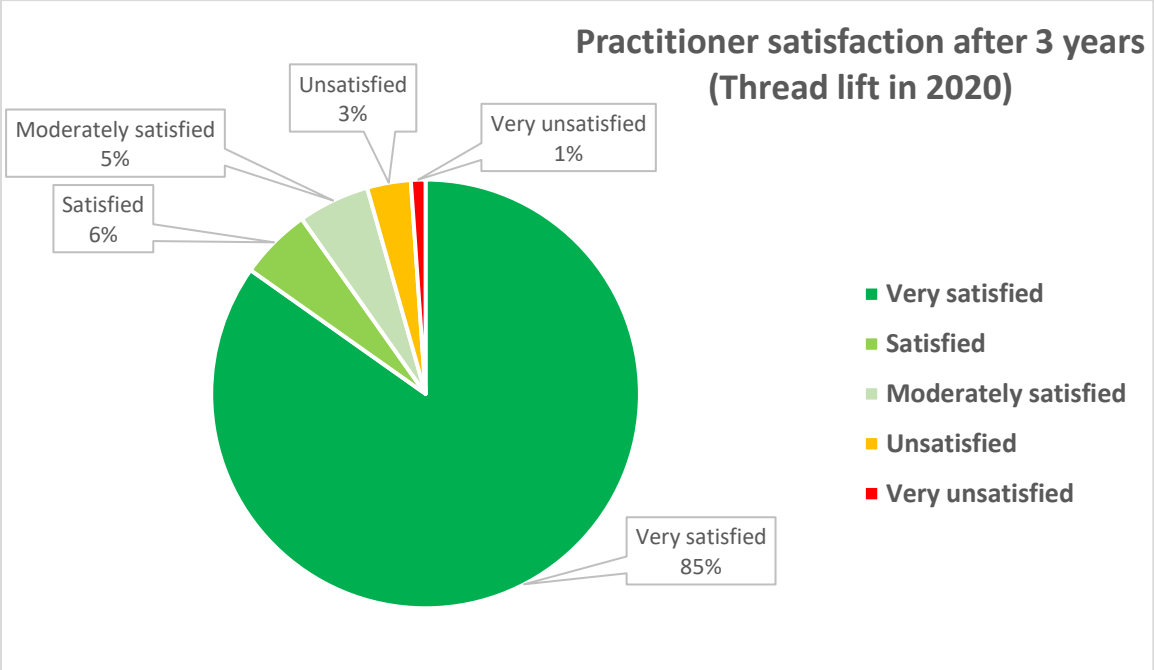
Table 6: Practitioner satisfaction rate on 430 patients controlled in 2023



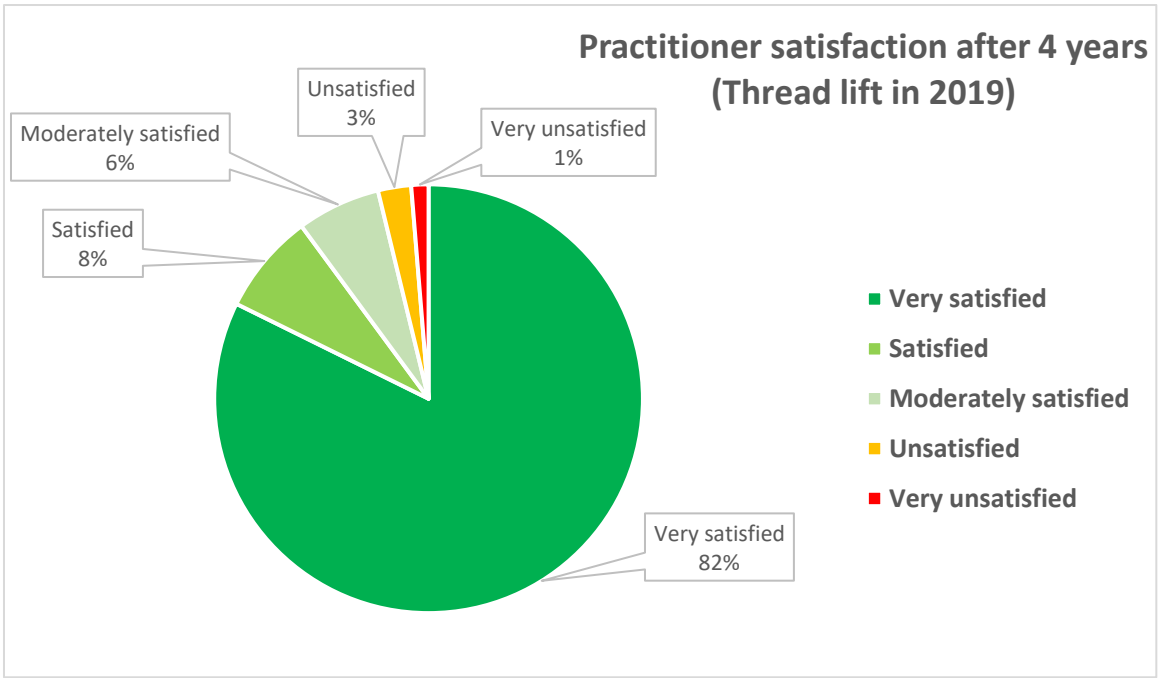
Graph 9: Practitioner satisfaction after 1 year in 2023 on 98 patients



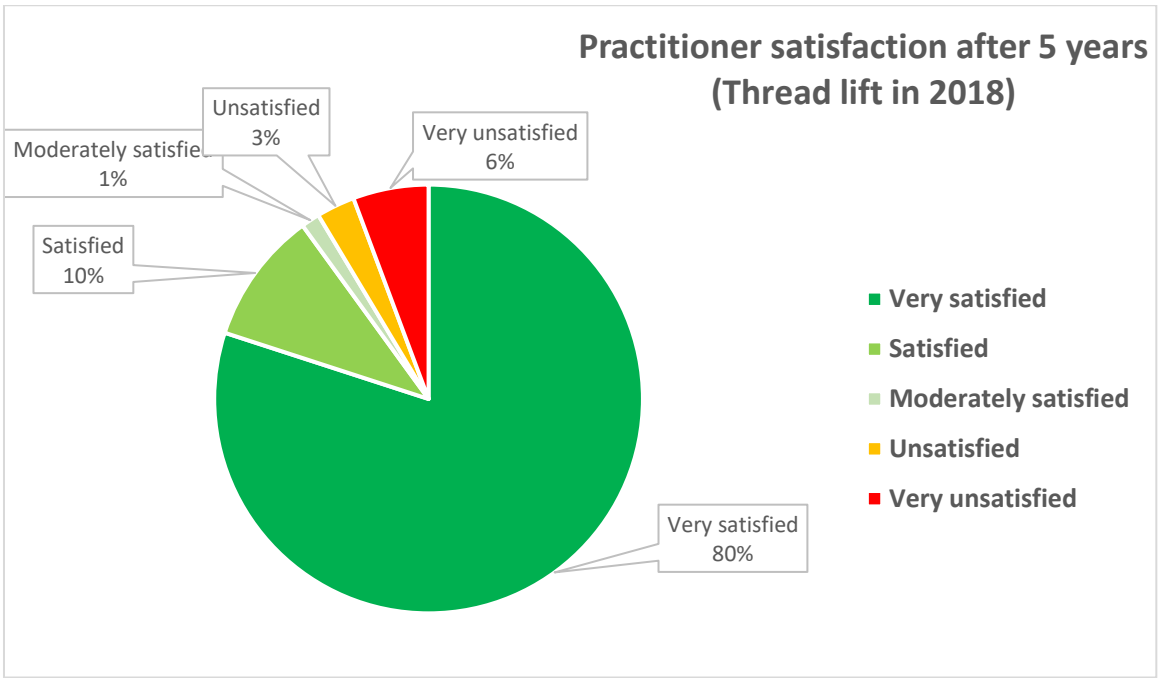
Graph 10: Practitioner satisfaction after 2 years in 2023 on 91 patients



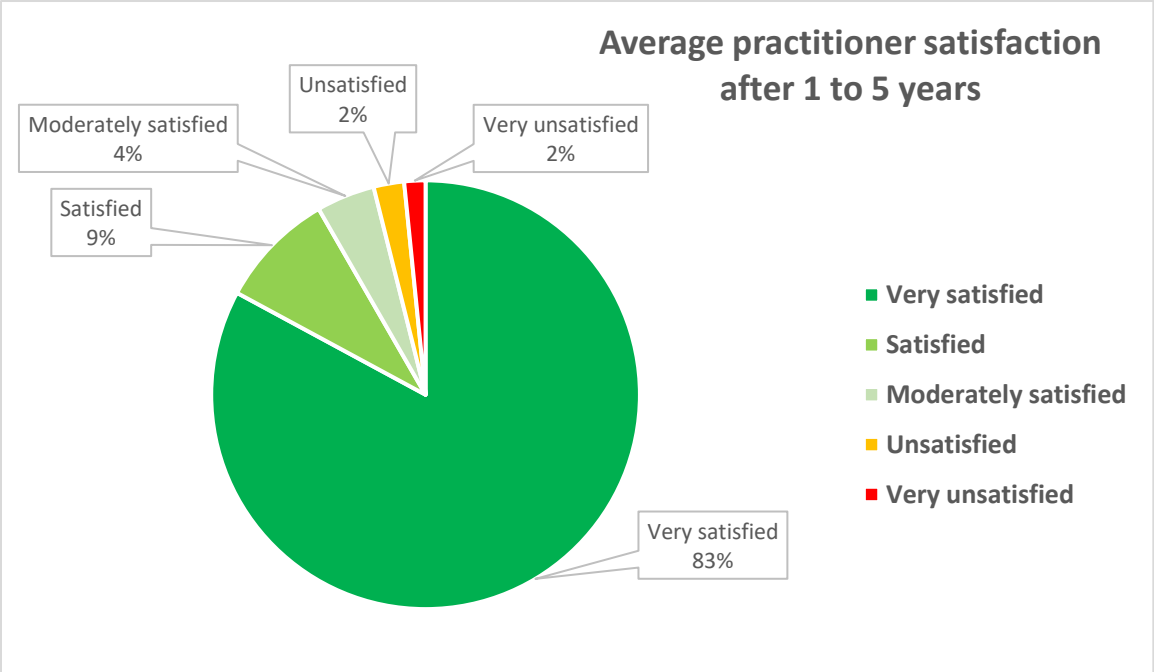
Graph 11: Practitioner satisfaction after 3 years in 2023 on 92 patients



Graph 12: Practitioner satisfaction after 4 years in 2023 on 79 patients



Graph 13: Practitioner satisfaction after 5 years in 2023 on 70 patients



Graph 14: Average practitioner satisfaction after 1 to 5 years on 430 patients controlled in 2023

4. Comparison of subject and practitioner satisfaction

The level of satisfaction ("Very satisfied" and "Satisfied") is on average 91.6% for the practitioner and 83.9% for the patients.
Although the level of satisfaction ("Very satisfied" and "Satisfied") is always above 80% for each year of installation, for both patients and practitioners, we see a different distribution of this satisfaction.

For each year, the practitioner is "Very satisfied" more significantly than when we question the patients, with an average of 82.8% for the practitioner and 66% for the patients.

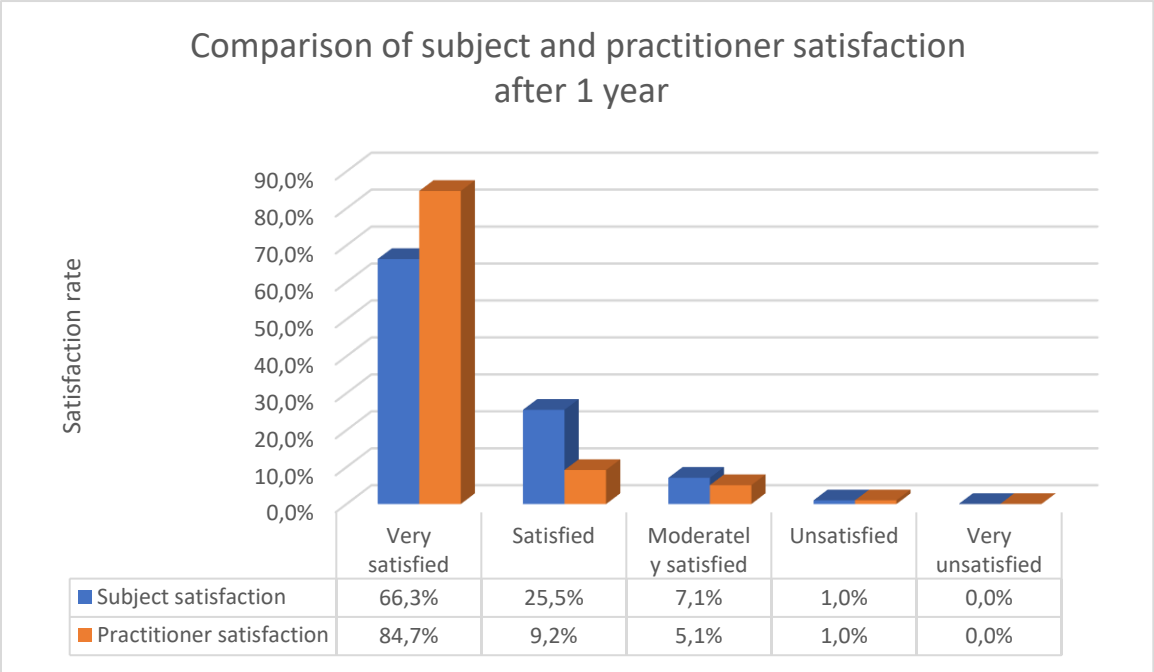
We therefore note a gap of 16.8 points higher among practitioners for the "Very satisfied" score.

We see the opposite phenomenon regarding the "Satisfied" level, with an average of 8.8% for the practitioner and 17.9% for the patients.

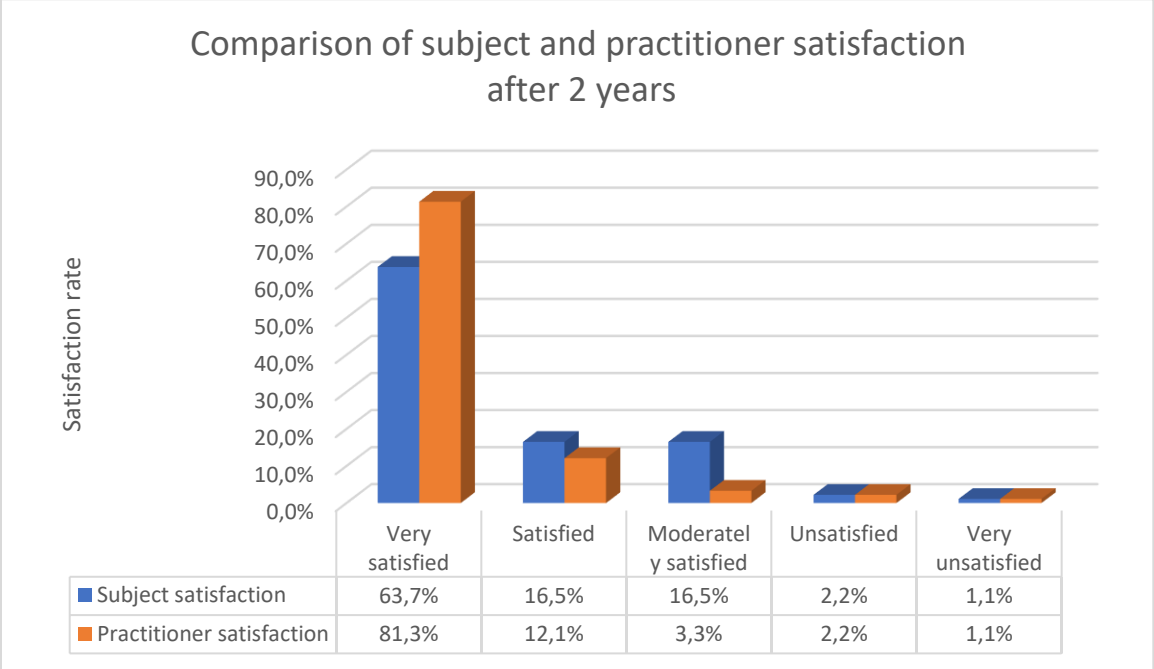
We therefore note a difference of 9.1 points greater among patients for the "Satisfied" score.

The difference in the level of satisfaction ("Very satisfied" and "Satisfied") is therefore found in a predominance of "Moderately satisfied" patients on average of 11.9% compared to 4.4% for the practitioner.

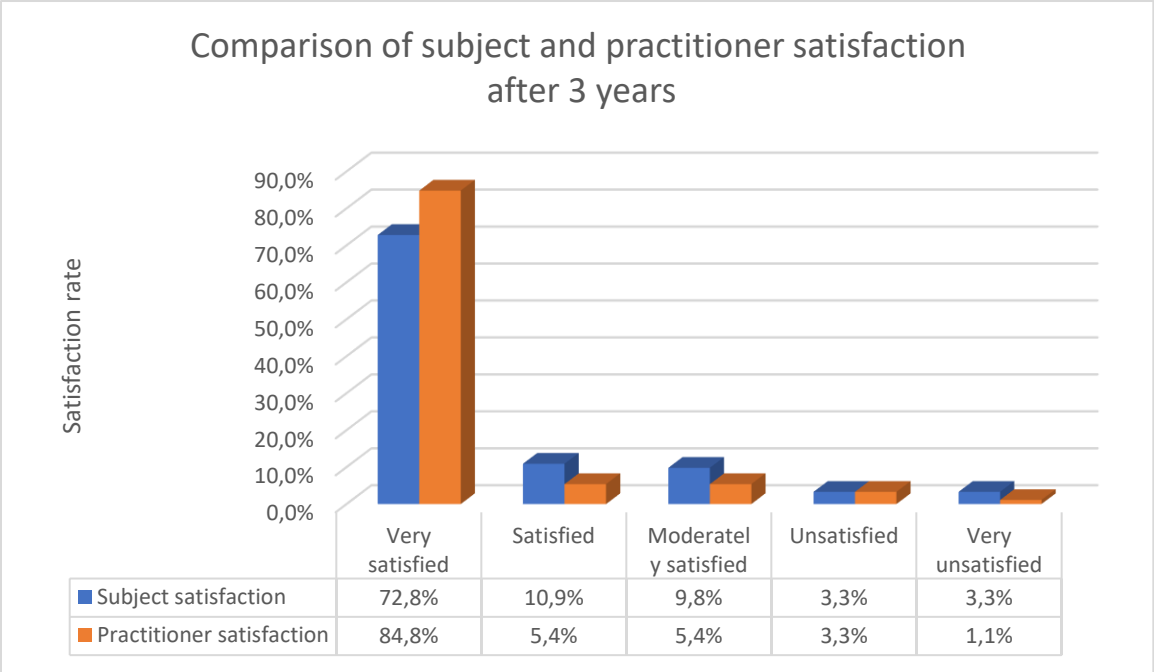
The study does not show a significant difference in the rating of unsatisfaction between practitioners and patients. We find an “Unsatisfied” average of 2.3% among practitioners and 2.8% among patients, and a “Very unsatisfied” average of 1.6% among practitioners and 1.4% among patients.



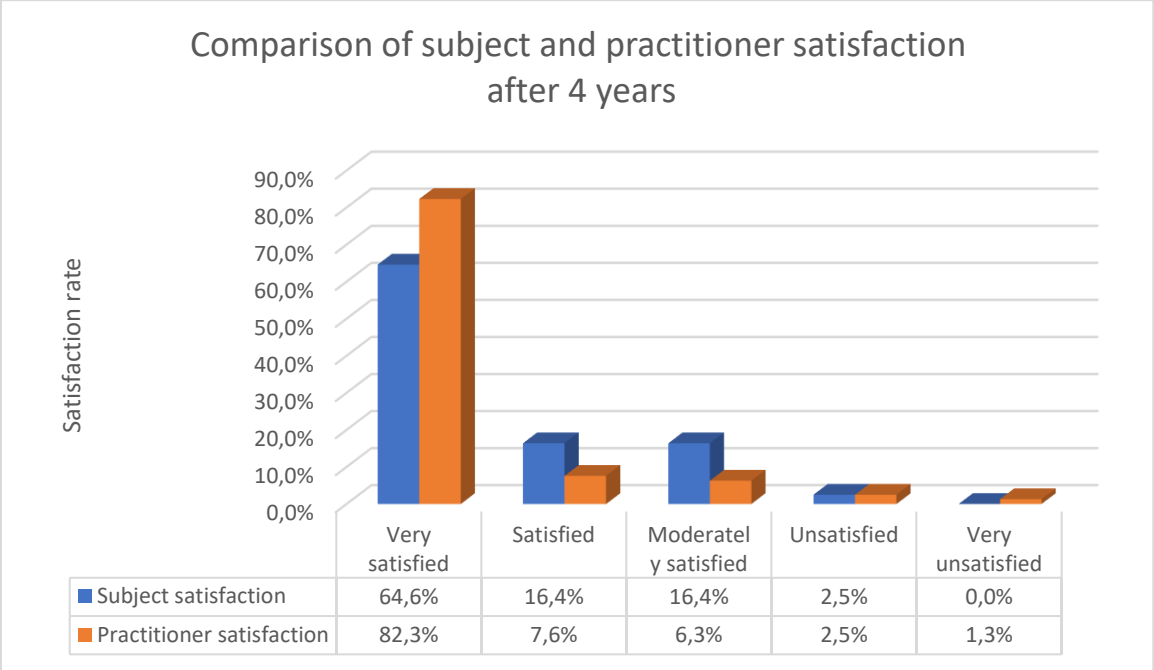
Graph 15: Comparison of patient and practitioner satisfaction after 1 year in 2023 on 98 patients



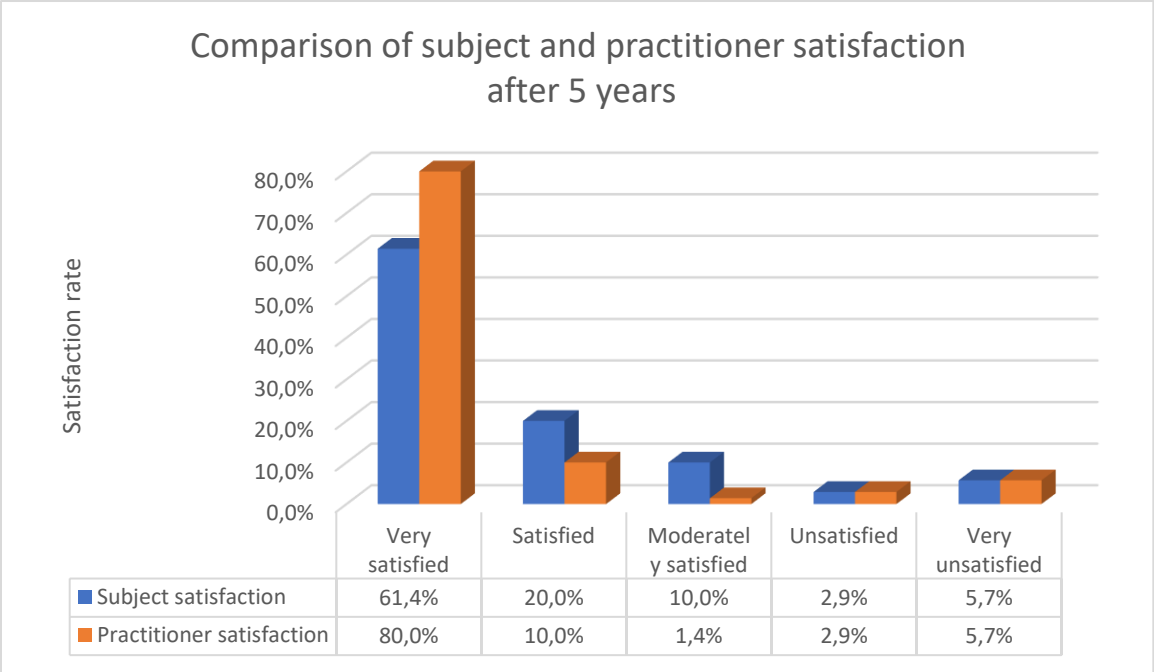
Graph 16: Comparison of patient and practitioner satisfaction after 2 years in 2023 on 91 patients



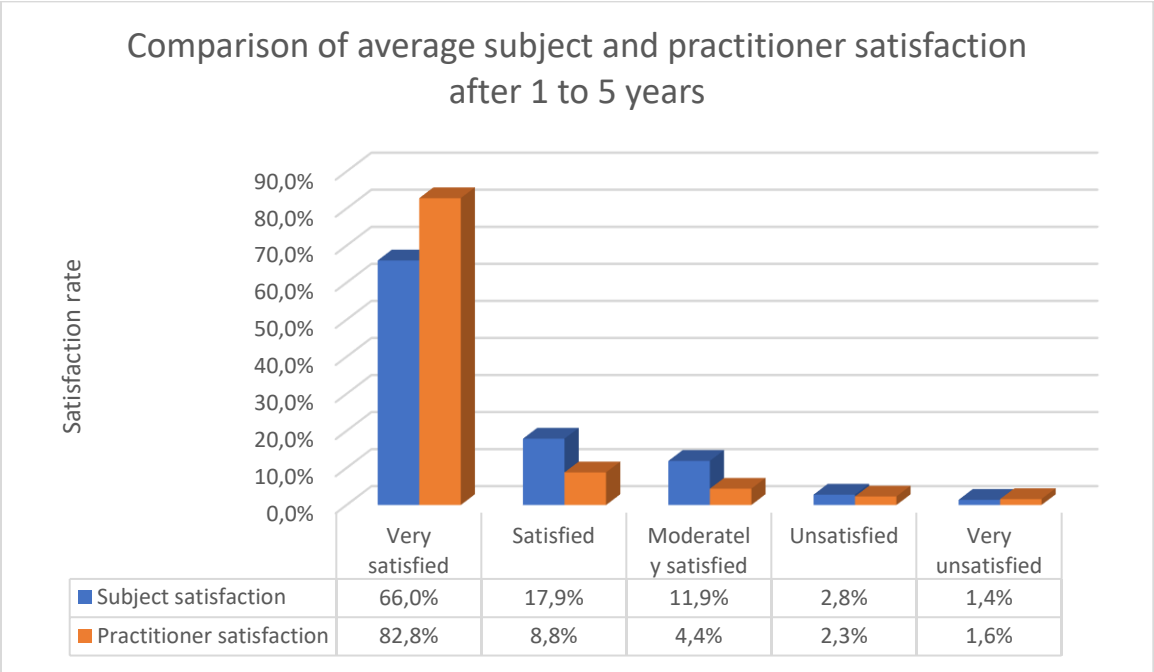
Graph 17: Comparison of patient and practitioner satisfaction after 3 years in 2023 on 92 patients



Graph 18: Comparison of patient and practitioner satisfaction after 4 years in 2023 on 79 patients



Graph 19: Comparison of patient and practitioner satisfaction after 5 years in 2023 on 70 patients



Graph 19: Comparison of average patient and practitioner satisfaction after 1 to 5 years on 430 patients controlled in 2023

VII. DISCUSSION

The permanent suspension threads with cogs (Infinite-Thread®) manufactured by the Thread & Lift laboratory are of excellent quality thanks, in particular, to their flexibility and the molded cog distribution on its outer coating in solid medical grade silicone.

They make it possible to treat significant ptosis of the face and neck, therefore going further than the indication of low to moderate ptosis generally accepted for other suspension threads, and to obtain a natural-looking result without surgery with moderate post-operative follow-ups as well as complications that are also moderate and still treatable.

The installation of the “Infinite-Thread®” requires vigilance and experience from the practitioner in order to obtain the best possible result without creating visible defects, due to the effective hooking of the thread. Training by the laboratory is mandatory for any practitioner wishing to use this medical device in their activity.

Beyond the intrinsic quality of this suspension thread and the mandatory training, which are two important criteria, the installation technique used and chosen by the practitioner obviously represents the third criterion impacting the quality and durability of the result obtained.

The installation technique varies according to the following characteristics:

- The choice of implantation vectors
- The choice of implantation depth
- The choice of the number of threads implanted

Despite the fundamentals in the choice of these installation technique characteristics, due to anatomical and physical realities, each practitioner's sensitivity and experience will lead him or her to favour one or other installation technique. *A fortiori* also depending on the areas to be treated and the patient's indication.

The installation technique will obviously vary even more depending on whether the thread is placed in combination with surgery, during a cervico-facial lift for example, or without surgery. I only use thread without surgery, not being a surgeon.

I have described the techniques that I prefer, and which are used in this study in chapter 5 “Installation techniques used”.

For information, the Thread & Lift laboratory recommends the installation of 8 “Infinite-Thread®”, 4 per half-face, for the treatment of a face.

The infectious risk encountered is very low (1.17%). It is due to the presence of a foreign body that may have penetrated the body during installation or following the procedure before the entry or exit points of the threads had been completely closed. It is very important to note that the presence of a hair, half in the entry point and half outside, is a very big facilitator of infection. It is therefore absolutely necessary to take care to check the absence of this risk, using forceps during the procedure, in order to drastically limit the risk of infection occurring.

Given that the effectiveness of the thread implies the perfect mastery of it, combined with the risks of infection inherent to any implant, *especially in* the long term, we welcome the laboratory's approach making its individual training compulsory for any practitioner wishing to obtain authorization to buy and use “Infinite-Thread®”. We consider this training effective because it includes, beyond the theory, a practical part

consisting of the installation of “Infinite-Thread®” on a patient *in vivo* under the supervision of an expert trainer.

Removal of the thread was always made possible, but it must be carried out as soon as possible, in the event of infection. The time limit recommended by the laboratory for withdrawal is 15 days after the first signs of infection appear. Indeed, within this delay, there will still be some edema, hence making the removal procedure more straightforward.

This specific 15 days delay only concerns the case of infected thread(s) as there is, in the common case, no time limit to the removing of an “Infinite-Thread®”.

Beyond this time, removal of the device will be less easy, as a consequence of fibrosis and inflammation around the thread, although still possible with strict compliance with the removal protocol.

In the case of removal of a non-infected thread, the delay is of no importance and the procedure will include a first step of hydro dissection. Of the 512 patients treated, no removal was necessary or requested by a patient without cases of infection.

It therefore appears to us, in view of the consequences and complications encountered in a very large cohort of patients, that the “Infinite-Thread®” thread presents a high level of safety and an excellent risk/benefit ratio.

This prospective study over 5 years shows a very high level of satisfaction over time for both the subjects and the practitioner.

The average level of unsatisfaction is approximately the same among the subjects questioned and for the practitioner, and does not exceed 4.2%, i.e. 18 subjects out of 430 controlled in 2023.

All of the 412 other subjects surveyed in 2023 were “Moderately satisfied” at 11.9%, “Satisfied” at 17.9% and “Very satisfied” at 66.0%.

There is no obvious negative correlation between these satisfaction rates depending on the length of time elapsed since the procedure. The subjects indicated that they were “Very satisfied” after 1 year at 66.3%, at 2 years at 63.7%, at 3 years at 72.8%, at 4 years at 64.6% and at 5 years at 61.4%.

Patient satisfaction therefore appears stable over 5 years.

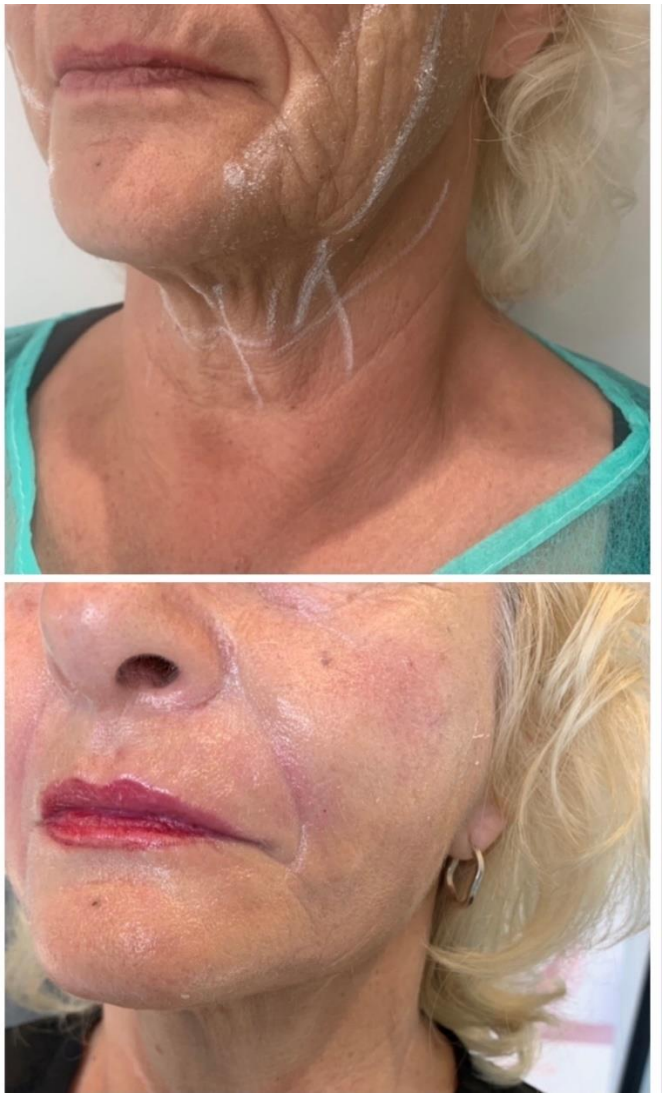
It should be noted that satisfaction obviously depends on criteria specific to the intervention, the quality of the result and its durability being dependent on the practitioner, but also on criteria specific to the patient, their age, their lifestyle, the quality of their connective tissue but also its own sensitivity to the quality of the result which will impact its rating.

Nevertheless, we consider the cohort is large enough to draw the conclusion of the significant quality of the long-term results of the “Infinite-Thread®” procedure despite the existence of these patient-specific criteria.

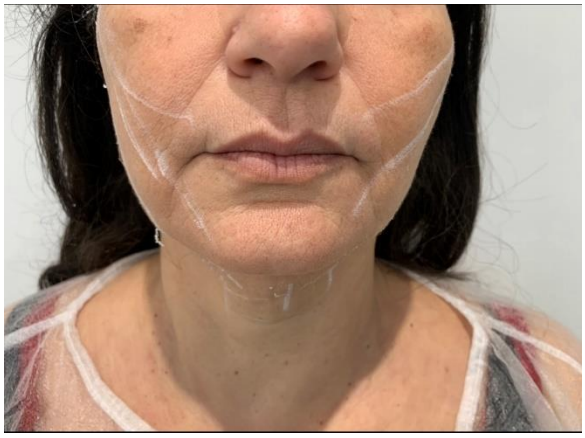
Of course, the impact of this study is partly limited by the fact that there is only one investigator, and it will be necessary, to conclude more broadly, other prospective studies carried out by several investigators.

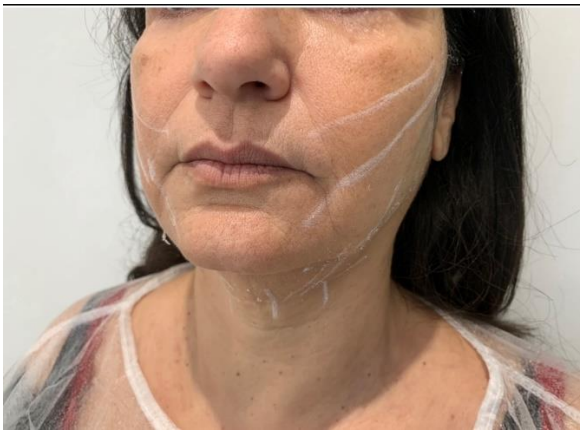
VIII. APPENDICES - PHOTO BEFORE/AFTER 5 YEARS

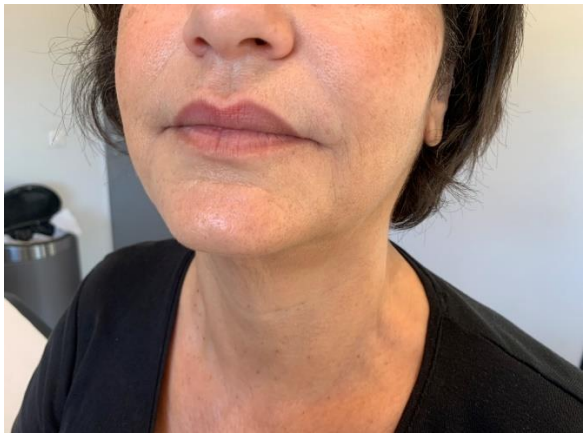
Patient 1



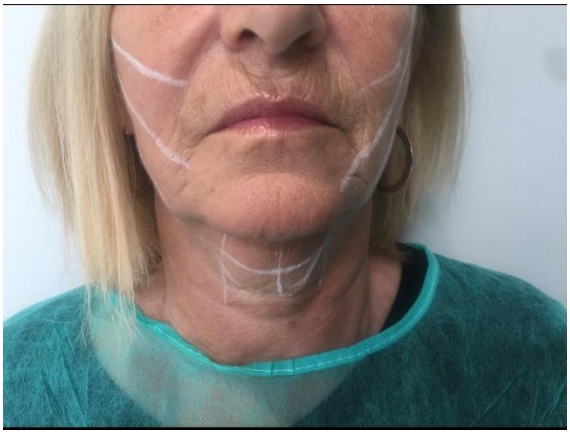
Patient 2

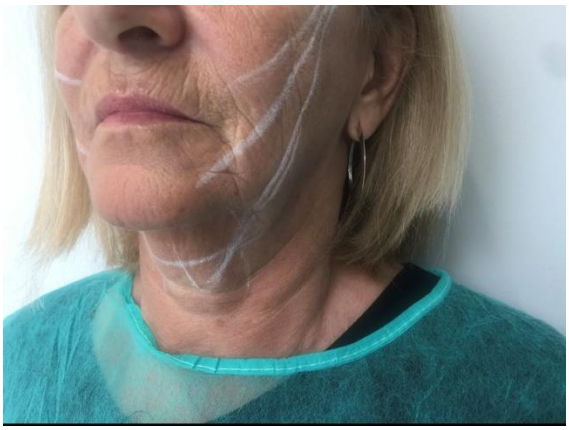




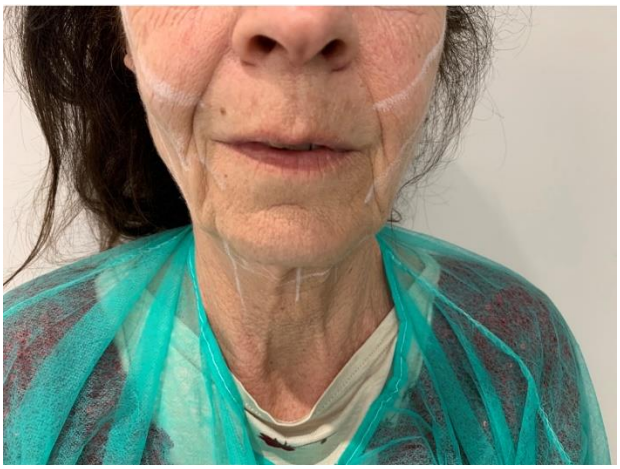
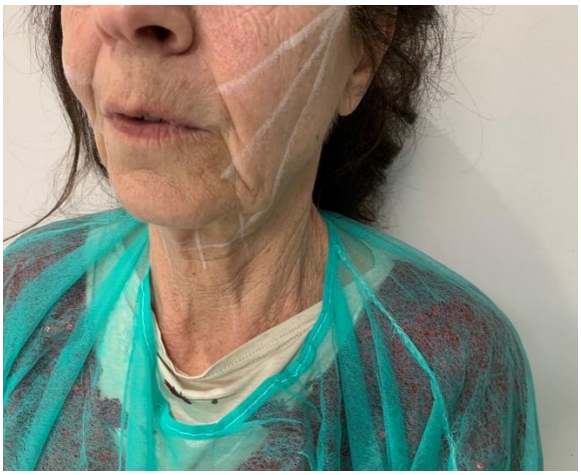
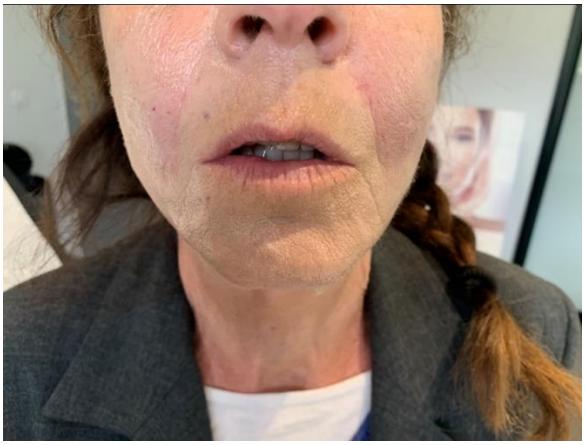
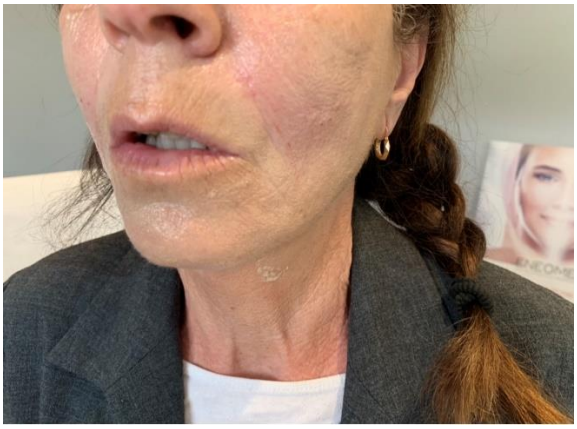


Patient 3





Patient 4

Patient 5