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How Long Should a Tracheal Stent Remain Implanted? Healing of Stenosis 10, 16, and 22 Years After Implantation

¿Cuánto tiempo debe permanecer un stent traqueal implantado? Curación de la estenosis luego de 10,16 y 22 años de implante

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ABSTRACT

Three tracheal stents were removed after 10, 16, and 22 years, followed by healing of tracheal stenosis.

Two new cases of benign tracheal stenosis are reported, treated with silicone prostheses, which presented for follow-up after very long absences: 16 years in one case and 22 years in the other. They add to a previously published case that was healed 10 years after the stent was implanted, which also had a wide and stable tracheal lumen after removal. The endoscopic findings are described, and reflections are included on the healing of the observed stenosis in all cases and its probable relationship with the prolonged indwelling of the prostheses. The physical properties of the stents are investigated after such a long period since implantation, and they are compared with a new device. A proposal is put forward that could lead to the healing of tracheal stenosis with endoscopic treatment and prolonged indwelling of the stent.

Key words: Tracheal stenosis; Tracheal stent; Tracheal prosthesis; Indwelling time of tracheal stent; Healing of benign tracheal stenosis

RESUMEN

Tres *stents* traqueales fueron removidos luego de 10, 16 y 22 años, a lo que le siguió la correspondiente curación de la estenosis traqueal.

Se reportan dos nuevos casos de estenosis traqueal benigna, tratados con prótesis de silicona, que se presentaron a control luego de muy largas ausencias: 16 años en uno y 22 en otro. Se suman a un caso anteriormente publicado y curado luego de 10 años de permanencia del *stent,* que también presentó una amplia y estable luz traqueal luego la remoción. Se describen los hallazgos endoscópicos, y se incluyen reflexiones sobre la curación de la estenosis observada en todos ellos y su probable relación con el largo tiempo de permanencia de las prótesis. Se investigan las propiedades físicas de los stents, luego de tan prolongado lapso de implante y se las compara con un dispositivo nuevo. Se emite una propuesta que podría conducir a la curación de las estenosis traqueales con tratamiento endoscópico y stent por tiempo prolongado.

Palabras clave: Estenosis traqueal; Stent traqueal; Prótesis traqueal; Tiempo de permanencia de un stent traqueal; Curación de la estenosis traqueal benigna

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INTRODUCTION

This publication can be considered a continuation of a previous one,[1] published in 2016 by the same author and titled "Tracheal Prosthesis. Prolonged Implant: 10 Years".

Such publication provides a "definition of tracheal stenosis" and another one of the "healing of stenosis". Finally, there is a table that organizes clinical criteria, symptoms, and their relationship with the anatomical dimension of the tracheal lumen after endoscopic treatment, along with the timing of appearance or absence of recurrence.2

All of this allows the physician to have a guide for understanding and determining healing of stenosis or treatment failure.

The circumstances in which healing can be established are also explained, even if the tracheal lumen has not regained its original diameter.

Healing criteria[1]

Tracheal stenosis, defined as a "symptomatic reduction of the airway" requires a healing criterion that involves at least the reversal of the aspects indicated by its definition. Therefore, healing demands the disappearance of the symptoms caused by this obstruction, as well as the recovery of the airway lumen.

Once again, these two seemingly fixed concepts –symptoms and airway lumen– are highly variable and will be considered separately. Symptoms that are absent at rest might appear during physical activity. Additionally, a complete recovery of the tracheal lumen, determined by its diameter or useful section, is not necessary for the symptom of stridor to disappear, even during exercise (Table 1).

With a tracheal lumen diameter of 8 mm or more, there will be no stridor at rest when the stenosis is simple and its length does not exceed 20 mm.

After analyzing all the elements that define the framework of symptomatic airway stenosis, patients who remain asymptomatic two months after completing their treatment, maintaining a fixed tracheal lumen that is sufficient for the performance of their activities, are considered healed. This is possible when, in anatomical terms, the tracheal lumen is equal to or greater than 50% of the healthy trachea lumen in the same patient.

We will refer to this as "complete" healing, even though it is anatomically partial.

The following considerations will complete the previous ones: the healing criterion must encompass and include asymptomatic cases, with a fixed or stable tracheal lumen that isn't sufficient for the performance of all the patient's activities, thereby allowing them to carry out their daily tasks with limitations.

We will refer to this anatomically partial healing as "incomplete".

Given the fact that the case described in the previous publication was successfully healed without complications, when the silicone stent was removed after 10 years, temptation arose to support a line of reasoning suggesting that a longer indwelling time of the stent could be associated with a higher likelihood of stabilizing the tracheal wall and healing. It is observed that in other clinical situations, this process occurs naturally.[1] Additionally, in other medical specialties, treatments involving long-term stents or supports increase

TABLE 1. Healing of tracheal stenosis

Definition: "It is the reversal of symptoms with a stable recovery of the lumen that is sufficient to enable the patient to perform their usual activities."

Asymptomatic at rest and during exercise	Stable lumen after 2 months. Around 100%	Anatomical reversal: Total	Complete healing
Asymptomatic at rest and during exercise	Stable lumen after 2 months ≥ 50%	Anatomical reversal: Partial	Complete healing
With symptoms during exercise that DON'T limit the patient's activities	Stable lumen after 2 months ≥ 50%	Anatomical reversal: Partial	Incomplete healing
With symptoms during exercise that LIMIT the patient's activities	Stable lumen after 2 months ≤ 50%	Anatomical reversal: Partial	No healing
With symptoms at rest	Stable lumen after 2 months ≤ 50%	Anatomical reversal: Partial	No healing

the probability of success, and these are implanted with the intention of never being removed.

To the case described with 10-year stent indwelling, two more cases are added, where the stents also remained implanted without medical control for 16 and 22 years.

Thus, their description can be outlined as follows:

Case 0: characteristics of a new and unused stent

Case 1: stent that remains in the trachea for 10 years

Case 2: tracheal stent with an indwelling time of 16 years

Case 3: tracheal stent with an indwelling time of 22 years

Type of study

In vitro/in vivo observational study.

MATERIALS AND METHODS

One new silicone stent. Another identical stent, implanted and removed after 10 years of biological use. One stent implanted during 16 years and the other one during 22. All the stents were made using the same process and raw material: silicone for use in human patients.

The study was based on

- the comparison of the hardness and elasticity of the stents extracted from the patients with respect to the corresponding values of a new stent.
- the analysis of the results of the treatment of benign tracheal stenosis in the three patients.

Clinical case zero

Represented by the control stent. New, unused. Manufactured with silicone for medicinal purposes.

Characteristics of the new stent

Aspect: Translucid (Image A)	
*Shore A Hardness Scale**:	78
*Expansion of rupture (Mpa***):	5.3
Presence of secretions or inlays:	Not applicable
Proximal or distal granulomas:	Not applicable

*Determined at the National Industrial Technology Institute (INTI, for its acronym in Spanish). Argentina.

** Measurement of elastic modulus. Preferred for rubber. It measures the rebound height or penetration of a pyramidal cone.

***It is the maximum stress before fracturing by cross-sectional area. Measurement in Newton/square meter × 10 raised to 6^a (mega Pascal).

Case 1

60-year-old female patient presented with stridor caused by central tracheal stenosis located 3 centimeters next to the vocal cords. The treatment involved endoscopic resection of the stenosis, followed by the implantation of a silicone stent. The stent model used was designed for tracheal stenosis, with a diameter of 14 mm at the ends, 12 mm in the central area, and a length of 40 millimeters.

There were no immediate complications.

We lost contact with the patient, and ten years later, she spontaneously returned to the endoscopic center without experiencing any symptoms.

A flexible respiratory endoscopy was performed, revealing that the stent was in the correct position and fully permeable. No inlays or secretions were observed. (Figure 2)

The stent was removed and sent to the National Industrial Technology Institute for physical examination. (Figure 3)

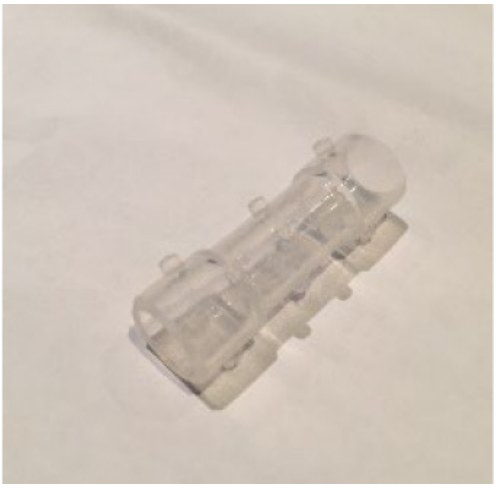

Figure 1. New stent.

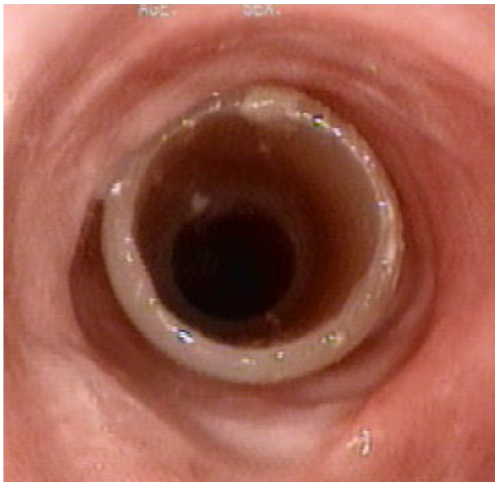

Figure 2. Tracheal stent in central position, with floating end and no contact with the tracheal wall, 10 years after implantation.

Figure 3. Aspect of the stent removed 10 years after implantation.

Characteristics of the stent removed 10 years after implantation

Aspect:	Ochre-translucid
Shore scale hardness:	It was reduced from 78 to 71 Shore A units
Expansion of rupture:	It was reduced 0.3 Mpa (average of three measurements)
Presence of secretions or inlays	NO
Proximal or distal granulomas	NO

After the removal of the prosthesis, the trachea maintained a wide diameter similar to that of the removed stent, without deformations or localized malacia. Endoscopic control was carried out every 10 days, showing a slight, slow, and progressive reduction in the diameter of the lumen in the stenosis area. This retractile phenomenon stops, and the lumen stabilizes at the sixth week after the prosthesis was removed, with a diameter exceeding 50% of what corresponds to a healthy trachea. (Figure 4).

With a lumen diameter of more than 50% of the original, after two months, it was considered healed.[1]

Case 2

66-year-old male patient who was treated 16 years ago for stridor caused by postintubation benign tracheal stenosis. The patient underwent endoscopic treatment involving resection and dilatation, along with the implantation of a silicone stent identical to the model of the previous case: a diameter of 14 mm at the ends and 12 mm in the central area, with a length of 40 millimeters.

Sixteen years later, the patient requested a follow-up appointment, reporting shortness of breath on exertion.

An endoscopy revealed partial obstruction of the lumen distal to the stent with tissue that had the macroscopic features of granulomas. (Figure 5)

A rigid bronchoscopy was performed, and the prosthesis was removed. (Figure 6)

The extracted device was sent to the National Industrial Technology Institute for physical examination.

After 8 weeks, the tracheal lumen was wide and exceeded 50% (Figure 7). The patient was asymptomatic.

With a wide lumen, whose diameter was similar to that of the normal trachea, stable after two months, the patient is considered healed[1].

Figure 4. Tracheal diameter 6 weeks after removal.

Figure 5. View from the inside of the tracheal prosthesis: large granulomas in contact with the distal end partially obstruct the lumen.

Figure 6. Aspect of the tracheal stent removed 16 years after implantation.

Characteristics of the stent removed 16 years after implantation

Aspect:	Opaque. Ochre color.
Shore scale hardness:	70 (8 units lower than a new stent)
Expansion of rupture:	4.5 Mpa (0.8 Mpa lower than a new stent)
Presence of secretions or inlays	NO
Distal granulomas	YES

Note: these deviations from the physical parameters with reference to those of a new stent are not considered significant.

Figure 7. Aspect of the tracheal lumen after 2 months: healing.

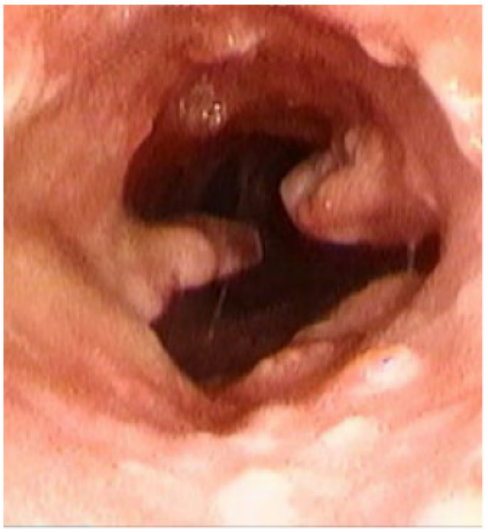

Figure 8. Lateral granulomas and tracheal lumen after removal.

Figure 9. Tracheal stent removed 22 years after implantation

Figure 10. Tracheal lumen two months after removal.

Case 3

45-year-old male patient who suffered from postintubation benign tracheal stenosis located very close to the vocal cords. After being admitted due to an episode of obstructive ventilatory difficulty, endoscopic recovery of the tracheal lumen was performed, along with the implantation of a classic straight silicone stent, with an external diameter of 16.25 mm and a length of 40 mm. Then, the ventilatory function was immediately stabilized.

All of this happened 22 years ago.

The patient did not attend the follow-up appointments until he felt compelled to do so due to the appearance of late symptoms consistent with noisy breathing and isolated episodes of blood expectoration, so he attended the hospital service, 22 years later.

The endoscopic examination revealed the presence of a dark-looking stent at 2 cm from the vocal cords, with secretions inside that were insufficient to obstruct the airflow, particularly in a stent of such a large caliber. However, the tracheal lumen was greatly constricted at the end of the prosthesis, with the appearance of a linear groove, due to the presence of two large contact granulomas positioned laterally at 9 and 3 o'clock. (Figure 8)

A rigid bronchoscopy was performed and the endoprosthesis was removed. (Figure 9)

Two weeks later, the patient was breathing normally and the aspect of the trachea was very satisfactory.

Following the same criteria1, after two months with a lumen 50% larger than the original, the patient is considered healed. (Figure 10)

Characteristics of the stent removed 22 years after implantation

Aspect:	Opaque. Dark brown
Shore A Hardness Scale:	N/A*
Expansion of rupture:	N/A*
Presence of secretions or inlays	NO
Distal granulomas	YES

*Device lost in the laboratory

DISCUSSION

The following considerations on the matter that is being studied, while not definitive or conclusive, will organize the knowledge on the subject.

TABLE 2. Relationship between indwelling time, final lumen and results

	Case 1	Case 2	Case 3
Indwelling time of stent (years)	10	16	22
Tracheal lumen 2 months after removal	Larger than 50%	Larger than 50%	Larger than 50%
Results:	Healed	Healed	Healed

In all cases, the stents were removed. The reasons can be found in the lack of understanding with regard to the necessary period or at least the preferred duration for the implant to produce a cure, as well as in the limited availability of studies that clarify doubts on this matter. Periods of 10, 16, and 22 years turned out to be empirically very long. The decision to remove the stents, initially intuitive, was later based on the acceptable reason for extracting a product after such a prolonged presence.

Regarding the mechanical viability of the device, no further explanations will be added because, as we already mentioned before, these are scarce or nonexistent, and the present study aspires to additionally provide detailed knowledge on this point, which can be found in Annex I at the end of the text.

Absence of complications after implantation or silent course complications can be suspected in all cases, since it was only in this way that patients were able to avoid clinical monitoring.

On the other hand, the experience strongly suggests that if these complications do not appear within the first 6 months, they will not occur.[1] However, in contrast, Verma and colleagues believed and published that stents weren't well tolerated over long periods.[5]

In order to leave behind the unappealing question about how long a silicone stent "is able" to fulfill its supporting function in the airway, it seems reasonable to say that very extended periods far exceeding the usage time estimated by manufacturers do not appear to be a problem, since it has been observed that the hardness and elasticity of silicone change very little after 10 years in vitro and in the patient.[1]

Other justifications can be found in exceptional experiences like those presented here, which didn't show any defects in the supporting function of the prosthesis after so many years. Physical and dynamic studies of the materials that make up the stents are scarce or nonexistent.[1] Other reasons, though empirical in nature, can provide reassurance, such as the absence of problems in treated, referred, or published cases as a consequence of defects in the implanted stent over long periods.

Finally, from a technical standpoint, the study presented in Annex I show that the stent maintains its primary function during prolonged periods of implantation.

Now, if we replace "is able" with how long a stent "should" remain implanted in order to heal stenosis, an uncomfortable question arises. The same question that students always ask, and for which they receive unconvincing answers, even after more than three decades of experience with the use of prostheses in the airway.

The review of publications reveals that initially the prostheses remained implanted for short periods, from 6 to 18 months[2-4], as recommended by F. Dumón in the beginning, although later he considered that probably there were fewer recurrences in patients who had stents for a longer time.[6] Publications or recommendations about the indwelling time of a stent are very difficult to find.

Long indwelling periods occur occasionally and have been reported.[5-6]

We had a tendency to keep the stents for longer periods,[7] with the conviction that the passing of time can contribute to a firm healing of the tracheal wall, as it happens in diseases of other organs.

Gathering statistically robust information on the results of endoscopic treatment of benign stenosis can also be difficult because of its limited availability.[7]

So, in our series of 198 cases, the stents remained implanted between 13 and 36 months, with an average of 28.6. The healing that was achieved combining the methods of thermal or mechanical endoscopic resection, with or without dilatation, was 42%. It's the same as admitting that for 42% of those patients, the treatment has been very good, and for the rest, it was very bad.

Now, these results show that almost one every two patients will relapse and return to the starting point of their tracheal disease to restart the long path of decisions and therapies, with a discouragement that is difficult to hide.

CONCLUSION AND RESULTS

All three cases of occasional indwelling of a tracheal stent for 10, 16, and 22 years were healed after stent removal.

This cannot lead to any conclusions; however, there is a feeling of astonishment that all three patients healed immediately, along with the inevitable regret that there wasn't a larger number of cases.

This striking circumstance invites us to wonder and discover if, through a statistical analysis, the healing of tracheal stenosis around the prosthesis is necessarily related to the prolonged indwelling time of the stent, and if much longer periods than those used so far are required.

Conversely, medium and short periods of implantation could be the cause of poor results.

It must be made very clear that only patients who do not show immediate complications or complications during the first year of stent implantation, such as the formation of bacterial plaque inlays,[7] excessive secretions, the development of granulomas, or other, would be candidates to participate in a study with extended periods of stent implantation. Experience has shown that if patients don't show these complications in the first year, they don't tend to ever show them.[1]

Finally, since the short periods were insufficient and those of 28 months on average only healed 42% of the cases, it is inevitable to propose a longer indwelling time of the stents for benign stenosis.

And these considerations lead to the unavoidable question: how long should the indwelling period be?

Before hastily proposing the controversial period of 10 years, in order to obtain better adaptation to change, we can reflect on the matter.

We can begin by admitting, in the first place, that the stent indwelling times already established or used so far are insufficient. Secondly, we still don't know which should be the sufficient times, and the little information we have about this (three cases with 10, 16, and 22 years) is invalid or barely worthy of consideration from the statistical or almost any other point of view.

Still, given the need to improve the results of a treatment that has been administered for almost three decades, we could propose an initial period of 10 years, as it corresponds to the case we have presented with the shortest indwelling time and the best result.

Thus, a study that allows us to know the percentage of healing after ten years would enable the examination of a new series in the following study, with a shorter indwelling period, thus repeating the trial until the appearance of an increase in the recurrence rate allows the determination of the best period in years for stent indwelling time; that is to say, the shortest period that produces the highest healing rate, which, based on the information presented on the topic, falls between 28 months and 10 years.

Conflict of interest

The costs of physical/dynamic examinations of the stents were covered by Stening SRL. The stents used in the patients, extracted and analyzed were manufactured by Stening SRL, Argentina. The author Ricardo Isidoro is partner and general manager of Stening SRL.

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ANNEX I

DETERMINING THE LIFE OF TRACHEOBRONCHIAL STENT FAMILY IMPLANTS

Jorge Gallo, Engineer

1. Theoretical introduction

In order to determine the shelf life of this family of implants, we use the mathematical model of Exponential Distribution, which is the one that best fits for analyzing the durability of implants. This is derived from the general expression of the Weibull distribution, whose mathematical expression is as follows:

$$R(t) = e^{-\left(\frac{t}{\theta}\right)^{b}} \tag{1}$$

Where:

R(t): the probability at a given moment for a medical device to still have the potential to fulfill its intended use; abbreviated as reliability. Reliability is a variable that decreases over time (t) due to the negative factor in the exponential expression (1).

q: a statistical value referred to as characteristic life, the meaning of which will be analyzed further in this report.

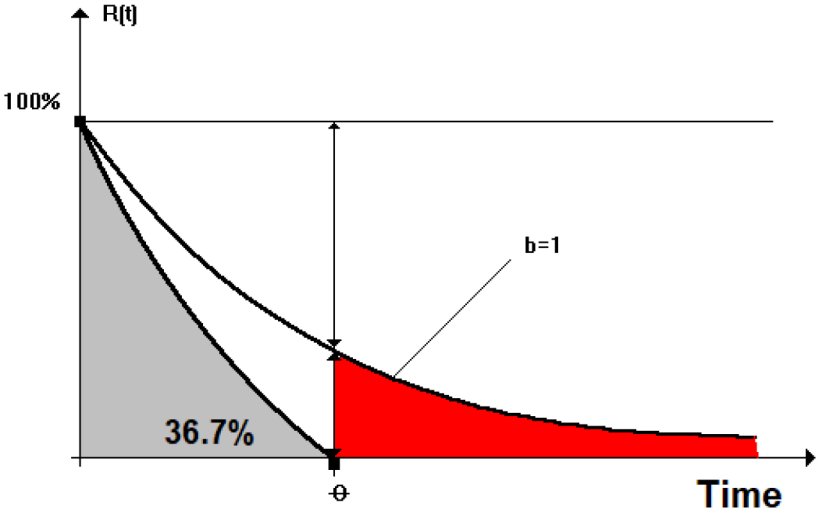
e: the base of natural logarithms.

b: another statistical value of the distribution, which is different for the Weibull distribution compared to the Exponential Distribution, where it equals one.

So, the expression (1) for b = 1 becomes:

$$R(t) = e^{-\frac{t}{\theta}}$$

which is the one we have used in our work and allows for the following graphical representation



If we analyze this chart we can see that mathematically speaking, the characteristic life "θ" is the time it takes for the "no defects" probability (reliability) to decrease to approximately 37%, which is its mathematical definition.

In our work, we adopted the distribution that defines the shaded area in the previous chart, thus ignoring the asymptotic nature of the original mathematical model. However, this conservative simplification allows us to establish the second, more practical definition of "θ" which is the one we use in this study considering it as *the end of the device's shelf life*. This is also known as the **predictable durability of the stent**.

For these distributions, we work with data obtained from implants that fail after being placed. Since there are no defective implants in our sample, we must use an attributive method to graphically determine the value of "**R**" and then that of "θ", for a confidence level of C = 95%.

Description of the applied methodology

2. Input and output data

In our case, we have a sample of implants that have worked properly up to the date of this analysis (January 31, 2019). These data are presented in the table of Annex II.

Based on the data summarized in this table, we obtain the following input data for our analysis:

- Sample size **N = 18**
- Average aging time of the sample (implantation) was **t = 618** days (we do not use the average because the distribution of this variable is not Gaussian).
- Number of items whose performance goes according to specifications (number of OKs in the sample) **18**

With this data, we need to determine the characteristic life "q" as the output data of the calculation process.

2.2. *Calculation process used*

We need to determine the q value. To do this, we use the attribute-graph that was created basing on a confidence level of **C = 95%** using the curve for zero defects in the sample, entering horizontally with the value of **"n"** and extracting the corresponding value of **"R(t)"** from the chart.

Once we knew this value of **R(t)**, we used the mathematical expression of the exponential distribution to obtain the value of the characteristic life q as follows:

$$R = e^{\frac{-t}{\theta}}$$
$$Ln(R) = \frac{-t}{\theta} \therefore \theta = \frac{-t}{Ln(R)} \quad (1)$$

3. Case resolution

3.1. *Input data*

With the data available in the Annex of this report, we have the following input data for the calculation:

- **Sample size:** 18
- **Median time of aging with no defects** (the average was not used because the time column is not a Gaussian distribution): 618 days
- **Number of items meeting the intended use**: all of them (there wasn't any "Not OK" in the sample)

3.2. *Output data*

Using the input data and the chart of Annex II, we obtained:

R = 0.85 (see graphical solution on the next page).

Then, by applying the expressions (1), we obtained the following output data from our work:

$$\theta = \frac{-t}{Ln(R)} = \frac{-618}{Ln(0.85)} = 3,803 \text{ days } (10.4 \text{ years})$$

The predictable or inferred durability of a stent manufactured by the company is 10.4 years.