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Case Report

Tracheal Prosthesis: Comparative Analysis of the Physical and Functional Properties in a Silicone Tracheal Stent after 10 Years of Implantation

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Abstract

The prosthesis extracted from a patient with benign tracheal stenosis was analysed, after 10 years of implantation and compared with two new prostheses, one of them subjected to simulation tests of aging in the laboratory through the analysis of physical and functional properties. The results were used to analyse the causes of therapeutic failures and to propose modal changes in the endo-surgical therapeutic behaviour of tracheal stenosis.

Keywords: *Tracheal Stenosis; Silicone Stent; Tracheal Prosthesis*

Introduction

Type of study: observational/*in vitro*/*in vivo.*

The Materials used and method of analysis adopted:

- A new silicone stent (prosthesis).
- A stent that was implanted for 10 years in a human patient.
- A stent that was aged in a laboratory test.
- Comparative determination of the degree of hardness according to the Shore scale of these samples.
- Comparative determination of the physical properties of the samples through tensile tests (tensile strength and specific elongation).

Clinical Case

A 60-year-old female patient treated for dyspnea with inspiratory stridor, normal respiratory rate without involvement of accessory muscles.

She underwent a respiratory endoscopy that showed the existence of a central tracheal stenosis 3 centimetres from the vocal cords, with an approximate length of two centimetres. The state of the mucosa was congestive and the light available for ventilation was 6 millimetres in the major section.

This device had a classification of risk III, according to the British standard ISO: 10993-1, for being invasive of permanent contact, for more than 29 days [3] and was made with biocompatible silicone, without metal inserts. The model used, SET14-12-14 of 40 millimetres in length, had a design of variable diameters that make it appropriate to adapt to the anatomical situation imposed by a tracheal stenosis, had a greater diameter at its ends and a smaller one in its central portion.

During its application there were no complications, nor in the medium and long term. After the implant the patient experienced immediate relief of her painful breathing and the stridor disappeared. In the following months, she attended the clinical controls, not seeing any symptomatology that would justify a new endoscopic exploration.

The follow-up was interrupted after six months because the patient left the controls and we lost contact with her.

Ten years later, she attended the clinic spontaneously, she was asymptomatic, without excessive halitosis, cough or bronchial secretions.

A flexible endoscopy was performed in which the stent was observed in the correct position and permeable, without incrustations or secretions.

In the image A the correct disposition of the prosthesis can be appreciated, since its end is „floating".

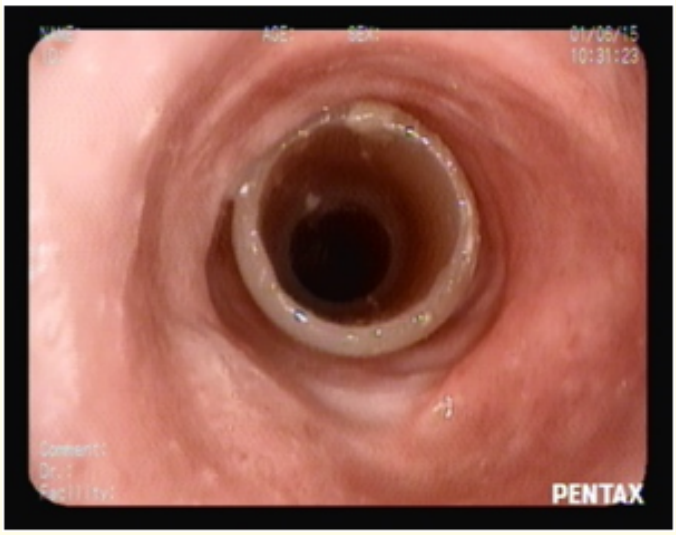


Figure A: *Stent in the air track with 10 years of permanence.*

Although its contour shows contact at 10, 11 and 12 hours, there are no reactive signs of the tracheal wall indicating that the contact is intermittent and of low pressure.

It could be verified that during the breathing, the stent accompanied the respiratory movements, moving away and approaching the tracheal wall. At the time of the photographic capture the stent was in partial contact.

Immediately after the extraction of the prosthesis, the trachea maintained a diameter similar to that of the removed prosthesis, without local deformation. Endoscopic controls were performed every 10 days during the first month showing a slow but progressive reduction of the light in the area of the stenosis. The retractable phenomenon finally stopped, stabilizing at the sixth week of stent removal. Tracheal space retained a diameter greater than 50% of what corresponds to the healthy trachea of the patient (Image B).

No variations were observed in the subsequent controls; the patient remained asymptomatic and was finally considered cured.

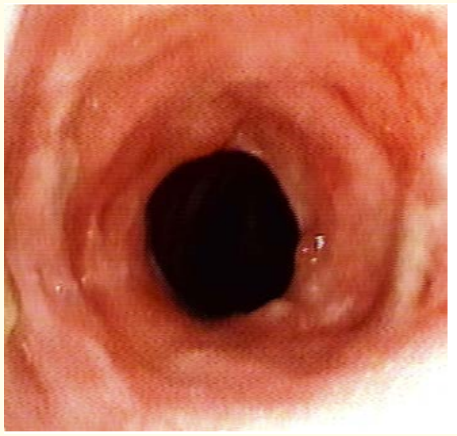


Figure B: *Air track after the extraction of the prosthesis.*

Healing criterion

1. The notion of healing of the affections acquires different aspects according to the disease and the morbid condition. Sometimes healing requires the anatomical restitution „ad integrum", in others the recovery of the function of the organ or system, completely or even partially.
2. It may simply consist in the disappearance or removal of the injurious noxa. It is also accepted as a cure the restitution of the functions to a degree that allows sufficient performance of the patient. Thus considered, the concept of healing is nurtured in a variety of components
3. Since laryngo-tracheal stenosis is a „symptomatic reduction of the airway", the criterion of applied healing requires at least the reversion of the aspects of its definition. Therefore, healing requires the disappearance of the symptoms that the obstruction causes and also the recovery of the tracheal space [4,5].
4. These two seemingly fixed and independent concepts: symptom and tracheal space are actually variable and should be considered separately. In this way, the absent symptoms at rest can appear with physical activity. At the same time, it is not necessary for the stridor symptom to disappear the total recovery of the tracheal space, even with physical activity (Image 1).
5. When the stenosis is simple and its length does not exceed 20 mm, with a diameter in the tracheal track of 8 mm or more, there will be no stridor at rest [7].
6. After the analysis of all the components that delimit the symptomatic stenosis of the tracheal air track, those patients who, two months after the end of their treatment, remain asymptomatic, with a stabilized tracheal space sufficient to carry out their activities, have been considered cured. This is possible when, in anatomical terms, the tracheal space is equal to or greater than 50% of that of the healthy trachea of the same patient [7].

We define as „complete" this partial healing.

The following considerations complete our definitions:

- The criterion of cure must contemplate and include asymptomatic cases.
- With fixed and stable tracheal space but that is not sufficient for all the activities that the patient performs, so that it allows him to do your daily chores but with limitations.
- We define as „incomplete" this partial healing.

7. Defined in this way the concepts, healing by the method used results in the majority of cases partial although sometimes it is complete.

It seems that healing is better linked to symptomatic reversal than to anatomical recovery, which is its consequence.

Patient condition	Tracheal space	Reversion type	Healing level
Without symptoms at rest or in exercise	Stable tracheal space at 2 months. Greater than 50%	Partial anatomical reversion in all cases	Complete healing
With symptoms in exercise that do NOT limit their activities			Incomplete healing
With symptoms in exercise that limit their activities	Stable tracheal space at 2 months. Equal or less than 50%		Without Healing
With symptoms at rest			

Table 1: *Tracheal stenosis healing.*

Note 1: This table was made according the following tracheal stenosis definition: "Healing is the reversal of symptoms with stable recovery of sufficient space to perform the patient's usual activities".

Discussion

The maintenance of a stent in the airway for such a prolonged period, like the one described, is beyond any medical-therapeutic intention. Nevertheless, for different reasons that will not be examined in this report, prolonged stent implantation times occur occasionally and have been published [6].

Thus, in a symptomatic and acute tracheal stenosis or at least rapidly progressive, when applying a tracheal stent we will know that:

- Immediate relief to ventilation is provided.
- The stent will act as an effective support over time, maintaining space in the airway.
- As the first weeks pass, the stenosis „hugs" the stent, fixing it.
- The consolidation stage of the stenosis will then begin.
- The airway will be insured, until another possible treatment is carried out or it is continued in the same therapeutic line.

Now, it is also true that we will face other somewhat opposed facts such as:

- The time required for the consolidation stage is not known.
- This stage does not always occur, or at least is not completed during the period in which the stents remain implanted; this time period is not always recorded in the specialty publications.

In our series of 126 cases, recurrence was present in 56% of the cases. In our series of 126 cases, recurrence was present in 56% of the cases.

In turn, publications define a variable frequency of recurrences after different endoscopic treatment techniques [7-9].

Duration of the implant

This time is not well established [10]. In the original publications, the prostheses remained installed for short periods, from 6 to 18 months [11,12] and the reasons for the removals are not correctly defined. Gradually, the implant's duration was increased over the years.

There is a natural and intuitive tendency to hope that the definitive tracheal healing or „consolidation" of the stenosis, which is the one that finally ensures a stable diameter of the tracheal space and sufficient ventilation, occurs with a higher frequency when the residence

time of the Stent is long. In this sense, more time of permanence would be equal to greater probability of stable healing or consolidation. But the reasonableness of this event rests only in association with other healing processes known in medicine in which the time elapsed is an inevitable ingredient to achieve healing. The concrete knowledge of the relation between the time of permanence of the prosthesis and the healing remains unknown, as „the partial but sufficient recovery of the tracheal space".

These evidences convincing in appearance, have not yet been enough weight for the surgeon to feel authorized to keep a prosthesis implanted for long periods of time because questions are immediately presented related to the implants used, such as:

- Can a tracheal stent maintain its effectiveness and effectiveness over time?
- What is that time?
- Would the qualities of the stent vary after its implantation?

Test experiences

Stening Argentina, has examined the devices, in an environment *in vitro*, in which were simulated the conditions of accelerated aging equivalent to a life of 4 years, according to the ASTM D 573-04 standard, that analyses the deterioration of the physical properties of the raw material produce by the oxidation and thermal aging [12,13].

The properties were measured in:

- A new stent (without use);
- Another of the same model artificially aged,
- The stent extracted from the patient after 10 years.

Image C1 shows the hardness determinations in an unused stent, expressed in Shore A units and the tensile properties (stretching) through the length that the stent can be elongated before its fracture (See annex).

In the image C2, the same determinations were made on a device that has been aged in the laboratory (See annex).

Test results

1. The test shows that accelerated aging produces an increase of 4 points in Shore hardness with respect to the new device, without aging; with reduction of 9% in tensile strength and 34% in breaking strength.
2. The test was repeated in a new device and in another in which accelerated aging was induced in vitro in an isotonic saline solution (Image D). After aging in continuous immersion in this saline solution at high temperatures, there was no change in hardness, the resistance to traction was reduced by 4% and the elongation to breakage by 6%.
3. After 10 years of implant the Shore A hardness decreases 7 units after 10 years of implant the tensile strength decreases 0.3 units.
4. As explained, the determinations of the hardness of the stent were made according to the Shore A scale, which is related to the resistance to the penetration of a conical tip, in compliance with the American standard ASTM D2240. There is no relationship between hardness with other mechanical properties; materials with equal hardness can be completely different in their behaviour. What is observed in the tests has a comparative value between physically and operationally similar elements
5. A result obtained was that after 10 years of being implanted, the prosthesis decreased its hardness by 10% and the resistance to traction by 6.12%. These determinations were selected for the examination because they are the ones that best translate the adaptive behaviour of the stent to the movement of the organ that houses it.

Although there is a lack of studies that determine what is the optimum hardness and elasticity and what is the admitted variation of these properties over time, it was empirically demonstrated that stents fulfil their purpose in the air track, as happened in the clinical case presented. Failures in healing in high percentage of cases could not be attributed or linked to failure in the dynamic behaviour of silicone prostheses.

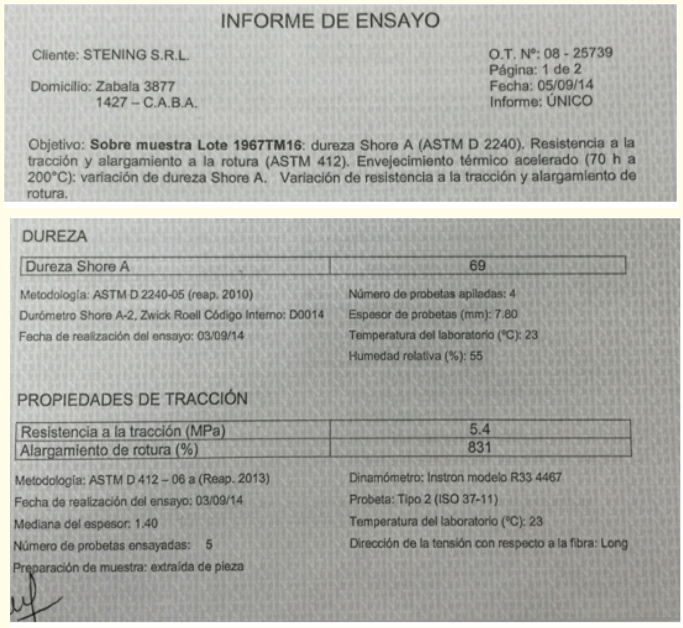
On the other hand, the healing of the stenosis by consolidation or stable healing of the affected area may be reasonably related to the implant's residence time, disconcertingly poorly known despite its widespread use for more than 25 years.

Note: In the annex you can see the images related to what was treated in these points.

Conclusions

- The tests carried out demonstrate that the devices used in the endoscopic treatment of tracheal stenosis retain their functions and effectiveness during their implantation in the patient at least for 4 years of aging simulated in laboratory tests. Its properties and effectiveness were preserved and were present in the stent removed from the patient 10 years after its implantation.
- In spite of this, the prostheses are continuously removed after a variable number of months, without supporting information or effective knowledge about the minimum necessary duration of the implant. Approximately 50% or more of these patients suffer a recurrence of the stenosis and are forced to restart the complex therapeutic pathway.
- After the implant is placed, may occur variable percentages of migration, incrustation by secretions and contact granulomas. The Experience strongly suggests that, if these complications do not appear in the first 6 months, they will not be presented later, so there is no reason to justify the removal of the prosthesis. Remember that in other medical specialties stents are implanted to never be removed.
- It is reasonable to accept that a longer implantation leads to tracheal consolidation and stabilization. It arises from the observations of the report presented, the proposal to increase the time of implantation of the prosthesis in the endo-surgical treatment of tracheal stenosis.
- An inverse analysis, based on the knowledge of the failures that are around 56% [7] in patients with a stent for periods of 22 to 28 months, leads to the conclusion that a longer period of implant is necessary.

Annexes



INFORME DE ENSAYO

Cliente: STENING S.R.L.

Domicilio: Zabala 3877
1427 – C.A.B.A.

O.T. Nº: 08 - 25739
Página: 1 de 2
Fecha: 05/09/14
Informe: ÚNICO

Objetivo: **Sobre muestra Lote 1967TM16**: dureza Shore A (ASTM D 2240). Resistencia a la tracción y alargamiento a la rotura (ASTM 412). Envejecimiento térmico acelerado (70 h a 200°C): variación de dureza Shore A. Variación de resistencia a la tracción y alargamiento de rotura.

DUREZA

Dureza Shore A	69

Metodología: ASTM D 2240-05 (reap. 2010)
Durómetro Shore A-2, Zwick Roell Código Interno: D0014
Fecha de realización del ensayo: 03/09/14

Número de probetas apiladas: 4
Espesor de probetas (mm): 7.80
Temperatura del laboratorio (°C): 23
Humedad relativa (%): 55

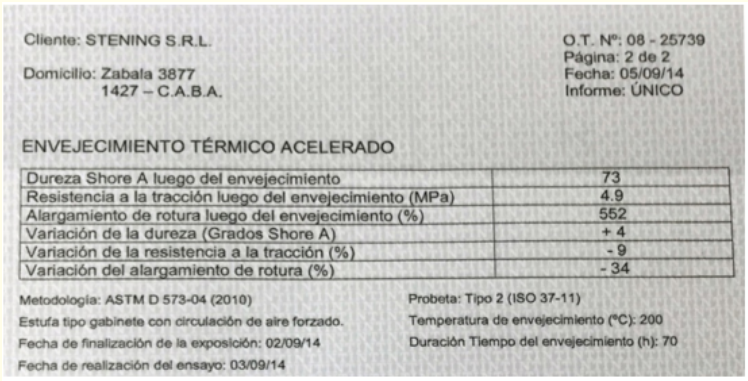
PROPIEDADES DE TRACCIÓN

Resistencia a la tracción (MPa)	5.4
Alargamiento de rotura (%)	831

Metodología: ASTM D 412 – 06 a (Reap. 2013)
Fecha de realización del ensayo: 03/09/14
Mediana del espesor: 1.40
Número de probetas ensayadas: 5
Preparación de muestra: extraída de pieza

Dinamómetro: Instron modelo R33 4467
Probeta: Tipo 2 (ISO 37-11)
Temperatura del laboratorio (°C): 23
Dirección de la tensión con respecto a la fibra: Long

Figure C1: *Hardness and tensile strength in new device.*



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Página: 2 de 2
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Informe: ÚNICO

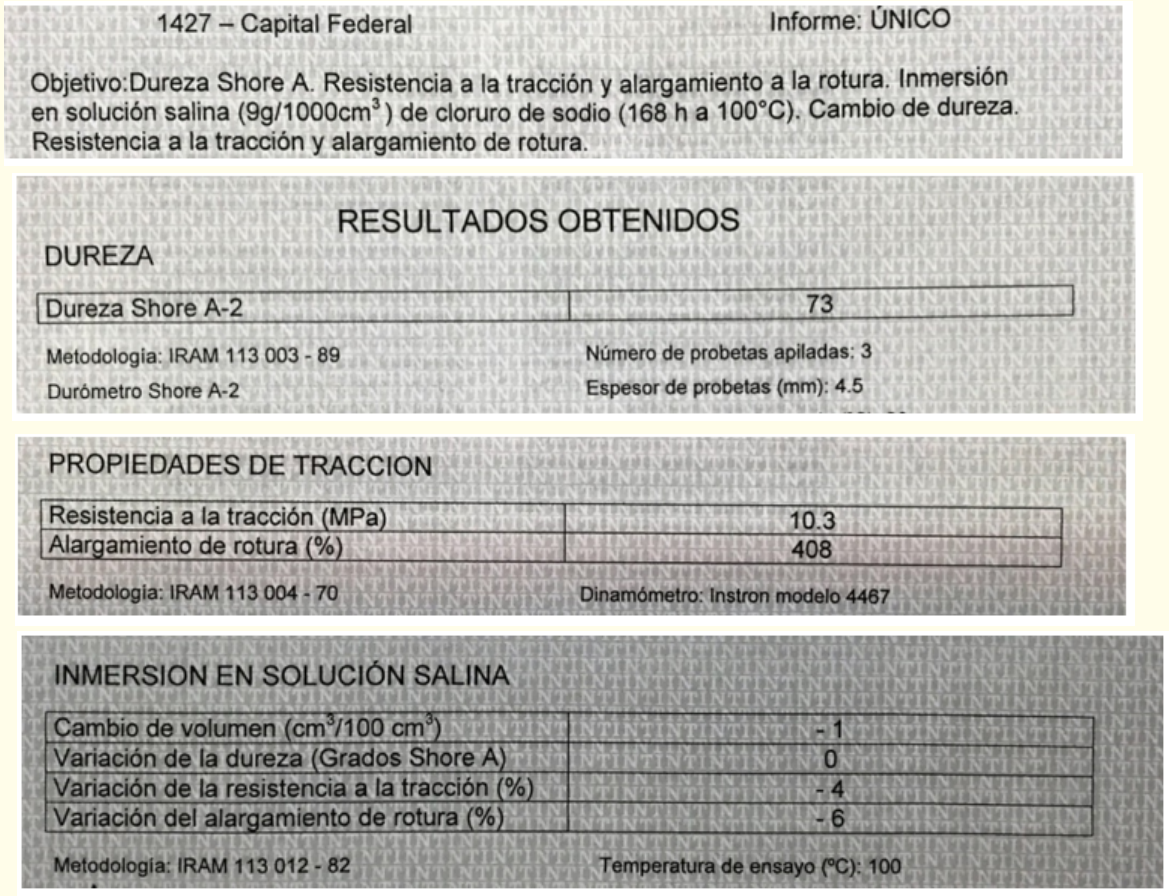
ENVEJECIMIENTO TÉRMICO ACELERADO

Dureza Shore A luego del envejecimiento	73
Resistencia a la tracción luego del envejecimiento (MPa)	4.9
Alargamiento de rotura luego del envejecimiento (%)	552
Variación de la dureza (Grados Shore A)	+ 4
Variación de la resistencia a la tracción (%)	- 9
Variación del alargamiento de rotura (%)	- 34

Metodología: ASTM D 573-04 (2010)
Estufa tipo gabinete con circulación de aire forzado.
Fecha de finalización de la exposición: 02/09/14
Fecha de realización del ensayo: 03/09/14

Probeta: Tipo 2 (ISO 37-11)
Temperatura de envejecimiento (°C): 200
Duración Tiempo del envejecimiento (h): 70

Figure C2: *Hardness and tensile strength after in vitro accelerated aging.*



1427 – Capital Federal — Informe: ÚNICO

Objetivo:Dureza Shore A. Resistencia a la tracción y alargamiento a la rotura. Inmersión en solución salina (9g/1000cm^3) de cloruro de sodio (168 h a 100°C). Cambio de dureza. Resistencia a la tracción y alargamiento de rotura.

RESULTADOS OBTENIDOS

DUREZA

Dureza Shore A-2	73

Metodología: IRAM 113 003 - 89
Durómetro Shore A-2

Número de probetas apiladas: 3
Espesor de probetas (mm): 4.5

PROPIEDADES DE TRACCION

Resistencia a la tracción (MPa)	10.3
Alargamiento de rotura (%)	408

Metodología: IRAM 113 004 - 70
Dinamómetro: Instron modelo 4467

INMERSION EN SOLUCIÓN SALINA

Cambio de volumen (cm^3/100 cm^3)	- 1
Variación de la dureza (Grados Shore A)	0
Variación de la resistencia a la tracción (%)	- 4
Variación del alargamiento de rotura (%)	- 6

Metodología: IRAM 113 012 - 82
Temperatura de ensayo (°C): 100

Image D: *Hardness and tensile strength after in vitro aging in a isotonic solution.*

Image E: *Stent extracted after 10 years of permanence.*

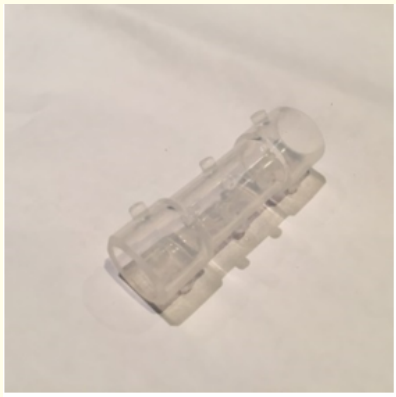


Image F: *New Stent with the same characteristics.*

Muestras identificadas por el cliente como: "STENT SET 14-12. Condición NUEVO SIN USO" y "STENT SET 14-12. Condición IMPLANTADO 10 AÑOS".
Determinaciones Requeridas:
Dureza Shore A (ASTM D 2240). Resistencia a la tracción (ASTM D 412)
Fecha de recepción: 16/06/2015
Fecha de ensayos: 17/07/2015

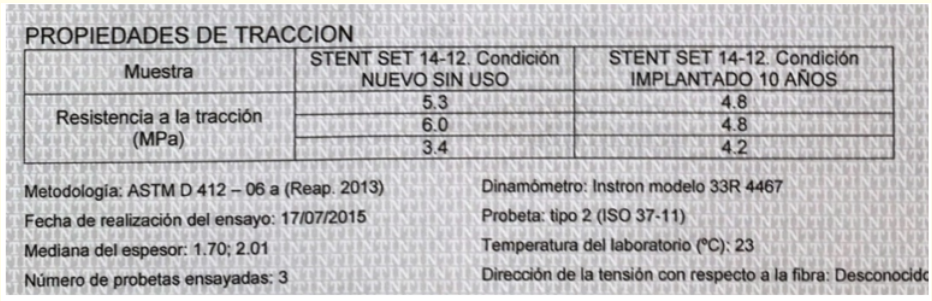
Resultados:

DUREZA

Muestra	STENT SET 14-12. Condición NUEVO SIN USO	STENT SET 14-12. Condición IMPLANTADO 10 AÑOS
Dureza Shore A	78	71

Metodología: ASTM D 2240-05 (reap. 2010)
Durómetro Shore A-2, Código interno: D0005
Fecha de realización del ensayo: 17/07/2015
Número de probetas apiladas: 4
Espesor de probetas (mm): 6.2; 6.0
Temperatura del laboratorio (°C): 23
Humedad relativa (%): 50

Image G: *Comparison of hardness in a new stent and in another 10 years after implantation.*



PROPIEDADES DE TRACCION

Muestra	STENT SET 14-12. Condición NUEVO SIN USO	STENT SET 14-12. Condición IMPLANTADO 10 AÑOS
Resistencia a la tracción (MPa)	5.3	4.8
	6.0	4.8
	3.4	4.2

Metodología: ASTM D 412 – 06 a (Reap. 2013)
Fecha de realización del ensayo: 17/07/2015
Mediana del espesor: 1.70; 2.01
Número de probetas ensayadas: 3
Dinamómetro: Instron modelo 33R 4467
Probeta: tipo 2 (ISO 37-11)
Temperatura del laboratorio (°C): 23
Dirección de la tensión con respecto a la fibra: Desconocido

Image H: *Comparison of resistance between a new stent and another 10 years after its implantation. In vivo.*

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