A NEW DEVICE TO IMPROVE CAPSULAR CONTRACTURE IN THE AUGMENTATION AND RECONSTRUCTION MAMMAPLASTY

PHYSIA TECHNIQUE

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INTRODUCTION

One of the most intractable complications in breast augmentation and reconstruction using prosthesis, is capsular contracture[1]. This contraction results from thickening of periprosthetic capsule, which forms around the prosthesis body and causes a tightening at the touch of the breast[2]. When the degree of contracture is severe, it can even alter the shape of the breast.

PATHOGENY

The etiology of capsular contracture undergoing breast implants is multifactorial and remain unclear. Although the use of rough surface implants the percentage of contraction has decreased and it still happens. This complication occurs to about 5% of cases of breast augmentation in the world literature. Contracture can occur unilaterally or bilaterally, from weeks to years after surgery, developed with varying degrees of severity, often asymmetrically. The improved design of the implants, fillers and surface coatings, has helped reduce the number of postoperative contractures. Similarly, variations in surgical techniques, implant position and various administrations of drugs have been recommended for the prevention of capsular contracture but with mixed results. Although significant results have been obtained by reducing the percentage of contractures, the risk still exists.

HISTOLOGY OF THE CAPSULE

With the introduction of a foreign material within the body, it has three modes of action: destruction, expulsion or isolation. Unable to destroy or remove the implant, the body activates the mechanism of isolation, creating fibrin capsule around it in a few days after implant placement.

The histology of the periprosthetic capsule is a foreign body reaction, with all the characteristic cellular elements, i.e., polymorphonuclear cells, macrophages, lymphocytes, eosinophils and occasional multinucleated giant cells, fibrin and fibroblasts also. In a few days you can distinguish a well-developed capsule where initial cellular elements disappear and others will have a stronger presence and importance, as is the case of fibroblasts, myofibroblasts, histiocytes and connective tissue. Once the capsule describes a basic morphological pattern that includes an inner layer fibrous-histiocytic, adjacent to the prosthesis and not necessarily attached to it, which is followed by a more or less thick fibrous layer, consisting of fibroblasts, few polymorphonuclear and abundant collagen. On this common pattern is added to other cellular components, which vary according to different reports and research papers [3].

CLINICAL CALSIFICATION OF CONTRACTURE

The Baker scale is used to determine the degree of capsular contracture and is divided into four grades as follows.

Baker Grade 1 – Normally soft and natural appearance
Baker Grade II - The breast is a little firm, but appears natural.
Baker Grade III - The breast is firm, and is beginning to appear distorted in shape.
Baker Grade IV - The breast is hard, and has become quite distorted in shape. Pain/discomfort may be associated with this level of capsule contracture.

CURRENT METHODS TO IMPROVE CONTRACTURE

Surgical methods:
- Closed capsulotomy (disrupting the capsule via external manipulation), a once-common maneuver for treating hard capsules, was discontinued because it might rupture the breast implant.
- Open capsulectomy: the correction of capsular contracture might require the surgical removal (release) of the capsule, or the removal, and possible replacement, of the breast implant, itself.
Non-surgical methods include massage, external ultrasound, treatment with leukotriene pathway inhibitors (e.g. Accolate, Singulair), and pulsed electromagnetic field therapy.

PHYSIA SYSTEM

The *De Sisti Lighting SpA Research Centre* (Italy), in collaboration with the *Heimp Medical and R+D Departments* (Spain) have developed a treatment system using the specific physiological frequency microcurrent: The Physia® system.
Physia® is a noninvasive active medical device in Class IIa, which complies with Directive 93/42/EEC health care, which includes the CE mark guaranteeing the quality and production control and product safety.
The technology CPM Tech® (cell physiological modulation) is patented. It is based on the issuance of specific physiological frequencies Physia ® allow contact with the cells, taking into account individual differences, Physia® system uses a customized self-regulatory mechanism. Unlike other methods, this system has been a breakthrough, as it is not necessary to wait for a recovery time between sessions to be a cellular regenerator non-invasive, no side effects and no contraindications. Thanks to a sophisticated electronic system, Physia ® ensures that the frequencies, and both current vehicle, arriving at the cellular level with the precise values required by the human body. These physiological frequencies reach the tissue and act on 3 of the 5 cellular transport mechanisms: membrane potential, intracellular signals (AMPc, tyrosine kinase) and intracellular metabolites (ATP, pH). They also contribute to eliminating detritus from the intercellular matrix, resulting in total regeneration of the cells and connective tissue.
Develop specific frequencies, in particular, an action of physiological normalization and energy rebalancing treated tissues, regenerating and revitalizing whole.
Its action occurs at different levels. In connective tissue, it acts on the specific fibres of the intercellular matrix: collagen, elastin and reticular, increasing the support and filling functions that are characteristic of this tissue. A vascular tone at the vessel walls, reducing ectasia of capillary and the precapillary venules. Make venotropo and lymphotropic effect, stimulating venous return and also favors the drainage of waste products of cellular metabolism.

PHYSIA SYSTEM AND CAPSULAR CONTRACTURE

This study had to test whether treatment with specific frequencies could change and improve capsular contracture patients undergoing breast augmentation.

MATERIAL AND METHODS

Five patients were analyzed, all with subpectoral implant and periareolar approach. Four patients with bilateral contracture and one with unilateral contracture (Case 1). All patients had a grade IV Backer (Table I).
Prior to treatment is made a biopsy of fragment of a capsule, carrying the incision through the scar of the initial approach (medial half of the periareolar scar) and performed a histological study.
For this study 20 sessions are arbitrarily taken as a benchmark to assess the effectiveness of treatment. Therefore performed in all 20 sessions, 2 per week. The sessions last for 1 hour.
After the treatment another breast biopsy is performed through the lateral half of the scar approach and histologically analyzed again.

HISTOLOGICAL ANALYSIS
Biopsies were removed in each patient before and after treatment from periprothesic tissue. The specimens were fixed in 10% formaldehyde and paraffin embedded. The sections were stained with haematoxylin and eosin and the features considered were: fibrosis, hyalinization, cellular density, inflammation, giant cell reaction, presence of foreign body and vascularisation. Cases 4 and 5 were stained with haematoxylin and eosin, tricromic and periodic acid-Schiff (PAS).

PHYSIA: TECHNIQUE

Before treatment protocol ("Protocolo Antes Tratamiento" PAT). (Table II). Initial maneuver whereby Physia® calculated the resistance to current flow (impedance) of the patient and adjusts the formula for the frequencies are modulated and ensure that they arrive at the cellular level. When selecting a treatment, Physia® automatically begins a 13 minute PAT.

Closing PAT. (Table III). Upon completion of the specific treatment it is necessary to conclude with closing PAT, consisting of 3 minutes to complete rebalancing treatment cell

PHYSIA: METHOD (Fig .1)

Protocol "capsulitis"	Sessions 1 to 5	Sessions from 5:
1st	PAT	PAT
2nd	neck lymphatic drainage	neck lymphatic drainage
3rd	20' drainage 10' tone / celulitis	10' drainage 20' tone / celulitis
4th	Closing PAT	Closing PAT

PHYSIA: CONTRAINDICATIONS TREATMENT

- Pace-maker
- Fever or active infectious process
- Pregnancy
- alteration lymph nodes
- hyperthyroidism
- acute renal failure
- heart failure
- malignant tumors

RESULTS

CLINICAL RESULTS

After the 20 sessions all 5 patients noticed a clear improvement of contracture.
Case 1 (unilateral case) went from a grade IV with pain and important adhesion to costal plane, to grade II painless and completely free from costal plane. However, this patient underwent an open capsulectomy and implant replacement surgery because it never resembled with the normal contralateral breast.
Three patients (Case 3, 4 and 5) have an improvement, going from a grade IV to grade III (Fig 3 and 4) and one case (Case 2) have a marked improvement from a grade IV to grade II (Fig 2) (still the best result with breast little firm, but appears natural). There is a complete upgrade, i.e. no passing grade I. But these changes are sufficient to avoid suffering further surgery.
The pain disappears in any case in all patients treated. Adherence to the costal plane of the implants disappeared in all patients. So, none of them had to undergo surgery as they were satisfied.

HISTOLOGICAL RESULTS (Table IV)

The degree of fibrosis was similar in all cases, except case 5 (the most early treatment) that was higher than in normal breast tissue, although in all cases the fibrosis remains similar, there is a significant change in the orientation of collagen fibers, and this is more homogeneous and organized after treatment.
In cases 1 to 4 there was more hyaline fibrosis in the specimens after treatment than the observed in the pretreatment ones. Normally this implies a loss of cellularity and contractile activity, probably responsible for improving the contracture. In case 5 the fibrosis was more prominent after treatment (Fig. 9).
The cellular density was variable among the patients and pre y post treatment specimens. Chronic inflammation was more prominent in biopsies after treatment in three cases. Giant cell reaction could be seen in three cases, in two of them independent of the treatment and in one, only in after treatment tissue. Foreign body was present in three cases. Vascularization was variable among the tissues examined.
Biopsies after treatment were usually less cellular, high hyalinizated, with scanty inflammatory infiltrate.
The histological findings were variable according the time elapsed between surgery and the treatment, thus case 5 (Fig. 9) with only 6 months after surgery showed less degree of hyalinization more cellularity and inflammation after treatment, and the long-standing case 4 (Fig. 10) revealed similar degree of fibrosis, hyalinization, cellularity and inflammation between before and after treatment.

CONCLUSIONS

So far the study is small and we can not talk about entirely conclusive results, however, the treatment of capsular contracture with Physia® seems to be effective, both histologically and clinically observing in all cases the disappearance of pain, and the disappearance of the costal plane adhesions.

The case 5 (treatment at 6 months after surgery) shows that Physia® treatment do not get an improvement in terms of the histological findings, even when clinically do observe, that is why we must wait at least 6 months from surgery to initiation of treatment.

Physia® treatment is an alternative to consider in all cases of capsular contracture because if not contraindicated, is simple to perform, does not cause discomfort to patients, it is noninvasive and produces no side effects.

Being established as a parallel treatment using ultrasound 2Hz, before opting for open or closed capsulotomy.

However, other studies required to assess its effectiveness as prophylaxis for postoperative surgical patients and patients with a history of capsular contracture recurrence.

TABLES

TABLE I

		Time of contracture before treatment	Age	Grade contracture
Case 1	Unilateral	2 years	20-30	IV Baker
Case 2	Bilateral	4 years	30-40	IV Baker
Case 3	Bilateral	6 years	20-30	IV Baker
Case 4	Bilateral	20 years	30-40	IV Baker
Case 5	Bilateral	6 months	50-60	IV Baker

	Surface implants	shape
Case 1	Textured	Anathomical
Case 2	Textured	Anathomical
Case 3	Textured	Anathomical
Case 4	Textured	Anathomical
Case 5	Microtextured	Round

TABLE II

Application movement	Time	Fixed	Time
Fixed on the soles of the feet	1 sec	Fixed in the head	30 sec
Down the right side of body from head to toe	predefined	Fixed in the toes	1 sec
Up from toe to head on the left side	predefined	Fixed in the head	30 sec
Down the right side of body from head to toe	predefined	Fixed in the toes	1 sec
Up from toe to head on the left side	predefined	Fixed in the head	1 sec

TABLE III

Application movement	Time	Fixed	Time
Up from toe to head on the left side	2 sec	head	1 sec

TABLE IV

Case	Treat. After surgery		Fibrosis	Hyalinization	Cellularity	Inflammation	Giant Cell	Foreign Body	Vascularization
1	2 years	B	++	+	+	+	+	-	++
		A	++	++	+	++	+	+	+
2	4 years	B	++	+	++	++	-	+	++
		A	++	++	++	+	-	+	+
3	6 years	B	++	+	+	+	-	-	+
		A	++	++	+	++	+	+	++
4	20 years after surgery	B	++	+	++	+	+	+	+
		A	++	++	+	+	+	+	+
5	earlier treatment (6 months after surgery)	B	+	++	+	+	-	-	+
		A	++	+	++	++	-	-	++

B: Before treatment.
A: After treatment

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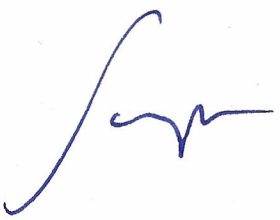

Dr. Albert Samper Sgrañes

FIGURES

Fig 1. Physia method

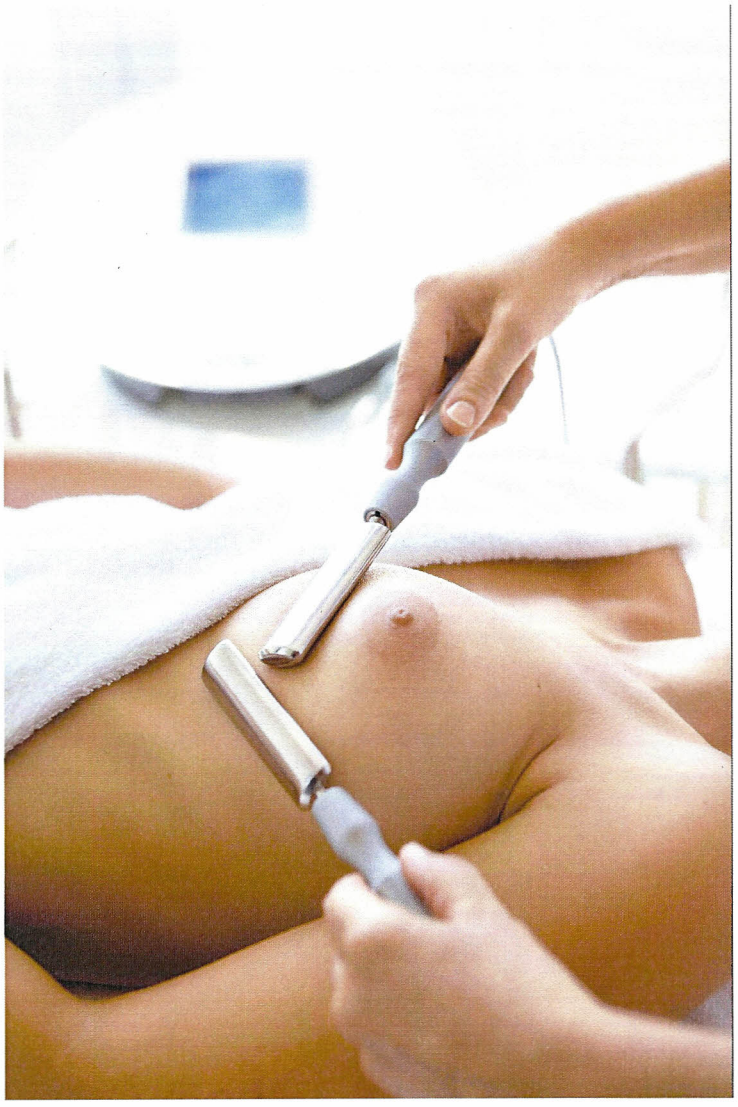

Fig 2. Case 2. Left image before treatment with a grade IV contracture. The image on the right shows the improvement to state II.

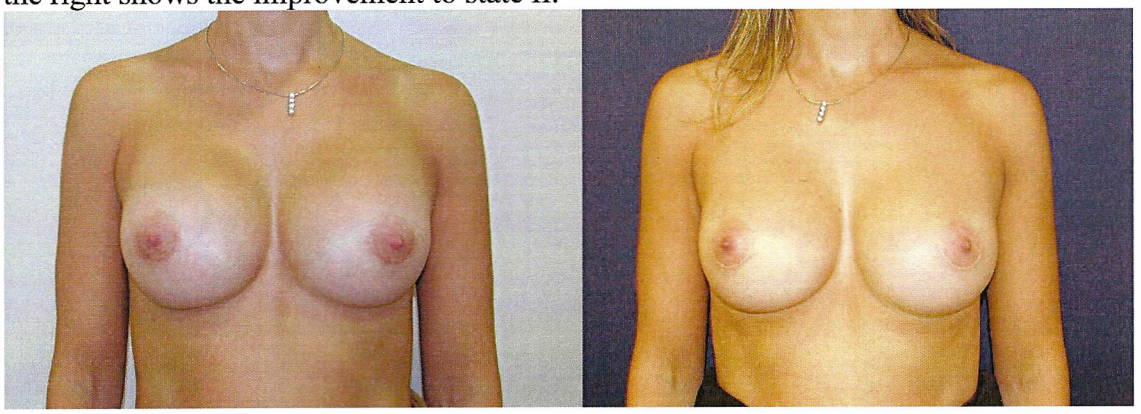

Fig 3. Case 3. Left image before treatment with a grade IV contracture. Right image with grade III after treatment.

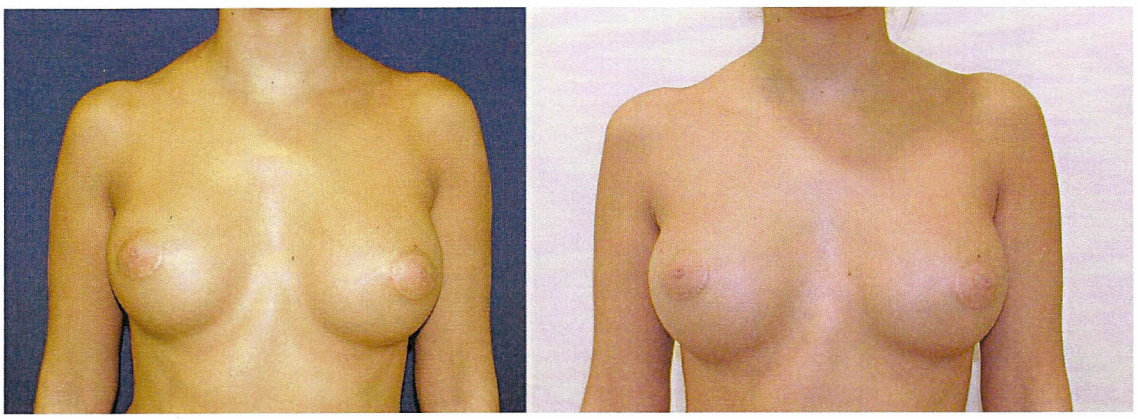

Fig 4. Case 4. Left image before treatment with a grade IV contracture. Right image with grade III after treatment.

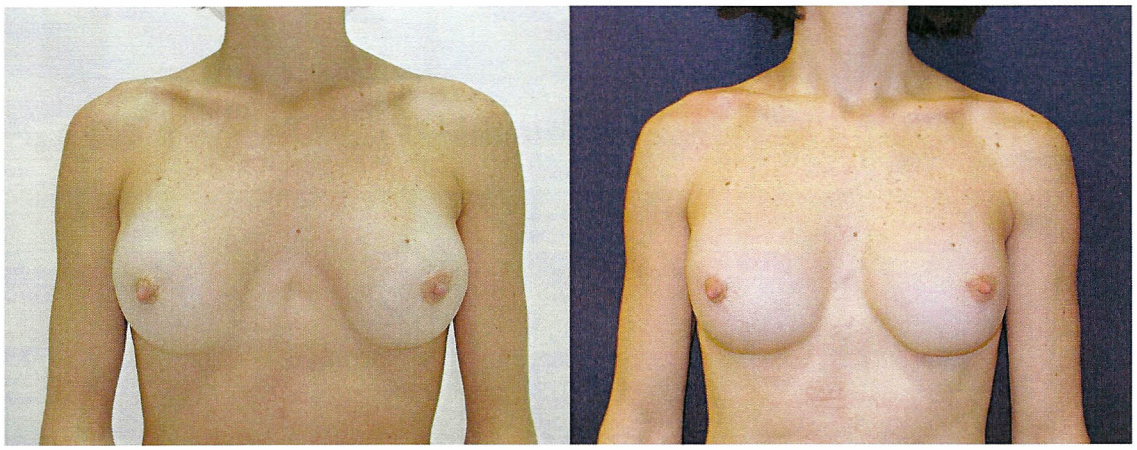

Fig 5. Case 2. Before treatment. Haematoxylin and eosin.

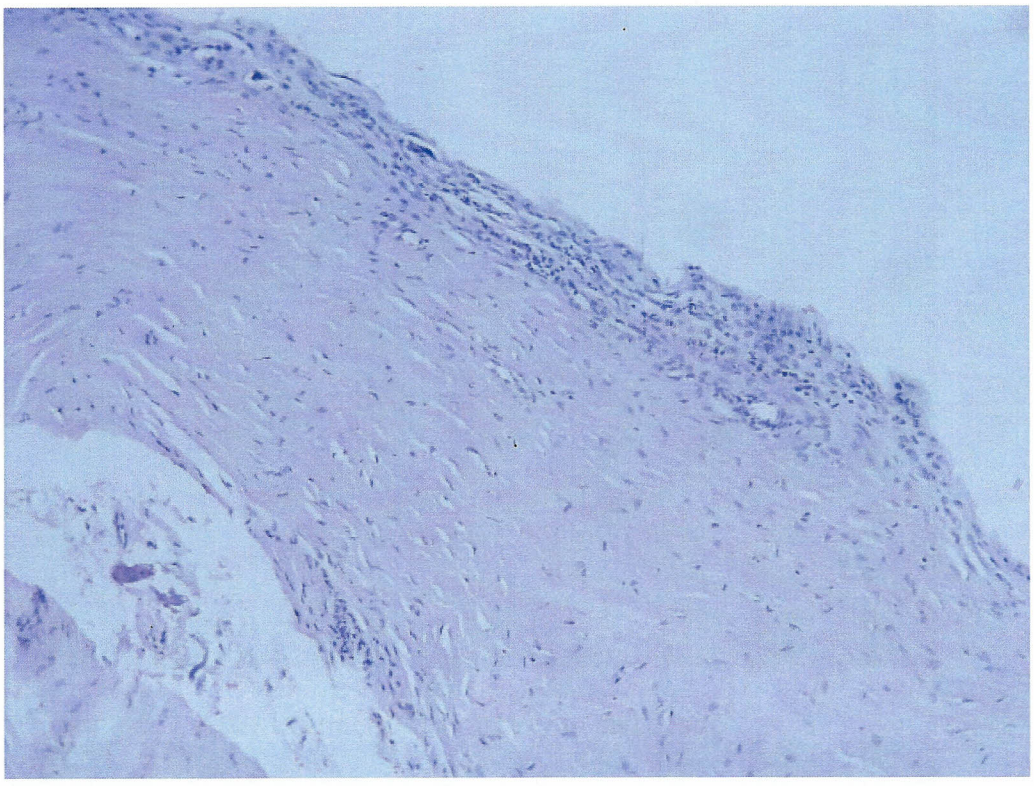

Fig 6. Case 2. After treatment. Haematoxylin and eosin.

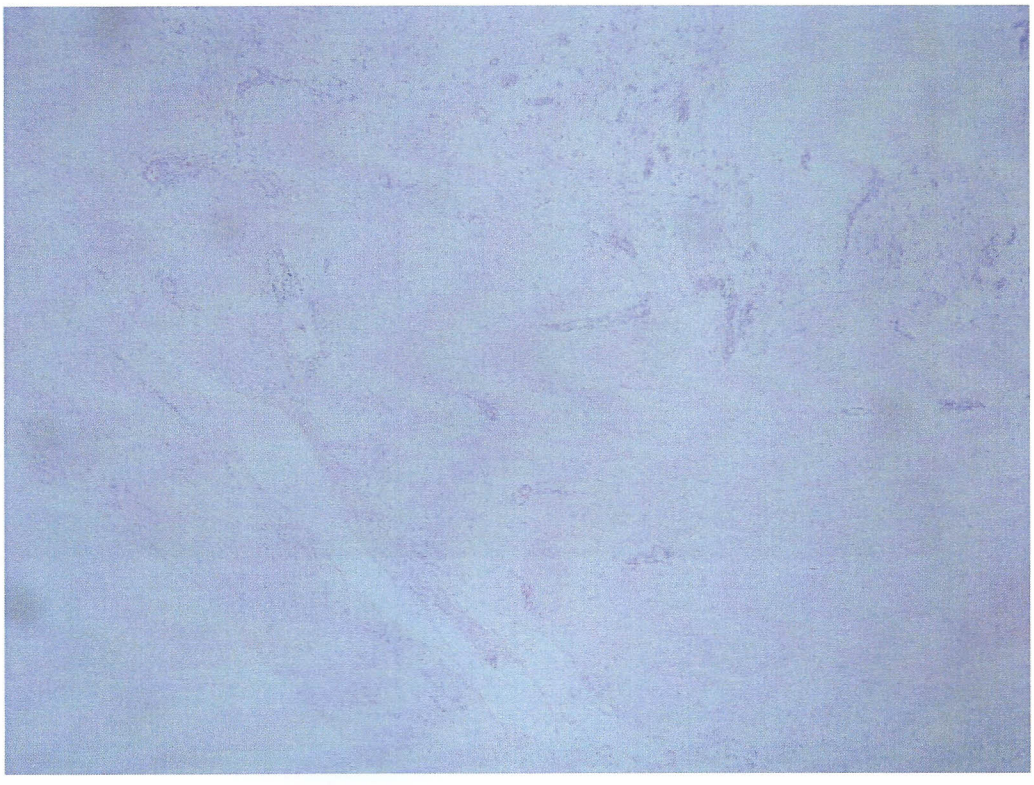

Fig 7. Case 3. Before treatment. Haematoxylin and eosin.

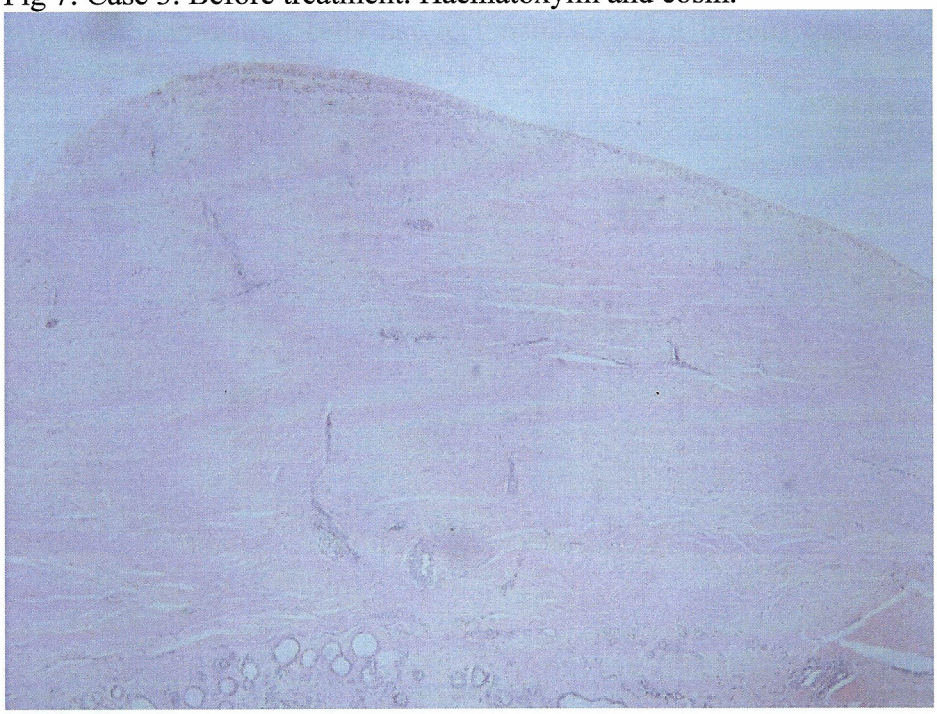

Fig 8. Case 3. After treatment. Haematoxylin and eosin.

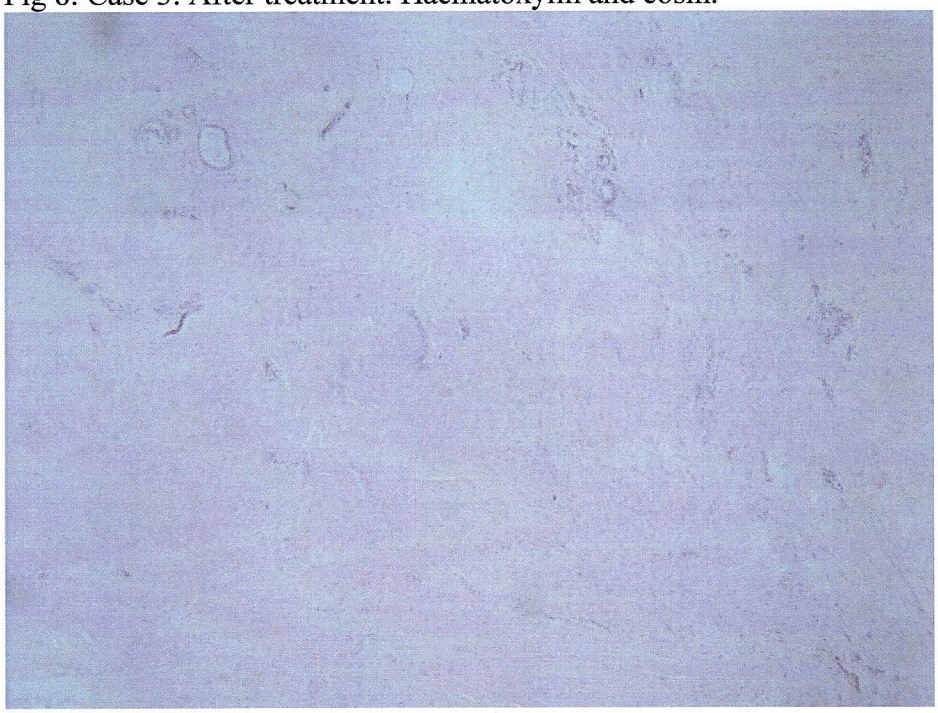

Fig 9. Case 5. Histology of the capsule showing a scanty cellular hyalinized tissue without inflammatory cells before treatment and a fibrous tissue with inflammatory cells after treatment.

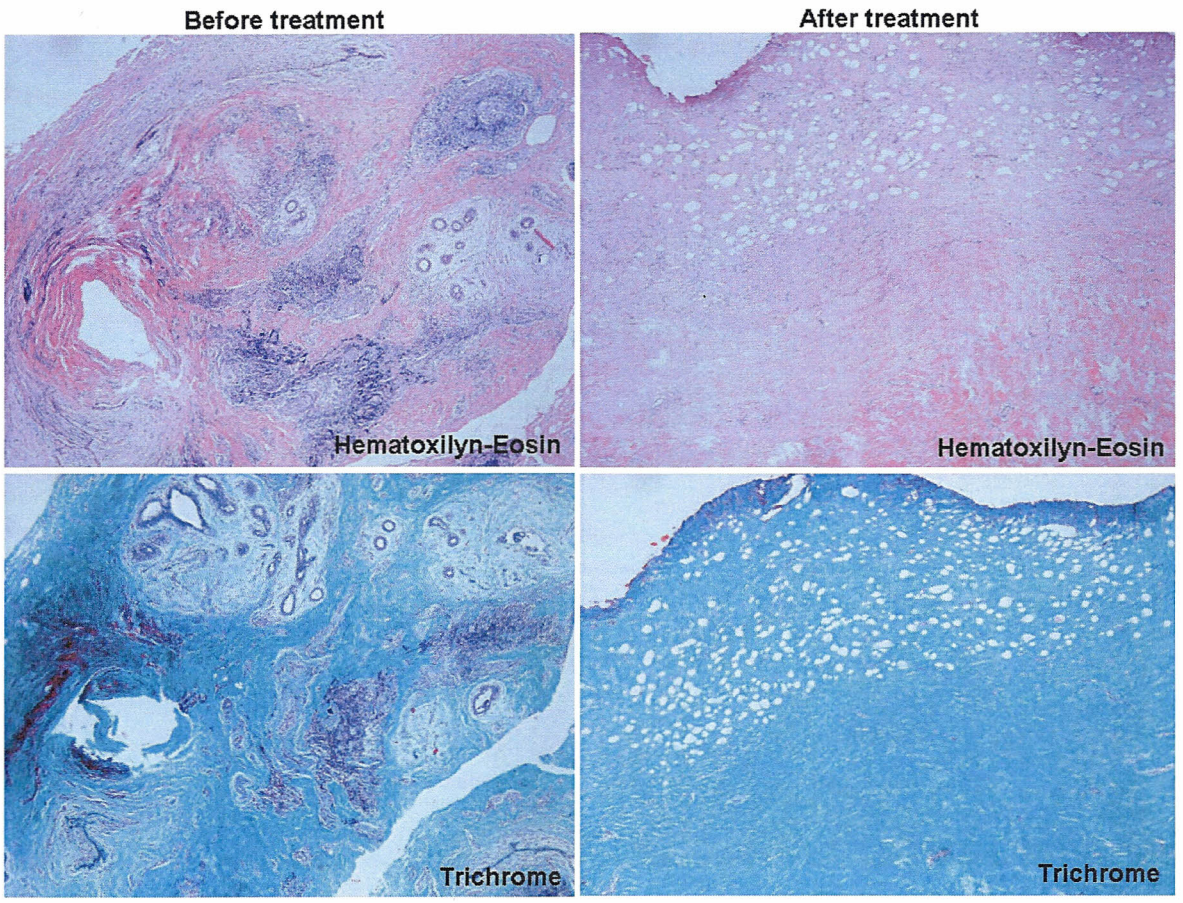

Figure 10. Case 4. Histology showing similar degree of fibrosis, hyalinization, cellularity and inflammatory cells before and after treatment.