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Aesthetic Plastic Surgery

Five-Year Experience on Ultrasonic Treatment of Breast Contractures

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Abstract. The authors report their experience in five years of treating breast implant capsular contractures with an external ultrasonic device that facilitates the closed capsulotomy technique. A set of 52 patients have been treated with a 82.6% of improvement at a year follow up. Methods of application and results are discussed.

Key words: Ultrasonic treatment—Breast implant—Capsular contracture—Closed capsulotomy

Etiological aspects of capsular contractures around breast implants are multifactorial and remain unclear [3, 7,13]. Although the implantation of rugous surface coating implants [4,8,10,15] and several drug administrations [1,2,5,6,12,17] have diminished the percentage of contracture, they still occur. External ultrasonic treatment has proven to be effective on wound healing and it is used in disorders such as cellulitis, keloidal scarring, sclerodermia, Dupuitren's, Peyronie's diseases and joint alterations [9,16,18]. Five years ago we started applying external ultrasounds to treat breast contractures. Preliminary results were so satisfactory that we were encouraged to continue [14].

In this study we investigate the results of ultrasound treatment of contractured breast implants. The principal statistical characteristics of the population under study are described in relation to their age and initial implant contracture grade. A total of 52 patients are analyzed, 25 of which have bilateral contractures; these patients make up 48% of the patients in the study and contribute to 65% of the contractured implants.

The distribution of the number of ultrasound treatment sessions per patient is also studied, together with its correlation to implant contracture improvement, as assessed by its Baker grade. The principal investigation method used to analyze the effect of the treatment on the implant contracture grade is expressed through the change between initial and post-treatment assessments. In patients with bilateral contractures, a differential analysis is also conducted so as to establish whether the effects of the treatment are essentially of local or non-local nature.

Particular attention is paid to a subset of the population under study which outperforms the full set. An explanation of its behavior is sought by comparing this subset, which is referred as subset A, to the full set distributions in age, initial assessment contracture, and number of ultrasound sessions.

Description of Population in Study

Description of data. The data collected in this study can be divided into two general categories: patient-specific data and implant-specific data. Patient-specific data includes: an identifier, age, brand, surgical plane, the number of ultrasound sessions, three parameters giving the contracture onset time (period following implant, in which it formed), and its assessment time (period in which the patient had a formed contracture before coming in for treatment). Implant-specific data includes the side of the patients on which the specific prosthesis is placed, its volume, and the contracture grade at the initial assessment, post-treatment, and follow-up.

Age distribution. The patients were 21 to 52 years old, with an average age of 33.

Initial assessment grade. The distribution of the initial assessment grade for the full set of contractured implants is shown in Fig. 1. Only 19% of the implants have a contracture grade of IV on the Baker scale, while the

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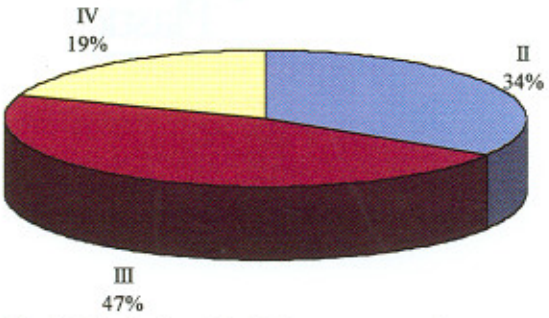

Fig. 1. Distribution of initial assessment grade.

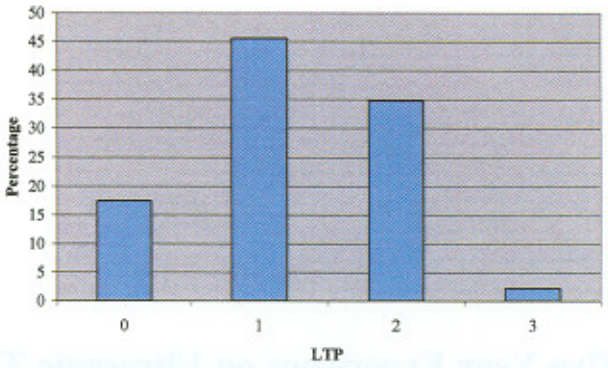

Fig. 2. Distribution of long-term progress (LTP).

remaining 81% are distributed in the III and II Baker scale grades. In fact, almost half of the implants have an initial Baker grade of III.

Bilateral implants. Patients having bilaterally contractured implants represent 48% of the cases, but contribute to 65% of the contractures, and so require special attention when effects of non-local nature may be important. The results indicates that the vast majority of patients have similar contractures on both breasts. This may indicate that what determines the initial contracture degree in a patient is non-local in nature.

Analysis of the Effects of the Treatment

Analysis of the Ultrasonic Sessions

The number of sessions is determined during treatment by evaluating the actual improvement. Patients are treated by repeated ultrasonic applications, ranging from 2 to 16 sessions. The average number of sessions is 6.4.

The experimental protocol followed during the ultrasonic treatment may be the key in explaining the distribution obtained; requests on the part of the patients for both terminating prematurely or extending the number of applied ultrasonic sessions, are followed. This indicates that patient satisfaction is an important element of this study. In the paragraph dedicated to the correlation of change with number of ultrasound sessions, a further breakdown of this data may be found.

Comparison of Change Between Initial and Post-treatment Assessments

As a direct measurement of the effect of the treatment on the implants, the difference between assessments is analyzed. This change is expressed by subtracting the Baker scale value of the final state from that of the initial state. In all cases a positive difference indicates an improvement in the patient's condition. Short term progress was studied by looking at the changes between the initial assessment and post-treatment assessment, while long term effects were studied using the differences between initial and follow-up assessments. Post treatment evolution was analyzed by examining the changes between the post-treatment and follow-up stages. The maximum value these indices can have is 3, in the case of an improvement from a value of IV to a value of I in the Baker scale.

Long-term progress. The data available for the analysis of the long-term effects of the treatment does not encompass the full statistical population, as only a subset of patients were interviewed long after the treatment. In fact, these implants represent 65% of those in the study, so that a substantial variation with respect to the full population may be expected. This important aspect is investigated in the section dedicated to the analysis of subset A.

The analysis of this long-term progress, which is shown in Fig. 2, is based on 48 implants. It indicates that an improvement, given by a change of greater than 0 in the Baker assessment grade, is observed in 82.6% of the implants. Furthermore, recalling that the experimental protocol calls for feedback regarding patient satisfaction, it is plausible that this will have a noticeable effect on the magnitude of improvement. This aspect is also considered in the paragraph dedicated to the correlation of change with number of ultrasound sessions.

Short-term progress. The analysis of the short-term progress, which is represented in Fig. 3, is based on 77 implants, and indicates that an improvement, given by a change of greater than 0 in the Baker assessment grade, is observed in 76.6% of the implants.

Post-treatment analysis. As well as the properties of the progress indices, the post-treatment state can be analyzed so that the overall behavior of the patient population can be described. In Fig. 4, the distribution of the contractures at this stage is shown, while in Table 1 the percentages of this distribution are compared to those prior to treatment and at long term. In absolute term, almost half of the implants achieve the best possible post-treatment assessment grade. For subset A, the results are even better (Tables 2, 3). Tables 2 and 3 compare the results of the full set (2) to those of subset A (3). The number of implants which obtain the assessment grade is listed in the row, and the number which had an assessment prior to treatment is listed in the column.

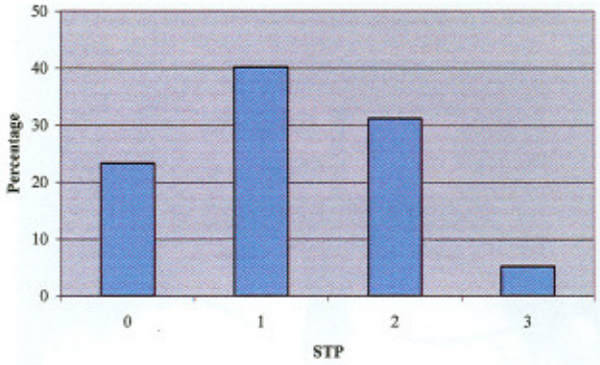

Fig. 3. Distribution of short-term progress (STP).

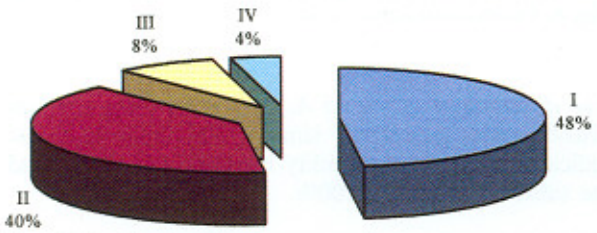

Fig. 4. Distribution of contractures after treatment.

Table 1. Distribution of contractures post-treatment.

Distribution				
Assessment grade	I	II	III	IV
Prior	0%	34%	47%	19%
Post	48%	40%	8%	4%
Long term	62%	32%	5%	0%

Table 2. Full-set post-treatment assessments.

Prior	II	III	IV
Post			
I	17	16	4
II	9	14	8
III		6	0
IV			3

Bilateral Contractures

Limiting this short-term analysis to cases with bilateral contractured implants, a comparison of the evolution of the two contractures on the same patient can be made. Specifically, the difference in improvement between the two implants is shown indicating that 28% of the bilateral contractures improves in to a different degree. One possible explanation for this slight asymmetric behavior, is that the effect of the treatment is of local nature. This effect is also portrayed in the comparison of bilateral asymmetries in pre-treatment and in post-treatment assessments where, for differences greater than one, the post-treatment implants have a greater presence.

Table 3. Subset A post-treatment assessments.

Prior	II	III	IV
Long term			
I	11	11	1
II	3	6	3
III		2	0
IV			0

Relationship of change to number of ultrasound sessions. The question of how many ultrasound sessions are optimal from a treatment point of view is important. In order to identify the relationship between the number of sessions a patient receives and the effect that they produce, it is necessary to recall that the experimental protocol includes the patient satisfaction factor which is a subjective evaluation of the effective change. It is interesting to note that the 4 cases with the maximum amount of change (3) are obtained with just 5 sessions. There seems to be no evidence suggesting that more sessions result in a greater effect. In fact, with fewer than 8 sessions we obtain a satisfactory result on 75% of contractures.

Relationship of short-term progress to surgical plane. The breakdown of the data regarding surgical plane as a function of short-term progress is the basis of the analysis of the correlation between these two variables. As we can see in Table 4 the mean for short-term progress related to cases with a pre-pectoral surgical plane is greater than the mean related to cases with a retro-pectoral surgical plane (Table 4). In Fig. 5 the normalized breakdown of the surgical plane is given for each value of short-term progress.

Analysis of Subset A

The data regarding the follow-up assessment grade is not comprehensive of the full set of patients, but pertains to a portion of these who were interviewed a substantial period after the application of the ultrasound treatment. This group of patients shall be referred to as subset A. Some of subset A's properties are given special attention in this analysis.

Introduction of subset A group. The population of subset A is composed of 34 patients, 14 of whom have bilateral contractures, for a total of 48 implants. Therefore, the 59% of patients included in the subset that have unilateral contractures only make up 42% of the subset's total number of implants. This is similar to the full set population where they represent 52% of the patient population 35% of the implants.

The comparison on the basis of initial assessment of the full data set to that of subset A, indicates that these two sets are compatible. The probability associated to the chi-squared statistic comparing these two data sets is 92%, so it is reasonable to assume that there was no

Table 4. Surgical plane and short-term progress.

Surgical plane	PP	RP	Post mastectomy
STP			
0	10	4	1
1	21	5	0
2	20	2	1
3	4	0	0
Total	55	11	2
Mean	1.3	0.8	2

STP: short-term progress.
PP: pre-pectoral.
RP: retro-pectoral.

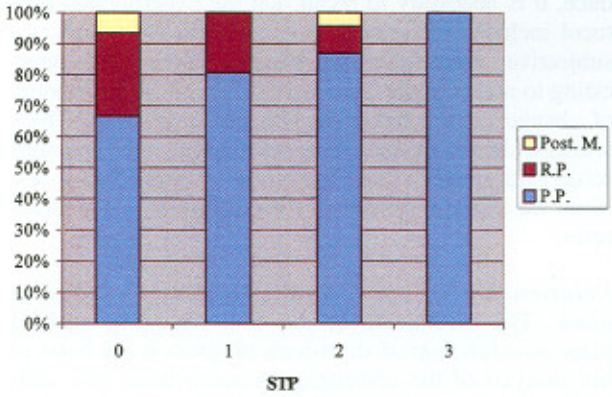

Fig. 5. Normalized breakdown of surgical plane versus short-term progress. Abbreviations used: STP, short-term progress; Post. M., postmastectomy; R.P., retro-pectoral; P.P., pre-pectoral.

substantial difference in the distribution of their initial assessment grade.

Short-term progress in subset A. Differences made evident comparing long-term progress to short-term progress are significant, so a specific analysis was used to determine the cause of this disagreement. As previously indicated, no significant differences in the initial assessment distribution are found in the full set population as compared to subset A. However, the short-term progress made by these to groups differs slightly when analyzed using the short-term change statistics and the post-treatment assessment statistics of these two groups.

Regarding short-term change, the probability associated to the chi-squared statistic comparing these two groups is 18%, so that it is possible to assume that there is a difference between these two. Specifically, the full set group has a noticeably greater number of cases with no short-term change. However, the post-treatment assessment results do not conclusively indicate whether the full set and subset A distributions differ in respect to this parameter. The probability associated to the chi-squared statistic is 60%.

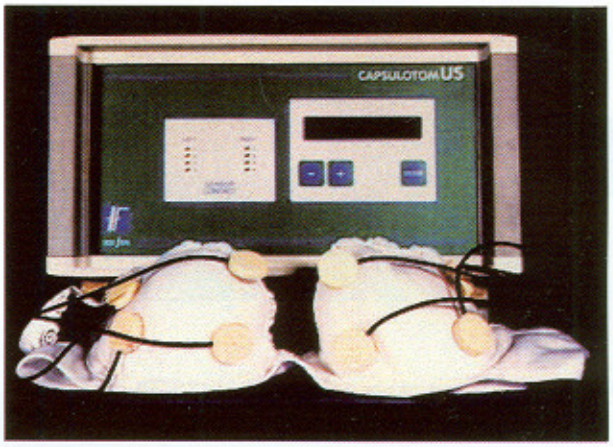

Fig. 6. External ultrasonic device.

Age distribution of subset A. The analysis of the age distribution is remarkably similar. The chi-squared test indicates an age compatibility between the full set and the subset A of almost 100%.

Distribution of ultrasound sessions in subset A. Comparing the distribution of the number of ultrasound session applied to the patients, similar results are obtained. The chi-squared statistic indicates that the full set and subset A groups are compatible with a probability of 99.7%. This is a strong indication that this parameter does not distinguish the two groups.

Materials and Methods

The ultrasonic device we used in our treatments is similar to the one applied for superficial soft-tissue treatment. A 2 MHz generator permits us to reach deep layers of fibrotic tissue. The device is connected to 8 transducers, 4 on each breast, oriented towards the capsule, with adjustable power per outlet, varying from 1 to 15 W to produce a maximum power density of 3 W/cm^2 (Fig. 6). The setting used was 15 W with a power per transductor of 500 W/cm^2. The device could be set in continuous or pulsed emission. In any case once the values of power emission per outlet and of total produced energy have been set, the appliance automatically calculated the cycle duration needed to distribute that energy to the transducers. We used the pulsed emission since the cycle is up to five times longer in that position, to minimize the overheating effect of ultrasonic energy on tissues. The sessions were scheduled every 24 h, until a good and stable result was obtained. The external capsulotomy was tried after five sessions.

Complications

The only complication was a case of first degree burn at the transductor's application area. It was treated with

nitrofurazone leaving no saequela. We recommend applying enough gel to the transductors to avoid this kind of complication.

Discussion

Little and Baker [11] reported in 1980 that the higher recurrence rate of post treatment capsular contractures can be detected within 6 months. The overall recurrence rate at the year follow-up is at least 33%. Only 67% of treated patients obtained good and long-lasting results.

In our study we obtained an overall improvement rate of 82.6% at the year follow-up, with almost half of the contractures reaching total softness.

In a preceding study of 24 patients, not included in this work [14], but treated equally to this set, we found that 82% of cases resulted in Baker I state, and in 97% of cases the contracture improved by at least one Baker degree. Joining both studies, we found that 58.6% of contractures improved to Baker I, and 83.8% improved at least one degree at the year follow-up.

The terminal effect of the ultrasonic energy increases the speed of cellular metabolism and stimulates fibroblast activation and wound healing [9, 16]. In continuous emission the termical effect can produce burns and protein denaturation. To avoid these complications we have applied pulsed emission. The effects of the external ultrasonic administrations are maximized at the interface between two layers of tissues with different characteristics of acoustic impediment. The contracted fibrous capsule and the mammary implant surface are a acoustic interface. Lesesne [10] demonstrated that there is a high rate of silicone droplets enclosed in the capsular tissues. In our opinion, all these events can contribute to change the implant capsular structure, improving tissue metabolism and preventing its fibrotic contracture.

Conclusions

Results obtained in this work (83.8% improvement at a year follow-up) can confirm the evidence of capsular softening and easier closed capsulotomy after external ultrasonic treatment. In most cases a limited number of sessions, fewer than 8, are enough to obtain a long-term result. We also can confirm that cases in which the implant was placed in the pre-pectoral plane, the percentage of improvement was higher. Furthermore, external ultrasonic treatment has proved easy to apply, well-accepted by the patient, cost-effective, and free of significant complications. We are currently evaluating this therapy's potential in the prevention of capsular contracture, the results of which we will publish in the future.

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